Assessment of Selected Six Sigma Tools to Improve Food Safety Outcomes in a Fresh - Cut Produce Plant

by

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Abstract

Using a carrot processing line in a fresh-cut produce processing plant, it was found that Failure Mode and Effects Analysis (FMEA) provided a more accurate portrayal of the risk that is associated with a fresh-cut processing line than that provided by a conventional Hazard Analysis. This conclusion is based on the fact that FMEA clearly indicates the residual risk that is left after risk-mitigating activities are in place, and identifies the variables responsible for the remaining risk factor. This methodology also requires examination of the risk associated with all product and process changes that are involved in processing, with an integral part of this approach being the need for continuous improvement. FMEA, therefore, has the potential to decrease the likelihood that food processors will sell contaminated food to consumers because they have not detected when their biological hazards are not being adequately controlled, a classical type 2 error.

It was also demonstrated that FMEA required a rating of the hazard detection method which drives the need to examine detection methods for hazards. In this example, a Run Chart was used to indicate changes in the microbiological status of a fresh-cut processing line. While the Run Chart successfully indicated this change, the information gained was not useful for showing the presence of a significant biological hazard. It was determined that this occurred because the information was not provided sufficiently in time to prevent the sale of contaminated carrots to customers.

Use of a Defect Opportunity Checklist (DOC) was assessed to detect defects in a sanitation process; in effect, whether or not planned activities were being followed. This information was subsequently analyzed and an improvement plan was developed. While the DOC successfully performed this function, it was not adopted by the processing site because the current methods for verifying the sanitation indicated that the process was acceptable. This suggests that there may be

limited acceptance of FMEA and DOC by food processors if it is perceived they perceive that their hazards are fully controlled by their existing food safety methodologies.

Lay Summary

Failure Mode and Effects Analysis (FMEA) gives a more accurate description of the risk associated with fresh-cut produce processing than a conventional Hazard Analysis (HA) because residual risk is evident. Processors can use this information to implement practices that both decrease occurrence and increase detection of biological hazards thereby reducing the likelihood of selling contaminated food to consumers.

Run Charts were examined for their ability to detect changes in the microbiological status of a fresh-cut carrot processing line. While they successfully indicated this change, the information was not provided in time to prevent sale of contaminated carrots to customers.

A Defect Opportunity Checklist (DOC) was investigated to determine it's ability to indicate if proper sanitation procedures were being followed. While DOC successfully performed this function, it was not adopted by the processing site because their current sanitation program evaluation methods did not indicate any problems.

Preface

Some of the material presented in Chapter 4 was included in a poster presented at the 2018 CIFST (Canadian Institute of Food Science and Technology) annual conference entitled: Assessment of a Six Sigma Method to Verify a Sanitation Process in a Fresh Cut Produce Plant. A Case Study.

The author, Rebecca Robertson, conducted the work in this thesis under the guidance of Dr. David Kitts, Richard Vurdela and Dr. Siyun Wang.

The work in this thesis is original and has not been previously published save for the poster described above.

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Abbreviations and Terms

APC	Aerobic Plate Count
Best Practices	"a procedure that has been shown by research and experience to produce optimal results and that is established or proposed as a standard suitable for widespread adoption" (Merriam-Webster Online, n.d.)
Boxplot	Boxplots are used to examine the variability and centering of data. Data is segmented into quartiles which identify the 25th, 50th and 75th percentile so boxes represent 50% of the data. The lower and upper lines of boxes represent the median of the lower and upper half of data respectively while the ends of vertical lines represent no more than 1.5 times the length of the box. Dots represent outliers (Six Sigma Academy, 2002).
Cause and effect diagrams	These diagrams display the possible causes of a problem so as to help identify root cause(s) (Six Sigma Academy, 2002).
Contingent Actions	Pre-planned steps that are followed when defects or failures occur (Lean Six Sigma Glossary, n.d.).
Continuous improvement	Ongoing, incremental efforts to improve products or processes (Lean Six Sigma Glossary, n.d.).
Control measures	Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (FAO/WHO, 1969).
Controls	Methods or actions that are currently planned, or are already in place, to reduce or eliminate the risk associated with each potential cause (Carlson C. S., 2012c).
Critical limit	A criterion which separates acceptability from unacceptability (FAO/WHO, 1969).
Critical Control Point (CCP)	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level (FAO/WHO, 1969).
Cross-contamination	Inadvertent transfer of bacteria or other contaminants from one surface, substance, etc., to another especially because of

	unsanitary handling procedures (Merriam-Webster Online, n.d.)
Environmental sampling program	Monitors and verifies that hygienic practices are effective and being properly performed (Tompkin, 2004).
FMEA	Failure Mode Effects Analysis.
FAO	Food and Agriculture Organization
FIFO	First-In, First Out. Items purchased first are used or sold first.
GAP	Good Agricultural Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point. A system which identifies, evaluates, and controls hazards which are significant for food safety (FAO/WHO, 1969).
HACCP Plan	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration (FAO/WHO, 1969).
Hazard	A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (FAO/WHO, 1969).
Histogram	A graphical method for displaying the distribution of data where the data is grouped. The number of data points in each group is counted and put into a bar. The resulting bar graph illustrates the shape, centering and spread of data (Six Sigma Academy, 2002).
Lean Manufacturing	Procedures that are designed to eliminate waste from manufacturing processes and standardize work.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control" (FAO, 1997). These activities are generally performed in "real-time" (FAO, 2008).

Pareto charts	A bar chart that illustrates the relative frequency of problems in descending order thus indicating where corrective actions should be applied (Breyfogle III, 2003)
Pre-operational inspection	A visual and organoleptic examination of a food processing line to ensure it is ready for manufacturing (Cramer M. M., 2013c)
Preventive Control (CFIA)	A preventive control helps prevent food safety hazards and reduce the likelihood of contaminated food entering the market (CFIA, 2019d)
Preventive Control (FDA)	Risk-based measures designed to or prevent identified hazards (FDA, 2018).
Preventive Control Plan	A written document that demonstrates how risk to food and food animals are identified and controlled (CFIA, 2019g).
Processor	A company that transforms food from one form into another.
Producer	An enterprise that produces the original, raw food that subsequently enters the food supply chain.
Residual risk	The risk that remains after risk treatment (ISO, 2018).
RPN	Risk Priority Number
Six Sigma	Six Sigma is a disciplined, statistical-based, data-driven approach and continuous improvement methodology for eliminating defects in a product, process or service (Lean Manufacturing and Six Sigma Definitions, n.d.).
Validation	Obtaining evidence that a control measure is effective (FAO/WHO, 1969).
Verification	Verification procedures assess the effectiveness of the HACCP Program and ensures that planned activities are being followed (FAO, 1998).
WIP	Work-in-Process. Work that has entered a process but has not been completed (Lean Six Sigma Dictionary, n.d.)

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To Richard Vurdela; your insights and advice made it possible for me to apply continuous improvement techniques from other manufacturing sectors into food manufacturing.

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To Dr. Paula Brown who gave me the time and encouragement to complete this work.

Finally, I wish to thank the fresh-cut produce processor that provided the site for my experiments; this research would not have been attainable without your support.

Dedication

I dedicate this thesis to my husband, Geoff Matheson, who cheered me on and never complained throughout my many hours of writing.

Chapter 1. Literature Review

1.1 Introduction

1.1.1 Significant Foodborne Outbreaks are still Occurring

Significant foodborne outbreaks continue to be attributed to food processing facilities, even though food safety programs based on Hazard Analysis and Critical Control Point (HACCP) programs have been recommended by the Food & Agriculture Organization (FAO) since 1993 (FAO, 1998). Since this time, the FAO has also advocated a "Food Chain Approach to Food safety and Quality" which featured the adoption of Good Agricultural Practices (GAPs) for producers (FAO, 2003).

In 2017 – 18, South Africa had the largest listeriosis outbreak ever recorded; 1,064 people, including 444 neonates, were infected of which 214 people died from eating contaminated polony, a ready-to-eat (RTE) meat product (NICD, 2018). Europe also had a listeriosis outbreak in 2018; contaminated frozen corn and other frozen vegetables caused 47 infections including 9 deaths. The strains of *Listeria monocytogenes* associated with this outbreak were detected in the processing facility in 2016, 2017 and 2018, suggesting that the strains were persistent (EFSA, 2018). In the United States in 2018, romaine lettuce contaminated with *Escherichia coli* caused 210 illnesses including 5 deaths. The cause of this outbreak was found to be contaminated canal water near where the lettuce was grown (FDA, 2018). Other notable outbreaks include *L. monocytogenes* in deli-meats in 2008 (Weatherill, 2009), cantaloupe in 2011 (FDA, 2011), ice cream in 2015 (FDA, 2015), and bagged salads in 2016 (FDA, 2016); Shiga toxin-producing *E. coli* O157 (STEC O157) in beef in 2012 (Lewis, Corriveau, & Usborne, 2013); and *Salmonella* in chocolate bars in 2006 (FSA, 2006) peanut butter in 2008-09 (CDC, 2010) and ground turkey in 2011 (CDC, 2011).

In Canada it was estimated in 2016 that foodborne illness cause an estimated 4 million illnesses each year, including 11,600 hospitalizations and 238 deaths (Government of Canada, 2016) while in the United States foodborne illness causes approximately 56,000 hospitalizations and 1,351 deaths per year (Scallon, et al., 2011)

1.1.2 Trends in Foodborne Illness

A retrospective review of foodborne illness in the United States from 1996-2013 indicates that there were early declines in illness followed by a plateau, or no trend starting in the early 2,000s for *Campylobacter*, STEC O157, *Listeria*, and *Yersinia* (Powell, 2016). *Shigella* showed a continuous decline, *Vibrio* showed a continuous increase while the data for *Salmonella* is inconclusive as to whether there is no trend or an increasing trend (Powell, 2016). The 2016 European Union summary of foodborne outbreaks reports that *Campylobacter*, *Yersinia*, and STEC O157 plateaued during 2012-2016 while *Salmonella* cases increased (ECDC ECDPC, 2017). The prevalence of *L. monocytogenes* has decreased since the 1990s, particularly in meat and meat products, while the rate of illness has remained the same since 2006 with the more severe form of listeriosis occurring more frequently in smaller outbreaks (Buchanan, Gorris, Hayman, & Jackson, 2017).

This suggests that there are some persistent problems occurring in the food industry that are resistant to the current HACCP system approach.

1.2 Evolution of HACCP

1.2.1 Origin of HACCP

The HACCP System was originally conceived by Pillsbury in the early 1960s, the original food contractor for the National Aeronautics and Space Administration (NASA). NASA set two significant requirements for food; it had to be free of both crumbs and pathogens (Cronk, 1994). The crumb-free specification was easy to meet while ensuring the food was free of pathogens was not so easily achieved. It was quickly evident that using traditional methods of product testing meant that, for the low levels of pathogens expected in the food being supplied to NASA, a large part of a batch would need to be tested, thus leaving a small amount for the space flights (Bauman, 1990). If the batch had a 0.1% contamination rate, for example, 3,000 samples would need to be tested to detect a positive with 95% confidence (Taylor, Sofos, Bodnaruk, & Acuff, 2015). Bauman (cited in (Ross-Nazzal, 2007) also stated that they could not find a standard quality control program in the food industry that could be used to solve this problem.

The answer lay within NASA itself. NASA required that all contractors employ a zero defects program for all hardware being designed. A Failure Mode, Effect, and Criticality Analysis (FMECA) was required to "discover critical failure areas and remove susceptibility to such failures from the system" (Lachance, 1997) (NASA, 1963). NASA also stated that each potential failure had to be "considered in light of probability of occurrence and should be categorized as to probable affect [*sic*] on mission success of the space program" (NASA, 1963) In addition, formal and documented design reviews were required and described as "comprehensive critical audits of all pertinent aspects of the design" (NASA, 1963) which provided NASA with documentation of all hardware being used in the space program. This audit or traceability requirement suggested to Pillsbury that they had to develop a system by which to prevent problems before they occurred by

identifying and mitigating potential hazards that could occur throughout the supply chain from harvesting to final packaging (Cronk, 1994).

1.2.2 Translation of FMECA to HACCP

As stated in section 1.2.1, NASA required an FMECA be performed on all hardware to identify and prevent or mitigate potential failures. This stringent approach, originally a 1949 military standard, Military Procedure (MIL-P)-1629, (Carlson C. S., 2012g) consisted of a Failure Mode Effect Analysis (FMEA) for every system function or component after which a Criticality Analysis (CA) was performed. The FMEA included of a description of the system function or component, a reference to a schematic or drawing, a statement of the function performed, the specific failure modes, the cause of each failure, phase of mission for each failure, effect of each failure on the component and its effect on the next higher assembly, the effect on the system, the methods by which the failure is detected, the corrective actions, and the useful life of the item. The CA identified the critical failure modes after which critical numbers were computed. An FMECA summary table was then prepared (NASA, 1966).

Pillsbury adopted this systematic approach by requiring an examination of all ingredients and manufacturing processes for possible hazards. Ingredients were evaluated through each processing stage and each point of manufacturing was evaluated and Critical Control Points (CCPs) were set up for areas identified as being sensitive (Bauman, 1990). This was accomplished by answering the following three questions: what is the process from harvest to final use? At which points in the process could contamination occur? How can contamination be prevented at these points? This lead to the development of the first three HACCP principles: (1) conduct a hazard analysis (HA), (2) determine the critical control points (CCPs) and (3) establish a system to monitor procedures. Two more principles were added after Pillsbury gained some experience with the new system: (4) establish critical limit(s) and (5) establish the corrective

action to be taken when monitoring indicates that a particular CCP is not under control (Cronk, 1994). The last two principles, (6) establish procedures for verification to confirm that the HACCP system is working effectively and (7) establish documentation concerning all procedures and records appropriate to these principles and their application, were added later by the NACMCF (National Advisory Committee on Microbiological Criteria for Foods) (Cronk, 1994) (NACMCF, 1998).

1.2.3 Adoption of HACCP by the Food Industry

Interestingly, Pillsbury did not adopt the HACCP approach for its own food processing facilities until 1971 when Pillsbury had to recall baby cereal because it contained glass shards. Dr. Howard Bauman, one of the key individuals that developed HACCP, was placed in charge of this change (Ross-Nazzal, 2007). Bauman also presented HACCP concepts to the first National Conference on Food Protection in April 1971 as a means to prevent contamination of processed foods (APHA, 1971). Later that year, two incidents of botulism in the canning industry led the National Canners Association to push the FDA to update their industry's regulatory requirements to adopt HACCP principles in 1973 (Ross-Nazzal, 2007).

There was little uptake of HACCP by industry over the next ten years even though the canning industry had demonstrated its value through improved safety programs and FDA inspections now followed a nationwide, uniform model (Ross-Nazzal, 2007). It took two major outbreaks in the dairy sector in 1985, salmonellosis in fluid milk and listeriosis in soft cheese, to stimulate the regulatory agencies to set up the National Advisory Committee on Microbiological Criteria for Foods which, as described in section 1.2.1, developed the seven HACCP principles still in use today (Cronk, 1994). In 1993, the Codex Alimentarius Commission issued the *Guidelines for the Application of the Hazard Analysis Critical Control Point System* (CAC, 1996). The need for

HACCP was underlined by significant foodborne outbreaks in the meat industry in the United States in 1993 (Ross-Nazzal, 2007).

1.2.4 HACCP Guidance for Industry

1.2.4.1 ICMSF

The International Commission for the Microbiological Safety of Foods (ICMSF) gave early HACCP implementation leadership to the food industry through "Microorganisms in Foods Volume 4: Application of the Hazard Analysis Critical Control Point (HACCP) System to Ensure Microbiological Safety and Quality" (ICMSF, 1988). This guidance indicated that the HACCP system incorporates hygienic practices based on the Codes of Hygienic Practice published by the FAO/WHO Codex Alimentarius Commission in 1983. These hygienic practices, referred to by Codex (Codex Alimentarius Commission) as prerequisite programs, cover: design, construction, maintenance and sanitation of the premises, equipment and facilities; personal hygiene; transportation; product information and consumer awareness; and training (CAC, 1999). These prerequisite programs should be "well established, fully operational and verified" before implementing HACCP so as to facilitate a successful HACCP system (CAC, 1999).

The ICMSF also provided guidance for conducting a HA and determining CCPs. All potential hazards are identified at each process step and the risk of them occurring considered. CCPs are then placed at points at which control can be applied to prevent or eliminate a hazard that has been determined to be at high risk of occurring. The ICMSF (ICMSF, 1988) also stated that "the analysis of hazards must be quantitative if it is to be meaningful" and that this evaluation "requires considerable technical expertise" This means that every hazard needs an assessment of their likelihood and severity. The book also states that applying HACCP to a new product may need up to 14 different specialists to be involved, including a microbiologist.

1.2.4.2 *Codex (FAO/WHO)*

Codex simplified this by developing a 12 step process illustrated below in Figure 1 along with a training manual that provided a set of questions and recommended forms to assist with identifying hazards (CAC, 1999) (FAO, 1998).

1. Assemble HACCP Team
2. Describe Product
3. Identify Intended Use
4. Construct Flow Diagram
5. On-site Confirmation of Flow Diagram
6. a. List all Potential Hazards
6. b. Conduct a Hazard Analysis (Principle 1)
6. c. Consider Control Measures
7. Determine CCPs (Principle 2)
8. Establish Critical Limits for each CCP (Principle 3)
9. Establish a Monitoring System for each CCP (Principle 4)
10. Establish Corrective Actions (Principle 5)
11. Establish Verification Procedures (Principle 6)
12. Establish Documentation and Record Keeping (Principle 7)

Figure 1 – Codex 12 Step HACCP System Process

The FAO training manual also included information as to how to determine which hazards may be potentially present in both the ingredients and manufacturing processes. Each hazard must then be considered as to its likelihood of occurrence and severity should it occur as part of determining whether or not it must be controlled through a CCP. This FAO guidance was adapted and somewhat modified by each country to fit their individual circumstances.

1.2.4.3 *Global Food Safety Initiative (GFSI)*

The GFSI was established in 2000 by the food industry to "provide continuous improvement in food safety management systems to ensure confidence in the delivery of safe food

to consumers worldwide" (GFSI, 2019). The two major outcomes of this initiative were to reduce food safety risks and reduce audit duplication and related costs. GFSI developed benchmarking requirements against which it measured and recognized ten different certification standards for different food sectors from around the world, including three most commonly used in food processing facilities: Safe Quality Food (SQF), British Retail Consortium (BRC) and FSSC 22000. These standards have extensive criteria that must be met including the requirement to incorporate HACCP Principles into the food safety program (GFSI, 2019). Each standard offers training courses that cover how to meet requirements.

1.2.5 Conducting a Hazard Analysis

1.2.5.1 Hazard Analysis

William Sperber (2001) , an early authority in HACCP, defined what a hazard analysis is within the context of HACCP and how it differs from a risk assessment. He stated that a hazard analysis, comprised of hazard identification and hazard evaluation, is a relatively short qualitative process that is used to determine if the hazard is significant enough to require control through a CCP. This was compared to a risk assessment which is a quantitative process that determines a numerical degree of risk and is usually performed by a multi-disciplinary group over months or years.[1]

1.2.5.2 Hazard Identification

The first part of a hazard analysis, hazard identification, was described by Sperber (2001) "as an open-ended brainstorming process to determine potential hazards" that is performed by the HACCP team. The team examines the ingredients, the process steps, equipment, the final product and associated storage and distribution methods as well as its intended use and the

[1] There is some confusion associated with this definition because a Hazard Analysis is a Risk Assessment method as defined in the Risk Management Guidelines published by (ISO, 2018).

profile of the product's consumers. From this examination, a list of potential biological, chemical and physical hazards that may be "introduced, increased, or controlled at each step of the production process" was developed (NACMCF, 1998). The CFIA recommends that hazard identification also be based on employees' knowledge and experience, documented product problems, and external references such as the reference texts recommended by the (FAO, 1998), the Canadian Reference Database for Hazard Identification (CFIA, 2014b), and food safety information published by regulatory agencies and industry associations.

Each identified biological, chemical and physical hazard is listed in table form, examples of which are given in Figure 2 to Figure 4 below; column 1 of each example contains the location of each hazard and the hazard is described in column 2.

(1) Ingredient/Material or Process Step	(2) Identified Hazards	(3) Controlled at

Figure 2. FAO & CFIA Food Safety Enhancement Program Hazard Identification Template (FAO, 1998), (CFIA, 2014b)

(1) Input, process step or cross contamination point	(2) Hazard and cause	(3) Control measure	(4) Is the hazard significant?	(5) Justification

Figure 3. Safe Food for Canadians Regulations (SFCR): Hazard Identification and Evaluation Template (CFIA, 2018a)

(1) Ingredient/	(2)	(3)	(4)	(5)	(6)

processing step	Identify potential food safety hazards introduced, controlled or enhanced at this step	Are any potential food safety hazards requiring a preventive control?	Justify your decision for column 3	What preventive control measure(s) can be applied to significantly minimize of prevent the food safety hazard?	Is the preventive control applied at this step?

Figure 4. FDA Food Safety Modernization Regulations: Hazard Analysis Template (FDA, 2018)

It is crucial to identify and list all potential hazards because, if a hazard is omitted, this may mean a needed control measure is missing which can leave a significant gap in the HACCP System (Wallace, Holyoak, Powell, & Dykes, 2014).

1.2.5.3 Hazard Analysis

The next step is to evaluate the significance of the hazard. Sperber (2001) stated that "an identified hazard is either significant enough to warrant inclusion in the HACCP Plan or it is not" while the FAO training manual (FAO, 1998) states that "the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity". The International Life Sciences Institute has defined significant hazards as: "hazards that are of such a nature that their elimination or reduction to an acceptable level is essential to the production of safe foods"[2] (ILSI, 1999). Significant hazards are generally controlled by a Critical Control Point [CCP][3] which is a "step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level" (CAC, 2009).

In contrast, "hazards of a low probability of occurrence and a low severity" should be controlled "by the application of Codex General Principles of Food Hygiene, good manufacturing practices

[2] This definition was adapted from (FAO/WHO, 1969).
[3] The US FDA Food Safety Modernization Act now refers to CCPs as "Process Preventive Controls".

(GMPs) or good hygienic practices (GHPs)". Codex (CAC, 2009) refers to these as prerequisite programs (introduced in section 1.2.4.1 above) because they should be "well established, fully operational and verified" before a HACCP system is put in place. In Canada, prerequisite programs have been replaced by preventive controls which include programs for managing: sanitation, pest control and non-food agents, conveyances and equipment, conditions respecting establishments, unloading (receiving), loading (shipping) and storing, competency and hygiene, supplier food safety assurance programs, and programs for controlling allergens, gluten and added sulphites (CRC, 2019) (CFIA, 2019c). These programs are monitored and verified to ensure the program activities being performed and are effective (CFIA, 2019e).

The NACMCF initially published "Hazard Analysis and Assignment of Risk Categories" in 1989 (NACMCF, 1989) as a guide for evaluating hazards but Sperber found there was little uptake by industry because, as cited by Wallace et al. (2014) "the process was not found to be helpful". After this, the recommended tools for hazard evaluation included the use of risk matrices and decision trees, examples of which are shown in Figure 5 and Figure 6 (NACMCF, 1998) (FAO, 1998) In 2013, Manning listed out 11 different hazard evaluation or risk ranking tools that were available to assist industry (Manning & Soon, 2013).

1.2.6 Problems with the Hazard Analysis

1.2.6.1 Lack of Training and Tools

In 2013, the BRC found that deviations to the HACCP system was the leading cause of non-conformances found during BRC third party audits in North America since the requirement for implementing a HACCP system was introduced into the BRC standard in 2011 (Huffman & Jespersen, 2013). Most of these non-conformances were associated with developing and verifying

Likelihood of Occurrence					
	High	Sa	Mi	Ma	Cr
	Medium	Sa	Mi	Ma	Ma
	Low	Sa	Mi	Mi	Mi
	Negligible	Sa	Sa	Sa	Sa
			Low	Med	High
			Severity of Consequences		

Significance of the hazard
Sa = Satisfactory (negligible)
Mi – Minor
Ma – Major
Cr - Critical

Figure 5 – FAO Two Dimensional Risk Matrix (FAO, 1998)

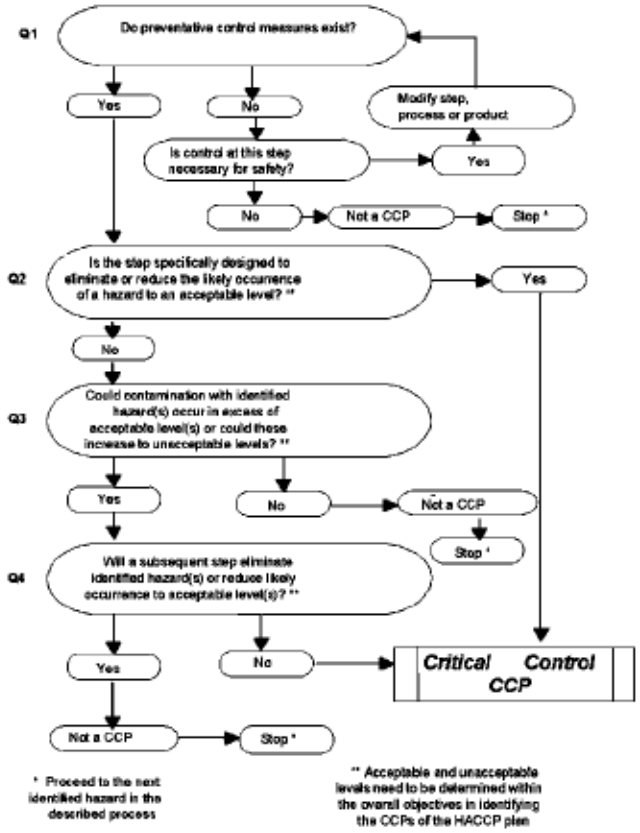

Figure 6 – Codex Decision Tree Example to Identify CCPs. From CAC (2009). *Food Hygiene. Basic Texts 4th Ed.*, Rome: Codex Alimentarius.

the process flow diagrams and conducting the hazard analysis. In 2005, (Wallace & Powell, 2005) examined fourteen food manufacturing sites in eight countries and classified all of them as "unsafe" with respect to effective HACCP implementation. Most of the sites were considered "marginal" for hazard analysis and CCP identification and control. In 2014, Wallace et al also found that a majority of the 166 study participants were unable to identify the factors that must be considered when performing the hazard analysis, namely likelihood of occurrence and severity of outcome (Wallace, Holyoak, Powell, & Dykes, 2014).

Wallace et al. (2014) suggested the problems with performing a hazard analysis may be attributed to the "lack of guidance/tools, training, expertise and experience in the hazard analysis

process". This gap is illustrated by the fact that of the eleven different hazard evaluation tools listed by Manning (2013), five are presently unavailable and five are not designed for this purpose leaving just 1 tool, Risk Ranger, that can be used by food safety practitioners for some situations. Risk Ranger provides a relative risk ranking between 1 and 100 for various product, pathogens and process combinations with 100 indicating that everyone eating the food in question will consume a lethal dose of the hazard being evaluated (Ross & Sumner, 2002). There is also no global standard for HACCP training nor is there accredited certification of trainees (Huffman & Jespersen, 2013). This training gap is also evident in food science curriculum because neither hazard analysis nor risk assessment is listed in the Institute of Food Science (IFT) table of standards and essential learning outcomes for accredited undergraduate food science programs (IFT, 2019).

1.2.6.2 Contradictory Guidance for Hazard Evaluation

It seems that some of the confusion around hazard evaluation may be a result of contradictory guidance. As indicated in the previous section, Sperber (2001) states that "an identified hazard is either significant enough to warrant inclusion in the HACCP Plan, or it is not" and is a "simple, qualitative process decision made by the plant's HACCP team".

In contrast, the original (ICMSF, 1988) HACCP guidance stated that "the analysis of hazards must be quantitative if it is to be meaningful" and that this evaluation "requires considerable technical expertise" and goes on to suggest that applying HACCP to a new product may need up to 14 different specialists to be involved including a microbiologist.

The FAO (1998) recommends that "the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity" which implies a more nuanced answer than "yes" or "no" to the question of hazard significance. To this end, the FAO provided an example of a two dimensional risk matrix (Figure 5) to help make this

determination. The training material, however, does not give any guidance as to how this risk matrix should be used. Instead, the material states that all hazards should be assessed using the Decision Tree in Figure 6 to determine if "yes", they are fully controlled "by the application of Codex General Principles of Food Hygiene, good manufacturing practices (GMPs) or good hygienic practices (GHPs) or "no", they are not and are controlled through a CCP.

1.2.6.3 Current Status of Hazard Analysis in Canada and United States

Canada and the United States have recently implemented new food safety regulations: Canada's Safe Food for Canadian's Act and Regulations came into effect in 2019 and the American Food Safety Modernization Act was enacted in 2011 (CFIA, 2019a) (FDA, 2019). While the guidance documents state the importance of considering severity and likelihood when evaluating hazards, neither provide comprehensive instructions as to how to actually perform this assessment. This omission is reflected in the Canadian and American hazard analysis templates illustrated in Figure 3 and Figure 4 in which the user is asked "is the hazard significant?" or "are there are any potential food safety hazards requiring a preventive control?", both of which require the answer "yes" or "no". Because a "yes" or "no" answer does not compel the user to perform a true assessment of severity and likelihood, this lack of instruction remains unaddressed.

1.3 Failure Mode Effect Analysis (FMEA)

It is suggested that the solution to the lack of Hazard Analysis guidance is to return to the original hazard analysis methodology used by NASA; Failure Mode and Effects Analysis or FMEA.

1.4 History and Current Use

FMEA was originally developed by the United States military in 1949 to examine the "potential effect of each functional or hardware failure on mission success, personnel and system

safety, system performance, maintainability, and maintenance requirements" (MIL-STD-1629A, 1980). This methodology was later adopted by NASA's Reliability and Quality Assurance program to "improve and verify the reliability of space program hardware" (Dept. of the Army, 2006) which was "helpful in avoiding errors on small samples sizes of costly rocket technology" (Ericson, 2005).

In the 1970s, Ford Motor Company began using FMEA to prevent the problem of exploding gas tanks in a line of cars while in 1993, the Automotive Industry Action Group and the American Society for Quality Control copyrighted FMEA standards for the auto industry (Ericson, 2005) after which there was substantive uptake of FMEA by automakers worldwide (Catic, Arsovski, Jeremic, & Glisovic, 2011). In 2010, Carlson reported that a survey of approximately 500 reliability professionals indicated that FMEA is considered the most important task being performed in their reliability program plans (RPP)[4]. Industries that use FMEA including "aerospace, medical, appliances, electronics, automotive, chemical, energy, services, and information" rely on FMEA to deliver products and services that meet customer requirements while ensuring reliability and safety (Carlson, 2012).

1.4.1 FMEA as a Means of Continuous Improvement.

FMEA is now considered to be a Lean Six Sigma tool which can be used, along with many other methodologies, to drive continuous improvement[5]. The American Society for Quality (ASQ) defines Lean Six Sigma as a "fact-based, data-driven philosophy of improvement that values prevention over defect detection. It promotes customer satisfaction and bottom-line results by reducing variation, waste and cycle time, while promoting the use of work standardization and flow, thereby creating a competitive advantage. It applies anywhere variation and waste exist, and

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[4] (Carlson, Sarakakis, Groebel, & Mettas (2010) state that "the objective of the RPP is to focus on the best practice tasks that are most effective and applicable in providing highly reliable systems and products".
[5] FMEA is also a Project Management tool.

every employee should be involved" (Kubiak & Benbow, 2009). Six Sigma emphasizes the reduction of process variation and improving process control by eliminating the root cause of problems while Lean focuses on reducing waste and fosters work standardization and flow (Kubiak & Benbow, 2009) (Costa, Filho, Fredendall, & Paredes, 2018).

1.4.2 Use of Lean Six Sigma Tools in the Food Industry

There are many Lean Six Sigma tools available including statistical process control, value stream mapping, process mapping, cause and effect diagrams, Pareto charts, Statistical Process Control (SPC), and Design of Experiments. A comprehensive list of these tools can be found in "The Quality Toolbox" written by Tague (2005)

The food industry has not embraced the use of lean six sigma techniques including FMEA even though this approach has been demonstrated to "improve performance as measured by quality, cost, delivery and customer satisfaction" while at the same time providing a return of 1-2% of sales/year for large companies and 3-4% of sales/year for small to medium size companies that will continue year after year if continuous improvement is sustained over time (Snee, 2010). Two recent literature reviews concluded that there was low uptake of Lean Six Sigma methodologies in the food industry (Costa, Filho, Fredendall, & Paredes, 2018) (Lim, Antony, & Albliwi, 2014) while a survey of Canadian food manufacturers found that 17.3% had implemented Six Sigma and 21.7% had implemented lean manufacturing or Total Quality Management (TQM)[6] (Scott, Wilcock, & Kanetkar, 2009). While these researchers concluded that their results suggested that "continuous improvement tools are an integral component of business strategy" in the food manufacturing sector, the response rate to their research survey was lower than expected at 11%. Costa et al. (2018) indicated that the low uptake of Lean Six Sigma may be partly attributed

[6] TQM – a continuous improvement-based management system that achieves success through customer satisfaction (ASQ, n.d.)

to a lack of literature demonstrating how to implement these programs in a food industry context while Lim et al. (2014) thought that the low uptake of SPC may be attributed to low levels of statistical thinking, a lack of SPC guidelines specifically for the food industry, and the perception that SPC is too advanced for use by food companies.

1.5 FMEA

1.5.1 Description

In FMEA, each potential failure is identified in a given system, then further examined as to the failure's probable effect on the system and its probability of occurrence. Methods for detecting each failure mode are also described and rated as to their relative efficacy (Dept. of the Army, 2006) (Carlson, 2012c). The risk associated with each failure mode is evaluated and prioritized after which corrective actions are performed for the most serious items (Carlson, 2012c).

Design FMEAs[7] focus on ensuring the product is designed such that it is safe and reliable throughout the expected life of the product while Process FMEAs, which focus on control, examines the manufacturing process to ensure the product is safely produced to design specifications in an efficient manner (Carlson, 2012c) (Tague, 2005).

[7] The three most common types of FMEA are System FMEA, performed at an early, conceptual stage, and Design and Process FMEAs (Carlson C. S., 2012c)

Item	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Controls	Detection	RPN	Criticality	Corrective Actions	S	O	D	RPN	Criticality
1	2	3	4	5	6	7	8	9	10	11	12				13	

1. Item – The Product or Service in a Design FMEA or a Process Step in a Process FMEA
2. Function – what the item or process step is meant to do
3. Potential Failure Mode – how the item may fail to deliver the intended function
4. Potential Effect(s) of Failure – the consequence of the failure on the system or end user
5. Severity (S) – a rating associated with the most serious effect of the failure mode, commonly a scale of 1 to 10 with 1 being insignificant and 10 being catastrophic.
6. Cause – reason for the failure
7. Occurrence (O) - a rating of the probability of failure because of the cause, commonly a scale of 1 to 10 with 1 being extremely unlikely and 10 being inevitable.
8. Current Controls – methods currently planned to reduce or eliminate the risk associated with each potential cause
9. Detection (D) – a rating of how well the control measures can detect either the cause or failure mode, commonly a scale of 1 to 10 with 1 being detection is certain and 10 being detection is impossible.
10. Risk Priority Number (RPN) = S x O x D. The RPNs are used to prioritize which potential failures should be addressed.
11. Criticality = S x O. This calculation helps with prioritizing the potential failures.
12. Corrective Actions – these may be design or process changes or additional controls to reduce the risk by lowering severity or occurrence. Detection may also be improved through additional controls.
13. New SOD ratings and RPN/Criticality numbers after the corrective actions are completed.

Figure 7. FMEA Template Example and Column Descriptions (Carlson, 2012c) (Tague, 2005)

Table 1 presents the suggested criteria for rating Severity, Occurrence and Detection which were adapted from Carlson (2012c) and Tague (2005). Detection criteria was customized by the author to suit the food industry. These ratings can be adapted to the type of FMEA being performed and to the organization or industry sector (Tague, 2005).

Table 1. Proposed Severity (S), Occurrence (O), and Detection Ratings (D) for Food FMEAs

	Criteria		
Rating	Severity	Occurrence	Detection
1	Unnoticed by customer.	Highly unlikely. < 1 in 1.5 million opportunities	Continuous monitoring plus fail-safe systems.
2	Some customers will note failure. Very minor effect on product or system.	Extremely rare. 1/150,000 opportunities	Continuous monitoring with notification of operator.
3	Most customers will note failure. Minor effect on product or system.	Rare. 1/15,000 opportunities.	Continuous monitoring.
4	Slightly annoyed customers. Slightly impaired product or system.	Few. 1/2,000 opportunities.	Online checks by operator during processing plus checks by Quality.
5	Customer annoyed. Noncritical problems with product or systems.	Occasional. 1/500 opportunities.	Online checks by operator during processing.
6	Customers have discomfort or are inconvenienced. Noncritical elements are inoperable.	Often. 1/100 opportunities.	Online checks by Quality during processing.
7	Very dissatisfied customers. Partial loss of primary function, other systems affected.	Frequent. 1/20 opportunities.	Tests performed post-processing with immediate results. May also be some testing with delayed results.
8	Highly dissatisfied customers. Loss of function, still safe.	Repeated. 1/10 opportunities.	Tests performed post-processing with delayed results.
9	Customer safety or regulatory compliance jeopardized, with warning	Common. 1/3 opportunities.	Failure mode not easily detected.
10	Catastrophic. Customer safety or regulatory compliance jeopardized, without warning	Almost certain. > ½ opportunities.	Cannot detect failure mode, or not analyzed.

1.5.2 FMEA Procedure

Figure 7 illustrates and describes an FMEA template that can be used for both Design and Process FMEAs. A multi-disciplinary team is assembled and all of the *potential failure modes* are listed for each *item* after which the *potential effects of failure* are identified. The failure effect is "the consequence of the failure on the system or end user" (Carlson, 2012e) which could be its effect during manufacturing, on the system as a whole, or the end user or customer. *Severity* (S) of the effect is now rated for the most serious failure mode effect using an agreed-upon severity scale an example of which is in Table 1. This is a relative rating that is determined without consideration of occurrence and detection. The *potential causes* for each failure mode are now identified using the experience of the team and, as needed, six sigma root cause analysis techniques such as "Five Whys", Pareto Charts, Cause & Effect Diagrams, Scatter Plots and others. After this, the *occurrence* (O) rating is assessed for each cause of the failure mode; this is the likelihood that this failure mode/cause will occur during the lifetime of the product or during manufacturing as appropriate. Similar to the severity rating, it is a relative rating that is determined without consideration of severity or detection using an agreed-upon severity scale (see Table 1). Next, the *current controls* are identified. These controls are the methods that are currently planned or in place to either prevent or detect problems during the product design phase (Design FMEA) or during manufacturing (Process FMEA). The prevention controls are intended to reduce the occurrence rating while detection controls impact the detection rating. The d*etection* (D) rating is now considered for each detection control. This rating is the likelihood that the current controls can detect the cause or its failure mode either before the design is released in the case of Design FMEA or before the product leaves the manufacturing plant in the case of Process FMEA. Detection is determined without regard to severity or occurrence using an agreed-upon scale (see Table 1). Detection is somewhat complicated in that it is not just the

likelihood of detection that must be considered but the timing of the detection opportunity and the integrity of the test method (Carlson, 2012e). The *risk priority number* (RPN) and *criticality* numbers are calculated by multiply SxOxD and SxO respectively and used to prioritize the order in which failure mode/causes to address through *corrective actions* (Carlson C. S., 2012e) (Tague, 2005). Items with high severity are given first priority after which the team will look at the RPN and Criticality numbers. Items with the highest RPN are dealt with first, then the team addresses lower RPNs given the associated detection rating, the available resources and the purpose of the FMEA. Sometimes the RPNs are ranked and an agreed-upon percentage of total issues are worked on (Carlson, 2012f). Criticality may also be used as a prioritization tool as long as the risk associated with detection is considered (Carlson, 2012e)

There are some points that must be considered for this prioritization. There are only 120 possible values even though the RPN scale is between 1 and 1,000. Some RPN values are associated with up to 24 problem descriptions while just one problem description is associated with others (Wheeler, 2011). These duplicate RPNs also do not have the same risk associated with them. For example, the risk associated with a problem description having severity of 1, occurrence of 8 and detection of 8 is very different than a problem description with severity of 8, occurrence of 3 and detection of 3 even though they both have a RPN of 72. The criticality score (S x O) can help mitigate this issue because this number highlights the need to address elevated severity and occurrence scores. In this example, the first problem has a criticality score of 8, while the second has a score of 24 meaning that the team should prioritize the second problem description over the first. It is also best to use the RPN and Criticality as a means to prioritize risk rather than to establish thresholds above which actions are taken because these thresholds are arbitrary and there may be some items that still should be addressed, even though the RPN is low. For instance, problems with high severity ratings should be prioritized no matter what their RPN is (Carlson,

2012e). Similarly, problems with high detection ratings may also need to be prioritized even if the criticality number is low because the failure mode cannot be detected should it occur.

The corrective actions for reducing the risk for the prioritized failure modes or causes are now identified. Severity and occurrence ratings are reduced by effecting product and/or process design changes while detection is improved by improving the current controls, implementing controls that already exist or by developing new detection controls (Carlson, 2012f). Once the corrective actions have been implemented, the new RPN and Criticality numbers are recalculated from the revised S, O and D ratings. If the risk is still unacceptably high, then more effective corrective actions are needed (Carlson, 2012f).

The risk that is left after all the corrective actions are implemented is the residual risk which is the risk that remains after risk treatment which is, in this context, the action(s) taken to reduce the risk of negative consequences (ISO, 2018). If the residual risk is not considered tolerable, then further risk treatment through corrective actions is needed. If further actions are too costly or are effectively impossible to perform, then a decision needs to be made as to whether or not to accept this risk or to explore other risk treatment options.

1.5.3 Risk Anticipation

A major goal of the FMEA process is to "maximize opportunities to anticipate risk" so that rare and unexpected events with high impact, called "Black Swans" by Nassim Taleb (Taleb, 2007), are brought forth and considered (Carlson, 2012b)

1.6 Why FMEA could be a solution for the problems with Hazard Analysis

1.6.1 The FMEA provides a Structure for a Comprehensive Risk Assessment

It is useful to compare FMEA with the SFCR Hazard Identification and Evaluation template for fluid milk pasteurization, a food example, to illustrate how the FMEA provides a structure for a comprehensive risk assessment.

Figure 7 illustrates an example SFCR table while Figure 8 illustrates an example Design FMEA for milk pasteurization.

Input, process step or cross contamination point	Hazard and cause	Control measure	Is the hazard significant?	Justification
Pasteurization	Pathogen contamination of incoming raw milk because of contamination at the farm.	Pasteurization	Yes	If pasteurizing time and temperature parameters are not met, there is a probability that pathogens could be present in the final milk products and consumers could get food poisoning.

Figure 8. Safe Food for Canadians Regulations (SFCR) hazard identification and evaluation template example for biological hazards for fluid milk pasteurization (incomplete).

Item	Function	Potential Failure Mode	Potential Effect(s) of Failure	S[1]	Potential Cause(s) of Failure	O[2]	Design Controls	D[3]	RPN[4]	Criticality	Recommended Actions	S	O	D	RPN	Criticality
Fluid Milk	To provide a container of milk that will not cause foodborne illness	Pathogen contamination of incoming raw milk.	Illness or death of a consumer.	10	Contamination of the milk at the farm.	9	All milk producers belong to the "Canadian Quality Milk Program". No controls for detection.	10	900	90	Pasteurize milk in licensed high temperature short-time pasteurizer that meets CFIA criteria with fail-safe mechanisms and validated to ensure temperatures and times meet specifications. Performed by a licensed operator. Daily and bi-annual checks are performed to verify function.	10	1	1	10	10

Figure 9. Design FMEA Example for Fluid Milk Pasteurization (Incomplete)

[1] S = Severity
[2] O = Opportunity
[3] D = Detection
[4] RPN = Risk Priority Number

While both the SFCR table and the FMEA indicate that pasteurization is an important process for controlling the risk of pathogen contamination capable of causing foodborne illness in fluid milk, the FMEA contains much more information about the nature of the risk associated with the milk pasteurization process. This is because the FMEA requirement for rating the severity, occurrence and detection associated with each failure mode/cause, using a table similar to Figure 7, drives the team to look for and analyze supporting information to support these ratings. Such information is gathered from literature searches, industry associations, regulatory agencies, test results, experience with similar systems and similar.

In this example, severity (S) was rated as 10 because pathogens such as *Escherichia coli (E. coli), Salmonella spp., Listeria monocytogenes* and others which are commonly associated with raw milk (Griffiths, 2010) are capable of causing severe illness or death of a consumer (Scallon, et al., 2011) without warning because pathogens generally cannot be detected in food being consumed. Occurrence (O) was rated as 9 because the prevalence of pathogens in raw milk has been found to range between 0 and 35% depending on the pathogen and "no husbandry practices have been identified that can guarantee that milk will be free of pathogens" (Griffiths, 2010). Detection (D) was rated as 10 because it is not possible to determine for certain whether or not raw milk is contaminated by performing standard raw milk tests such as measuring the titratable acidity or examining the milk for off-odours (Wehr & Frank, 2012). Microbiological tests take time to perform and have limits of detection (Bradley Jr., Houck, & Smukowski, 2015) which make them impractical for this purpose.

The FMEA, therefore, tells a more comprehensive story than the SFCR about the nature of the risk associated with milk pasteurization. The risk that raw milk contains a pathogen is exceedingly high with a RPN of 900 and Criticality of 90, which is close to maximum values of 1000 and 100, respectively. The FMEA also tells us that this risk can be mitigated by heat treating raw milk in a continuous, high temperature-short time (HTST) pasteurizing unit designed to have

fail safe capability (CFIA, 2019f) and the capacity to achieve pasteurizing times and temperatures that have been validated to kill milk-associated pathogens (CAC, 2009). The new ratings for O and D indicate that pasteurization has lowered the occurrence rating to 1 and improved detection to a 1, so the RPN and Criticality numbers are reduced to 10. The residual risk of 10 remains because the severity rating for pathogens cannot be mitigated. This amount of risk reduction has actually transpired in the dairy industry as evidenced by the fact that dairy products now cause fewer outbreaks of food borne illness, per weight consumed, than any other food category in the US (CSPI, 2015) as compared to 1938 when milk was responsible for an estimated 25% of all American food and water-borne diseases (FDA, 2017).

1.6.2 The Comprehensive Risk Assessment provided by an FMEA indicates when a Design Change may be needed

As discussed in section 1.5.2, elevated severity and occurrence ratings should trigger design changes in the product and/or the process so as to decrease risk, as indicated by the decreased RPN and Criticality numbers. For FMEAs examining the biological hazards associated with a product or process, occurrence is the only metric that can be manipulated because the impact of an organism on a consumer cannot be altered by the processor. The occurrence rating is therefore a key indicator of whether or not a product or process needs to be redesigned.

1.6.2.1 The occurrence rating is measuring the effectiveness of the control measures

The occurrence rating is a measure of how successfully the product or process as designed prevents, eliminates or reduces hazards (the failure mode/cause in FMEA terminology)[8] to an acceptable level. This statement means that this rating is measuring the effectiveness of the

[8] Failure mode/causes will be referred to as hazards in this research paper

control measures[9] that are in place. Control measures for biological hazards include; processes designed to reduce pathogens such as thermal processes, washing, or sanitation; processes designed to minimize an increase in microorganisms such as refrigeration, handwashing or separating raw from cooked RTE foods, and processes designed to control the initial level of pathogens such as approving new suppliers through a Supplier Quality Assurance program.

The effectiveness of the various control measures should ideally be measured against whether or not the Performance Objective (PO) is being met for the process, as illustrated in the ICMSF *conceptual equation* (ICMSF, 2018):

$$H_0 - \Sigma R + \Sigma I \leq \text{FSO or PO}$$

where H_0 is the level of the hazard in the raw material, ΣR is the total effect of the processes that reduce hazard levels, ΣI is the total effect of the processes where hazard levels may increase, FSO is the food safety objective and PO is the performance objective. All of the variables are expressed in $\log_{10}$ units so the exponential processes of microbial growth or inactivation are correctly modelled but arithmetic processes like cross-contamination are less well described (Ross & McMeekin, 2009).

Codex (2015) defines the FSO as "the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)" which is the "level of risk a society is willing to accept"[10] (ICMSF, 2006). A PO is "the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable" (CAC, 2015). Examples of FSOs are: the level of *L. monocytogenes* in RTE foods must

[9] Control measures are defined as any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (CAC, 2009)
[10] The ALOP is related to the residual risk in the process as discussed in section 1.5.2

not exceed 100 cfu/g or the concentration of *Salmonella* spp. must be less than 1 cfu/100 kg of milk powder. Examples of POs are: the prevalence of *Salmonella* spp. in neck skin samples taken after the carcass chill step for raw poultry meat carcasses should be ≤10% or the level of pathogenic *E. coli* shall not exceed 1 cfu/10 L when fruit juice is packaged for distribution (ICMSF, 2018).

The entire supply chain contributes to the FSO as illustrated in Figure 10 below. Each participant in the food supply chain operates a set of control measures that presumably meet the needed Performance Objective. It should be noted that the concept of FSOs and POs is still emerging so POs and FSOs have still not been formally established in many segments of the food industry. However, the equation is still a useful tool for industry to visualize some concepts. For

$H_{o\text{-}1} - \Sigma R_1 + \Sigma I_1 \leq PO_1 \quad (=H_{o\text{-}2})$	Stage 1 - Primary Production
$H_{o\text{-}2} - \Sigma R_2 + \Sigma I_2 \leq PO_2 \quad (=H_{o\text{-}3})$	Stage 2
$H_{o\text{-}3} - \Sigma R_3 + \Sigma I_3 \leq PO_3 \quad (=H_{o\text{-}4})$	Stage 3
...	
$H_{o\text{-}n} - \Sigma R_n + \Sigma I_n \leq PO_n \quad (=FSO)$	Final Stage

where $H_o - \Sigma R_{1 \rightarrow n} + \Sigma I_{1 \rightarrow n} \leq FSO$ represents the effect of all processes throughout the food supply chain.

Figure 10. The ICMSF Conceptual Equation for the Food Supply Chain.
Adapted from *Risk Assessment and Pathogen Management* (p. 143), by T. Ross and T.A. McMeekin, in Foodborne Pathogens edited by C. de W. Blackburn and P. J. McClure. 2009 by Woodhead Publishing Ltd.

example, the equation illustrates that if one participant has an ineffective control measure or set of control measures resulting in an elevated H_o, all subsequent participants will have an elevated H_o. This means that the control measures being practiced later in the supply chain may not effectively control the higher load of microorganisms entering the process.

If the FMEA indicates that the current control measures are inadequate as indicated by an elevated occurrence rating, then the team can take action by redesigning the process. The

FMEA can therefore be a useful tool for processors to ensure their control measures are adequate and not disturbing the equilibrium of the supply chain with respect to hazards.

1.6.2.2 *An increase in the occurrence rating can indicate the need for a redesign of a product or process*

FMEAs should be performed whenever there are changes that potentially impact risk (Carlson, 2012d), with emphasis on the occurrence rating because this is a major indicator that a redesign of the product or process may be needed. This means that a Design FMEA should be performed whenever new products are developed or existing products are modified, or when the target customer for the product has changed. This is especially important if these customers are vulnerable to foodborne illness because of factors that include, age, pregnancy, illness, treatment or medication (Lund, 2019). FMEA would also be prompted when a process changes, such as when production volumes substantively increase or new equipment is purchased[11]

The need to perform a Design FMEA for new products could potentially have averted the 2007 *Listeria* outbreak in deli meats. Customers had requested reduced sodium deli meats in a larger package for consumers in hospitals and long-term care facilities. The increased likelihood that a foodborne illness would occur in this particular scenario was not recognized because it was assumed that the company's current control measures for controlling biological hazards in these types of products were adequate (Weatherill, 2009). If a Design FMEA had been performed, it is likely that the increased occurrence rating associated with increasing the water activity through salt reduction (FDA, 2003), changing the packaging configuration thus altering the product-to-headspace volume (Loss & Hotchkiss, 2001), and serving these products to vulnerable consumers

[11] A Reliability - Centered Maintenance (RCF) FMEA could be performed to identify equipment preventive maintenance needs and other activities that ensure the equipment is safe and reliable (Carlson C. S., 2012c)

(Lund, 2019), would have produced an increase in the RPN and Criticality number. Product design changes would have been performed to counteract the change in risk.

The requirement to perform an FMEA for significant process changes also has the potential to prevent foodborne outbreaks. In the 2007 *Listeria* outbreak in deli meats, production volumes had increased 100 fold which lead to the sanitation program being compromised to a point whereby complete cleaning of the plant only occurred on weekends and scheduled equipment tear-downs for sanitation were not performed regularly (Weatherill, 2009). It is possible that an FMEA focused on examining the effect of this significant change in production volumes on risk may have identified the increase in the occurrence rating and related RPN and Criticality number for biological hazards which would have triggered a redesign of the process.

1.6.3 FMEAs examine Detection

1.6.3.1 FMEA requires consideration of detecting the hazard

A notable difference between FMEA and the matrices and decision trees currently used for identifying significant hazards in a Hazard Analysis is that FMEA requires a rating of how likely the detection controls, called monitoring and verification procedures in HACCP terminology (CAC, 2009), will detect the hazard before the product is in distribution. This is a significant feature because it is important to consider if the detection methods in place adequately assess whether or not the product and processes that have been designed to reduce or eliminate a hazard, i.e. the control measures, are achieving the goal of producing a food that will not cause harm to a customer.

It is important to remember that detection does not mitigate hazards; rather they are mitigated by reducing the severity and/or occurrence of the hazards through design-based control measures as discussed in section 1.5.2 above. This underscores the importance of the criticality

number (S x O) because it reflects how effectively the product and process design[12] control the hazards. Hence an RPN score of 10 x 10 x 1 is still very high risk even if the hazard is always detected because a great many deviation procedures[13] would need to be followed to manage the high amount of nonconforming product that would be produced by this process.

The ICMSF conceptual equation in Figure 10 also illustrates the significance of rating detection because it highlights the importance of understanding the risk associated with incoming materials (H_o) and whether or not each process step has achieved the needed reduction (ΣR) or minimized an increase (ΣI) in biological hazards.

1.6.3.2 Detecting biological hazards in incoming materials

Considering the detectability of biological hazards in incoming materials is important because this affects the ability of a manufacturer to produce food that meets the needed PO and ultimately the FSO. It is difficult to measure biological hazards of incoming materials because, as discussed in section 1.2.1, the prevalence of pathogens is often so low they are difficult to detect without sampling a great amount of material. This is compounded by the fact that there is often non-random distribution of microorganisms, even in liquid products, due to the ingredient's manufacturing conditions (ICMSF, 2018). The FMEA emphasizes this problem because the detection rating for this scenario is a 9 or a 10 thus increasing the RPN which, in turn, compels the team to formally consider whether or not feasible detection controls are available.

The 2008-09 *Salmonella* outbreak in peanut butter illustrates the benefit of this approach. This outbreak caused 714 confirmed infections and 9 deaths over a period of seven months (CDC, 2010) which means that approximately 11,000 illnesses likely occurred because of underreporting (Cavallaro, et al., 2011). Of note in this outbreak was that while the peanut

[12] The control measures in HACCP terminology.
[13] Contingent actions in FMEA terminology

processor handled less than 2% of the American peanut supply, the recall involved 3,900 products including peanut butter, crackers, ice cream, snack bars, baked goods, and food bars (FDA, 2017) from 200 companies (Wittenberger & Dohlman, 2010). The problem with *Salmonella* contamination in peanut butter is that the organisms become "unusually heat resistant" because peanut butter is a low-moisture food (Ma, et al., 2009). This means most of the companies that purchased the peanut butter would not have had a thermal process capable of achieving the required log reduction of *Salmonella* needed to produce a food that was safe for consumers, especially given that a dose of 1 cell can be infective in some conditions (FDA, 2012).

An FMEA would have brought out the higher risk associated with peanut butter because there had been an outbreak of *Salmonella* in peanut butter in 2007 (CDC, 2007). This elevated risk therefore increases the occurrence rating so the commensurate elevated RPN and Criticality number would likely have triggered an evaluation of Detection (D) for the incoming peanut butter. The rating for detection of *Salmonella* is a 9 or 10 because no microbiological test would reliably detect the low prevalence of this organism thus leading the FMEA team to come up with other actions for reducing occurrence. Interestingly, one large multi-national company did just that by performing a second party audit of the peanut processor's facilities. They did not approve them as a supplier because they rated the risk level associated with the facility as "high" (Leighton, 2016). As a result, they did not become part of this recall. In response to this large outbreak, the FDA now requires that all manufacturers have a risk-based supply chain program that clearly indicates which entity in the supply chain is mainly responsible for controlling the hazard (FDA, 2018). In this case it is the processor that roasts the peanuts, because this is where the reduction in *Salmonella* occurs (FDA, 2009).

1.6.3.3 Detecting biological hazards during processing

While the ICMSF conceptual equation underlines the importance of detecting biological hazards during processing, it is challenging to detect them. The reason is because of the time

required to conduct and receive the results of most microbiological analyses and the relative insensitivity of even the most stringent sampling plans, (ICMSF, 2018). This problem is amplified when the prevalence of pathogens is less than 0.1% as expected in RTE foods. For this reason, other tests are generally performed as a proxy for microbiological testing. Milk pasteurization is demonstrated by measuring pasteurizing time and temperature as described in Section 1.6.1. Other physical-chemical measurements, such as pressure, pH, a_w, moisture content, physical dimensions, chemical concentration are also used to assess the efficacy of a food process with respect to pathogen reduction.

Periodic microbiological testing is still needed to verify that biological hazards are being reduced or being prevented from increasing during processing as stated in Section 1.6.3.1. Mesophilic aerobic plate counts (APC) have been used by others to examine sanitation, adherence to GMPs, and shelf life (Ryser & Schuman, 2015). Coliforms and *E. coli* are historically used as indicator organisms, signaling the possible presence of a pathogen, even though studies have shown that they can be unreliable for this function (Kornacki, Gurtler, & Stawick, 2015). Pathogen testing may also be performed when processing foods that have a higher likelihood of pathogen contamination such as beef trim. Most of these processors perform N60 sampling programs for *E. coli* O157:H7 whereby 60 samples are combined, then subjected to a rapid 12 to 18 hour test (Danilson, 2011). The test results for this periodic microbiological data can be trended and statistically analyzed over time and used with multiple lots, so as to understand what the usual baseline is when processes are in control. The underlying assumption of this approach is "when a process is statistically in control, the "between-batch" variability will be small and the overall variability is termed stable" (ICMSF, 2018).

Examination of the detection rating of biological hazards during processing means that the FMEA team formally examines how effectively the current control measures detect improper processing conditions and, if the RPN and Criticality number is high, will decide if more rigorous

detection methods are needed. The team must also examine the associated microbiological testing to determine if the program's stringency matches the attendant risk.

1.6.3.4 Detecting rare events

The detection rating also brings out consideration of another phenomenon, the exceedingly rare event or "Black Swan" as introduced in section 1.5.3. These are hazards that have high severity and very low likelihood of occurrence but cannot be detected as described by an SOD rating of 10 x 1 x 10 resulting in a RPN of 100 and Criticality number of 10. While the RPN is not exceedingly high, this problem description warrants examination as to whether or not this residual risk is acceptable given the severe consequences to the customer.

1.6.4 FMEA Training Standardization and Availability

Users learn the same FMEA methodology no matter where it is offered including ASQ, Six Sigma Academy, APICS, or PMI PMBOK (Carlson C. S., 2012c) (Ericson, 2005) (Kubiak & Benbow, 2009) (Six Sigma Academy, 2002). In addition, FMEA training is readily available because it is a lean-six sigma tool and is thus offered through associations such as the American Society for Quality (ASQ) or the Association for Operations Management (APICS) and through post-secondary institutions such as the British Columbia Institute of Technology that provide operations management curricula in lean six sigma and/or continuous improvement principles. This would address some of the problems with performing the Hazard Analysis which were ascribed to a lack of guidance for industry as described in Section 1.2.6 (Wallace, Holyoak, Powell, & Dykes, 2014).

1.6.5 Use of Food-Related FMEA Research for Training

The use of FMEA as a food safety risk assessment tool has been presented by others for red pepper spice (Ozilgen, Bucak, & Ozilgen, 2013), pastry (Varzakas, 2011), corn curls (Varzakas & Arvanitoyannis, 2011), fresh-cut produce (Varzakas & Arvanitoyannis, 2009), salmon

(Arvanitoyannis & Varzakas, 2008), snails (Arvanitoyannis & Varzakas, 2010), strudel (Arvanitoyannis & Varzakas, 2007), potato chips (Arvanitoyannis & Varzakas, 2007) along with an FMEA template for food processing (Ozilgen & Ozisgen, 2017). It is, however, challenging to use the presented information as a teaching tool because the criteria for assigning the severity, occurrence and detection ratings were not bench-marked so the logic for these ratings in the example FMEA tables is not obvious. These papers also imply design changes that are needed to reduce elevated RPNs automatically reduce both occurrence and detection ratings which is not necessarily true unless the process change includes detection controls. Finally, these papers recommend using a RPN threshold for performing corrective actions rather than prioritizing corrective actions as described in Section 1.5.2 which means that some potentially hazardous conditions may remain unaddressed.

1.7 Description of other Six Sigma Tools used in this research

Other Six Sigma tools were used when performing this research as described below:

1.7.1 Run Charts

A run chart is a line graph where a process measurement is plotted against a time or sequence scale. A reference line indicating the process measurement median or mean is added after a sufficient amount of data is collected. In a random process there is a 50% probability that the next data point will be above or below the median or mean. If the process is non-random, the run chart will reveal patterns that signal this status as follows (Anhoj & Olesen, 2014):

Pattern 1. ***Shift:*** Too many consecutive points on one side of the median; 8 points in a row, 10 points on one side out of 11, 12 points out of 14 or 16 out of 20. The basis of this rule is that the length of the longest run in a sequence can be predicted within limits depending on the total number of elements in the sequence (Schilling, 2012) (Anhoj & Olesen, 2014)

Pattern 2. ***Runs:*** The average line is crossed too few or too many times as indicated by a runs test table as outlined by the Runs Test for Detecting Non-randomness (NIST/SEMATECH, 2013)

Pattern 3. ***Trend:*** On a chart with 20 to 100 points, there should be no more than six points steadily increasing or decreasing (Tague, 2005). Olmsted as cited in (Anhoj & Olesen, 2014), developed tables and formulas outlining the probability of different lengths of trends occurring based on the total number of data points.

Pattern 4. ***Astronomical Point:*** a point that is clearly different from the other points; anyone examining the chart sees that the point is different (Perla, Provost, & Murray, 2011).

The first three rules are used to objectively analyze a chart for non-random patterns based on an alpha error of $p<0.05$ whereas an astronomical point is a subjective observation (Perla, Provost, & Murray, 2011).

1.7.2 Pareto Charts

The Pareto chart is a bar chart that illustrates the relative frequency of problems in descending order thus indicating where corrective actions should be applied (Breyfogle III, 2003).

1.7.3 Cause & Effect Diagrams

A cause & effect diagram, sometimes called a fishbone diagram, graphically displays the important causes of an effect or problem. It can be used to identify the cause of a problem or help with brainstorming (Tague, 2005).

1.7.4 Defect Opportunity Checklist (DOC)

A DOC is an adaptation of a six sigma performance metric, defects per opportunity (DPO). The DPO metric is derived from identifying all the opportunities for a defect in a unit or process, then counting how many defects actually occur after the unit is built or when a process runs. (Breyfogle III, 2003). The need for a DOC is based on risk as would be indicated in an FMEA. The first step of a DOC is to analyze a process, identify the defect opportunities, then develop the checklist. The process is then observed to see how many of the potential defects actually occur and the proportion or % defect rate is calculated. The defects that occur can be categorized and plotted on a Pareto chart that can be used to identify the main focus of corrective actions. A cause

& effect diagram is also used to examine the underlying reasons for the observed defects. The DOC is repeated after the corrective actions are performed to determine whether or not they were effective.

1.8 Research Objective

The literature has reported many cases where foodborne-pathogen derived outbreaks occur because food manufactures assume that their processes adequately control the biological hazards that enable pathogen contamination of food to occur. In fact, this assumption, when it leads to a corresponding negative outcome pertaining to a breach in food safety, represents a classical type 2 error. For example, the null hypothesis that is represented in this example of practice considers that food safety protocols adequately control for biological hazards, where in actual fact they do not. The result is that foodborne outbreaks indeed do occur when food manufacturers fail to realize that their null hypothesis should be rejected. This research thesis presented herein has been designed to examine how the food industry can prevent a miscalculation that involves food pathogen contamination due to limitations in the traditional hazard analysis methodology through use of Failure Mode and Effects Analysis (FMEA).

Chapter 2. Comparison of Failure Mode and Effects Analysis with a Hazard Analysis using the Safe Food for Canadians Regulations Recommended Templates for Assessing the Risk associated with Biological Hazards on a Fresh-Cut Carrot Processing Line

2.1 Introduction

The experiments outlined in Chapters 2 (and also 3) were performed on a carrot processing line located in a fresh-cut produce plant that produces upwards of 275 different products from 92 produce inputs. This processing line, described in Section 2.1.1 following, was chosen because it is part of the produce sector. The produce sector, including fresh-cut produce plants, has been increasingly associated with foodborne outbreaks (Lynch, Tauxe, & Hedberg, 2009) to the point that the Food & Agriculture Association (FAO) specifically examined the risk of microbiological hazards in fresh fruits and vegetables in 2008 (FAO/WHO, 2008) and the United States Food & Drug Agency (FDA) enacted a specific rule for produce safety covering the growing, harvesting, packing and holding of produce under the Food Safety Modernization Act (FSMA) in (2015).

Fresh-cut produce has been defined by the International Fresh-Cut Produce Association[14] as "fruits or vegetables that have been trimmed, peeled or cut into a 100% usable product which has been packaged to offer consumers high nutrition and flavor, while still maintaining its freshness" (Jideani, Anyasi, Mchau, Udoro, & Onipe, 2017). Shelf life may be extended by packaging in an appropriate modified atmosphere and plastic package to retard the respiration rate of the produce while maintaining the appropriate sensory qualities (Caleb,

[14] Now the United Fresh Produce Association.

Mahajan, Al-Julanda Al-Said, & Opara, 2013) for a shelf life of between 9 and 12 days (Cantwell & Suslow, 2002). The test site for these experiments processes this wide variety of fresh-cut fruits and vegetables, including the carrots in this study, as either single products or in various vegetable and/or fruit combinations. A significant volume of the shredded carrots produced by the site are an ingredient in ready-to-eat prepackaged salads.

2.1.1 Carrot Process Description

Commercially grown carrots (*Daucus carota*) are generally Imperator-type hybrids because qualities such as uniform roots, deep orange colour, high yield and long storage potential are desirable (Nunez, Hartz, Suslow, McGiffen, & Natwick, 2008) (Saskatchewan Government, 2019). Carrots undergo many different processes before being shipped to fresh-cut processing plants including growing, harvesting, soil removal, storage (optional), second soil removal, washing, polishing, rinsing and packaging (Nunez, Hartz, Suslow, McGiffen, & Natwick, 2008) (Brook & Van de Vegte, 2016). The packaged carrots are then shipped to distributors, retailers and fresh-cut processors.

Figure 11 illustrates the process flow of the carrots once they arrived at the test site. Jumbo carrots were received from suppliers in 50 lb. poly bags and stored in a refrigerated warehouse until needed for production; a time period generally ranging from a few hours to several days. The carrots were then transferred to a refrigerated processing area where they were staged, then manually removed from the bags, inspected and fed into a knife peeler. Peeled carrots were then conveyed to a cutting machine which removed the tip and tail before segmenting the carrots. The segmented carrots were then conveyed through a peroxyacetic acid/hydrogen peroxide (PAA/HP) water bath set at 50-75 ppm PAA[15] for at least 1 minute, then

[15] This is the concentration recommended by the sanitizer manufacturer.

manually placed in plastic, multi-use crates. They were then transferred to a shredder and cut into smaller pieces (1/16 inch x 1/2 to 1 inch pieces) and dropped into a reusable mesh bag. The mesh bags were then placed in a centrifuge after which more peroxyacetic acid/hydrogen peroxide solution (50-75 ppm PAA) was poured through. The mesh bags of shredded carrots were centrifuged and placed into large transfer buckets where they are held until the packaging area is ready for them. The shredded carrots were then dumped onto packing tables where they were manually packaged as shredded carrots, or mixed with other fresh-cut produce. The carrots and carrot blends were then placed into plastic packaging, sealed and distributed the same day under refrigeration. The carrot-containing salad blends were sold as RTE products (ready-to-eat) with the assumption that consumers will not be rewashing the produce (Health Canada, 2019).

Figure 11. Fresh-Cut Carrot Process Flow.

2.1.2 Food Safety & Quality Points

The fresh-cut carrot processor's food safety program, the Hazard Analysis Critical Control Point (HACCP) System, meets the requirements of a Safe Food for Canadians Regulations (SFCR) preventive control plan which means the site operated monitored and verified preventive control programs as described in Section 1.2.5.3 of the Literature Review. They also performed a Hazard Analysis (HA) by which their Critical Control Points (CCPs) were determined. The site controlled the hazard associated with each CCP by monitoring the validated control measures to ensure the critical limits were met for preventing, eliminating, or reducing it to an acceptable level. Defined corrective action procedures were followed if monitoring procedures indicate the critical limits were not met and verification procedures were performed to ensure these procedures were being followed and were effective.

The site operated a Supplier Food Safety Assurance Program which required that all carrots be purchased from producers and processors that were qualified and audited by a specified company that specializes in produce to ensure they meet appropriate food safety and quality specifications. Once the carrots arrived at the plant, the receiver checked the shipment to ensure it was the correct shipment, that it was shipped under required conditions, and met specifications. If problems were found, the shipment was conditionally received and examined to see which cases could be accepted and which rejected. While first in-first out (FIFO) procedures were usually followed when drawing carrots from inventory, a lot may be drawn out of turn if it is showing signs of deteriorating quality. During processing, sub-standard carrots were graded out by the operator transferring whole carrots into the peeler and by the operators that were manually placing the peeled and segmented carrots into cases after they were conveyed through the peroxyacetic acid/hydrogen peroxide water bath. Sub-standard carrots were off-size or had bruising or excessive cracks. The refrigerated warehouse and production floors were monitored and the maintenance department was immediately notified if the temperature rose above 4°C. The quality department (Quality) verified that warehouse procedures were being followed. The grading checks were performed to ensure that the finished products met specifications. Scheduled, periodic microbiological tests including aerobic plate counts, *E. coli*, coliform, and pathogen testing were performed on finished products. The processing line was examined by Quality before start-up (pre-operational inspection), and environmental swabs were performed to ensure the effectiveness of the sanitation program.

2.2 Research Goal and experimental hypothesis:

The overarching research goal of Chapter 2 was to compare use of an FMEA with a conventional HA using SFCR recommended templates (SFCR HA) to examine the effect of the FMEA on the risk assessment of biological hazards of a fresh-cut carrot processing line. While the use of FMEA for examining the risks associated with food processing has been reported by others (Arvanitoyannis & Varzakas, 2010) (Varzakas & Arvanitoyannis, 2009) (Ozilgen & Ozisgen, 2017) (Ozilgen, Bucak, & Ozilgen, 2013), this research thesis was untaken to determine if it could provide more information as to how the ratings for severity, occurrence and detection were derived and how to prioritize corrective actions.

Given this information, the following research hypothesis was developed:

H_0: FMEA does not improve the risk assessment of biological hazards of a fresh-cut carrot processing line compared to a conventional SFCR HA.

H_1: FMEA improves the risk assessment of biological hazards of a fresh-cut carrot processing line compared to a conventional SFCR HA.

2.3 Research Objective:

Two risk assessments for biological hazards will be performed on a fresh-cut carrot processing line; one will follow the FMEA methodology while the other will follow the SFCR methodology.

The two methodologies will be compared as to how they describe the biological risk associated with fresh-cut carrot processing.

2.4 Materials and Methods

An FMEA and a conventional SFCR HA for potential biological hazards was performed on a subset of the process steps: Receiving, Storage, Peeling, Washing, Shredding, Transferring/Waiting, and Packaging of a fresh-cut carrot processing line (Figure 11). Receiving was chosen because this is where all incoming materials are first assessed to ensure the shipment is correct, meets quality specifications and has no indicators of possible food safety hazards such as elevated product temperatures, off-odours, mixed loads, product damage or deterioration, or signs of pests. Storage was evaluated because improper storage temperatures could lead to pathogen growth and there is the potential for microbial cross-contamination if correct warehousing procedures are not followed. Peeling was selected because at this step a substantial number of microorganisms are removed with the peel (Delaquis, Fresh-Cut Vegetables, 2006). Recontamination of the freshly peeled carrots is also possible if the peeler is not cleaned or maintained properly. Washing is significant because washing effects a reduction in the microbial load of the carrots (Sapers, 2001) (ICMSF, 2011) (Gil, Selma, Lopez-Galvez, & Allende, 2009). The wash water must also contain a specified concentration of sanitizer to kill suspended pathogens thereby preventing pathogen cross-contamination (Allende, Selma, Lopez-Galvez, Villaescusa, & Gil, 2008) (FDA, 2008) (Gil, Selma, Lopez-Galvez, & Allende, 2009). Shredding is important because if the shredder is not well cleaned, microorganisms will contaminate the shredded carrot surfaces possibly leading to a reduction of shelf life (Cramer M. , 2013b) or, over time, a foodborne outbreak (Beach, 2016). Transferring/waiting was evaluated because the carrots sit as Work-in-Process (WIP) for up to several hours, waiting for packaging at this point. Packaging was chosen because there is potential for recontamination of the carrots by poor employee handing practices.

The FMEA process was followed as described in Section 1.5.2. A FMEA template was partially filled in up to where the first Risk Priority and Criticality numbers were calculated. The

failure mode/causes were then prioritized for corrective actions after which a set of possible corrective actions were proposed.

The SFCR HA was performed using the three steps listed on the webpage "Conducting a Hazard Analysis"; identify all hazards, evaluate each hazard, and determine the control measures (CFIA, 2019b).

The biological failure modes or hazards[16] and associated causes for both FMEA and the SFCR HA were identified for each process step using the CFIA Reference Database for Hazard Identification (CFIA, 2013) and on-site observations including observations of in-plant practices, discussions with plant personnel and, if available, an examination of a small sampling of records related to the process step[17]. After this, a risk analysis literature review (RALR) was performed to examine the biological risks associated with fresh-cut carrot processing and to investigate the severity, likelihood of occurrence and detection of the identified failure modes or hazards and associated causes. This RALR was performed by examining peer-reviewed literature, reference texts, regulatory information and information published by produce sector associations. The CFIA "HACCP Generic Model for Ready-to-Eat Fresh-Cut Vegetables" (CFIA, 2014c) and an FSPCA "Food Safety Plan Teaching Example for a Broccoli, Carrot and Pecan Salad" (FSPCA, 2014)[18] were included in this review because these documents provide information on the guidance being provided by the CFIA and USFDA to the produce industry for controlling their biological hazards.

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[16] Biological failure mode and biological hazard are equivalent terms. FMEA uses the term failure mode while SFCR HA uses hazard.

[17] It should be noted that the on-site observations did not include a comprehensive evaluation of the various in-house monitoring and verification tests that were performed as would normally be done when performing an FMEA or SFCR HA. The results presented in Table 2 and Table 3a and b therefore provide a demonstration of an FMEA and SFCR HA and cannot be taken as the full measure of the site's food safety program.

[18] The Food Safety Preventive Controls Alliance is an American public private alliance of industry, academic and government stakeholders whose mission is to develop curriculum and training to assist companies with meeting the requirements of the Food Safety Modernization Act (FSMA) that was enacted in 2011 and gives the United States Food and Drug Administration (USFDA) more authority to regulate the food industry (FSPCA, n.d.).

In the FMEA, this information was used when following the FMEA process outlined in Section 1.5.2 of the Literature Review. A FMEA table listing the biological failure mode/causes for each process step was filled in up to the point at which the Risk Priority and Criticality Numbers were calculated from the severity (S), occurrence (O) and detection (D) ratings that were assigned using the criteria listed in Table 1 of the Literature Review. The failure mode/causes were then prioritized for corrective actions after which potential corrective actions were identified.

In the SFCR HA, this information was used when following the hazard analysis procedure recommended by CFIA (2019b). The current control measures were identified for each biological hazard and cause listed for each process step after which the significance of each hazard was evaluated using the example hazard identification and evaluation table provided by the CFIA (2018b). If the control measure was associated with a preventive control, as described in Section 1.2.5.3 of the Literature Review, then it is likely not a significant hazard because these programs are monitored and verified (CFIA, 2019b). The remaining hazards were then evaluated as to their significance as indicated by the RALR and on-site observations. If the hazard was significant, it was transferred to Table 3b to determine if the hazard was a CCP. As with the FMEA, the CFIA "HACCP Generic Model for Ready-to-Eat Fresh-Cut Vegetables" (CFIA, 2014c) and an FSPCA "Food Safety Plan Teaching Example for a Broccoli, Carrot and Pecan Salad" (FSPCA, 2014) were also examined.

A variable from the ICMSF conceptual equation was assigned to each process step to signal the effect of that step on the level of microorganism growth detected.

2.5 Results

2.5.1 FMEA

The FMEA results up to the initial RPN and Criticality number are presented in Table 2a. The logic underlying the FMEA severity, occurrence and detection ratings are found in Appendix A. The suggested prioritization of failure mode/causes for corrective actions are found in Table 2b and Table 2c describes possible corrective actions to reduce the risk associated with the prioritized hazards.

2.5.1.1 FMEA Table

The highest RPN in the FMEA Table in Table 2a was scored 400 out of a maximum of 1000 for pathogen contamination significant enough to cause illness in a consumer at *receiving* if the site purchases carrots from an unknown supply chain due to an extraordinary event. There are two RPNs of 200; at *receiving* for the same hazard when the site purchases carrots from approved suppliers and for pathogen growth sufficient enough to cause illness at *transferring/waiting*. The next highest RPN is 140 which is associated with pathogen contamination at levels that can cause illness from unsanitary equipment at *peeling, washing, shredding, transferring/waiting,* and *packaging*. The fourth highest RPN, 120, is associated with warehouse practices at *storing*, namely FIFO and storing carrots in designated areas while the fifth highest RPN, 100, is associated with pathogen contamination at higher levels than can be removed from the carrots at the *washing* step.

The RPNs for the remaining failure mode/causes were scored at 80 for pathogen contamination from improper employee hygiene practices and washing the mesh bags at *peeling, shredding, transferring/waiting and packaging*, 40 for pathogen growth because of improper refrigeration temperatures on the production floor at *transferring/waiting* and 10 for pathogen contamination because the carrots were not washed at *washing*.

The Criticality numbers ranged between 10 and 40 out of a maximum of 100. The difference in these values is due to the occurrence rating which ranged between 1 and 4 because severity is always a 10 for biological hazards as described in Appendix A.

Four failure mode/causes had detection ratings of 10 indicating that the hazard would not be detected should it occur; two of these hazards were at *receiving*, one at *washing* and one at *transferring/waiting*. The detection rating related to unsanitary equipment was a 7 and the detection ratings associated with warehouse practices were 6. The remaining 14 failure mode/causes had detection ratings between 1 and 4.

2.5.1.2 *Prioritization of Failure Mode/Causes for Further Corrective Actions*

The major determinant of prioritization in this experiment was the RPN because biological hazards have high, unalterable severity ratings. The hazard with the highest RPN and Criticality number was associated with purchasing carrots when the usual supply chain was interrupted because of an extraordinary event because there will not be enough information about compliance to FAO/WHO requirements for producing and processing produce (FAO/WHO, 2008). It is also not possible to detect this hazard if it is present. The rest of the prioritized hazards had an occurrence rating of just 1 or 2 but the RPNs were elevated because they either cannot be detected, or the current detection controls do not provide sufficient assurance that the hazard is not occurring.

2.5.1.3 *Possible Corrective Actions to Reduce the Risk Associated with Prioritized Failure Mode/Causes*

Possible corrective actions are presented for the prioritized hazards in Table 2c; they are provided as examples only as other corrective actions may make sense for other sites. As discussed in Section 1.5.2, the most effective corrective actions are design changes that reduce the occurrence rating of the hazard because just improving detection means that the hazard will still occur albeit it may now be detected before the defective product is shipped to a customer.

For this reason, one suggested corrective action for the highest priority hazard, purchasing carrots during an extraordinary event, is to design and execute a plan for developing alternate supply chains and associated approved suppliers so as to reduce the risk to that associated with the current supply chain. The likelihood of this hazard occurring, however, would also be greatly reduced if there was a method by which pathogens could be reliably detected in the incoming carrots. This detection control would also greatly reduce the likelihood of biological

hazards during *receiving* and *washing*. Chapter 3 of this thesis explores a possible detection control. The suggested corrective action for the hazard associated with *transferring/waiting* is to design a method by which operators can see the order in which the transfer buckets of carrots should be used while simultaneously visualizing if they are being used out of order. The suggested corrective actions for hazards related to unsanitary equipment and warehouse practices are not as prescriptive because these are complex processes and more knowledge of the whole operation is needed before changes can be made. Chapter 4 of this thesis examines the site's sanitation program in more detail. Finally, the possible corrective actions at *washing* includes investigating the status of other methods that are being designed to reduce the pathogen level on carrots and other produce. Possible solutions include use of electrolyzed water, ultrasonic processing, irradiation, ultraviolet light treatment, ultrasound, cold plasma technology or gaseous chlorine dioxide (Siddiqui, 2018).

Table 2a. Partial FMEA table for the Biological Failure Mode/Causes at the Receiving, Storing, Washing, Peeling, Shredding, Transferring/Waiting and Packaging Process Steps of a Fresh-cut Carrot Processing Line (Corrective Actions and updated SOD and RPN/Criticality columns not included for table clarity).

Item (Process Step)	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Criticality
Receiving (H_0)	To ensure correct shipment received and that quality and food safety specifications have been met.	Contamination with pathogens Norovirus or *Salmonella* spp. (for example)	Illness or death of a consumer	10	Contamination during primary production, processing or distribution significant enough to cause illness in consumers.	2	Supplier Food Safety Assurance Program (SQA) in place. Carrots purchased from approved, audited suppliers including producers and packing facilities/processors. Receiver inspects truck and does not accept product from unapproved suppliers or product that does not meet product specifications. No feasible detection controls identified.	10	200	20
				10	Approved supply chain not available because of an extraordinary event like crop failure, extreme weather, earthquake, or similar.	4	Current process controls not effective because approved suppliers unavailable. No detection controls in place for this hazard.	10	400	40
		Growth of pathogens		10	Time/temperature abuse because truck reefer not turned on or malfunctioning.	2	Receivers measure the temperature of the incoming load to ensure ≤4°C. Trucking companies have been approved through the SQA program. Trucks have dataloggers recording distribution temperature throughout the trip.	2	40	20
Storing (*I*)	Refrigerated storage (≤4°C) to maintain quality and prevent growth of microorganisms including pathogens.	Pathogen growth	Illness or death of a consumer	10	Time/temperature abuse because of faulty equipment or from power failure.	2	The refrigeration system is maintained by the maintenance department. Warehouse temperature continuously monitored and alarmed. If temperature >4°C, then maintenance is alerted. A set of planned procedures are then followed.	2	40	20
				10	Time/temperature abuse because First in-First out (FIFO) is not followed.	2	Forklift drivers trained to follow FIFO. Daily monitoring of warehouse procedures by Quality.	6	120	20
		Pathogen contamination from cross-contact with other produce		10	Carrots stored in designated areas.	2	Forklift drivers trained. Daily monitoring of cooler storage conditions by Quality.	6	120	20

Item (Process Step)	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Criticality
Peeling (*R*)	To peel the carrots before further processing.	Contamination with pathogens	Illness or death of a customer	10	Carrot peeler malfunctions and leaves some carrot peel on carrots resulting in excessively high microbial numbers on peeled carrots.	2	The operators that handle the carrots after peeling grade out improperly peeled carrots and have maintenance correct problems with peeler equipment settings.	3	60	20
				10	Sub-standard carrots not graded out.	2	Operators trained to grade out substandard carrots. Every carrot evaluated as it is manually placed in the peeler. The line speed is set to facilitate this process. Quality monitors this aspect at specified intervals.	3	60	20
				10	Unsanitary equipment.	2	Sanitation SOPs are in place. The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.	7	140	20
				10	Improper employee hygiene and/or handling practices.	2	Employees wear company-supplied gear and are trained to follow good hygiene and handling practices. Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.	4	80	20
Washing (*R*)	To remove pathogens from the carrot surface and to inactivate pathogens that are released into the water.	Insufficient pathogen removal	Illness or death of a customer	10	Carrots not washed.	1	Carrot process is designed to convey carrots through washer. Dwell time is set for one minute and is confirmed daily.	1	10	10
		Cross-contamination with pathogens		10	Low concentration of PAA means pathogens removed from the carrots not inactivated so live organisms may redeposit back onto carrots.	2	Operators are trained to put the correct amount of water and PAA in the wash tank. Written procedures are also in place. The PAA concentration is monitored by operators at scheduled intervals. If the sanitizer is out of range, the level is adjusted and all produce that has been washed since the last check is rewashed. Quality confirms the PAA concentrations are correct.	4	80	20

Item (Process Step)	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Criticality
				10	Excessively high load of microorganisms or inaccessible microorganisms because of problems during primary production, processing or distribution leading to insufficient numbers of pathogens removed during washing.	1	No detection controls in place for this cause.	10	100	10
				10	Unsanitary equipment because wash water not changed each day and carrot washer cleaned and sanitized.	2	Sanitation SOPs are in place. The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.	7	140	20
Shredding (*I*)	To cut the carrot into smaller pieces for use in salads	Contamination with pathogens	Illness or death of a consumer	10	Unsanitary equipment.	2	Sanitation SOPs are in place. The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.	7	140	20
				10	Improper employee hygiene and/or handling practices.	2	Employees wear company-supplied gear and are trained to follow good hygiene and handling practices. Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.	4	80	20
Transferring /Waiting (*I*)	Mesh bags containing shredded carrots are placed in plastic transfer buckets and moved to packaging area. They sit as WIP	Contamination with pathogens	Illness or death of a consumer	10	Unsanitary equipment (transfer buckets).	2	Sanitation SOPs are in place. The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.	7	140	20
				10	Contaminated mesh bags.	2	Mesh bags washed by trained, designated people following validated procedures. Bags are placed in dips monitored by production to ensure they have	4	80	20

Item (Process Step)	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Criticality
	until packaged.						the correct concentration of sanitizer.			
				10	Improper employee hygiene and/or handling practices.	2	Employees wear company-supplied gear and are trained to follow good hygiene and handling practices. Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.	4	80	20
		Pathogen growth because of extended time sitting before packaging		10	FIFO not being followed for waiting carrots.	2	The processing area is a monitored, refrigerated environment. Employees place the transfer buckets in a prescribed order while they waiting for packaging. Packaging employees draw carrots for packaging in correct order. No detection control in place to confirm FIFO is being followed.	10	200	20
				10	Time/temperature abuse because of faulty equipment or from power failure.	2	Production floor temperature continuously monitored and alarmed. If temperature >4°C, then maintenance is alerted. A set of planned procedures are then followed.	2	40	20
Packaging (*I*)	Carrots manually placed in a in a package and manually sealed closed and coded with best before date.	Contamination with pathogens	Illness or death of a consumer	10	Improper employee hygiene and/or handling practices.	2	Employees wear company-supplied gear and are trained to follow good hygiene and handling practices. Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.	5	100	20
				10	Pathogens enter package because not sealed properly.	3	Sealing equipment is maintained to work correctly. Each package is checked by the operator to make sure it is sealed properly. Quality periodically checks the	2	60	30

Item (Process Step)	Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Detection	RPN	Criticality
							packaging operation throughout the day.			
				10	Unsanitary equipment (transfer buckets).	2	Sanitation SOPs are in place. The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.	7	140	20
		Pathogen growth		10	Incorrect or illegible best before date applied to package which results in the consumer keeping the package for too long.	2	The best before date is set on dating machine by quality before start-up each day. The operators ensure the date is legible when applying the best before date sticker. Quality periodically checks the packaging operation throughout the day.	2	40	20

Table 2b. Suggested Prioritization of Biological Failure Mode/Causes for Corrective Actions on a Fresh-Cut Carrot Processing Line.

Priority	Process Step(s)	Failure Mode/Cause	S	O	D	RPN	Criti-cality	Comment
1	Receiving	Pathogen contamination because approved supply chain not available because of an extraordinary event like crop failure, extreme weather, earthquake, or similar.	10	4	10	400	40	Highest RPN. Hazard not detected should it occur.
2	Receiving	Pathogen contamination because of contamination during primary production, processing or distribution significant enough to cause illness in consumers.	10	2	10	200	20	2nd highest RPN. Hazard not detected should it occur.
2	Transferring/ Waiting	Pathogen growth because FIFO not being followed for waiting carrots.	10	2	10	200	20	2nd highest RPN. Hazard not detected should it occur.
3	Peeling, Washing, Shredding, Transferring/ Waiting, Packaging	Pathogen contamination because of unsanitary equipment.	10	2	7	140	20	3rd highest RPN. Affects many process steps.
4	Storing	Pathogen growth because of time/temperature abuse because FIFO is not followed.	10	2	6	120	20	4th highest RPN.
4	Storing	Pathogen contamination from cross-contact with other produce.	10	2	6	120	20	4th highest RPN.
5	Washing	Pathogen contamination because of excessively high load of microorganisms or inaccessible microorganisms because of problems during primary production, processing or distribution leading to insufficient numbers of pathogens removed during washing.	10	1	10	100	10	5th highest RPN. Hazard not detected should it occur.

Table 2c. Possible Corrective Actions to reduce the risk associated with prioritized Failure Mode/Causes on a Fresh-Cut Carrot Processing Line.

Priority	Process Step(s)	Failure Mode/Cause[1]	Before Corrective Action					Possible Corrective Actions	After Corrective Action				
			S	O	D	RPN	Cr[2]		S	O	D	RPN	Cr[2]
1	Receiving	Pathogen contamination because carrots from the usual supply chain cannot be purchased because of an extraordinary event like crop failure, extreme weather, earthquake, or similar.	10	4	10	400	40	Create and test a plan for managing extraordinary events. Develop alternate supply chains and ensure these suppliers demonstrate compliance to FAO/WHO produce recommendations. Investigate test methods that have the potential to signal that the incoming carrots may be contaminated. *This is further examined in Chapter 3*	10 10	2 ?	10 ?	200 ?	20 ?[3]
2	Receiving	Pathogen contamination because of contamination during primary production, processing or distribution significant enough to cause illness in consumers.	10	2	10	200	20	Investigate test methods that have the potential to signal that the incoming carrots may be contaminated. *This is further examined in Chapter 3.*	10	?	?	?	?[3]
2	Transferring/ Waiting	Pathogen growth because FIFO not being followed for waiting carrots.	10	2	10	200	20	Set up a visual method that indicates the order in which the waiting carrots are packaged.	10	1	3	30	10
3	Peeling, Washing, Shredding, Transferring/ Waiting, Packaging	Pathogen contamination because of unsanitary equipment.	10	2	7	140	20	Determine if sanitation program is meeting Best Practices. Make improvements as indicated. *This is further examined in Chapter 4.*	10	?	?	?	?[3]
4	Storing	Pathogen growth because of time/temperature abuse because FIFO is not followed.	10	2	6	120	20	Examine warehouse operations to determine if warehouse Best Practices are being met. Make improvements as needed.	10	?	?	?	?[3]
4	Storing	Pathogen contamination from cross-contact with other produce.	10	2	6	120	20	Examine warehouse operations to determine if warehouse Best Practices are being met. Make improvements as indicated.	10	?	?	?	?[3]
5	Washing	Pathogen contamination because of excessively high load of microorganisms or inaccessible microorganisms because of problems during primary production, processing or distribution leading to insufficient numbers of pathogens removed during washing.	10	1	10	100	10	Investigate the latest research into other methods for reducing pathogen contamination on produce. Investigate test methods that have the potential to signal that the incoming carrots may be contaminated. *This is further examined in Chapter 3*	10	?	?	?	?[3]

[1]Failure mode/causes are called hazards in a conventional Hazard Analysis

[2]Criticality

[3]More information is needed before new O, and D ratings and resulting RPN and Criticality numbers can be approximated.

2.5.2 SFCR HA

The SFCR hazard identification and evaluation results are presented in Table 3a while Appendix B contains the logic underlying the significance of the listed hazards. The SFCR Critical Control Point Determination Table in Table 3b indicates which of the significant hazards were determined to be a Critical Control Point (CCP).

2.5.2.1 SFCR Hazard Identification and Evaluation Table

Two of the hazards in Table 3a were considered significant; buying carrots from an unknown supply chain at *receiving* because of an extraordinary event and insufficient PAA in the wash water at w*ashing*. The other hazards were considered insignificant because they were being controlled through preventive control programs as outlined in Section 1.2.5.3 of the Literature Review.

2.5.2.2 SFCR Critical Control Point Determination Table

When the two significant hazards were examined through use of the Decision Tree embedded in Table 3b, it was determined that ensuring the carrots are washed in 50 – 75 ppm PAA sanitizer is a critical control point (CCP) because this activity prevents cross-contamination of pathogens onto the carrots at *washing* and there is also no subsequent step that will mitigate this hazard. The table also indicated that control measures were needed to control the heightened risk of pathogen contamination when the usual carrot supply chain is unavailable because of unusual events. The suggested control measures are a CCP because, again, no subsequent step will adequately reduce pathogens.

Table 3a. SFCR Hazard Identification and Evaluation Table for the Biological Hazards at Receiving, Storing, Washing, Peeling, Shredding, Transferring/Waiting and Packaging Process Steps of a Fresh-cut Carrot Processing Line.

Input, Process Step or Cross-Contamination Point	Hazard and Cause	Control Measure	Is the Hazard Significant?	Justification
Receiving (H_0)	Pathogen contamination significant enough to cause illness in consumers because of contamination during primary production, processing or distribution. Norovirus, *Salmonella* spp. (for example)	Supplier Food Safety Assurance (SQA) Program in place so produce purchased from approved suppliers. Receiving Standard Operation Procedure (SOP) in place.	No	Carrots that have been purchased from an approved, audited producer and packing facility/processor have an extremely rare chance of being contaminated with pathogens. The receiver inspects truck and does not accept products from unapproved suppliers or product that does not meet specifications.
	Pathogen contamination because approved supply chain not available because of an extraordinary event like crop failure, extreme weather, earthquake, or similar.	No control measures currently in place for this scenario.	Yes	Carrots that are purchased from unapproved supply chain may contain pathogen levels sufficient to cause illness in customers because it has not been demonstrated that the suppliers meet FAO/WHO produce standards.
	Pathogen growth because of time/temperature abuse.	SQA Program and Receiving SOP in place.	No	Receivers check the temperature of the incoming carrots. Trucking companies have been approved through the SQA program. They also have data loggers recording the temperatures throughout the trip.
Storing (*I*)	Pathogen growth because of time/temperature abuse due to faulty equipment or from power failure.	Warehouse SOP in place. Warehouse temperature continuously monitored and alarmed if they increase to >4°C.	No	If temperatures are too warm, maintenance is alerted by test and a set of planned procedures are then followed.
	Pathogen contamination because FIFO not being followed.	Carrots are placed in the warehouse in a manner that facilitates stock rotation as described in the Warehouse SOP.	No	If carrots are left in the cooler too long, pathogens may have enough time to grow to levels higher than subsequent processes are designed for. Daily monitoring of warehouse conditions by Quality.
	Pathogen contamination from cross-contact with other produce.	Carrots stored in designated areas as described in the Warehouse SOP.	No	Forklift drivers trained. Daily monitoring of warehouse conditions by Quality.
Peeling (*R*)	Pathogen contamination of carrots because of faulty peeling thus causing excessively high microbial numbers on peeled carrots.	The peeler is maintained by the maintenance program. Operators cull improperly peeled carrots after the carrots are washed.	No	The operators that handle carrots after peeling grade out improperly peeled carrots and have maintenance correct problems with peeler equipment settings. The production line speed is set such that this step is facilitated.

Input, Process Step or Cross-Contamination Point	Hazard and Cause	Control Measure	Is the Hazard Significant?	Justification
	Pathogen contamination because not all sub-standard carrots graded out.	Every carrot is evaluated as it is manually placed in the peeler as outlined in the SOP related to this process.	No	The peeler operator is trained to perform this activity. The line speed is set up to facilitate this process. Quality monitors this aspect at specified intervals.
	Pathogen contamination from unsanitary equipment.	Sanitation program SOP in place – the peeler undergoes a full sanitation procedure each day.	No	The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.
	Pathogen contamination because of improper employee hygiene and/or handling practices	Employee Training & Retraining SOP in place. Monitoring procedures in place.	No	Employees are trained to follow good hygiene and handling practices. Employees wear full gear provided by the company and Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.
Washing (*R*)	Pathogen contamination because produce not washed.	All carrots are conveyed through wash water for one minute.	No	The processing line is designed to convey the carrots through the washer and the dwell time is set.
	Pathogen recontamination because wash water has a low PAA concentration.	Operators are trained to put the correct amount of water and PAA in the wash tank. Written procedures are also in place. Operators also monitor the PAA concentration of the wash water. Quality confirms that the concentration is correct. The dwell time is confirmed daily.	Yes	It is important to ensure the correct PAA concentration is met because otherwise pathogens that are removed from the produce may not be inactivated and be a source of cross-contamination back onto carrots thus causing illness in consumers because pathogens are present in the final product
	Excessively high load of microorganisms or inaccessible microorganisms because of problems during primary production, processing or distribution or mishandling at processor leading to insufficient numbers of pathogens removed during washing.	A Supplier Food Safety Assurance Program is in place. Receiving Standard Operation Procedure (SOP) in place. Carrots are culled if not peeled properly.	No	Carrots have low likelihood of causing illness if carrots are purchased through qualified and audited suppliers and if receivers ensure the carrots have come from these approved sources and the truck and shipment are inspected to ensure they meet specifications.
	Pathogen contamination from unsanitary equipment.	Sanitation program SOP in place – the carrot wash water is discarded each day and the carrot washer undergoes a full sanitation procedure.	No	The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.

Input, Process Step or Cross-Contamination Point	Hazard and Cause	Control Measure	Is the Hazard Significant?	Justification
Shredding (*I*)	Pathogen contamination from unsanitary equipment.	Sanitation program SOP in place – the shredder undergoes a full sanitation procedure each day.	No	The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.
	Pathogen contamination because of improper employee hygiene and/or handling practices	Employee Training & Retraining SOP in place. Monitoring procedures in place.	No	Employees are trained to follow good hygiene and handling practices. Employees wear full gear provided by the company and Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.
Transferring/Waiting (*I*)	Pathogen contamination from unsanitary equipment.	Sanitation program SOP in place – the transfer buckets undergo a full sanitation procedure each day.	No	The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.
	Pathogen contamination because of contaminated mesh bags.	Mesh bags underdo a full sanitation procedure each day. Bags are sanitized in sanitizer dips before use.	No	Mesh bags washed by trained, designated people following validated procedures. Bags are placed in dips monitored by production to ensure they have the correct concentration of sanitizer.
	Pathogen contamination because of improper employee hygiene and/or handling practices	Employee Training & Retraining SOP in place. Monitoring procedures in place.	No	Employees are trained to follow good hygiene and handling practices. Employees wear full gear provided by the company and Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.
	Pathogen growth because of extended time sitting before packaging.	Refrigerated processing environment. Employees place the transfer buckets in a prescribed order waiting for packaging. FIFO is followed when moving the transfer buckets to the packaging area.	No	Pathogen growth rate is controlled by the monitored, refrigerated environment. Employees receive specific training in managing this WIP.
	Pathogen growth because of time/temperature abuse due to faulty	Processing floor temperature continuously monitored and alarmed if they increase to >4°C.	No	If temperatures are too warm, maintenance is alerted by test and a set of planned procedures are then followed.

Input, Process Step or Cross-Contamination Point	Hazard and Cause	Control Measure	Is the Hazard Significant?	Justification
	equipment or from power failure.			
Packaging (*I*)	Pathogen contamination because of improper employee hygiene and/or handling practices	Employee Training & Retraining SOP in place. Monitoring procedures in place.	No	Employees are trained to follow good hygiene and handling practices. Employees wear full gear provided by the company and Handwashing is observed by supervisors because handwashing next to production office. Soap usage is monitored. Glove dips located next to peeling station. Glove dips monitored by production to ensure sanitizer concentration correct. Lead hands monitor practices on the production floor.
	Pathogen contamination from unsanitary equipment.	Sanitation program SOP in place – the transfer buckets undergo a full sanitation procedure each day.	No	The sanitation program is assessed by monitoring sanitizer chemical strengths and verifying the program through pre-operational inspections and environmental sampling program.
	Pathogen contamination because of improperly sealed package.	Sealing equipment is maintained to work correctly. Each package is checked by the operator to make sure it is sealed properly.	No	There is a preventive maintenance program that includes this equipment and an employee training program in place that includes training to this activity.
	Pathogen growth because of incorrect or illegible best before date applied to package.	Best before date is set up on dating machine by Quality before start up. The operators ensure the date is applied to each package and the date is legible.	No	There is an employee training program in place that includes training to this activity. Quality periodically checks the packaging operation throughout the day.

Table 3b. SFCR Critical Control Point Determination Table.

Process Step	Significant Hazards	Q1. Do control measures for this hazard exist at this step? If yes, proceed to Q2.	Q2. Is this step specifically designed to prevent or eliminate the hazard or reduce it to an acceptable level? If yes, this is a CCP. Proceed to the last column. If no, proceed to Q3.	Q3. Would a subsequent step eliminate the hazard or reduce it to an acceptable level? If yes, this step is not a CCP. Identify the subsequent step where the hazard would be controlled. If no, this step is a CCP and must be designed to control the hazard. Go to last column.	CCP Number
Receiving	Pathogen contamination because normal supply chain not available because of crop failure, weather, earthquake, or similar.	No. *Control measures need to be developed because this is a significant hazard.* Possible Control Measures: Create and test a plan for managing extraordinary events. Develop alternate supply chains and ensure these suppliers demonstrate compliance to FAO/WHO produce recommendations.	Yes		CCP 1 B
Washing	Pathogen contamination because wash water has insufficient PAA concentration.	Yes. Washing all carrots in 50-75 ppm PAA/HP sanitizer solution for one minute.	Yes	-	CCP 2 B

2.6 Discussion

The FMEA and the SFCR HA both indicate that there is substantive risk associated with purchasing carrots from an unknown supply chain during extraordinary circumstances. Interestingly, neither the CFIA generic model for produce nor the FSPCA example preventive control plan for salad listed this high risk hazard (CFIA, 2014c) (FSPCA, 2014).

These two methodologies, however, evaluate the risk associated with the rest of the biological hazards of a fresh-cut carrot processing line very differently.

The SFCR HA suggests that the risk of pathogens being present in the raw carrots is mitigated if the carrots are purchased from qualified suppliers, peeled, washed in wash water containing a specified concentration of sanitizer as managed through a CCP, and properly handled throughout processing by the application of preventive controls. The CFIA generic model for produce and the FSPCA example preventive control plan for salad concur with this description except that the CFIA generic model proposes that the risk associated with produce suppliers may be mitigated by educating the farmers about GAPs (CFIA, 2014c) (FSPCA, 2014).

FMEA reveals that, while the likelihood of occurrence of pathogens in incoming carrots from qualified suppliers at *receiving* is very rare, no detection controls have been identified that can detect this hazard, should it occur. Moreover, if contaminated carrots were received, there are currently no detection controls that would indicate that the washing step sufficiently reduced the pathogen numbers on the incoming carrots to levels that are safe to eat.

The risk associated with the fresh-cut carrot process as evaluated by the FMEA is validated by the information contained in "Receiving" under "Occurrence" in Appendix A which indicates that while produce outbreaks are extremely rare given the amount of produce being

eaten each year in Canada, they still occur without warning because there are no obvious signs that the produce is contaminated. The *E. coli* O157:H7 outbreak in romaine lettuce that occurred in the United States (U.S.) and Canada between October 5 and November 16, 2018 corroborates this observation. This outbreak, identified through epidemiological evidence, caused 44 illnesses in both countries. Because the source of the outbreak was initially unknown, the CDC issued a country-wide warning advising the public to stop consuming romaine lettuce in the U.S. while the Public Health Agency of Canada (PHAC) issued a similar warning to three provinces (CDC, 2018) (PHAC, 2019) thus impacting much of the produce supply chain in North America for several weeks. This is an example of a "Black Swan" event as described in Section 1.5.3.

The more accurate FMEA risk evaluation is a direct result of assigning 1 to 10 ratings for severity, occurrence and detection because the team must perform a literature review and in-depth investigations of in-plant practices before a rating is assigned. This provides a more nuanced understanding of the risk than that gained by assigning a yes or no answer for hazard significance with little consideration of detection in the SFCR HA.

SFCR HA and FMEA both require an examination of corrective actions by which to reduce the risk associated with purchasing carrots during an extraordinary event. The FMEA, in contrast, also requires a set of corrective actions to reduce the risk associated with the incoming carrots, washing, transferring/waiting, washing, and the sanitation program and warehouse operations. The FMEA therefore promotes risk reduction throughout the entire fresh-cut carrot process as demonstrated by the lower S, O, D, ratings and resulting RPN and Criticality number.

The FMEA also provides a better understanding of the residual risk associated with each hazard as indicated by the RPN while the SFCR HA indicates that the only residual risk is associated with purchasing carrots from an unknown supply chain.

2.7 Conclusion

This experiment showed that the FMEA provided a more accurate risk assessment of the biological hazards of a fresh-cut carrot processing line than the SFCR HA. This conclusion was made because data shows that foodborne outbreaks will very rarely occur in fresh-cut carrots even when purchased from approved suppliers because it is not possible to detect when the H_0 for pathogens is elevated in incoming carrots such that the processes designed to reduce pathogens, including peeling and washing, cannot reduce the pathogen load to a level that is safe to consume. This conclusion is supported by a previous studies that showed produce-related outbreaks continue to occur (Murray, Wu, Shi, Xue, & Warriner, 2017) (Lynch, Tauxe, & Hedberg, 2009) to the point that the United States has enacted the Produce Safety Rule within the FDA Food Safety Modernization Act (FSMA) to help prevent future produce-related outbreaks (FDA, 2018).

The SFCR HA, in contrast, indicates that purchasing carrots from approved suppliers and washing carrots will effectively reduce the number of pathogens on the carrots to levels not capable of causing illness.

The SFCR HA risk assessment therefore leads fresh-cut produce manufacturers to believe they are not at risk of a foodborne outbreak and, thus, do not need to examine other methods for reducing the likelihood of a foodborne outbreak. The FMEA does not lead a processor to such complacency because the FMEA compels the processor to perform continuous improvement through further corrective actions to reduce the likelihood of occurrence to even lower than "extremely rare". The success of these corrective actions are also captured by the FMEA; if the RPN is not substantively reduced through the improved S. O and D ratings, the residual risk will high which means the chance of an occasional foodborne outbreaks remains. If this residual risk is still unacceptable, this provides an impetus to the company to examine other risk reduction

measures; in this way FMEA also has the potential to drive innovative research to reduce this residual risk in produce.

Chapter 3. Investigation of a Run Chart for Detecting Changes in the Microbiological Status of a Fresh-Cut Carrot Processing Line.

3.1 Introduction

Chapter 2 described use of FMEA to assess the risk associated with the biological hazards of a fresh-cut carrot processing line wherein it became evident that much of the risk was due to the lack of a method for detecting pathogens in incoming carrots as described by an SOD rating of 10 x 1 x 10 for an RPN of 100. This means that there will be occasional foodborne outbreaks that are solely detected through epidemiological evidence with significant consequences for the people that became ill and the entire produce supply chain as described in Section 2.6; this is a "Black Swan" event.

While the carrots undergo process steps such as peeling and washing that will reduce the microbial load in the carrots, the ICMSF states that "these treatments cannot ensure the elimination of pathogenic microorganisms" (ICMSF, 2011). The ICMSF also states that using routine microbiological testing for determining if incoming produce is safe, i.e. meets H_0, at receiving in a fresh-cut carrot processing plant, is not feasible because of the perishability of produce and low frequency of contamination. The United Fresh Produce Association concurs with this observation (UFPA, 2014).

Targeted microbiological sampling, however, is recommended to verify that pathogen reduction control measures are working and that the sanitation program is effectively removing potential cross contamination from the plant environment (ICMSF, 2018). The microbiological tests suggested by the ICMSF for fresh-cut produce facilities include periodic tests of: paired samples such as before and after washing; food contact surfaces; and the processing environment for aerobic plate counts (APC) and *E.coli*. In addition periodic testing of the finished product for

an indicator organism, such as *E. coli* to verify process control and for trend analysis is also recommended (ICMSF, 2011).

A few produce processors have implemented substantive pathogen test-and-hold programs even though this approach is not recommended by the ICMSF. At one processor these procedures involve breaking larger lots into smaller units, compositing 60 samples from each unit into one sample, and performing a 12 hour polymerase chain reaction (PCR) test for *E. coli* O157:H7, non-O157 enterohemorrhagic *E. coli* (EHEC), *Salmonella*, and *Shigella*. The sampling rate is every 2000 lbs. for incoming produce and every two hours from every packaging line after which nothing is released for further processing or sale until the 12 hour test indicates the results are negative (Daniels, 2014). During the first 10 ½ months of performing this testing, 58/76,000 lots or 0.08% tested positive for pathogens and cost millions of dollars to implement (Cone, 2007).

3.2 Research Goal and experimental hypothesis:

Even though this information indicates that identifying contaminated shipments of carrots may not be practical, it would still be useful to explore methods that could potentially point to a change in the microbiological status of the incoming carrots thus signaling a possible change in the carrot H_0. The purpose of this experiment was therefore to investigate whether or not changes in the microbiological status of a fresh-cut carrot processing line can be detected by trending the mesophilic aerobic plate count (APC) and *E. coli* microbiological results on a run chart, a six sigma tool described in Section 1.7.1. In this experiment, APC and *E. coli* counts were chosen for the microbiological status assessment of processed carrots. The APC count is useful because of its utility for assessing sanitation and compliance to GMPs and because of its potential usefulness in signaling a change in processing conditions earlier in the produce supply chain (UFPA, 2014) (ICMSF, 2011). *E. coli* was chosen because, as discussed above, the ICMSF suggests using this test in fresh-cut

produce plants for process control verification and trend analysis. In this experiment, the test site uses 3M coliform/*E. coli* Petrifilm so both coliforms and *E. coli* were enumerated.

With this background information in mind, the following hypothesis was constructed:

Ho: trending of periodic microbiological data using run charts fail to signal a change in the microbiological status of fresh-cut carrots.

H1: trending of periodic microbiological data using run charts signals a change in the microbiological status of fresh-cut carrots.

3.3. Research Objective

The research objective of Chapter 3 was designed to determine if use of a Run Chart could detect a change in the microbiological status of fresh-cut carrots. In addition, an attempt was made to identify the factors affecting APC and coliform data collected from major sampling points, Raw Carrot, Carrot Peels, Peeled & Washed Carrots and Shredded Carrots. To this end, the effect of the sample location and the lot number on the APC and coliform counts of the carrot fresh cut processing line was assessed.

3.4 Materials and Methods:

3.4.1 Materials:

This experiment was performed on the same fresh-cut carrot processing plant as that described in Section 2.1.1 of Chapter 2.

3.4.1.1 Experiment A

Carrots from California, British Columbia, Ontario, Manitoba, Quebec and Mexico were sampled 57, 21, 17, 3, 3, and 2 times respectively for a total of 105 times, which was equivalent to about three times a week from four different locations on the carrot processing line. All

geographical locations were included in the trend analysis charts; with the exception of Quebec, Manitoba and Mexico, which were excluded from the one-way ANOVA because of insufficient data. The four carrot sampling points used in the analysis were raw carrots from the 50 lb. bag as delivered from the carrot supplier, carrot peels from the discard tubs below the peeler; peeled and washed carrots; and shredded carrots. Carrot wash water was also sampled 83 times over the same time period. The logic for these sample sites were; the carrots from the 50 lb. bag will have microbiological counts reflecting the activities of the carrot supply chain, the wash water can be a source of microbial contamination if the sanitizer level is not maintained, carrot peel contains most of the microorganisms on the carrot, and shredding because this was the usual microbiological sampling point for the site and the results reflect both the microbiological status of the supply chain and the site's hygiene, washing and sanitation programs.

3.4.1.2 Experiment B

Ten lots of British Columbia (BC) carrots were sampled 13 times over two months from four sample locations: raw carrots, carrot peels, peeled & washed carrots and shredded carrots. Each sample location was sampled 5 times (n=5) and plated in triplicate for APC for a total of 60 observations per lot except for lots 3, 6 and 7 which were sampled over two days for a total of 120 observations.

3.4.2 Methods:

3.4.2.1 Microbial Analyses

All samples were plated for APC using Acumedia Nutrient Agar pour plates. Coliforms and *E. coli* were enumerated using 3M *E. coli*/Coliform Petrifilm plates which use violet red bile agar as a selective media where *E. coli* presents blue colonies with gas production and other coliforms are red with gas production. Colonies that did not display these characteristics were counted and classified as "atypical" and were not included in the coliform count. The plates were

incubated at 35°C for 48 and 24 hours respectively. The raw carrots were swabbed with a cotton swab over a 2 x 10 cm area mid-point along the length of the carrot, vortexed into 5 ml of 0.1% of peptone diluent for 10 seconds, then diluted by 10^{-2} for *E.coli*/Coliform and 10^{-3} for APC, then plated. Approximately 100 grams of peel was sampled of which about 25 grams were diluted by 10^{-3} for E.coli/coliform and 10^{-4} for APC respectively into 0.1% peptone water, then plated. Peeled, cut and washed carrots were swabbed with a cotton swab over the length of the carrot, 10 cm x approximately 3-5 cm depending on the contour of the carrot, then vortexed in 5 ml of 0.1% of peptone water for 10 seconds, after which 1 ml was plated for *E.coli*/Coliform and APC. Approximately 300 to 500 grams of shredded carrots were sampled from which 10 to 25 grams sampled and diluted by approximately 10^{-1} in 0.1% peptone water, then 1 ml was plated for *E.coli*/Coliform and APC. About 250 ml of carrot wash water was sampled and 1 ml each were plated for each media. The microbial counts were normalized to $\log_{10}$ for data analysis except for the wash water which was reported as CFU/ml. When the microbiological plates did not have any colonies, the count was estimated to be the log of the reciprocal of the dilution rate for the sample. In Experiment A, the *E. coli*/Coliform media was plated as singlets and the APC media was plated in duplicate for each sample. Counts were estimated when the APC plates were above the countable range using the enumeration rules in the Compendium of Methods for the Microbiological Examination of Foods (Petran, Grieme, & Foong-Cunningham, 2015) and 3M rules were followed when the *E. coli*/coliform plates were crowded (3M, 2017). In Experiment B, the APC media was plated in triplicate and the Raw Carrots and Peeled & Washed Carrots results were transformed to APC/g by multiplying APC/cm^2 by the surface area of the carrot sample and dividing by the sample weight.

3.4.2.2 *Statistical Analysis*

The data were transferred to Run Charts that were set up using Microsoft Excel (Microsoft Office Professional Plus, 2013; Redmond WA, USA) to examine if non-random patterns existed in the data. Log10 CFU/g counts were plotted against a horizontal sequence scale where data was plotted in time order, then a reference line indicating the data median was drawn across the chart. The Run Charts were examined for patterns using the rules outlined in Section 1.7.1 of the Literature Review (NIST/SEMATECH, 2013); (Perla, Provost, & Murray, 2011) (Tague, 2005). Non-random patterns were matched against activities on the carrot processing line to identify if abnormal conditions in the plant existed. In experiment A, samples were grouped by geographical location and analyzed using a one-way ANOVA. If a significant difference was found with probability of <0.05, then a pairwise test, Fisher's LSD, was performed to examine which pairs of samples were significantly different at a 5% level of significance. RStudio (Version 1.0.153 – © 2009-2017 RStudio, Inc.) was used to perform the one-way ANOVA and to set up associated boxplots while Microsoft Excel was used to set up the histograms.

In experiment B, a two-way ANOVA was performed to examine the effects of lots and processing method on the APC/g counts at a 5% level of significance. RStudio (Version 1.0.153 – © 2009-2017 RStudio, Inc.) was used to perform the ANOVA and to derive the related boxplot.

3.5 Results

3.5.1 Experiment A

3.5.1.1 *Geographical Origin*

A breakdown of the geographical sampling order for the carrots is presented in Table 4. California (CA) carrots and British Columbia (BC) carrots were sampled over three time periods while Ontario (ON) was sampled over one time period. Carrots from Mexico (MX), Quebec (QC),

and Manitoba (MB), each of which were sampled over one time period, were interspersed throughout.

3.5.1.2 Run Charts

The Run Charts for APC and coliforms for each sampling location are presented in Figure 12a – Figure 15a and Figure 16a – Figure 19a respectively while the Run Chart Pattern Summary indicating Possible Non-Random Variation is presented in Table 5. Coliforms were reported because *E. coli* was not detected in any of the samples in this experiment.

The Run Chart Pattern Summary showed that "shifts" were present in the Washed & Peeled Carrots-APC, Shredded Carrots-APC and all four coliform run charts. The Raw Carrots and Carrot Peels APC and coliform charts had too few "runs", while the Carrot Peel-APC chart had two astronomical or outlier points.

3.5.1.3 Unusual Site Circumstances & Run Chart Signals

The only unusual circumstances that were experienced by the site during the 7 ½ month sampling period were between time points 73 and 91 which corresponded to the processing of ON carrots. Partial shipments were rejected at receiving because the carrots were larger in size than specified and showed signs of bruising. The carrots from cases that were accepted were graded out by the operator if they were bruised or discoloured at peeling or after washing. Customers that subsequently received the shredded carrots complained that the carrots became mushy several days before the end of the expected shelf life.

The run charts that exhibited patterns within time points 73 and 91 were the APC charts for Carrot Peels which displayed two astronomical points at time points 88-89, and Peeled & Washed and Shredded Carrots which displayed shifts from time points 82-88 and 75–90 respectively. The Shredded Carrots APC chart also had a shift that occurred outside of these time points. The coliform charts demonstrated shifts that either did not correspond with the

problematic time points (Raw Carrots Coliforms) or displayed several shifts that corresponded with more than these time points.

3.5.1.4 ANOVAs, Boxplots and Histograms

Figure 12b – Figure 19b report the results of the one-way ANOVAs, Figure 12c –Figure 19c report the boxplots and Figure 12d –Figure 19d report the histograms.

There was no significant difference between the Raw Carrots APC counts for BC, CA and ON carrots as indicated on the one-way ANOVA in Figure 12b. This result was reflected in the boxplots (Figure 12c) in which there was little spread between the medians for BC, CA and ON. The CA counts had the largest variability as shown by the widest boxplot. The boxplots for BC showed that the data skewed left while CA and ON data skewed right because the median lines were close to the bottom of the BC boxplot and the top of the CA and ON boxplots. The histogram in Figure 12d illustrating the distribution of all the data showed that most of the counts were at the high end of the scale resulting in a distribution that skewed left. The Carrot Peels APC one-way ANOVA and pairwise test (Figure 13b) showed there was a significant difference between the means of the CA and ON carrots. The medians are in the middle of the boxplots (Figure 13c) meaning that the data was quite evenly distributed. The overall distribution of data was also close to normal as displayed by the histogram (Figure 13d). The one-way ANOVA and pairwise test indicated there were significant differences between the mean APC counts for BC and ON and CA and ON Peeled & Washed Carrots (Figure 14b). The boxplots (Figure 14b) showed that the ON median and distribution of APC counts was higher than most of the CA and BC APC counts. This resulted in a plateau distribution in the histogram (Figure 14b) which indicated there was possibly more than one normal distribution of APC counts. The Shredded Carrots APC one-way ANOVA and pairwise tests (Figure 15b) also indicated a significant difference between the means of BC and ON and CA and ON carrots. The boxplot (Figure 15c) reflected this result because the ON boxplot was almost completely separated from those of BC and ON. The histogram (Figure 15d)

showed a peak at the low end of the scale corresponding to BC and CA data while ON data was spread out thus skewing the distribution to the right.

The Raw Carrots Coliforms one-way ANOVA and pairwise test (Figure 16b) showed a significant difference between the means of BC and ON and CA and ON carrots. The median line near the top of the BC boxplot (Figure 16c) indicated that this coliform distribution was skewed left while the ON boxplot showed the lowest counts and the greatest data variability. The histogram (Figure 16d) displayed a plateau shape that appears truncated because it does not have as many low and high values as might be expected in normal distributions. The one-way ANOVA and pairwise test for Carrot Peels Coliforms (Figure 17b) showed significant differences between the means of BC and ON, CA and ON and BC and CA carrots. Figure 17c reflected these results because the box plots for BC, CA and ON were almost completely separated. CA carrots exhibited the greatest data variability, BC's data was high thus skewing the distribution to the left and ON's data was low with very little variability. The distribution in the histogram (Figure 17d) exhibited a high frequency of data at the low end of the scale and also appeared truncated because of the lack of data below 3 $\log_{10}$. There was a significant difference between the means of the coliform counts for Peeled & Washed CA and ON carrots (Figure 18b). The boxplot (Figure 18c) shows that CA carrots have lower data variability than BC and ON while BC and ON have median lines near the bottom and the top of their boxplots thus indicating data distributions that are skewed right and left respectively. The data distribution in the histogram (Figure 18d) displayed a very high frequency of data at the lower end of the scale while also appearing truncated because of the absence of data below -1 $\log_{10}$.There were no significant differences between the means of the coliform counts for BC, CA and ON Shredded Carrots as indicated in Figure 19b. The boxplot (Figure 19c) shows that CA carrots have the greatest data variability while ON shows the least. The histogram is similar to that for Carrot Peels and Peeled & Washed Carrots in that there was a

high frequency of data occurring at the lower end of the scale but no data occurring below 1 $\log_{10}$ which produced a histogram that appears truncated.

3.5.1.5 Carrot Wash Water

Figure 3 reports the APC counts for the carrot wash water. There were no was *E. coli* or coliforms detected in any of the 83 samples. APC was detected in 10 of 83 samples at levels ranging between 0.5 and 2.5 CFU/ml.

3.5.1.6 APC, Coliform and Atypical Colony Comparison

The comparison between APC, coliform and atypical colony counts for Shredded Carrots is presented in Figure 21. The coliform count appears to decrease as the atypical and APC counts increase.

3.5.2 Experiment B

3.5.2.1 Carrot lot and sample location interactions.

Table 6 summarizes the significance of both the individual parameter effects that include lot number and sample location, as well as the interaction between these two parameters, on changes in microbial status of carrots for each sample location on the fresh cut carrot processing line.

3.5.2.2 Boxplot illustrating effect of lot and sample location on mean APC counts

The boxplot in Figure 22 illustrates the interactive effects of two primary parameters, namely the experimental sample lots and the carrot sample locations, on measured aerobic plate counts (APC) of the carrots. This figure also summarizes the mean and standard deviation for the four sample locations.

The APC results in the raw carrots contained mean counts of 4.8 ± 0.54 log CFU/g which dropped to a mean of 1.9 ± 1.0 log CFU/g during peeling and washing for a reduction of approximately

2.0 logs. After carrots were shredded, APC values exhibited a 1.4 log increase to a mean of 3.3 ± 0.67 log CFU/g. The APC from carrot peels had mean counts of 5.8 ± 0.41 log CFU/g. The changes in APC in carrots attributed to both lot number and location were highly significant ($P<0.05$); however, the interaction of both parameters was also significant ($P<0.01$) on the method of carrot processing. Thus the power of using the two-way ANOVA, to analyze the results from both the lot number and sample location on carrots handled differently signified that the effects of lot number and sample location interacted to produce the measured effect on aerobic plate counts.

3.5.2.3 *Comparison of APC between Experiment A and Experiment B*

Mean values for APC from Experiment A without ON, BC carrots, and Experiment B carrots (BC only) show that APC mean values form Experiment B's raw carrots were not different from those obtained from BC raw carrots in Experiment A; while APC means for the other sampling locations were within 0.2 logs. A comparison of Experiment B's carrots with all of experiment A's carrots except ON indicates that the means are the same for Carrot Peels and Raw Carrots within 0.2 logs for Raw Carrots and within 0.4 logs for Peeled & Washed Carrots.

The Shredded Carrots Run Chart (Figure 23) combining Experiment A and Experiment B's data indicates the Experiment B did not introduce any non-random patterns.

Table 4. Summary of the Geographical Location of Carrots Sampled at each Time Point in Experiment A

Geographical Location	CA	BC	MX	QC	CA	BC	MB	BC	ON	CA
Time Point	1-38	39-40	41-42	43-45	46-50	51-65	66-68	69-72	73-91	92-105

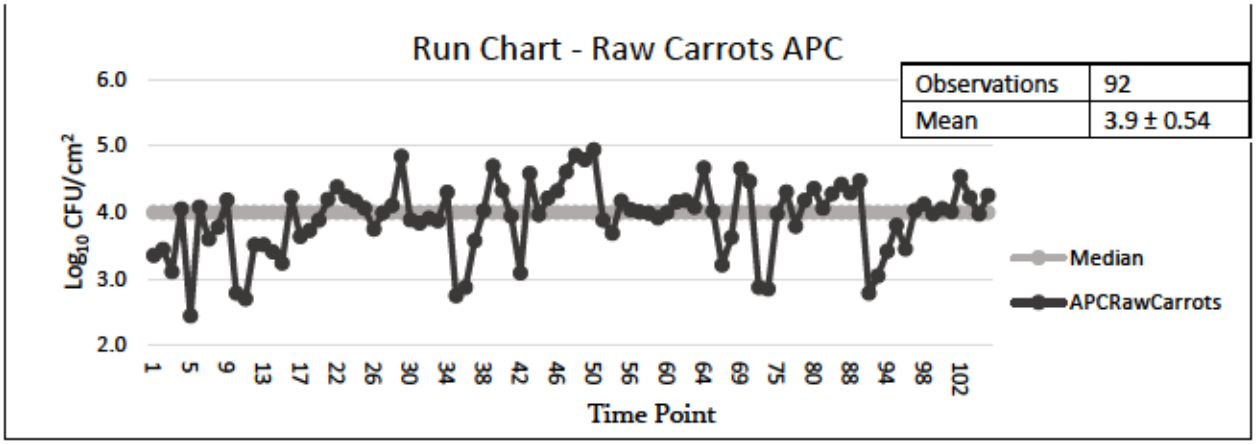


Figure 12a. Run chart for Raw Carrots APC.

	BC	CA	ON
Observations	18	54	12
Mean (log10 CFU/cm2)	4.1 ± 0.42	3.8 ± 0.57	4.0 ± 0.54

F-value	Mean Square	P-value*
1.689	0.2873	0.191

Figure 12b. Raw Carrots APC one-way ANOVA Results for British Columbia (BC), California (CA) and Ontario (ON) carrots.

**values <0.05 are significant*

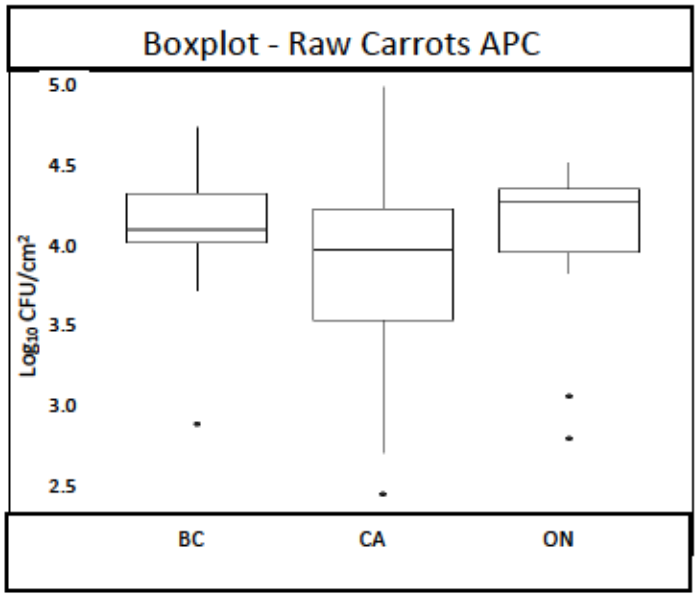


Figure 12c. Boxplot for Raw Carrots APC grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

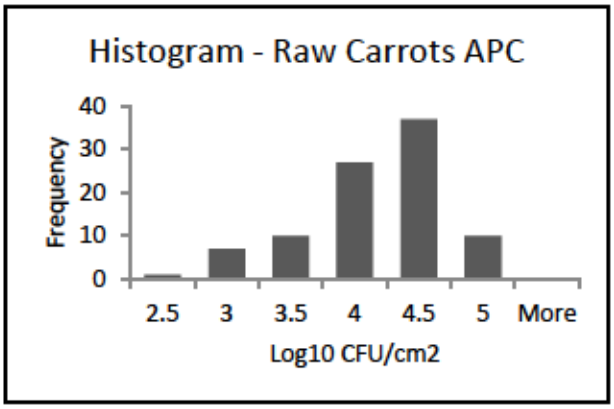


Figure 12d. Histogram for Raw Carrots APC

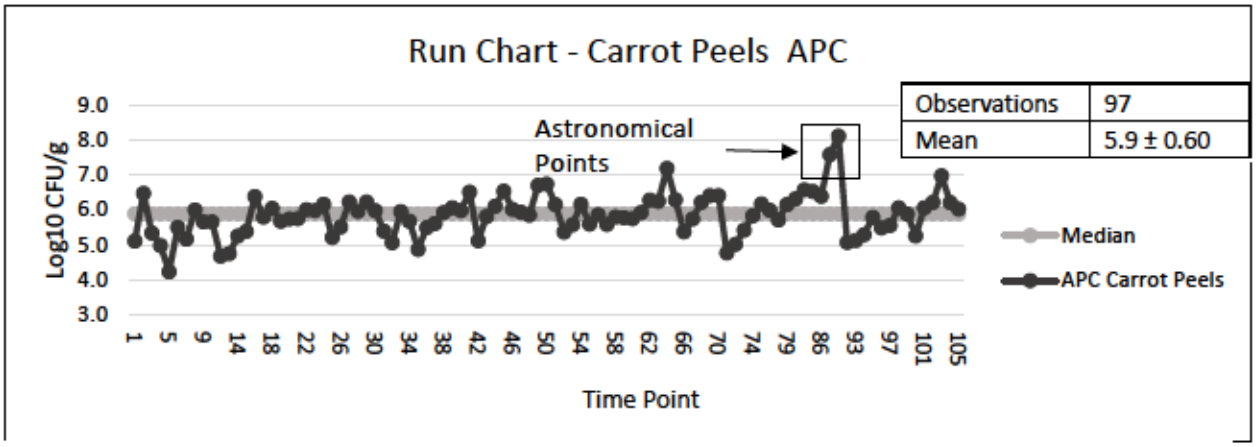


Figure 13a. Run chart for Carrot Peels APC.
Astronomical points are points that are noticeably different from other data points.

	BC	CA	ON
Observations	19	57	13
Mean (log_{10} CFU/g)	6.0 ± 0.67	5.7 ± 0.49	6.3 ± 0.85

F-value	Mean Square	P-value*
6.03	0.3285	0.0034

Fisher's LSD Test*		
	BC	CA
CA	0.0612	-
ON	0.1716	0.0017

Figure 13b. Carrot Peels APC one-way ANOVA Results for British Columbia (BC), California (CA) and Ontario (ON) carrots.

**values <0.05 are significant*

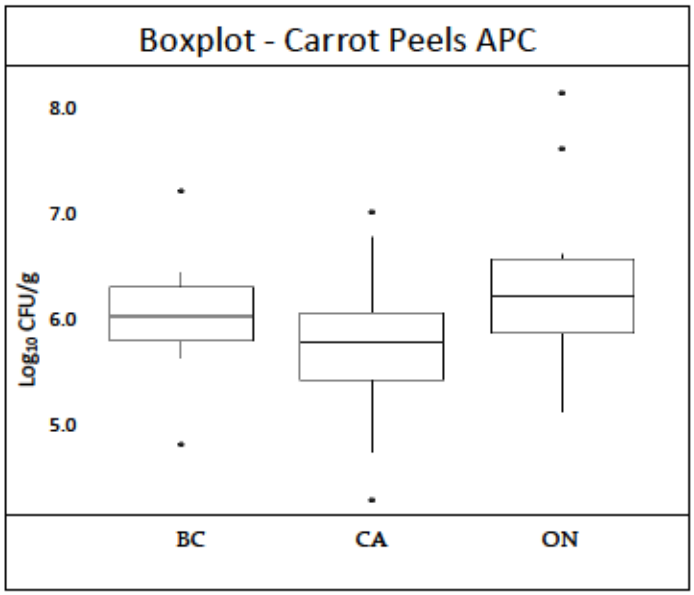


Figure 13c. Boxplot for Carrot Peels APC grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

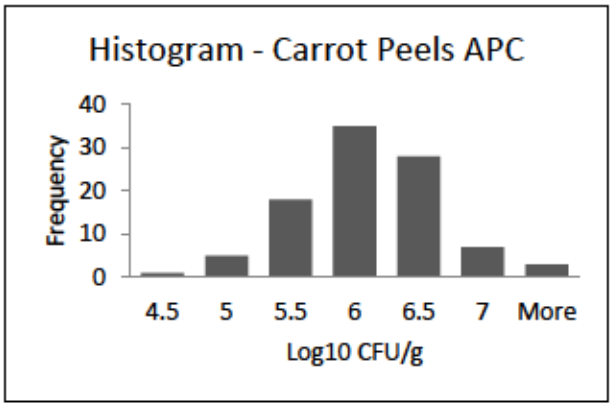


Figure 13d. Carrot Peels APC Histogram

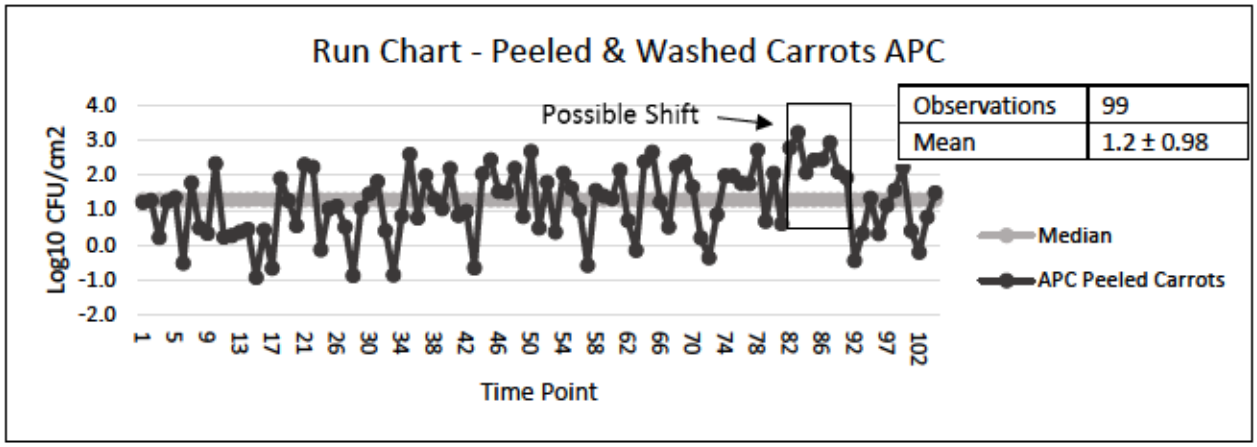


Figure 14a. Run chart for Peeled & Washed Carrots APC.
Shifts are six or more consecutive points above or below the median; $p<0.05$ of this event occurring in random data.

	BC	CA	ON
Observations	19	55	17
Mean (log_{10} CFU/cm_2)	1.3 ± 0.93	0.95 ± 0.91	1.9 ± 0.92

F-value	Mean Square	P-value*
7.884	0.836	<0.01

Fisher's LSD Test*

	BC	CA
CA	0.1565	-
ON	0.0353	<0.01

Figure 14b. One-way ANOVA Results for Peeled & Washed Carrots APC. **values <0.05 are significant*

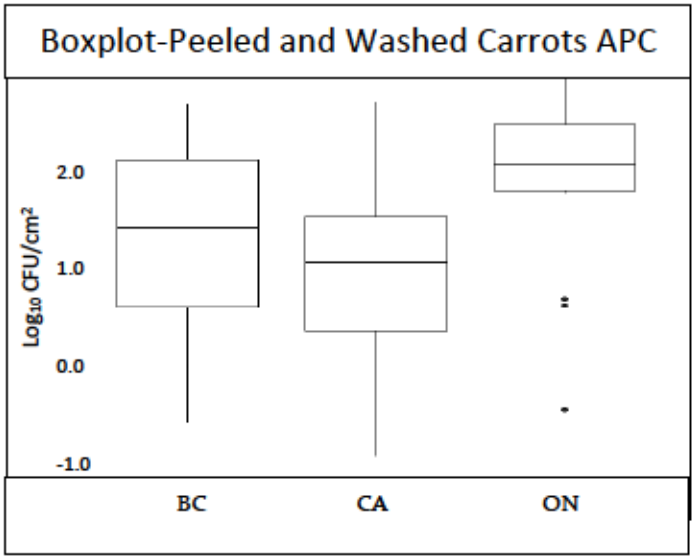


Figure 14c. Boxplot for Washed & Peeled Carrots APC grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

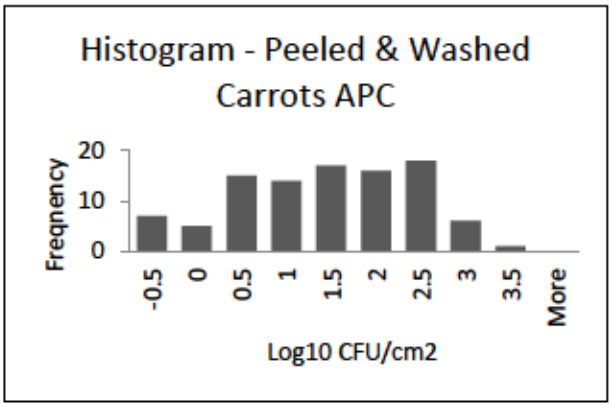


Figure 14d. Peeled & Washed Carrots APC Histogram

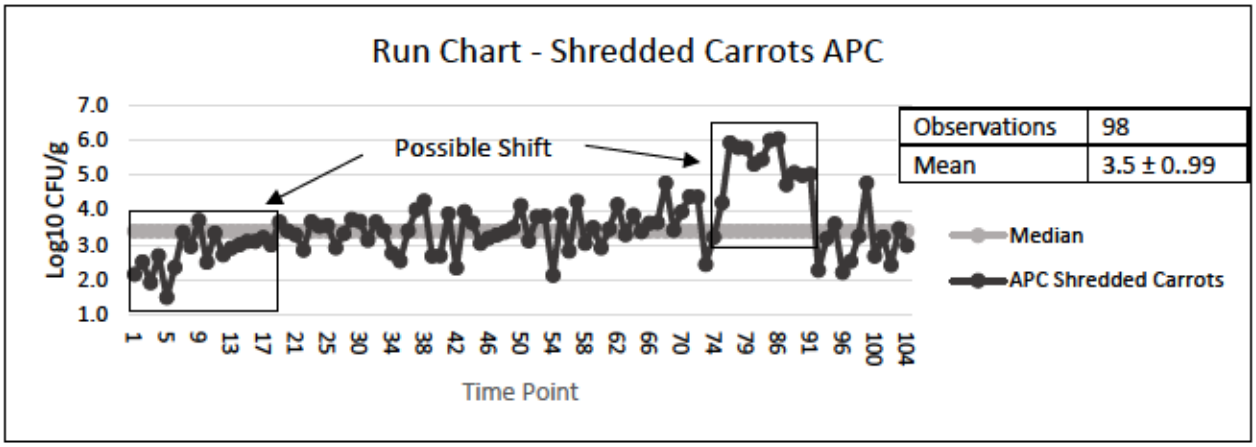


Figure 15a. Run chart for Shredded Carrots APC.
Shifts are six or more consecutive points above or below the median; p<0.05 of this event occurring in random data.

	BC	CA	ON
Observations	19	57	14
Mean (log_{10} CFU/cm_2)	3.4 ± 0.60	3.2 ± 0.61	4.8 ± 1.1

F-value	Mean Square	P-value*
31.77	0.496	<0.01

Fisher's LSD Test*		
	BC	CA
CA	0.2	-
ON	<0.01	<0.01

Figure 15b. One-way ANOVA Results for Shredded Carrots APC **values <0.05 are significant*

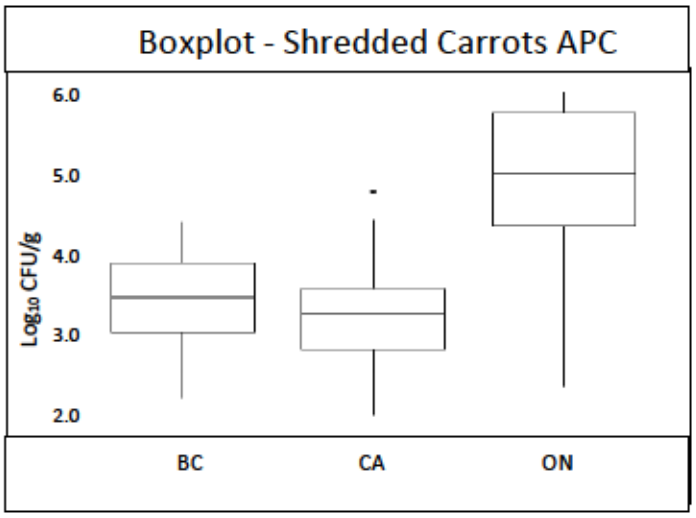


Figure 15c. Boxplot for Shredded Carrots APC grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

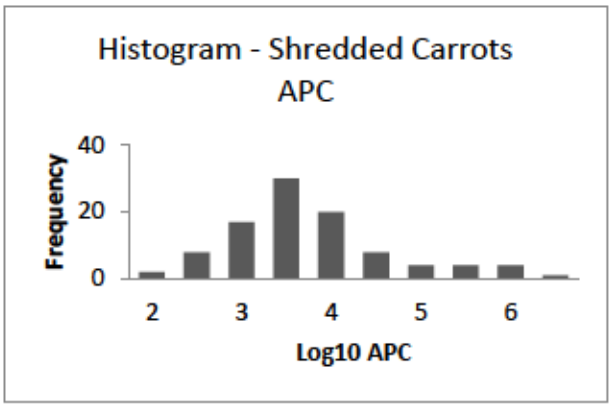


Figure 15d. Shredded Carrots APC Histogram

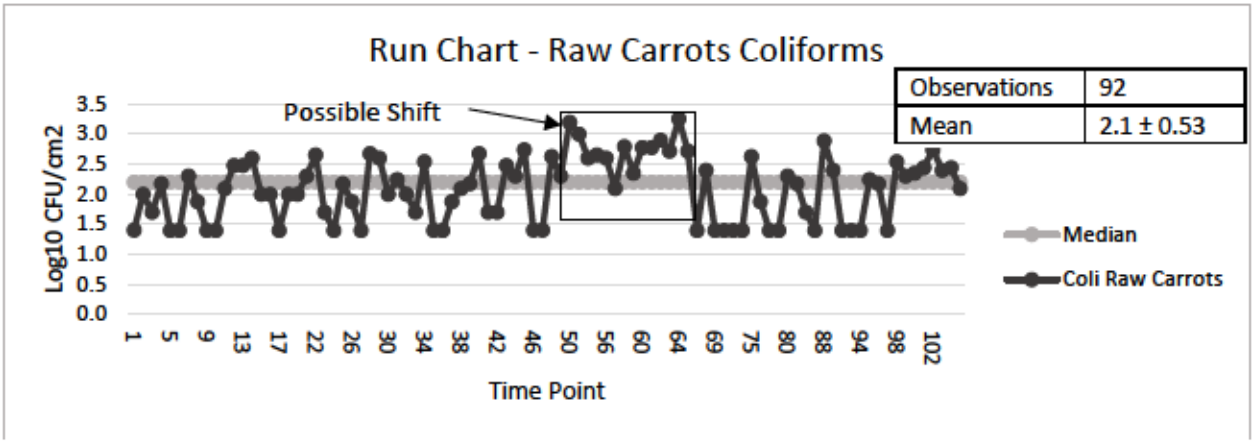


Figure 16a. Run chart for Raw Carrots Coliforms.
Shifts are six or more consecutive points above or below the median; $p<0.05$ of this event occurring in random data.

	BC	CA	ON
Observations	18	54	12
Mean (log_{10} CFU/cm_2)	2.5 ± 0.56	2.1 ± 0.59	1.9 ± 0.55

F-value	Mean Square	P-value*
3.744	0.3384	0.0279

Fisher's LSD Test*

	BC	CA
CA	0.027	-
ON	0.013	0.308

Figure 16b. One-way ANOVA Results for Raw Carrots Coliforms *values <0.05 are significant

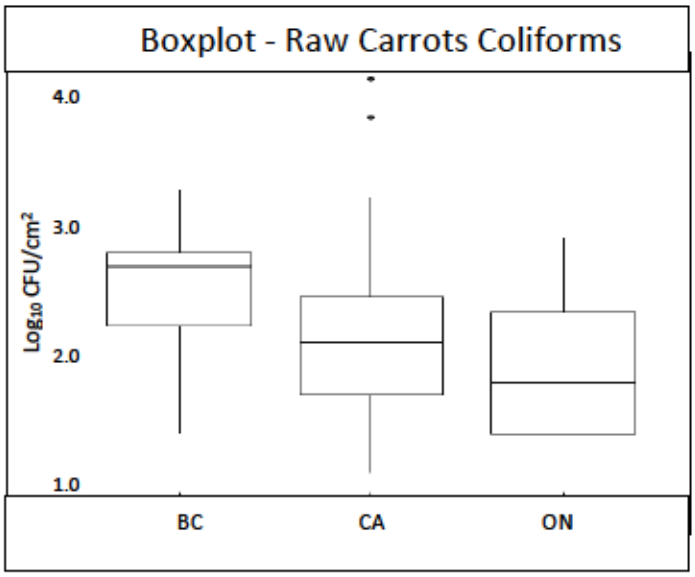


Figure 16c. Boxplot for Raw Carrots Coliforms grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

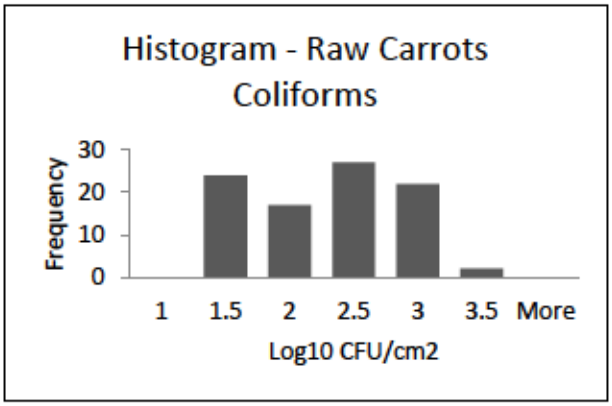


Figure 16d. Raw Carrots Coliform Histogram

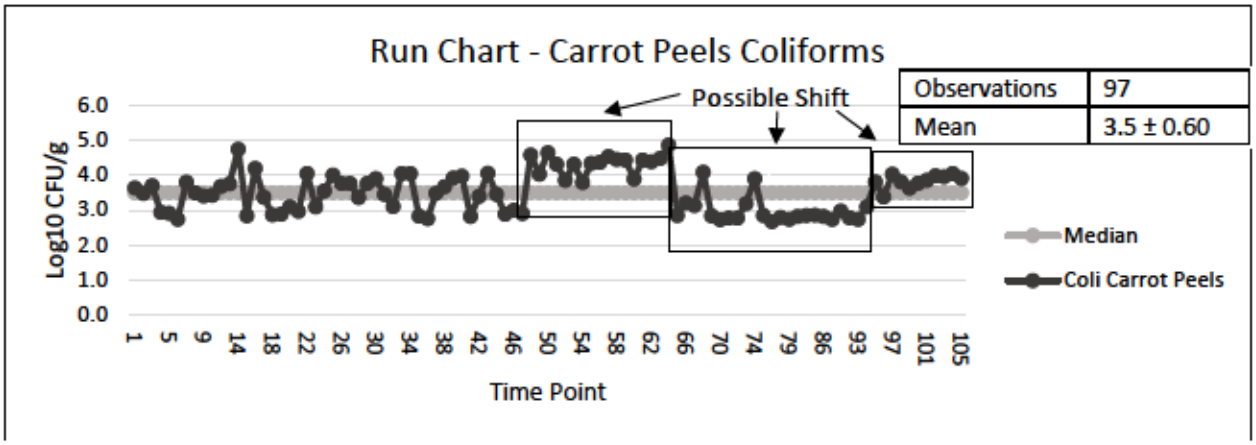


Figure 17a. Run chart for Carrot Peels Coliforms.
Shifts are six or more consecutive points above or below the median; $p<0.05$ of this event occurring in random data.

	BC	CA	ON
Observations	19	57	13
Mean (log_{10} CFU/g)	4.0 ± 0.67	3.6 ± 0.50	2.9 ± 0.31

F-value	Mean Square	P-value*
16.29	0.273	<0.01

Fisher's LSD Test*		
	BC	CA
CA	0.005	-
ON	<0.01	<0.01

Figure 17b. One-way ANOVA Results for Carrot Peels Coliforms *values <0.05 are

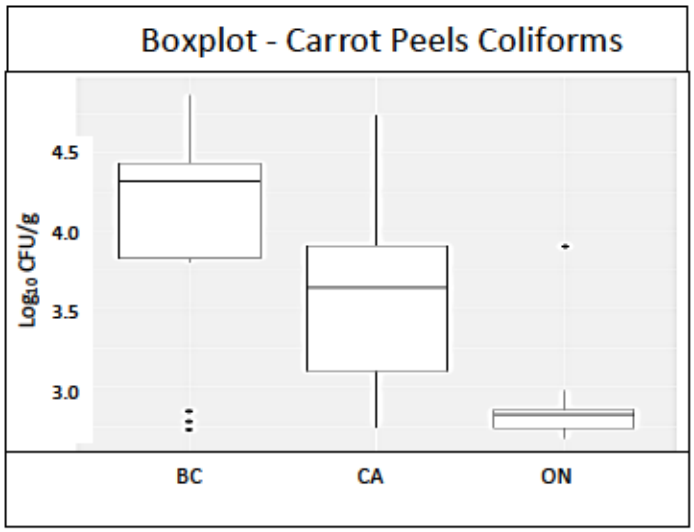


Figure 17c. Boxplot for Carrot Peels Coliforms grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

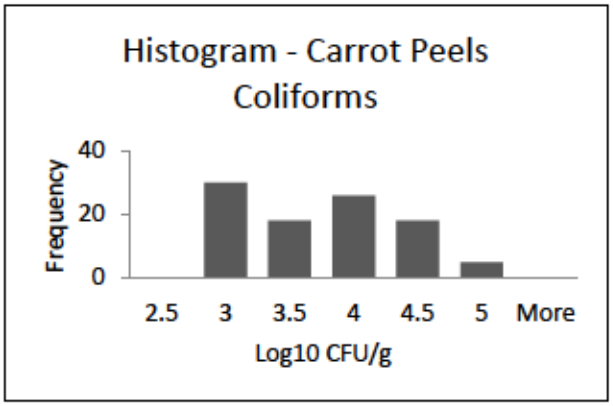


Figure 17d. Carrot Peels Coliform Histogram

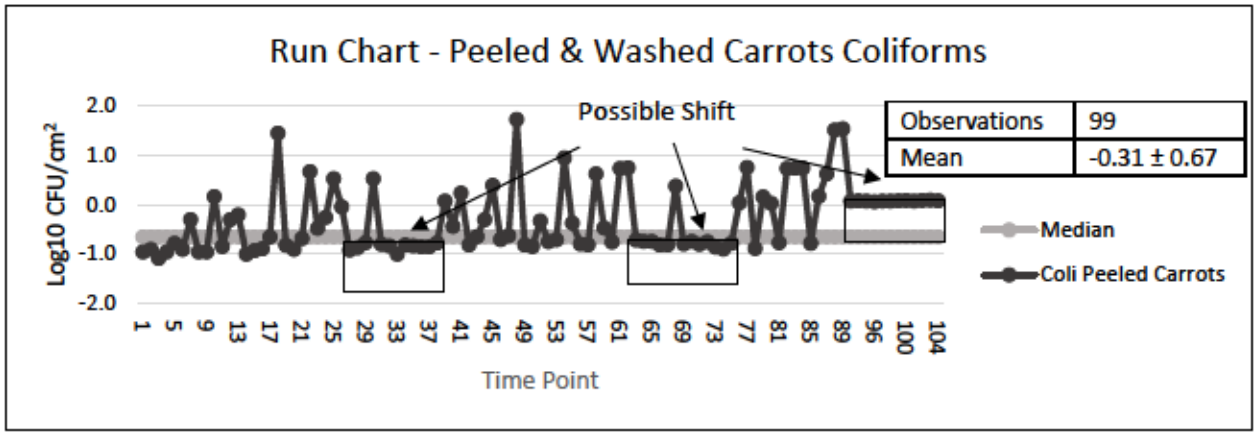


Figure 18a. Run chart for Peeled &Washed Carrots Coliforms.
Shifts are six or more consecutive points above or below the median; p<0.05 of this event occurring in random data.

	BC	CA	ON
Observations	19	55	17
Mean (log_{10} CFU/cm_2)	-0.32 ± 0.62	-0.60 ± 0.55	-0.097 ± 0.74

F-value	Mean Square	P-value*
5.127	0.362	<0.01

Fisher's LSD Test*		
	BC	CA
CA	0.01653	-
ON	0.2668	<0.01

Figure 18b. One-way ANOVA Results for Peeled & Washed Coliforms *values <0.05 are

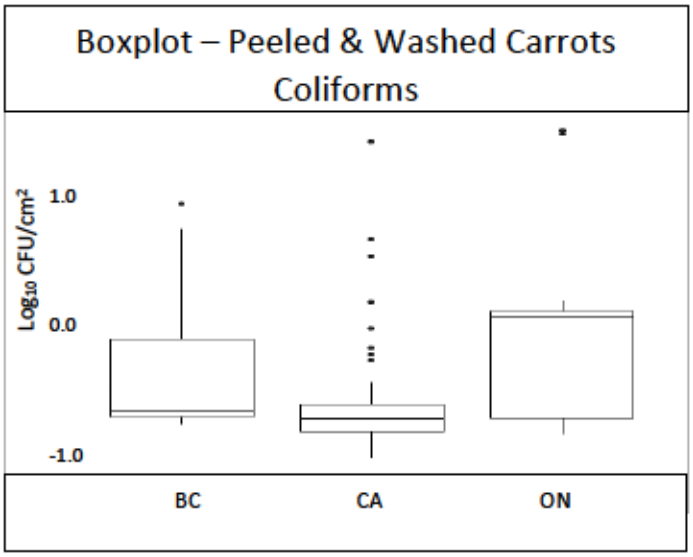


Figure 18c. Boxplot for Peeled & Washed Carrots Coliforms grouped by geographical location. Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

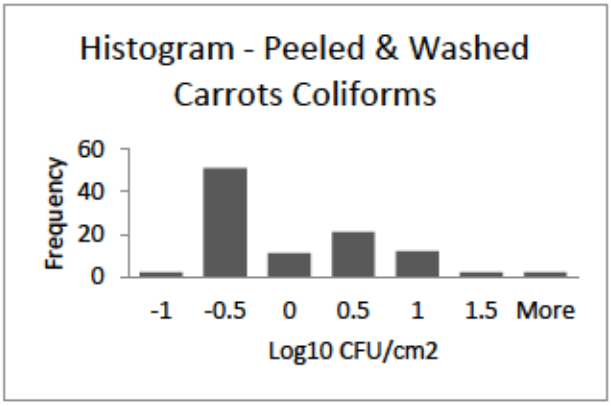


Figure 18d. Carrot Peels Coliform Histogram

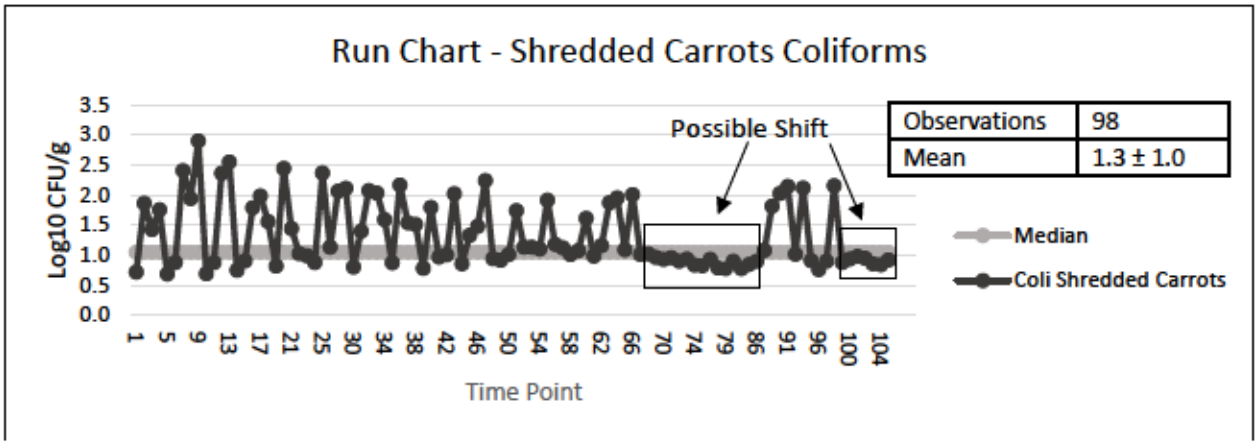


Figure 19a. Run chart for Shredded Carrots Coliforms.
Shifts are six or more consecutive points above or below the median; $p<0.05$ of this event occurring in random data.

	BC	CA	ON
Observations	19	57	14
Mean (log_{10} CFU/g)	1.3 ± 0.60	1.4 ± 0.61	1.2 ± 0.49

F-value	Mean Square	P-value*
1.591	0.3093	0.209

Figure 19b. One-way ANOVA Results for Shredded Carrots Coliforms *values <0.05 are significant

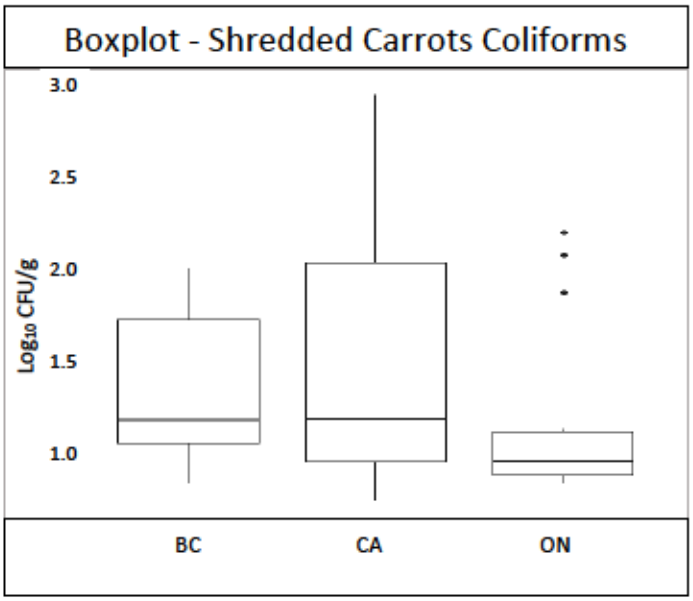


Figure 19c. Boxplot for Shredded Carrots Coliforms grouped by geographical location.
Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

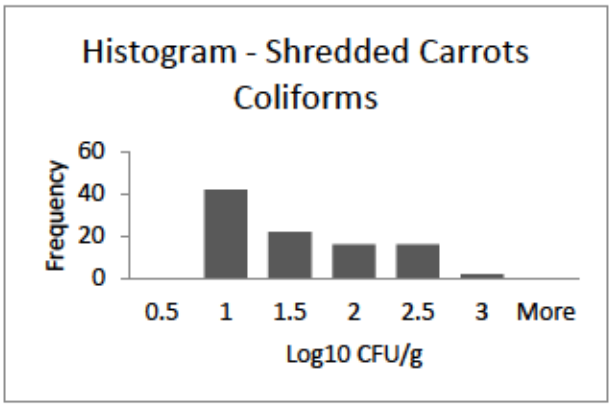


Figure 19d. Shredded Carrots Coliform *Histogram*

Table 5. Summary of Run Chart Patterns indicating possible non-random variation in Figures 14a - 20a.

Run Chart Pattern Summary								
Location	Raw Carrots		Carrot Peels		Peeled & Washed Carrots		Shredded Carrots	
Organisms / Pattern	*APC*	*Coliform*	*APC*	*Coliform*	*APC*	*Coliform*	*APC*	*Coliform*
Shift[1]	0	1	0	3	1	3	2	2
Runs[2]	30 Low	30 Low	29 Low	28 Low	41	36	39	35
Trend[3]	0	0	0	0	0	0	0	0
Astronomical Points[4]	0	0	2	0	0	0	0	0

[1]Shift - too many consecutive points on one side of the median; 8 points in a row or 10 points out of 11, 12 points out of 14 or 16 points out of 20 (Tague, 2005).
[2]Runs - the average line is crossed too few or too many times as indicated by a runs test table. There should be 35 – 56 runs in this dataset of 90-99 points.
[3]Trend – there should be no more than six points steadily increasing or decreasing (Tague, 2005).
[4]Astronomical point - a point that is clearly different from the other points (Perla, Provost, & Murray, 2011)

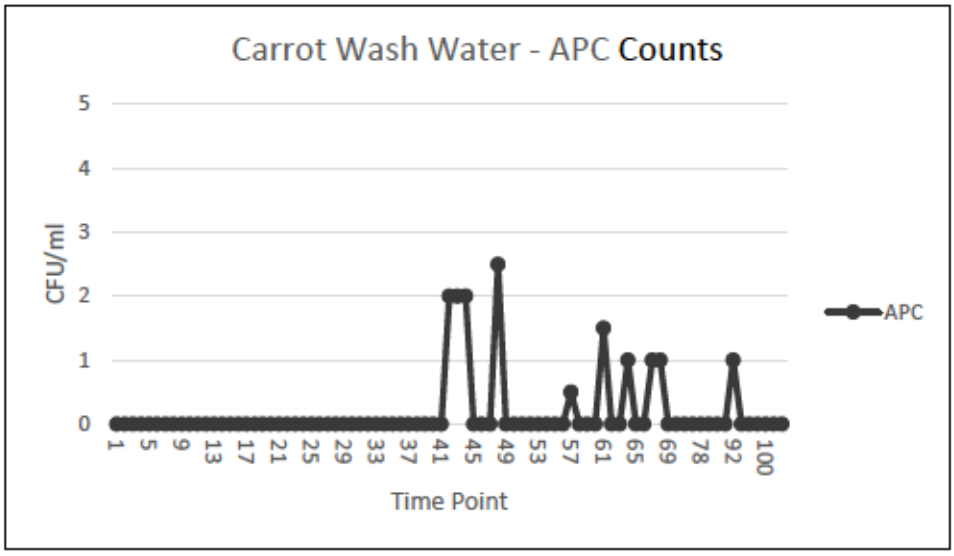


Figure 20. Carrot Wash Water APC counts/ml.

APC counts are CFU/ml because of the low bacterial numbers. No coliforms were detected throughout the duration of the experiment.

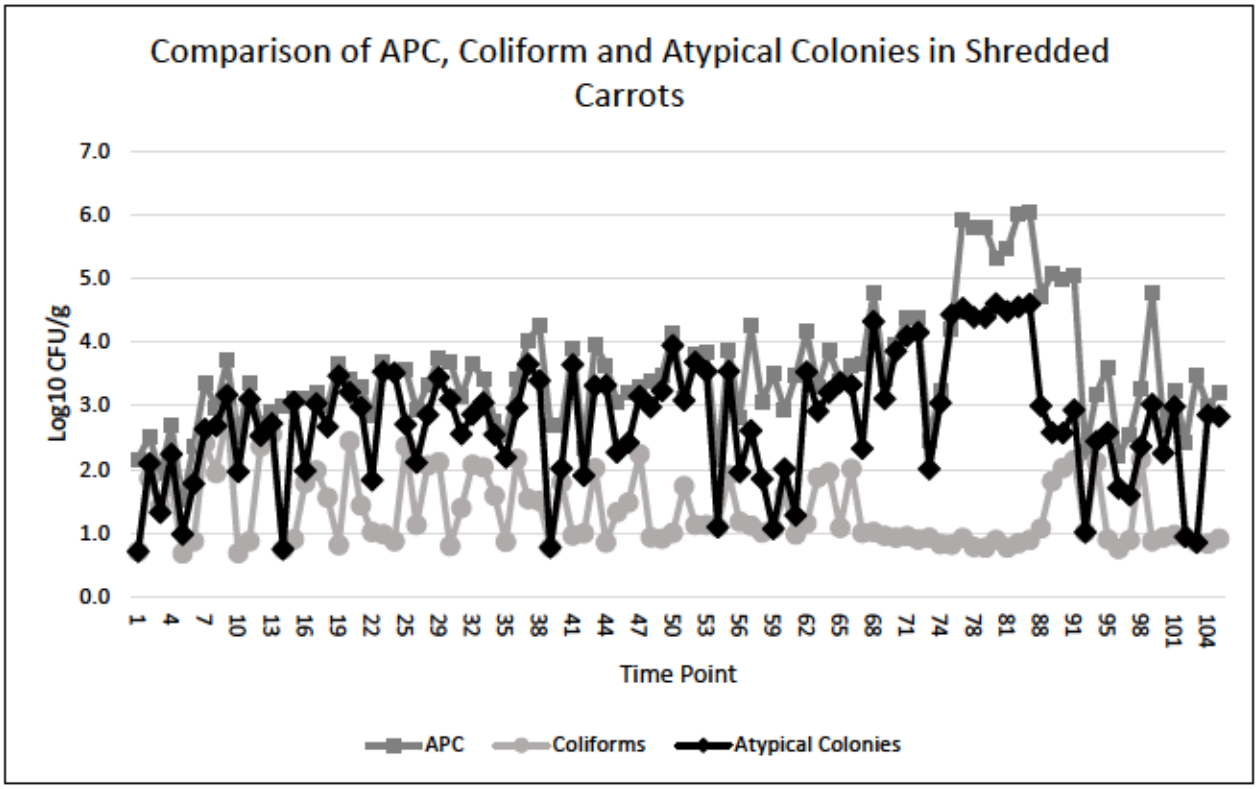
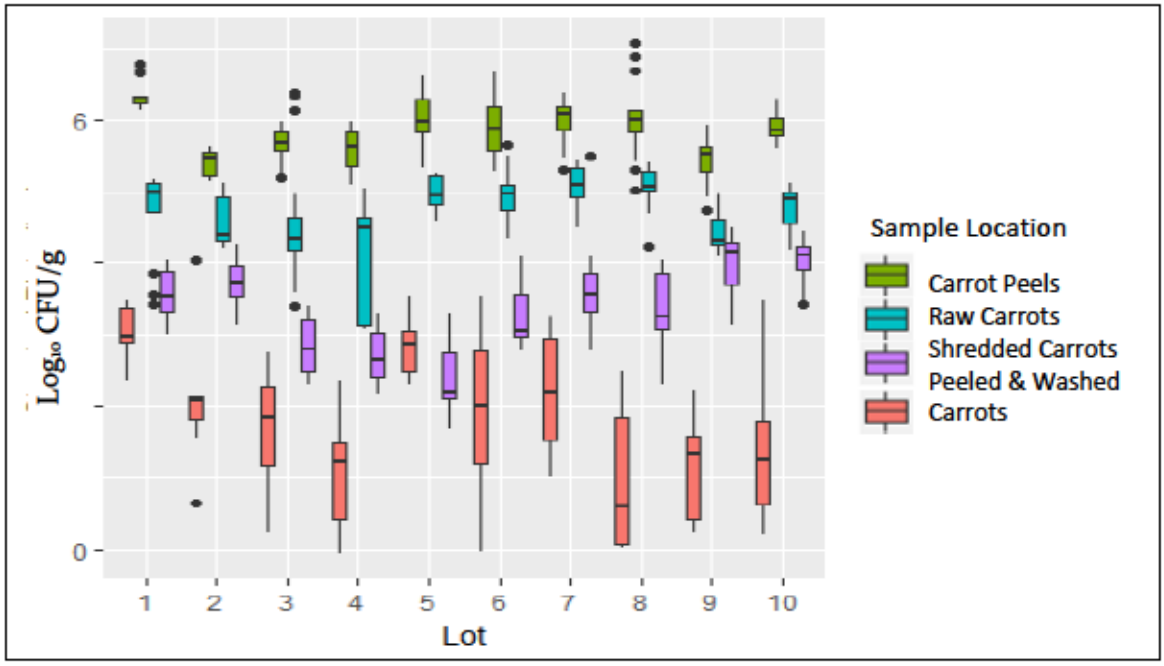


Figure 21. Comparison of APC, Coliform and Atypical Colonies in Shredded Carrots.

Table 6. Two-way ANOVA results indicating the effect of carrot lot and sample location on the APC counts (log10 CFU/g) of BC carrots.

Variable	P-value*
Carrot Lot	<0.01
Sample Location	<0.01
Lot: Sample Location	<0.01

*P-values less than 0.05 are significant



Sample Location	Raw Carrots	Carrot Peels	Peeled & Washed Carrots	Shredded Carrots
Mean APC (log10 CFU/g)	4.8 ± 0.54	5.9 ± 0.41	1.9 ± 1.0	3.3 ± 0.67

Figure 22. Boxplot illustrating the interactive effects of carrot lots and sample location on the APC counts (log10 CFU/g) of BC carrots including data summary of sample location APC means ± s.d. Horizontal lines in boxes represent the data median. Lower and upper lines of boxes represent the median of the lower and upper half of data respectively. Ends of vertical lines represent minimum and maximum values. Dots represent outliers.

Table 7. Comparison of Experiment A and Experiment B APC means for each sample location.

Experiment / Sample Location	Experiment A - w/o ON*	Experiment A - BC only	Experiment B BC
Raw Carrots (log CFU/cm²)	3.9 ± 0.54	4.1 ± 0.50	4.1 ± 0.54
Carrot Peels (log CFU/g)	5.8 ± 0.53	6.0 ± 0.52	5.8 ± 0.41
Peeled & Washed Carrots (log CFU/cm²)	1.0 ± 1.2	1.2 ± 1.0	1.4 ± 1.0
Shredded Carrots (log CFU/g)	3.3 ± 0.63	3.5 ± 0.63	3.3 ± 0.67

*ON was excluded because these carrots were poor quality

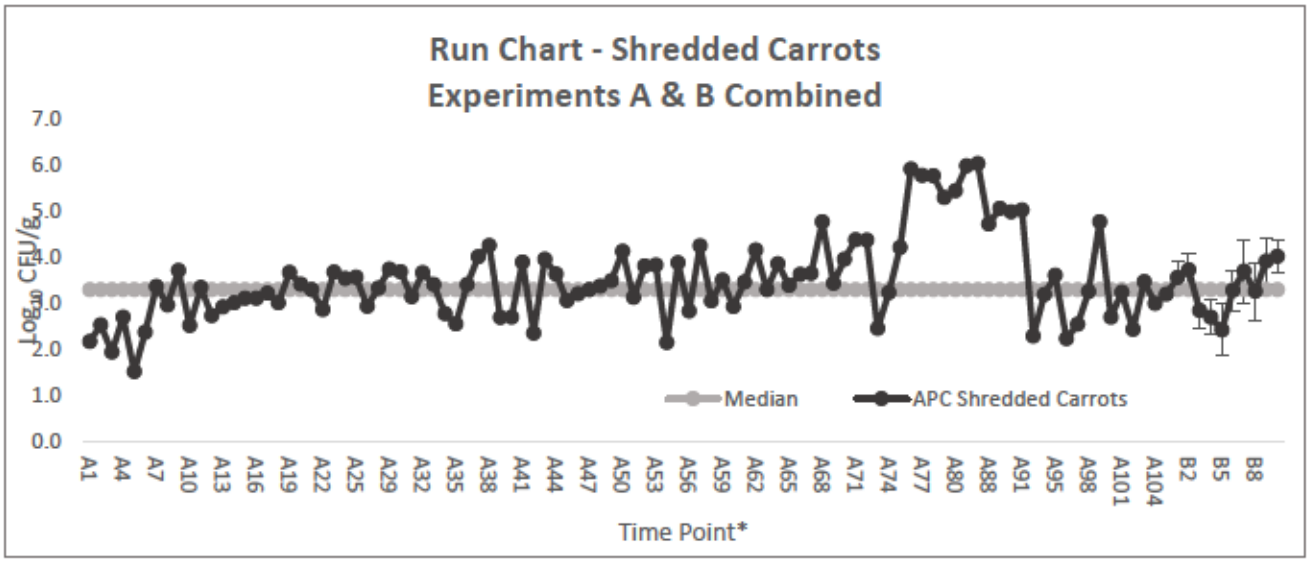


Figure 23. Shredded Carrots Run Chart combining Experiment A and Experiment B's data.
* A = Experiment A data, B = Experiment B data

3.6 Discussion

3.6.1 Experiment 3A

Throughout this experiment, there were no *E. coli* detected in either unwashed, processed or washed carrots. This finding validated the low *E. coli* contamination levels in carrots reported by Maatta et al. (2013) and the rarity of foodborne outbreaks caused by carrots (Erickson, 2010).

Despite the considerable data collection used herein to identify unusual circumstances occurring on the carrot processing line, only three run charts actually displayed changes in microbiological status when unusual circumstances occurred at the site during which poor quality carrots from ON were being processed from time points 73-91. Shredded Carrots-APC results provided the strongest signal by showing a shift of increased APC counts for 16 of the 19 time points monitored. In contrast, Peeled & Washed Carrots-APC and Carrot peel-APC results indicated weaker APC signals with elevated APC counts for only 8 of the 19 and 2 of the 19 time points, respectively.

It is likely the result obtained herein for raw carrots was attributed to the quality of samples and method of sampling; for example, the surface of just one carrot was swabbed at each time point for raw carrots. The weak signal for carrot peels is less easily explained because the carrot peel sample captured microorganisms associated with about half a millimeter of the outer layer, collected from approximately five carrots combined, thus increasing the probability of microbial recovery because others have reported significant microbial counts from carrot peels (Delaquis, Fresh-Cut Vegetables, 2006). In this instance, the peeled & washed and shredded ON carrots displayed elevated APC counts which suggests that a greater number of microorganisms

existed below the surface of the ON carrots than occurred on carrots from any of the other geographical areas. The spoiled ON carrots exhibited bruising which will occur if the carrots were mishandled sometime between harvesting or subsequent processing (Barth, Hankinson, Zhuang, & Breidt, 2009). It is postulated that spoilage microorganisms exploited this damaged tissue and, through extracellular lytic enzymes, digested the carrot's polysaccharide-based structural and storage compounds to release water and other nutrients (Barth, Hankinson, Zhuang, & Breidt, 2009). This situation likely caused the softening and liquefaction of carrot tissue (Tournas, 2008), which ultimately resulted in the excessively soft carrots that customers complained about. It should be noted that the site could not confirm the underlying reason for the poor quality carrots from the supplier.

Support for explaining the reason for obtaining the strongest APC signal from shredded carrots comes from the method of sampling, which consisted of obtaining a sample that was comprised of approximately 40 to 50 peeled carrots. Hence, this sampling method likely had a greater capacity to capture more of the APC variability between each carrot. In addition, this sampling method included both the inside and the outside of the carrot as compared to the other three sampling methods which mainly assessed bacterial numbers from the carrot's surface.

In this experiment, ANOVA was also used to provide additional support for the run chart analysis; for example, the run charts that had the strongest signals , Shredded Carrots and Peeled & Washed Carrots APC, respectively, showed significant differences between CA and ON locations, and between carrots derived from BC and ON, respectively. In contrast, the Carrot Peels APC, which had a weaker signal, only had a significant difference between the CA and ON carrots while the Raw Carrots APC, with no signal, did not display any significant differences between the three geographical areas.

A third approach to characterize these data used boxplots to compare APC signals between sample locations. Agreement between boxplot and run chart analyses were useful to confirm the run chart analysis. For example, the Shredded Carrots ON carrot boxplot was almost completely separated from the BC and CA carrot boxplots while the Peeled and Washed Carrots boxplots showed that ON was slightly overlapping with BC and mainly separated from CA. The related histograms reflect these observations; the peeled and washed carrots have a plateau distribution which indicates that more than one normal distribution may be present while the shredded carrots displayed a normal distribution for BC and CA carrots while the ON carrot results skewed this distribution out to the right. Boxplots describing APC counts for Carrot Peels and Raw Carrots had the greatest overlap of all three geographical areas while the related histograms look relatively normal for carrot peels and skewed left for raw carrots.

The signal obtained for coliform contamination in carrots was not as clear as that from the APC charts for the ON carrots. This result may be attributed to the fact that shifts occurred before time point 73 on all of the charts and after time point 91 on three charts. In fact, all four of the coliform run charts had shifts occurring at different time points in the experiment. The varying signals may be occurring because colonies without gas production grew on the *E. coli*/coliform plates which made it difficult to enumerate the coliforms, especially when bacterial numbers increased. These atypical colonies are likely *Pseudomonas* spp. because others have found that these organisms account for 23 – 73% of the APC count on carrots (Liao & Fett, 2001) and they will grow on violet red bile agar (Van Tassell, et al., 2012). This meant that as bacterial numbers increased, such as occurred with ON carrots, the coliform counts decreased because they could not be detected. This phenomenon was illustrated using the shredded carrots as an example (Figure 21), where the atypical colonies mainly lie between the coliform and APC counts, and roughly follow the same profile as the APC. The coliform counts show the expected variability until they could not be detected because of the increased numbers of atypical colonies. These

observations are supported by the Carrot Peels and Shredded Carrots boxplots in which the ON boxplots show very little variability and are concentrated the bottom of the scale. The histograms for all sample locations except Raw Carrots also indicate that most of the coliform counts are concentrated at the bottom of the scale below which they abruptly drop off. Interestingly, the Raw Carrots coliforms run chart indicates that all the BC carrots from time points 51 to 65 showed elevated coliform counts while the corresponding APC counts were close to the median on the run chart.

The wash water microbiological counts (Figure 20) were very low throughout the experiment and did not show any patterns that could be related to any of the sample location run charts.

3.6.2 Experiment 3B

Mean APC values for each sample location (Figure 22), which in this experiment were significantly different, provide a logical outcome. For example, the surface of the carrot contains the majority of microorganisms, which can be reduced by just over 2 logs by peeling (Garg, Churey, & Splittstoesser, 1990). Thus, the peel is expected to have higher APC levels than the interior of the carrot; which agrees with the results in this experiment where carrot peels had an APC count just over 1 log higher than raw carrots. Washing, as discussed in Section 2.10.1.3 of Chapter 2, also achieved a 1 to 3 log reduction in microorganisms as expected. In this experiment, peeled & washed carrots had a 2.9 log reduction in APC values. Finally, shredded carrots had a 1.4 log increase in this experiment; this increase is likely due to recontamination from the various food contact surfaces the carrots encounter between washing and shredding including contamination from workers' gloves, transfer cases, shredding equipment and packaging surfaces. In addition, the results herein also indicate that a significant number of microorganisms may also be associated with the internal portion of the carrot.

While the boxplots in Figure 22 illustrate these results, it can also be seen that there are some features that are likely associated with the significant interaction between lot and sample location as demonstrated by the fact that the sample location APC results did not cleanly increase or decrease simultaneously for each lot. There was a high variability in the peeled & washed carrots for some lots, which strongly suggest that there is overlap with the shredded carrot counts as was shown for Lot 6. This high variability was likely due to the fact that only one carrot was sampled for each peeled & washed replicate and that the bacterial numbers were at the low end of the log scale. Hence, a small change in bacterial numbers will effect a large change in log values. In addition, peeled & washed carrots with low variability overlapped with the shredded carrots counts as shown with Lots 1 and 5. Reasons for this finding could be that a lower microbiological load was added to the carrots after processing, or alternatively, there were lower numbers of microorganisms in the internal structures of these carrots. APC counts obtained for raw carrot and shredded carrots also overlap at times, in particular, for Lots 4 and 9. The high variability in the raw carrot counts observed for Lot 4 may reflect the fact that each of the replicates were sampled from just one carrot. The other overlaps may have occurred because a greater than usual microbial load was added to the carrots from the food contact surfaces at the site.

There was a significant difference between the lot numbers for the BC carrots examined in this experiment. This has implications for the use of Run Charts because, as discussed above, this experiment examined the use of the charts for periodic microbiological data which assumes that a process statistically in control has variability that is small between-batches and is overall stable (ICMSF, 2018). Experiment A only examined the differences between three different geographical locations rather than the differences between lots because periodic sampling by nature will not collect enough data from any individual lot. Instead, this approach examines individual samples across multiple lots over extended periods of time. It is therefore assumed that

carrots that are produced in conditions that meet appropriate food safety and quality requirements will have bacterial counts that fall within a similar range.

This aspect was examined more closely as shown in Table 7 which compared the APC means for each sample location from Experiments A data excluding ON, BC carrots from Experiment A, and Experiment B which only included BC carrots. For each sample location, the means were similar, within 0.2 logs of each other, except for peeled & washed carrots which had a difference of 0.4 logs. The standard deviation also remained much the same with carrot peels having the biggest APC difference (0.12) and peeled and washed carrots having the smallest difference (0.02). This suggests that normal variability of APC means for both geographical location and lot numbers may be close to 0.2 logs. The Run Chart combining the shredded carrot APC counts for the data from both Experiment A and B in Figure 23 also shows that there were no further non-random patterns introduced by Experiment B-BC carrots.

While this experiment demonstrated the value of tracking Shredded Carrot APC counts on a Run Chart, the results are available after some or all of the carrots are processed which means that the site is still at risk of shipping contaminated carrots to customers thus reducing its effectiveness as a detection control at Receiving in the Carrot Processing FMEA in Table 2. The site was also not successful in getting information from the carrot supplier as to what was causing the quality problem. The detection rating for biological hazards has therefore not improved using this approach.

The detection rating for a quality problem, as occurred in this experiment, has slightly improved because the site could potentially have stopped processing the ON carrots earlier and thus curtailed the number of customer complaints. In addition, the detection of internal problems related to unsanitary equipment or personal hygiene has also likely improved thus improving the detection rating for these failure mode/causes in the FMEA. This rating, however, is only slightly

improved because the test results are delayed because the microbiological tests take two days to complete. While it is possible to perform microbiological tests that take twelve hours to complete as described in this chapter's introduction, the processing site is unlikely to delay carrot processing or outgoing finished product shipments until these tests are complete because this approach requires more warehouse space to store these items and a reduction in finished product shelf life.

For the detection rating for biological hazards on incoming carrots to improve, it is likely that the site must examine the value of working with suppliers to implement process design and enhanced pathogen testing programs earlier in the supply chain because others have noted that many foodborne outbreaks originate at the field level or during initial processing with water being a significant contamination vector (Lynch, Tauxe, & Hedberg, 2009) (FDA, 2011). For example, physical or chemical disinfection of agricultural water combined with more stringent microbiological testing techniques may be a useful method for identifying contaminated carrots before they are processed by fresh-cut processors (Allende & Monaghan, 2015).

Given this information, it may also be useful for fresh-cut processors to investigate the use of rapid pathogen tests on in-plant wash water to determine if pathogens have been rinsed off the carrots such as the rapid polymerase chain reaction (PCR) tests being investigated for use in roof-harvested rainwater in Australia (Ahmed, Huygens, Goonetilleke, & Gardner, 2008).

3.7 Conclusion

In conclusion, a major finding of this experiment was that while plotting periodic Shredded Carrot-APC counts on a Run Chart can be an effective strategy to observe changes in the microbiological status of a fresh-cut carrot processing line, this strategy was insufficient to detect contaminated incoming carrots before they were processed because this information is being provided too late because produce plants begin processing incoming carrots almost

immediately. The site would need to develop a cooperative relationship with entities further back in the supply chain to understand when unusual circumstances are occurring that could potentially result in contaminated carrots. Ideally, this cooperation could potentially lead to identifying the points in the supply chain at which contamination with biological hazards is most likely to occur and to set up appropriate process design changes and commensurate microbiological testing programs.

This methodology has the potential to detect problems in quality or internal difficulties related to improperly performed employee handling practices or sanitation. However, the inherent struggles that revolve around the delay in obtaining the microbiological test results could result in situations where only minimal improvement in the FMEA detection rating for these failure modes occur. It would be more useful to examine whether or not the planned activities associated with these area functions are performed properly; Chapter 4 examines this approach in more detail.

Chapter 4. Assessment of a Defect Opportunity Checklist (DOC) and associated Pareto Charts and Cause & Effect Diagrams as Tools to Measure and Improve a Sanitation Process in a Fresh Cut Produce Plant

4.1 Introduction

Sanitation processes are very complex and, if standard operating procedures are not correctly followed, foodborne disease outbreaks and losses in food quality will undoubtedly occur. Significant foodborne outbreaks that have been in part attributed to failures in the sanitation program include, *Listeria monocytogenes* in hot dogs and deli-meats in 1998 (Fix, Young, & Taylor, 1999), 2008 (Weatherill, 2009), and 2018 (NICD, 2018), butter in 1999 (Lyytikainen, et al., 1999), ice cream in 2015 (FDA, 2015), bagged salads in 2016 (Beach, 2016), *Salmonella* in ground turkey in 2011 (USDA FSIS, 2011), and *Escherichia coli* in beef in 2012 (Lewis, Corriveau, & Usborne, 2013). The 2008 *Listeria* outbreak included a detailed explanation as to how a sanitation program break-down can occur in food processing plants (Weatherill, 2009). In this example, a 100 fold increase in production volumes of a particular finished product necessitated running double shifts and performing sanitation between midnight and morning start-up. Although food contact surfaces were cleaned daily, the increased production demands resulted in delaying complete cleaning of the plant until the weekend. Moreover, because of the time needed to disassemble the meat slicers and other equipment, not every piece of equipment was fully dismantled, even on the weekend. The adverse outcome of these changes in the sanitation program was that seven positive *Listeria* events on two production lines occurred over a period of fourteen months. The corrective action for each positive *Listeria* result was to sanitize all surfaces where the bacteria could grow on the production lines and in the plant environment. However, a significant shortcoming was the lack of trend analysis of the data. It should have been recognized that the source of the *Listeria* contamination was not eliminated by these corrective actions as evidenced

by the observed positive results that were repeatedly obtained. Ultimately, the source of the *L. monocytogenes* was found to be meat residue located deep inside the meat slicers on two production lines which subsequently contaminated the deli-meat. The extended timeline and the implication of two production lines indicate that long-term deficiencies in the sanitation program were not being addressed.

4.2 Sanitation Process Description

The main purpose of a sanitation program is to remove contaminating soil that can harbour microorganisms and provide nutrients for growth. It is also designed to kill contaminating microorganisms, including pathogens. In addition, sanitation removes allergens and enhances equipment efficiency by removing soil from heat contact surfaces. Carbohydrates are the easiest soil to remove followed by fats, proteins and minerals (Marriott, Schilling, & Gravani, 2018) (Cramer M. , 2013b).

The four factors that are exploited to accomplish sanitation are: type and concentration of detergent (chemical energy), temperature, mechanical or kinetic energy, and time (Jennings, 1965) (Holah, 2014). There are two basic wet sanitation[19] methods, open surface and closed surface cleaning. Open surface cleaning is used for items that are easily accessible for manual cleaning while closed surface cleaning, usually a "clean-in-place" (CIP) system, is performed on inaccessible pipelines, vats and equipment. Open surface cleaning may be practiced *in situ* or items are moved to specific areas and "cleaned-out-of-place" (COP) in COP tanks, dishwashers and tunnel washers (Holah, Sanitation, 2009). All food processing plants practice open surface cleaning as this is how utensils, small parts and the outside of equipment and pipelines are

[19] Wet sanitation processes use a significant amount of water as opposed to dry sanitation processes that are used for food products that do not contain significant amounts of water such as chocolate, peanut butter and dehydrated foods.

cleaned as well as floors, drains, walls and ceilings. While wet sanitation is comprised of just four basic steps - pre-rinse, wash, rinse and sanitize – there is great complexity to these steps as outlined below.

4.2.1.1 Step 1. Pre-Rinse

Pre-rinsing starts by preparing the area for cleaning and is comprised of a dry pickup of scrap, ingredient and product spills, packaging and similar. This pickup should be ongoing throughout production so as to minimize buildup and to prevent cross-contamination onto the processing lines. In a fresh-cut produce processing plant, this step is important because there are substantial numbers of microorganisms associated with ingredient spills and culls (Delaquis, Fresh-Cut Vegetables, 2006) (Keller, 2006). Ideally, the manufacturing crew will complete this at the end of their shift so as to ensure the sanitation crew has enough time to properly complete the needed sanitation procedures (Cramer M. , 2013b) (Holah, 2014).

Next, equipment is broken down to a level that facilitates cleaning and the parts placed in designated areas. Electrical panels and motors are covered to prevent water damage and equipment capable of moving is tagged or locked out.

The area is then rinsed with water at an appropriate temperature for the soil starting with the walls, floors and drains. The rinse temperature should not be high enough to denature proteins thus binding them to surfaces. Equipment is rinsed from the top to the bottom with high-volume, low pressure water to prevent atomization (Cramer, 2013b). Redemann (2005) states that if extra water pressure is needed to remove soils that are hard to remove, this is the step at which this should occur so as to minimize cross-contamination. Dismantled parts may be rinsed, then washed in a sink, COP tank, dishwasher or similar.

Plants that use CIP systems manually connect silos, tanks, vats, fillers and processing lines to the CIP system. The CIP sanitation cycle is customized for each item being washed and is generally automated.

4.2.1.2 Step 2. Wash

Equipment and plant surfaces are washed with detergent[20] , generally a caustic cleaner, and water. Chemical energy from the detergent breaks down the soil to make it easier to remove from the surface it is attached to and suspends it in solution to facilitate rinsing and discourage redeposition. The detergent solution may be applied by various means such as foaming, high or medium-pressure, low-volume spray units, steam guns, and combination centralized high-pressure and foam cleaning (Marriott, Schilling, & Gravani, 2018). High pressure cleaning must be carefully managed because it can scatter soil and microorganisms throughout the area. Brooms, brushes, scrapers, scrub pads, shovels, sponges, and squeegees are used to apply mechanical or kinetic energy for manual cleaning. These items perform specified functions and are generally assigned for use in designated areas and, to this end, they are often colour-coded to indicate when they are out of place. If a soil is proving difficult to remove, the four cleaning factors, type and concentration of detergent (chemical energy), temperature, mechanical or kinetic energy, and time, are manipulated to ensure complete soil removal.

If soil is not completely removed, a biofilm, defined by (Tarver, 2009) as "a thin layer of densely packed microorganisms encapsulated within an aqueous matrix of proteins, nucleic acids, and polysaccharides, may form. Biofilms start when organic or inorganic material accumulates on a food contact surface thus creating an environment to which bacteria can adhere (Cramer M. M.,

[20] Detergent is defined by (Bourne & Jennings, 1963) as "any substance that, either alone or in a mixture, reduces the work requirement of a cleaning process".

2013a). Over time the accumulating bacteria will change morphology and produce extracellular polysaccharides to the point that the bacteria are protected within the biofilm and become up to 100 fold more resistant to sanitizer (Cramer, 2013a). Extraordinary cleaning methods are needed to remove a mature biofilm.

Holah (2014) recommends that drains, walls, and floors be cleaned and rinsed in that order before the equipment is cleaned and rinsed to minimize the risk of cross-contamination of soil and microorganisms back onto equipment. The type and concentration of detergent and the treatment time and temperature is dependent on the area being cleaned and the application method. Some equipment may need to run on slow speed or a special cleaning cycle. Foam is applied from the bottom up to ensure all areas are covered. Marriott et al. (2018) recommends that high pressure washing be preceded by a low pressure rinse-down.

Sanitation personnel must wear appropriate safety equipment when making up and applying cleaning solutions. In addition, all cleaning solution containers, including the original container, transfer containers and applicator containers must be labelled such that they meet Workplace Hazardous Materials Information System (WHMIS) requirements.

4.2.1.3 Step 3. Rinse

The detergent is rinsed off walls, floors and equipment, in that order, with the lowest effective pressure and volume of water making sure that the equipment is rinsed from the top down. The temperature of water should be warm enough to effectively remove the detergent while causing a minimum of steam or condensation (Cramer M. , 2013b). Rinsing is complete once all of the detergent has been removed from the area being cleaned.

Processing plants that are removing complex soils from products such as milk which contains fat, protein, carbohydrates and minerals will also perform an acid wash, either in addition to a caustic detergent after the detergent has been rinsed off or performed periodically

instead of washing with a caustic cleaner (Marriott, Schilling, & Gravani, 2018). Acid washes are also required to descale equipment in areas with hard water.

4.2.1.4 Step 4. Sanitize

While washing removes the majority of the microorganisms from plant surfaces, a sanitizer is needed to further reduce the microbiological load (Holah, 2014). Health Canada (2018) describes chemical sanitizers as "a substance, or mixture of substances, that reduces the bacterial population on environmental surfaces and inanimate objects by significant numbers (e.g., a minimum 3 log10 reduction) due to the antimicrobial action of the active ingredient(s), but which does not destroy all bacteria." Various methods can be used for sanitizing including thermal (steam or hot water), radiation, ozone, and chemical sanitizers (Marriott & Gravani, 2006). Some plants use a combination of sanitizing methods because several methods work best for their particular combination of processing equipment. Chemical sanitizers are frequently used in the food industry because of the ease of applying them throughout the plant. There are several in common use including sodium hypochlorite, alcohols, quaternary ammonia compounds (QAC), and peracetic acid solutions (Holah, 2014) (Cramer, 2013b). Ideally, the equipment is inspected and deficiencies corrected before sanitizer is applied (Redemann, 2005). In the case of CIP systems, each area is checked after the CIP cycle is complete to confirm it is clean and that sanitizer was applied. The type of sanitizer and usage conditions including concentration, time and temperature are prescribed and will vary depending on the sanitizer in use and the area being sanitized. The environment may be treated with a higher concentration of sanitizer than food contact surfaces (Redemann, 2005). There may also be a combination of thermal and chemical sanitizers used in the plant. Food contact surfaces are treated with a no-rinse level of chemical sanitizer which is a level at which the sanitizer does not need to be rinsed before food processing begins. If higher sanitizer levels are needed to eliminate elevated microbiological loads, the sanitizer must be rinsed off and the no-rinse level of sanitizer subsequently applied. Sanitizers are

delivered by hand sprayers, centralized units, or sprayers mounted on processing equipment and may be applied by spraying, fogging, flooding, foaming, immersion or injected into water at the end of a CIP cycle. (Marriott, Schilling, & Gravani, 2018). As with cleaners, sanitation personnel must wear protective gear when applying sanitizers and sanitation chemical containers should be properly labelled.

This description of sanitation illustrates the many factors that must be considered when designing a sanitation process and the complexity that must be detailed when writing sanitation SOPs and training people to perform their sanitation procedures.

4.2.1.5 Sanitation Monitoring

Typical sanitation monitoring procedures include measuring chemical concentrations, sanitation cycle temperatures and times and performing visual inspections during sanitation at prescribed times and locations. Thermographs may also chart sanitation cycle temperatures and times during automated sanitation processes (Cramer, 2013b).

4.2.1.6 Sanitation Verification

Most sanitation verification activities do not examine the sanitation process in detail because they are performed after sanitation is finished and focus on looking for food residues or the presence of organic material through pre-operational inspections and the presence of microorganisms to indicate problems with the sanitation program. There are rapid tests that can be used to determine if soil is left on food contact surfaces including adenosine triphosphate (ATP) bioluminescence, protein and glucose residue swabs. Microbiological tests are also performed including finished product and shelf life testing, in-process tests and swabbing that includes both food contact surfaces and the environment (Cramer, 2013c) (Campbell, 2005) (Slade, 2002).

When verification specifications are met, it is often assumed that all planned activities have been followed and, more importantly, they are appropriate and effective. When specifications are not met, there may be a focus on cleaning up the particular area rather than looking at the bigger picture of whether the full sanitation and the sanitation verification program is designed properly at the outset and being followed. The 2008 *L. monocytogenes* outbreak described in Section 4.1 illustrates an undesirable consequence of this approach. In short, sanitation processes by nature are very complex and, if poorly designed and/or not correctly followed, will lead to potential foodborne disease outbreaks and losses in food quality.

It is suggested that sanitation program failures can be partly attributed to the fact that current sanitation monitoring and verification procedures do not systematically examine the sanitation process while it is being performed thus allowing long-term sanitation program deficiencies to occur.

4.3 Sanitation Process Measurement and Improvement through Use of a Defect Opportunity Checklist (DOC)

Pathogen contamination because of unsanitary equipment had a SxOxD rating of 10 x 2 x 7 resulting in a RPN of 140 which was given fourth priority for corrective actions in the fresh-cut carrot FMEA (Table 2) in Chapter 2. The main reason for this elevated number was because the detection controls for this hazard were performed after sanitation is complete through pre-operational inspections and the environmental swab program which provide immediate and delayed results respectively; this is a 7 when matched against the detection criteria listed in Table 1 in Chapter 2.

It is proposed that a Defect Opportunity Checklist or DOC introduced in Section 1.7.4 of the Literature Review is a tool that could potentially reduce the risk associated with a sanitation

program as evidenced by a reduction in the RPN. The detectability rating of this hazard may be improved because the DOC assesses the full sanitation process in real-time. The DOC also interacts with the occurrence rating; first, because it can provide more information about the real likelihood of occurrence of the hazard and second, because the DOC, when used in conjunction with Pareto charts and cause & effect diagrams, can potentially facilitate an improvement in the sanitation process through appropriate corrective actions and illustrate this improvement through a reduced % defect rate the next time the DOC is performed. This approach may lead to reduced O and D values thus resulting in a lower RPN which means the site has decreased the likelihood of having unsanitary conditions that, over time, may lead to a foodborne outbreak.

4.4 Research goal and Research Hypothesis

The research goal of this experiment was to examine the use of a Defect Opportunity Checklist (DOC) as a means to assess a full sanitation process in "real-time" and to use the DOC, in conjunction with Pareto charts and cause & effect diagrams, as a means to measure and improve the sanitation process in a fresh cut produce plant.

Given this discussion, the following hypotheses are proposed:

H_0: DOC does not measure the performance of a sanitation process in "real-time".

H_1: DOC measures the performance of a sanitation process in "real-time" and

H_0: DOC, in conjunction with Pareto charts and cause & effect diagrams, does not facilitate performance improvement of a sanitation process.

H_1: DOC, in conjunction with Pareto charts and cause & effect diagrams, facilitates performance improvement of a sanitation process.

4.5 Methods

This assessment was performed at the same fresh-cut produce site reported for experiments presented in Chapters 2 and 3. The site processes products in three rooms over two production shifts and a midnight sanitation shift each day. After production is complete, the

sanitation crew performs open sanitation procedures. Six hours of sanitation time is available for each room unless large orders or an equipment break-down necessitates the need for production to run over-time.

The main sanitation process is *in situ* open surface cleaning using a caustic detergent that is applied as a foam and manual cleaning of dismantled equipment parts, cutting boards, knives and produce transfer conveyances such as buckets, baskets and cases. A standard four-step cleaning process is followed: pre-rinse, wash, rinse, and sanitize.

4.5.1 Defect Opportunity Checklist (DOC)

In this experiment, the sanitation process at this site was analyzed to identify the defect opportunities and to develop a Defect Opportunity Checklist (DOC). The first step towards developing this checklist was to derive a set of sanitation best practices for fresh cut produce plants from literature (Cramer, 2013b) (Holah, 2014) (OMAFRA, 2006). These practices were compared to those stated in the site's existing Standard Operating Procedures (SOPs). Because there were significant items missing from the existing sanitation SOPs, sanitation Best Practices published in the manual, "Foods of Plant Origin. Cleaning and Sanitation Guidebook", published by the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA) (2006) were incorporated into the DOC. Items related to the type and use of detergents and sanitizers were taken from the site's SOPs and cross-checked against supplier specifications. The DOC also contained items related to worker safety as mishandling of commercial sanitation chemicals can lead to serious injuries or health problems.

The DOC was performed during the 12am – 8am sanitation shift (Run 1), then repeated after 3 months (Run 2) and 8 months (Run 3) to examine whether or not the corrective actions were effectively implemented.

The DOC was filled in while the sanitation process was observed; if the item was in compliance a "0" was entered indicating no defect and if there was a problem with the item, a "1" was entered. In this example, if the defect applied to all three rooms as a whole, the total available defects were classified as 1 or 1/3 for each room. The % defects was calculated by adding up the total number of identified defects, then dividing by the total possible defects.

The defects were classified into categories and plotted on a Pareto chart using Microsoft Excel (Microsoft Office Professional Plus, 2013; Redmond WA, USA). A cause & effect diagram was then developed using Microsoft Visio (Microsoft Visio Professional 2010) to illustrate the underlying reasons for the observed % defect rate in Run 1. The content for the cause & effect diagrams was developed through observation of the sanitation process and discussions with representatives from Sanitation, Production and Quality. The information was presented to the management team and a set of corrective actions was agreed upon.

The % defect rate was calculated after each run and the Pareto charts were repeated using the same categories. A second cause and effect diagram was then developed to illustrate the underlying reasons for the % defect rate results from Runs 2 and 3.

4.5.2 Microbiological Methods

Cleaned and sanitized plant surfaces were sponge swabbed after sanitation using 3M pre-moistened Sponge-sticks with D/E Neutralizing broth. Nine areas were swabbed for Run 1 while for Runs 2 and 3, these nine areas plus 12 more for a total of twenty-one were swabbed. All were food contact surfaces except for two swabs of the floor for runs 2 and 3. The size of the swabbed areas ranged between 490 and 9250 cm^2. The sponge swab was placed in a sample bag to which one 100 mL of 0.1% peptone was added and vigourously massaged for 1 minute. One mL samples were drawn and plated for APC using Acumedia Nutrient Agar pour plates and *E.coli* and coliforms using 3M *E coli*/coliform Petrifilm. The microbiological counts were normalized to logs

and the results were plotted on a Pivot Chart using Microsoft Excel (Microsoft Office Professional Plus, 2013; Redmond WA, USA).

4.6 Results

4.6.1 DOC

The DOC results are summarized and shown in their entirety in Appendix A. The defects were categorized as "Time-Related", "Worker Safety", "Incorrect Procedure" or "SOPs". The "Time-Related" category includes defects that either reduce the time available for sanitation or occur because of lack of time. "Worker Safety" defects may cause harm to sanitation personnel, "Incorrect Procedures" are incorrectly performed procedures and "SOPs" defects indicate that the SOPs either do not match Best Practices for the process or the SOPs are incomplete or out-of-date. The Pareto charts categorizing the defects for the three runs are found in Figure 24a to c while Figure 25a to b display two cause & effect diagrams illustrating the underlying reasons for the defects.

4.6.1.1 Run 1

The DOC Summary (Table 8) indicates that in Run 1, there were 39 defects out of a possible 99 for a defect rate of 39%; 25 defects were categorized as Lack of Time, 6 as Incorrect Procedures, 6 as Worker Safety, and 2 as problems with the SOPs. Figure 24a, the Run 1 Pareto chart, illustrates these results by category.

An examination of the cause and effect diagram Figure 25a, shows that the three time-related defects that reduced the lack of time for sanitation were: i) incomplete pick up of product spills (food scraps, product or input spills) during production; ii) raw materials, WIP and packaging were not removed from the processing area at the end of the production shift; and iii) raw materials for the next day's production were placed on the production floor before sanitation

was complete. The time-related defects that occurred because of lack of time were: equipment was cleaned before gross food residues were removed from the area; foam cleaner was not applied to the undersides of equipment, full sanitation procedures were not applied to all transfer conveyances (buckets, baskets and crates), full sanitation procedures were not performed on the lower walls and floors; equipment was not inspected before sanitizing; and sanitizer was not correctly applied.

The cause and effect diagram also indicates that the underlying reasons for the production rooms not being prepared for sanitation by removing product spills and raw materials, WIP and packaging was that the afternoon supervisor was inexperienced with sanitation and not scheduled to be present for the end of production. There were also not enough waste stations in place to capture product spills that occur during processing. In addition, the SOPs did not specifically state that product spills should be picked up by the end of production. Late ordering by customers was also allowed so production frequently runs overtime to fill these orders. Finally, raw materials for the next day of production were placed in the processing area before sanitation was complete because there was not enough room in the warehouse.

The six defects that occurred because of incorrect procedures were: i) foam cleaner was not applied from the bottom to the top of the item being cleaned; ii) small items were not placed in the appropriate area for cleaning in room 3, iii) several colour-coded cleaning aids in room 1 should have been in a different room, and iv) the sanitizer concentration was too low in room 2. The underlying reason that foam cleaner was improperly applied and equipment parts were placed in the wrong area for cleaning was that these procedures were not included in the SOPs. The sanitizer concentration was incorrect because there was a plumbing problem that had not yet been addressed and the colour-coded cleaning aids were in the incorrect cleaning area. The out of place cleaning aids were not being addressed because the environmental swab microbiological

counts were acceptable so controlling this potential source of cross-contamination was not prioritized.

The six defects associated with worker safety were: i)workers not wearing their safety goggles at all times during cleaner application because they would fog up and ii) chemical labels were missing or partly worn off the foamer, chemical containers and chemical transfer containers. The underlying reason for these defects was that management was unaware of these problems because they occurred on night shift and sanitation workers were not communicating that these problems existed because they were unaware of their importance.

SOPs were associated with two defects; the SOPs as written do not match sanitation best practices for fresh-cut product plants and they were incomplete and not up-to-date. The underlying reason for these defects is the sanitation program was not being prioritized by Production or Quality because the pre-operational inspections and the environmental swab microbiological counts used to verify the sanitation program were acceptable.

The Run 1 DOC, Pareto chart and cause and effect diagram was presented to the Production and Quality. The production management team decided they would address the lack of time for sanitation by hiring a supervisor with sanitation experience, changing the hours so the supervisor was present until the end of the afternoon shift, designating in-process production clean-up personnel, setting up in-process waste stations and incorporating in-process cleaning into training materials and training personnel to the changes. There were also actions set up for improving worker safety and reducing the defects in the incorrect procedures category.

4.6.1.2 Runs 2 and 3

Run 2, performed three months later, had 36 defects out of 99 for a defect rate of 36% while Run 3, performed 5 months after Run 2, had 35 defects out of 99 for a defect rate of 35%.

These results indicated a slight but limited improvement over Run 1, which had 39 defects out of 99 for a defect rate of 39%.

As illustrated in the Pareto chart in Figure 24b for Run 2, there were 21 time-related defects, 4 fewer than for Run 1. This change occurred because dry pickup of product spills was performed by the production shift in two of the three rooms, in room 2, the production shift had removed all raw materials, WIP, and packaging and in room 1, the equipment was inspected before sanitizing. There was no change in the defects related to worker safety and there was one more defect related to incorrect procedures because an incorrect concentration of sanitizer was applied in two rooms rather than just one. The other defects were basically the same as those in Run 1 except that several colour-coded cleaning aids in room 2 should have been in a different room. The defects associated with SOPs remained unchanged.

The defect rate in Run 3 was slightly lower than Run 1 and 2, respectively, because of the worker safety improvement; safety goggles were worn and some of the chemical containers were properly labelled. As illustrated in Figure 24c, Pareto chart in Run 3, had 23 time-related defects, or an increase of 2 over Run 2. This occurred because dry pickup of product spills were performed in just one of the three rooms; raw material; WIP and packaging were not removed at the end of production from any of the three rooms and there was no inspection of equipment before sanitizing in any of the three rooms. There was one improvement over both run 1 and 2 in that gross food residue was removed from equipment and the surrounding area before equipment cleaning began in room 3. The worker safety defects decreased from 6 to 2 because workers were wearing safety goggles and the chemical transfer containers were properly labelled. The incorrect procedures defects increased by 1 because the sanitizer concentration was incorrect in all three rooms. The other defects remained the same except that the defect associated with placing equipment and small items in the designated area for cleaning occurred in a different room. There was no change in the SOP-related defects.

The cause and effect diagram illustrated in Figure 2b indicates that the limited improvement in the defect rates for Runs 2 and 3, versus Run 1 is because the underlying causes of these defects remained. The three sanitation preparation tasks that reduce the amount of time available for sanitation if not performed were not being consistently executed. First, product spills were not being removed because the crowded production area makes them difficult to remove, production personnel were not assigned to remove product spills at the end of their shift because the supervisor's shift ends several hours before the end of production, and production often runs overtime because customers value being able to late-order. Second, raw materials, WIP and packaging were not removed because production personnel were not assigned to this task because, again, there was no supervisor at the end of the shift and third, raw materials were placed back in the production area before sanitation ends because there was not enough room for them in the warehouse.

Incorrect procedures and adherence to worker safety procedures were not focused on because current sanitation verification procedures, a daily pre-operational inspection of the equipment and processing and the environmental sampling program, both of which are performed after sanitation is complete, are not designed to examine these items.

The sanitation SOPs were not updated to meet sector Best Practices because the sanitation program was not prioritized by Production or the Quality department because the results of the site's sanitation verification activities were satisfactory. The SOPs were therefore not updated to include procedures for sanitation preparation.

4.6.2 Microbiological Results

It is suggested by Kornacki (2010) that, after cleaning the environment and equipment, there should not be APC counts in excess of 100 – 1,000 per ft^2 (930 cm^2), or the presence of

coliforms. In this experiment, microbiological counts were considered to be unsatisfactory if they were in excess of 1,000 (3 $\log_{10}$ APC) and/or if coliforms were present.

The microbiological results shown in Figure 26 indicate that no APC colony-forming units were detected in 3 out of 9 sampled surfaces in Run 1. The remaining 6 surfaces had APC counts between 1.5 and 2.9 log CFUs/930 cm^2, all of which met the satisfactory requirements of <3 $\log_{10}$/930 cm^2. No coliforms were detected in any of the swabbed surfaces.

In Run 2, no APC colony-forming units were detected in 12 of 21 surfaces while the 9 remaining surfaces had between 1.5 and 3.7 log CFU/930 cm^2. Three surfaces were unsatisfactory; the floor at the entrance to the plant had an elevated APC count, a transfer bucket had an elevated APC count and coliforms, and a transfer basket had coliforms.

Twelve of 21 surfaces swabbed in Run 3 had no detectable APC counts while the remaining 9 had APC counts between 0.9 and 4.5 $\log_{10}$ CFUs/930 cm^2. Four surfaces were unsatisfactory; the floor at the entrance to the plant and a transfer bucket had coliforms while a spinner and a transfer bucket had an elevated APC count.

Table 8. Summary of Defects for three Sanitation Runs, Run 1, Run 2 and Run 3.

Defect Category	Best Practice	Defect Opportunity	Run 1			Run 2			Run 3		
			Room			Room			Room		
			1	2	3	1	2	3	1	2	3
Time-Related	Dry pickup of scrap, product or input spills during processing and end of shift to prevent unsanitary processing conditions and to save the sanitation shift time and effort.	*No or incomplete dry pick of product spills during processing and end of production shift.*	1	1	1	1	0	0	1	0	1
Time-Related	Remove raw materials, WIP, and packaging from area at end of production shift	*Items not physically removed or adequately covered in room by production shifts.*	1	1	1	1	0	1	1	1	1
Time-Related	Do not place raw materials for next day's production onto production floor before cleaning is finished	*Materials placed on production floor before cleaning is complete.*	0	1	0	0	1	0	0	1	0
Time-Related	Physically remove as much soil as possible using brooms, shovels, squeegees, etc. before four step sanitation process begins.	*Gross food residue not removed from equipment and surrounding area (floor) before four step sanitation begins.*	1	1	1	1	1	1	1	1	0
Time-Related	Perform entire sanitation procedure on walls, floors and equipment.	*Walls only spot cleaned, floors not formally washed and sanitized.*	1	1	1	1	1	1	1	1	1
Time-Related	*Clean all produce transfer conveyances including crates, baskets, and transfer bins*	*Full sanitation procedures not applied to all transfer conveyances.*	1	1	1	1	1	1	1	1	1
Time-Related	Apply foam cleaner to undersurfaces of equipment	*Not applied to undersurfaces*	1	1	1	1	1	1	1	1	1
Time-Related	Inspect equipment before sanitizing.	*Equipment not inspected before sanitizing.*	1	1	1	0	1	1	1	1	1
Time-Related	Sanitize equipment starting with support structures and working upward.	*Sanitizer not applied from the bottom upward*	1	1	1	1	1	1	1	1	1
Worker Safety	Wear safety gear - gloves, apron goggles	*Safety gear not worn when making and applying solution (googles)*	1	1	1	1	1	1	0	0	0
Worker Safety	Use properly labelled soap foamer	*Soap foamer not properly labelled*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
Worker Safety	Use labelled containers for transferring chemicals	*Transfer containers not properly labelled*	1/3	1/3	1/3	1/3	1/3	1/3	0	0	0
Worker Safety	Use properly labelled chemical containers	*Chemical containers not properly labelled*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
Incorrect procedure	Place small items such as equipment parts, cutting boards and knives in designated areas for cleaning	*Small items not placed in designated areas for cleaning.*	0	0	1	0	0	1	1	0	0
Incorrect procedure	Apply foam cleaner from bottom to top	*Not applied from bottom to top*	1	1	1	1	1	1	1	1	1
Incorrect procedure	Use designated, colour-coded cleaning aids	*Colour-coded cleaning aids not in correct room.*	1	0	0	0	1	0	0	1	0
Incorrect procedure	Correct sanitizer concentration	*Incorrect sanitizer concentration*	0	1	0	0	1	1	1	1	1
SOPs	SOPs match Best Practices	*SOPs do not match sanitation best practices*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	/3	1/3
SOPs	SOPs are complete and up-to-date	*SOP are incomplete and not up-to-date*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
		Totals	12 2/3	13 2/3	12 2/3	10 2/3	12 2/3	12 2/3	12 1/3	12 1/3	10 1/3
		Total Defects	39/99			36/99			35/99		
		% Defects	39%			36%			35%		

/

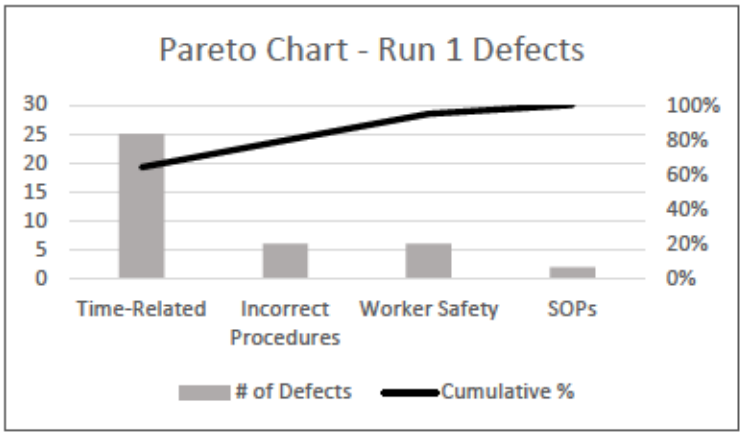


Figure 24a. Run 1 Pareto Chart – Sanitation Process Defect Categories in a Fresh-cut Produce Plant

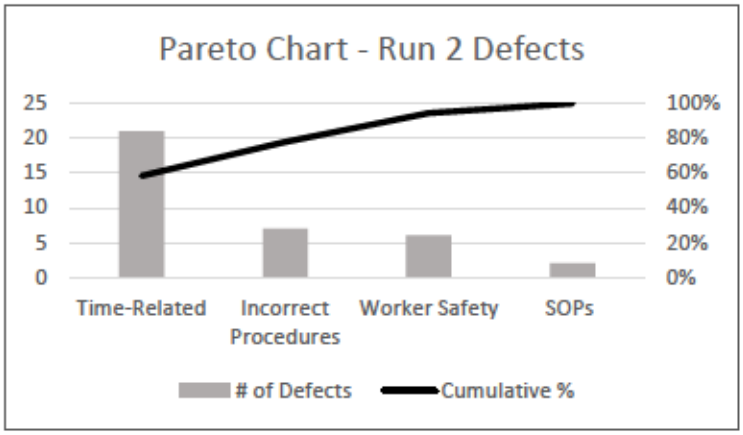


Figure 25b. Run 2 Pareto Chart – Sanitation Process Defect Categories in a Fresh-cut Produce Plant

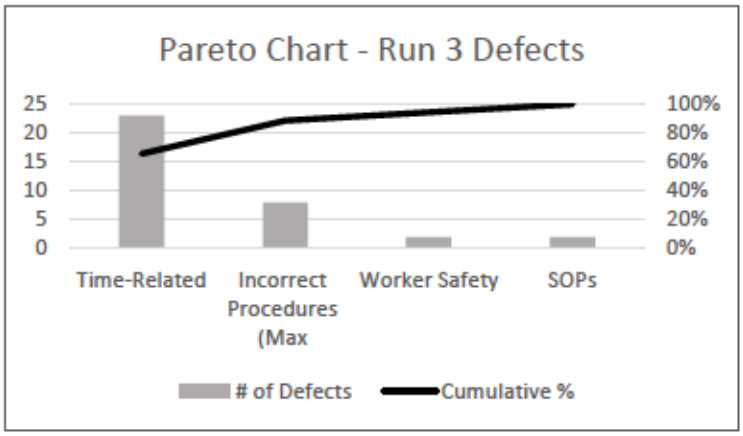


Figure 25c. Run 3 Pareto Chart – Sanitation Process Defect Categories in a Fresh-cut Produce Plant

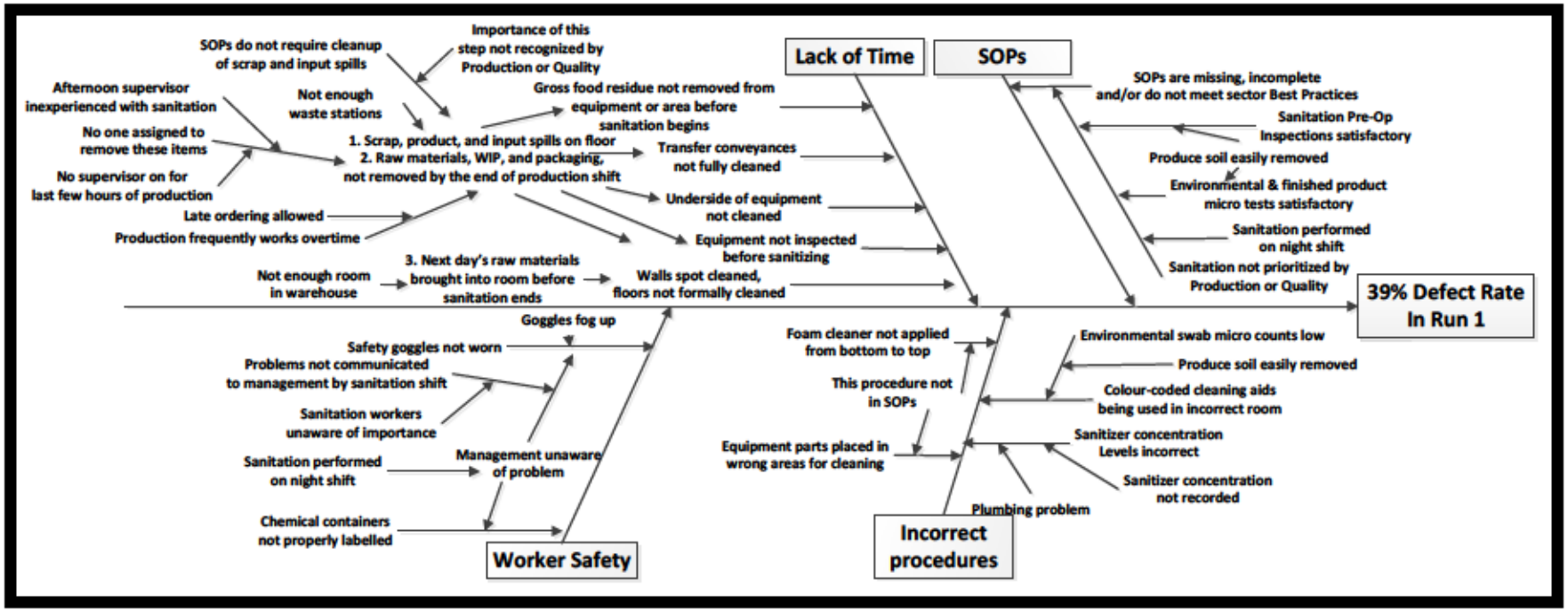


Figure 25a. Run 1 Cause & effect diagram indicating underlying reasons for the 39% defect rate.

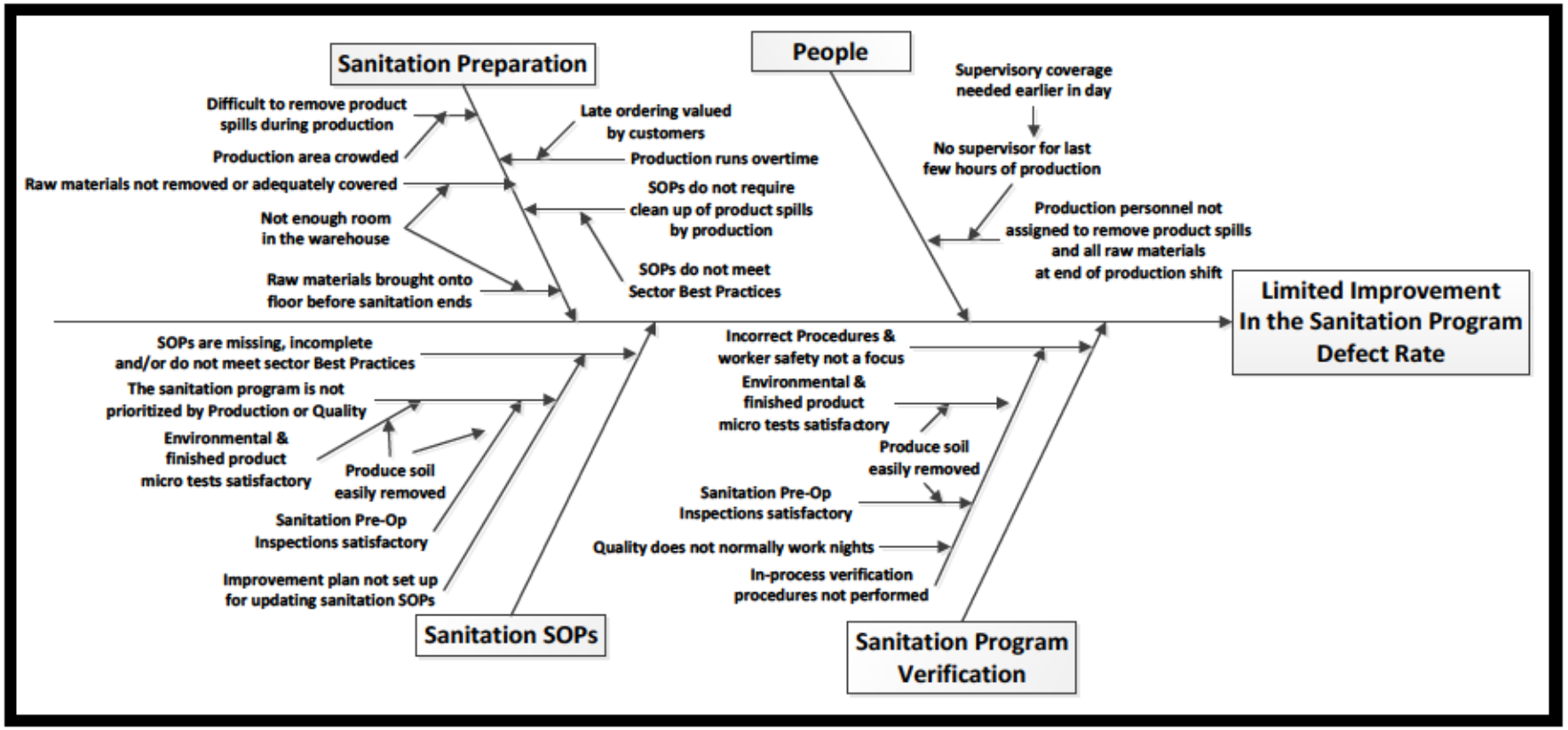


Figure 25b. Cause & effect diagram indicating underlying reasons for the limited improvement in the sanitation program defect rate.

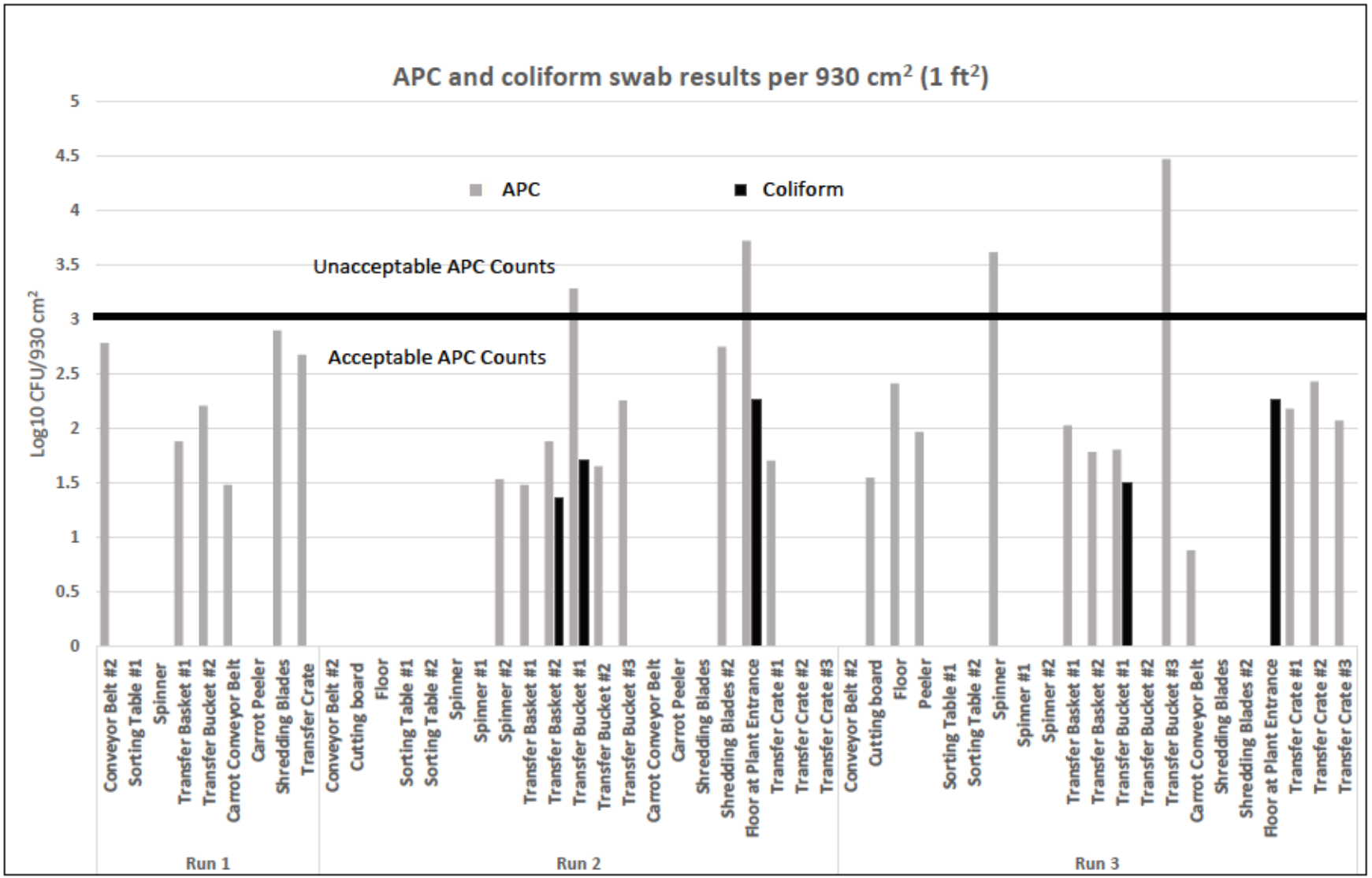


Figure 26. APC and coliform swab results per 930 cm² (1 ft²) from a set of cleaned and sanitized surfaces. APC values 3 logs/930 cm² (1 ft²) and all detectable coliform counts are unacceptable.

4.7 Discussion

The DOC, used in conjunction with Pareto charts and cause & effect diagrams[21], enabled the measurement of performance of a sanitation program, and furthermore clarified the underlying reasons for the defects that occurred. In this experiment, these tools elicited the understanding that many defects occurred because the production rooms were not prepared sufficiently for sanitation by the time the sanitation shift began. The sanitation crew had to take time to move raw materials, WIP and packaging from the area and they focused on cleaning the equipment before clearing away the product spills and gross food residue from the floor to ensure that the equipment was ready for production by the end of shift. This meant that the basic set of fresh-cut produce sanitation procedures to be followed were indeed not followed, as set out in the (OMAFRA, 2006) guidebook. Specifically, all produce spills and gross food residue should be removed from the production floors after which the walls and floors are pre-rinsed and washed, followed by cleaning and washing the equipment. Cleaning the equipment before food residues are completely picked up increases the risk of microbiological cross-contamination of equipment because product spills and residues contain high levels of microorganisms as discussed in Pre-rinsing in Section 4.2 . Similarly, the likelihood of cross-contamination between the equipment and floors and walls is also increased because, under these conditions, the floors and walls are not fully cleaned and sanitized. The microbiological results support this observation because the two swabs taken of the floor at the main entrance to the production area from Run 2 and Run 3 were unsatisfactory, which indicates that microorganisms were being transferred from this location to the rest of the production areas by plant personnel.

[21] DOC in conjunction with Pareto charts and cause & effect diagrams will be referred to as DOCPC for this discussion.

The microbiological results also indicated that the lack of time to clean produce transfer conveyances (buckets, crates and baskets) resulted in higher counts as evidenced by the fact that four of the seven unsatisfactory counts were associated with these items. This result means that these items could conceivably become a significant source of cross-contamination with the potential to affect the food safety and quality of finished products. These results also suggest that the occurrence rating associated with pathogen contamination, because of unsanitary equipment at *transferring/weighing* described in Chapter 2, should probably be higher than a given value of 2 because the number of microorganisms left in the transfer bucket after cleaning was sometimes unacceptable.

Developing the DOC for sanitation was not straight-forward because the sanitation SOPs at this site were missing, incomplete and/or did not meet the produce sector's Best Practices. In the author's experience, this is not an uncommon situation in food plants even with the uptake of Global Food Safety Initiative (GFSI) bench-marked food safety standards. The handbook, "Foods of Plant Origin. Cleaning and Sanitation Guidebook" published by OMAFRA (2006) was therefore used to develop much of the DOC. In addition, the checklist was adjusted while watching procedures when performing the DOC for Run 1. Putting in this effort; however, was productive because not only was a useful DOC developed, but the information could also be used to improve the sanitation program process and associated SOPs.

The SOP-related defects greatly affect the sanitation program because if SOPs are missing or incomplete, the sanitation program is by definition incomplete because plant personnel will not be trained to or perform the omitted activities. For example, a significant procedure not included in the SOPs was the need for production to remove product spills from the area before the production shift ends. The underlying reason for this appeared to be that the three sanitation program verification metrics: namely, the pre-operational inspection and the

microbiological results from the environmental sampling program and finished product, are generally acceptable. This meant that the quality department had no impetus to prioritize the completion of the sanitation SOPs or to change their work hours to observe sanitation during the night shift. Having sanitation performed in the middle of the night was also problematic, in so much that management was also unaware of the problems related to worker safety.

The results of the DOCPC can be used to inform the fresh-cut carrot processing FMEA presented in Table 2 in Chapter 2. While detection could potentially be improved by one or two points depending on the frequency, the DOC performed in this experiment demonstrated that the occurrence rating and associated RPN may actually be higher than values of 2 and 120, respectively, because the per cent defect rate remained between 35 and 39% throughout this experiment.

These results can also be used to inform the ICMSF conceptual equation outlined in Figure 10 in the Literature Review. The elevated per cent defect rate and the results of the microbiological swabs suggest that the Performance Objective (PO) may not be consistently met because the sanitation program does not effectively reduce microorganisms on some food contact surfaces.

The limited improvement in the defect rate associated with Run 2 and 3, as compared with Run 1 indicated that, in this experiment, the DOCPC did not facilitate improvement. This was illustrated in Figure 2b, the cause & effect diagram; whereby the site did not see the need for improvement because the current measurements of sanitation did not indicate problems with sanitation. This means that the significant resources needed to improve the program were likely not justifiable. In this experiment, effort would be needed on many fronts to: i) change the shift times for supervisors, ii) modify the set-up of the three processing area to facilitate the removal of product waste and spills during the day, iii) change how inventory is managed in the warehouse

to free up space, fix plumbing, and, iv) set up a project to update the sanitation SOPs. The site would also need workers trained in the use of DOCPC to both inform and improve the food safety & quality program.

This is a significant observation from this thesis, because it indicates that even though a six sigma tool can be shown to improve a food safety program, it may not necessarily be adopted unless the site is experiencing a problem with their current program.

4.8 Conclusions

This thesis showed that developing the checklist for the DOC was useful because this activity provided a structure by which to determine if the current sanitation program and related SOPs meet Best Practices. This case study also indicated that a sanitation process with a 35-39% defect rate can still have acceptable post-process pre-operational inspections and environmental sampling results. These defects could potentially, over time, lead to a foodborne outbreak if they are not corrected.

The main conclusion of this assessment is that, while the DOC provides detailed information about the deficiencies in a sanitation program, this information alone is not sufficient to stimulate a fundamental change in how the sanitation program operates when the current methods for measuring sanitation effectiveness do not indicate a problem exists.

Chapter 5. General Discussion and Conclusions

These experiments were performed on-site at a fresh-cut produce plant which means that while the results reflect an actual processing environment, some factors could not be controlled as much as they ideally should have been. This limitation greatly affected the carrot experiments in Chapter 3, where a more even distribution of samples from each geographical location would have been useful. The strength of this approach, however, is that this thesis presents some of the challenges that face fresh-cut processors. These include: raw materials, purchased from many different sources depending on supply, the reasons for quality problems that may never be identified, and finally challenges with having enough time to perform some processing activities such as sanitation.

FMEA provides a more accurate portrayal of the risk that is associated with a fresh-cut carrot processing line in a fresh-cut processing plant than a conventional Hazard Analysis such as the SFCR HA. This is because it clearly indicates the residual risk that is left after the risk mitigating activities are in place and what variables are responsible for this remaining risk. In the case of a fresh-cut produce plant, this residual risk was mainly associated with not being able to detect when incoming produce is contaminated with biological hazards at levels sufficient to cause illness in consumers. This indicates that FMEA has the potential to decrease the likelihood that food processors will sell contaminated food to consumers because they have not detected when their biological hazards are not being adequately controlled due to a classical type 2 error.

The FMEA, in contrast to the conventional SFCR HA, also obliges the team to examine all of the higher RPNs to determine if it is possible to further reduce risk through further corrective actions. The SFCR HA does not compel such actions because its structure makes it appear that all of the risks are being adequately managed. The FMEA thus becomes a driver for continuous improvement of the process.

This need for continuous improvement in these procedures means that fresh-cut produce plants, such as the one modelled in this thesis, must reexamine their current methods for detecting biological hazards in incoming produce. While this thesis indicated that detecting biological hazards in incoming produce is likely not possible without spending a very large amount of financial resources on a form of acceptance sampling, the FMEA also brings out that redesigning the process may be a more successful approach to reducing risk. Thus a fresh-cut produce plant similar to the one used herein, if using FMEA, might put more effort into examining new technologies for decontaminating produce. Alternatively, they could work more closely with entities further back in the supply chain to ensure known contamination sources such as irrigation water, soil amendments or the cleanliness of workers hands are being adequately controlled.

The DOC proved to be a useful tool for determining whether or not the planned activities of a sanitation process were being followed, thus improving the detection rating in an FMEA. This methodology can also be used to identify where process design changes are needed to reduce the defect rate, thus leading to a potential reduction in the FMEA occurrence rating. The most important learning from the DOC experiment, however, was the fact that a processor will not automatically adopt a new tool for improving food safety if the tools they are currently using are not signaling the existence of a food safety related problem. For this reason it is also unlikely that FMEA will replace SFCR HA and related hazard analysis techniques unless a significant foodborne outbreak is attributed to problems with hazard analysis methodology.

A possible solution to this dilemma might be to set up multi-disciplinary teams that include experts from other manufacturing sectors to perform research demonstrating improvement in food safety outcomes through use of FMEA and other six sigma techniques.

References

3M. (2017). *3M Petrifilm E.coli/Coliform Interpretation Guide.* Retrieved July 10, 2019, from 3M Petrifilm E.coli/Coliform Count Plates: file:///C:/Users/Rebecca/Downloads/multimedia%20(2).pdf

Ahmed, W., Huygens, F., Goonetilleke, A., & Gardner, T. (2008). Real-Time PCR Detection of Pathogenic Microorganisms in Roof-Harvested Rainwater in Southeast Queensland, Australia. *Applied and Environmental Microbiology, 74*(17), 5490-5496. doi:10.1128/AEM.00331-08

Allende, A., & Monaghan, J. (2015). Irrigation Water Quality for Leafy Crops: A Perspective of Risks and Potential Solutions. *International Journal of Environmental Research and Public Health, 12*, 7457 - 7477. Retrieved from 10.3390/ijerph120707457

Allende, A., Selma, M. V., Lopez-Galvez, F., Villaescusa, R., & Gil, M. I. (2008). Impact of Wash Water Quality on Sensory and Microbial Quality, including Escherichia coli Cross-Contamination, of Fresh-Cut Escarole. *Journal of Food Protection, 71*(12), 2514-2518.

Anhoj, J., & Olesen, A. V. (2014). Run Charts Revisited: A Simulation Study of Run Chart Rules for Detection of Non-Random Variation in Health Care Processes. *PLOS ONE, 9*(11). doi:10.1371/journal.pone.0113825

APHA. (1971). Proceedings of the National Conference on Food Protection. APHA.

Arthur, L., Jones, S., Fabri, M., & Odumeru, J. (2007). Microbial Survey of Selected Ontario-Grown Fresh Fruits and Vegetables. *Journal of Food Protection, 70*(12), 2864 - 2867.

Arvanitoyannis, I. S., & Varzakas, T. H. (2007). A Conjoint Study of Quantitative and Semi-Quantitative Assessment of Failure in a Strudel Manufacturing Plant by Means of FMEA

and HACCP, Cause and Effect and Pareto diagram. *International Journal of Food Science and Technology, 42*, 1156-1176. doi:10.111/j.1365-2621.2006.01301.x

Arvanitoyannis, I. S., & Varzakas, T. H. (2007). Application of failure mode and effect analysis (FMEA), cause and effect analysis and Pareto Diagram in Conjunction with HACCP to a Potato Chips Manufacturing Plant. *International Journal of Food Science and Technology, 42*, 1424-1442. doi:doi:10.111/j.1365-2621.2006.01361.x

Arvanitoyannis, I. S., & Varzakas, T. H. (2008). Application of ISO 22000 and Failure Mode and Effect Analysis (FMEA) for Industrial Processing of Salmon: A Case Study. *Critical Reviews in Food Science and Nutrition, 48*, 411-429. doi:10.1080/10408390701424410

Arvanitoyannis, I. S., & Varzakas, T. H. (2010). Application of Failure Mode and Effect Analysis (FMEA) and Cause and Effect Analysis in Conjunction with ISO 22000 to a Snails (Helix aspersa) Processing Plant; A Case Study. *Critical Reviews in Food Science and Nutrition, 49*(7), 607-625. doi:10.1080/10408390802145294

ASQ. (n.d.). Quality Glossary. Retrieved Sept 27, 2019, from https://asq.org/quality-resources/quality-glossary/t

Baert, L., Mattison, K., Loisy-Hamon, F., Harlow, J., Martyres, A., Lebeau, B., . . . Van Coillie, E. (2011). Review: Norovirus Prevalence in Belgian, Canadian and French Produce: A Threat to Human Health? *International Journal of Food Microbiology, 151*, 261-269.

Barth, M., Hankinson, T. R., Zhuang, H., & Breidt, F. (2009). Microbiological Spoilage of Fruits and Vegetables. In W. H. Sperber, & M. P. Doyle (Eds.), *Compendium of the Microbiological Spoilage of Foods and Beverages* (pp. 135-183). Springer Science+Business Media, LLC. doi:10.1007/978-1-4419-0826-1_6

Bauman, H. (1990). HACCP: Concept, Development, and Application. *Food Technology, 44*(5), 156-158.

Beach, C. (2016, April 29). *Dole Knew of Listeria, Feds Launch Criminal Investigation*. Retrieved from Food Safety News: http://www.foodsafetynews.com/2016/04/fda-report-shows-dole-officials-knew-about-listeria-in-facility/#.V7dmQKLCaOJ

Bohaychuk, V. M., Bradbury, R. W., Dimock, R., Fehr, M., Gensler, G. E., King, R. K., . . . Barrios, P. R. (2009). A Microbiological Survey of Selected Alberta-Grown Fresh Produce from Farmer's Markets In Alberta, Canada. *Journal of Food Protection, 72*(2), 415-420.

Bourne, M. C., & Jennings, W. G. (1963). Definition of Detergent. *J. Am. Oil Chemists Soc, 40*, 212.

Bradley Jr., R. L., Houck, K., & Smukowski, M. (2015). Milk and Milk Products. In Y. Salfinger, & M. L. Tortorello (Eds.), *Compendium of Methods for the Microbiological Examination of Dairy Products* (5th ed.). APHA.

Breyfogle III, F. W. (2003). Six Sigma Measurements. In F. W. Breyfogle III, *Implementing Six Sigma* (2nd ed.). John Wiley & Sons, Inc.

Brook, T., & Van de Vegte, J. (2016). Soil Removal and Turbidity Monitoring for Carrot Washing. OMAFRA. Retrieved May 15, 2019, from http://www.hmgawater.ca/uploads/1/7/2/8/17281360/mvgc_omafra_soil_removal___turbidity.pdf

Buchanan, R. L., Gorris, L. G., Hayman, M. M., & Jackson, T. C. (2017). A Review of Listeria monocytogenes: An Update on Outbreaks, Virulence, Dose-response, Eclology, and Risk Assessments. *Food Control, 75*, 1-13.

CAC. (1996). *Report of the Twenty-ninth Session of the Codex Committee on Food Hygiene.* Codex Alimentarius Commission.

CAC. (1999). *Recommended International Code of Practice General Principles of Food Hygiene.*

CAC. (2009). *Code of Hygienic Practice for Milk and Milk Products.* Codex Alimentarius Commission.

CAC. (2009). *Food Hygiene Basic Texts* (2nd ed.). Rome: Codex Alimentarius Commission.

CAC. (2015). *Procedural Manual* (24th ed.). Joint FAO/WHO Food Standards Programme.

Caleb, O. J., Mahajan, P. V., Al-Julanda Al-Said, F., & Opara, U. L. (2013). Modified Atmosphere Packaging Technology fo Fresh and Fresh-cut Produce and the Microbial Consequences - A Review. *Food and BioProcess Technology, 6*, 303-329. doi:DOI 10.1007/s11947-012-0932-4

Callejon, R. M., Rodriguez-Naranjo, M. I., Ubeda, C., Hornedo-Ortega, R., Garcia-Parrilla, M. C., & Troncoso, A. M. (2015). Reported Foodborne Outbreaks Due to Fresh Produce in the United States and European Union: Trends and Causes. *Foodborne Pathogens and Disease, 12*(1), 32-38. doi:10.1089/fpd.2014.1821

Campbell, B. (2005). Is Your Plant as Clean as it Looks? *Food Safety Magazine*, 61-62.

Cantwell, M., & Suslow, T. (2002). Fresh-Cut Fruits and Vegetables: Aspects of Physiology, Preparation and Handling that Affect Quality. In A. A. Kader (Ed.), *#3311 Post-Harvest Technology of Horticulture Crops.* UC Davis. Postharvest Technology Centre.

Carlson, C. S. (2012a). The Case for Failure Mode and Effects Analysis. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012b). The Philosophy and Guiding Principles for Effective FMEAs. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012c). Understanding the Fundamental Definitions and Concepts of FMEAs. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012d). Selection and Timing of FMEA Projects. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012e). How to Perform an FMEA Project: Procedure. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012f). How to Develop and Execute Effective Risk Reduction Actions. In *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C. S. (2012g). Failure Mode Effects and Criticality Analysis (FMECA). In C. S. Carlson, *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes Using Failure Mode and Effects Analysis.* John Wiley & Sons, Inc.

Carlson, C., Sarakakis, G., Groebel, D. J., & Mettas, A. (2010). Best Practices for Effective Reliablity Program Plans. *2010 Proceedings - Annual Reliablity and Maintainability Symposium.*

Catic, D., Arsovski, S., Jeremic, B., & Glisovic, J. (2011). FMEA in Product Development Phase. *5th International Quality Conference.* Center for Quality, Faculty of Mechanical Engineering, University of Kragujevac.

Cavallaro, E., Date, K., Medus, C., Meyer, S., Miller, B., Kim, C., . . . Behravesh, C. B. (2011). Salmonella Typhimurium Infections Associated with Peanut Products. *The New England Journal of Medicine, 365*(7), 601-610.

CDC. (2007, Mar 7). *Multistate Outbreak of Salmonella Tennessee Infections Linked to Peanut Butter (FINAL UPDATE)``*. Retrieved Aug 10, 2019, from https://www.cdc.gov/salmonella/2007/peanut-butter-3-7-2007.html

CDC. (2010, May 11). *Multistate Outbreak of Salmonella typhimurium Infections Linked to Peanut Butter, 2008-2009 (Final Update)*. Retrieved Aug 8, 2019, from https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html

CDC. (2011, November 10). *Multistate Outbreak of Human Salmonella Heidelberg Infections Linked to Ground Turkey (Final Update)*. Retrieved from CDC: https://www.cdc.gov/salmonella/2011/ground-turkey-11-10-2011.html

CDC. (2018, November 20). *CDC Food Safety Alert: E. coli Outbreak Linked to Romaine Lettuce*. Retrieved August 16, 2019, from https://www.cdc.gov/media/releases/2018/s1120-ecoli-romain-lettuce.html

CFIA. (2013, Jul 2). *Reference Database for Hazard Identification*. Retrieved from http://active.inspection.gc.ca/rdhi-bdrid/english/rdhi-bdrid/searece.aspx?i=11

CFIA. (2014a). *Targeted Survey Investigating Bacterial Pathogens and Generic E. coli in Fresh Leafy Green Vegetables.* CFIA. Retrieved from http://www.inspection.gc.ca/food/chemical-residues-microbiology/microbiology/fresh-leafy-green-vegetables/eng/1397089237909/1397089239191

CFIA. (2014b). *Food Safety Enhancement Program Manual.* Retrieved July 30, 2018, from http://www.inspection.gc.ca/food/safe-food-production-systems/food-safety-enhancement-program/program-manual/eng/1345821469459/1345821716482

CFIA. (2014c). *Archived - HACCP Generic Model for Ready-To-Eat Fresh-Cut Vegetables.* Retrieved August 10, 2019, from http://www.inspection.gc.ca/food/archived-food-guidance/safe-food-production-systems/haccp-generic-models-and-guidance-documents/generic-model-fresh-cut-vegetables/eng/1371034721098/1371034722410?chap=0#s8c4

CFIA. (2018a, June 13). *Hazard Identification and Evaluation Template.* Retrieved Dec 27, 2018, from Preventive Control Plan Templates for Domestic Food Businesses: http://www.inspection.gc.ca/DAM/DAM-aboutcfia-sujetacia/STAGING/text-texte/regs_safe_food_regulations_prvnttve_ctrl_plan_temp_dmstc_food_exp_d_1482250371604_eng.pdf

CFIA. (2018b, June 13). *Preventive Control Plan Templates for Domestic Food Businesses.* Retrieved June 16, 2019, from CFIA: http://www.inspection.gc.ca/food/requirements/preventive-control-plans/domestic-food-businesses/eng/1480440821364/1480440822085

CFIA. (2019a, Jan 8). *Safe Food for Canadians Regulations*. Retrieved from Canadian Food Inspection Agency: http://www.inspection.gc.ca/food/sfcr/eng/1512149177555/1512149203296

CFIA. (2019b, May 24). *Conducting a Hazard Analysis*. Retrieved June 20, 2019, from Food: https://www.inspection.gc.ca/food/requirements-and-guidance/preventive-controls-food-businesses/hazard-analysis/eng/1513283555932/1528205368359

CFIA. (2019c, Aug 10). *Preventive Controls for Food Businesses*. Retrieved from https://www.inspection.gc.ca/food/requirements-and-guidance/preventive-controls-food-businesses/eng/1526472289805/1526472290070

CFIA. (2019d, Mar 5). *Fact Sheet: Preventive Food Safety Controls*. Retrieved from https://www.inspection.gc.ca/food/toolkit-for-food-businesses/preventive-food-safety-controls/eng/1427304468816/1427304469520

CFIA. (2019e, Jun 20). *Evidence showing a control measure is effective*. Retrieved from https://www.inspection.gc.ca/food/requirements-and-guidance/preventive-control-plans/evidence-showing-a-control-measure/eng/1526316402003/1526316402300

CFIA. (2019f, January 11). *Dairy processing systems: High temperature short time (HTST) pasteurization*. Retrieved August 5, 2019, from Preventive Controls for Food Businesses: https://www.inspection.gc.ca/food/requirements-and-guidance/preventive-controls-food-businesses/dairy-products/htst/eng/1539614754038/1539614826437#a2

CFIA. (2019g). *Safe Food for Canadians Regulations: Glossary of Key Terms*. Retrieved Sep 11, 2019, from https://www.inspection.gc.ca/food/toolkit-for-food-businesses/glossary-of-key-terms/eng/1430250286859/1430250287405#a19

Cone, M. (2007, Aug 13). Stalking a Killer in our Greens. *Los Angeles Times*. Retrieved Aug 25, 2019, from https://www.latimes.com/archives/la-xpm-2007-aug-13-me-spinach13-story.html

Cook, N., Williams, L., & D'Agostino, M. (2019). Prevalence of Norovirus in Produce Sold at Retail in the United Kingdom. *Food Microbiology, 79*, 85-89. doi:10.1016/j.fm.2018.12.003

Costa, L. B., Filho, M. G., Fredendall, L. D., & Paredes, F. J. (2018). Lean, Six Sigma and Lean Six Sigma in the Food Industry: A Systematic Literature Review. *Trends in Food Science & Technology, 82*, 122-133. doi:10.1016/j.tifs.2018.10.002

Cramer, M. (2013b). Sanitation Best Practices. In M. Cramer, *Food Plant Sanitation. Design, Maintenance, and Good Manufacturing Practices* (2nd ed.). Boca Raton: Taylor & Francis.

Cramer, M. M. (2013a). Biofilms. In *Food Plant Sanitation* (2nd ed.).

Cramer, M. M. (2013c). Verification of Sanitation. In *Food Plant Sanitation. Design, Maintenance, and Good Manufacturing Practices* (2nd ed.). CRC Press.

CRC. (2019). *Safe Food for Canadians Regulations.* Retrieved from Justice Laws Website: https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/index.html

CRC. (2019). *Safe Food for Canadians Regulations.* Retrieved from Justice Laws Website.

Cronk, T. C. (1994). The Historic Evolution of HACCP: Better Questions, Safer Foods. *Food & Drug Law Journal*, 465-492.

CSPI. (2009). Outbreaks by the Numbers: Fruits and Vegetables 1990-2005. Retrieved 09 29, 2014, from http://www.cspinet.org/new/pdf/outbreakalertreport09.pdf

CSPI. (2015). *Outbreak Alert! A Review of Foodborne Illness in the US from 2004 - 2013.* Washington, DC: Centre for Science in the Public Interest.

Daniels, W. (2014). Pathogen Testing in Fresh Produce: Earthbound Farm. In J. Hoorfar (Ed.), *Global Safety of Fresh Produce: A Handbook of Best Practice, Innovative Commercial Solutions and Case Studies.* Woodhead Publishing Series.

Danilson, D. A. (2011, October/November). N60 - What It Is and What It Is Not. *Food Safety Magazone*. Retrieved Aug 26, 2019, from https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2011/n60what-it-is-and-what-it-is-not/

Delaquis, P. (2006). Fresh-Cut Vegetables. In G. M. Sapers, & A. E. Yousef, *Microbiology of Fruits and Vegetables.* Boca Raton: Taylor & Francis.

Delaquis, P., Bach, S., & Dinu, L. (2007). Behaviour of Escherichia coli O157:H7 in Leafy Vegetables. *Journal of Food Protection, 70*(8), 1966-1974.

Denis, N., Zhang, H., Leroux, A., Trudel, R., & Bietlot, H. (2016). Prevalence and Trends of Bacterial Contamination in Fresh Fruits and Vegetables Sold at Retail in Canada. *Food Control, 67*, 225-234.

Dept. of the Army. (2006). *Failure Modes, Effects and Criticality Analyses (FMECA) for Command, Control, Communications, Computer, Intelligence, Surveillance, and Reconnaissance (C4ISR) Facilities.* Retrieved from https://www.wbdg.org/FFC/ARMYCOE/COETM/tm_5_698_4.pdf

ECDC ECDPC. (2017). *The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016.* doi:10.2903/j.efsa.2017.5077

EFSA. (2018, July 3). *Listeria monocytogenes: Update on Foodborne Outbreak*. Retrieved from https://www.efsa.europa.eu/en/press/news/180703

Erickson, M. C. (2010). Microbial Risks Associated with Cabbage, Carrots, Celery, Onions, and Deli Salads Made with these Produce Items. *Comprehensive Review in Food Science and Food Safety, 9*, 602-619. doi:10.111/j.1541-4337.2010.00129.x

Ericson, C. A. (2005). Failure Mode and Effects Analysis. In *Hazard Analysis Techniques for System Safety.* John Wiley & Sons, Inc.

FAO. (1997). *Recommended International Code of Practice General Principles of Food Hygiene.* FAO. Retrieved from http://www.fao.org/docrep/005/y1579e/y1579e02.htm

FAO. (1998). *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System.* Rome: FAO.

FAO. (1998). The Hazard Analysis and Critical Control Point (HACCP) System. In *Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System.* Rome: FAO.

FAO. (2003). *FAO's Strategy for a Food Chain Approach to Food Safety and Quality: A Framework Document for the Development of Future Strategic Direction.* FAO. Retrieved from http://www.fao.org/3/a-y8350e.pdf

FAO. (2008). *Guidelines for the Validation of Food Safety Control Measures.* FAO. Retrieved March 20, 2019, from www.fao.org/input/download/standards/11022/CXG_069e.pdf

FAO/WHO. (1969). Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. In *Codex Alimentarius* (pp. 33-44). Rome: FAO of the UN/WHO.

FAO/WHO. (2008). *Microbiological Hazards in Fresh Fruits and Vegetables. Meeting Report.* FAO/WHO. Retrieved Aug 19, 2019, from https://www.who.int/foodsafety/publications/micro/MRA_FruitVeges.pdf

FDA. (2003). Factors that Influence Microbial Growth. *Comprehensive Reviews in Food Science and Food Safety, 2*, 21-32. doi:10.111/j.1541-4337.2003.tb00048.x

FDA. (2008). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.* USFDA. Retrieved Aug 12, 2019, from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables

FDA. (2009). *Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient.* Guidance Document. Retrieved Aug 10, 2019, from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-measures-address-risk-contamination-salmonella-species-food-containing-peanut#consider

FDA. (2011, October 19). *Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis.* Retrieved September 30, 2019, from FDA: http://wayback.archive-it.org/7993/20171114155057/https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm341476.htm

FDA. (2012). *Bad Bug Book*, 2nd edition. (CFSAN) Retrieved August 10, 2019, from https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition

FDA. (2015, June 10). *FDA Investigates Listeria monocytogenes in Ice Cream Products from Blue Bell Creameries.* Retrieved Nov 01, 2015, from Outbreaks: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm#What

FDA. (2015). Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. Food and Drug Administration. Retrieved June 15, 2019, from

https://www.federalregister.gov/documents/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption

FDA. (2016). *FDA Investigated Multistate Outbreak of Listeria in Dole Leafy Greens Products produced in the Dole facility in Springfield, Ohio.* FDA. Retrieved September 23, 2019, from https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigated-multistate-outbreak-listeria-dole-leafy-greens-products-produced-dole-facility

FDA. (2017, January 11). *2009 Recalls, Market Withdrawals, & Safety Alerts*. Retrieved August 10, 2019, from http://wayback.archive-it.org/7993/20170111131522/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2009/ucm2018297.htm?Page=18

FDA. (2017). *Grade "A" Pasteurized Milk Ordinance.* US Department of Health and Human Services. Retrieved Dec 22, 2018, from https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm612027.pdf

FDA. (2018). *FDA Investigating Multistate Outbreak of E. coli 0157:H7 Infections Linked to Romaine Lettuce from Yuma Growing Region.* FDA. Retrieved July 13, 2018, from https://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm6

FDA. (2018, Sep 12). *FSMA Final Rule for Preventive Controls for Human Food*. Retrieved Aug 10, 2019, from https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

FDA. (2018, Jan). *Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.* Retrieved from Risk-Based Preventive Controls for Human Food: https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517404.pdf

FDA. (2018, Aug 20). *What the Produce Safety Rule Means for Consumers*. Retrieved June 19, 2019, from Food Safety Modernization Act (FSMA): https://www.fda.gov/food/food-safety-modernization-act-fsma/what-produce-safety-rule-means-consumers

FDA. (2019, Jan 8). *FDA Food Safety Modernization Act (FSMA)*. Retrieved from US Food & Drug Administration: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

Fix, J. L., Young, A., & Taylor, J. (1999, Apr 16). Violations Numerous at Meat Plant Procedures, Unclean Practices Cited at Michigan's Bil Mar. *Detroit Free Press*. Retrieved Mar 18, 2015, from http://pqasb.pqarchiver.com/freep/offers.html?url=%2Ffreep%2Fdoc%2F436150623.html%3FFMT%3DFT%26FMTS%3DABS%3AFT%26type%3Dcurrent%26date%3D%26author%3D%26pub%3D%26edition%3D%26startpage%3D%26desc%3D

FSA. (2006, July 31). *Cadbury Recall Update 1 August 2006*. Retrieved December 22, 2010, from FSA: http://food.gov.uk/news/newsarchive/2006/aug/cadbury#h_2

FSPCA. (2014). *Selected Sections of a Food Safety Plan for Broccoli, Carrot, Pecan Salad Teaching Example.* FSPCA.

FSPCA. (n.d.). *FSPCA Food Safety Preventive Controls Alliance Home*. Retrieved October 25, 2019, from https://www.ifsh.iit.edu/fspca

Gain Report. (2016). *Retail Foods. The Retail Landscape of Canada.* USDA Foreign Agricultural Service. Retrieved June 17, 2017, from https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Retail%20Foods_Ottawa_Canada_2-15-2017.pdf

Garg, N., Churey, J. J., & Splittstoesser, E. F. (1990). Effect of Processing Conditions on the Microflora of Fresh-Cut Vegetables. *Journal of Food Protection, 53*(8), 701-703.

GFSI. (2019, Aug 30). *GFSI*. Retrieved from https://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html

Gil, M. I., Selma, M. V., Lopez-Galvez, F., & Allende, A. (2009). Fresh-Cut Product Sanitation and Wash Water Disinfection: Problems and Solutions. *International Journal of Food Microbiology, 134*, 37-45.

Government of Canada. (2016, Jul 5). *Yearly Food-borne Illness Estimates for Canada*. Retrieved from Food Recalls, Risks and Outbreaks: https://www.canada.ca/en/public-health/services/food-borne-illness-canada/yearly-food-borne-illness-estimates-canada.html

Griffiths, M. W. (2010). The Microbiological Safety of Raw Milk. In M. W. Griffiths (Ed.), *Improving the Safety and Quality of Milk: Improving Quality in Milk Products* (Vol. 1). Woodhead Publishing Ltd.

Health Canada. (2018, Jan). *Guidance document - Disinfectant drugs*. Retrieved Mar 20, 2015, from Drugs and Health Products: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/disin_desin-eng.php

Health Canada. (2019, May 30). *Produce Safety*. Retrieved June 17 2019, from Food Safety: https://www.canada.ca/en/health-canada/services/general-food-safety-tips/produce-safety.html#a5

Holah, J. T. (2009). Sanitation. In C. W. Blackburn, & P. J. McClure (Eds.), *Foodborne Pathogens. Hazards, Risk Analysis and Control* (2nd ed.). Boca Raton: Woodhead Publishing Ltd.

Holah, J. T. (2014). Hygiene Practices in Food Processing. In H. L. Lelieveld, J. Holah, & D. Napper (Eds.), *Hygiene in Food Processing - Principles and Practice* (2nd ed., pp. 258 - 304). Woodhead Publishing Ltd.

Huffman, R. D., & Jespersen, L. (2013). Food Safety Performance through HACCP; Regrets & Opportunities. *American Meat Science Association*(66th Annual Reciprocal Meat Conference). Retrieved July 20, 2019, from https://meatscience.org/docs/default-source/publications-resources/rmc/2013/rmc-2013-randy-huffman.pdf?sfvrsn=1a9bab3_0

ICMSF. (1988). *Microorganisms in Foods, Vol 4: Application of the Hazard Analysis Critical Control Point System to Ensure Microbiological Safety and Quality.* Blackwell Scientific Publications.

ICMSF. (2006). *A Simplified Guide to Understanding and Using Food Safety Objectives and Performance Objectives.* International Commission on Microbiological Specifications for Foods. Retrieved September 02, 2013, from http://www.icmsf.org/main/articles_paper.html.

ICMSF. (2011). *Microorganisms in Foods 8. Use of Data for Assessing Process Control and Product Acceptance.* (M. J. Swanson, Ed.) Springer. doi:10.1007/978-1-4419-9374-8

ICMSF. (2018). *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management* (2nd ed.). ((Chair), & R. L. Buchanan, Eds.) Springer Science.

IFT. (2019, January). *2018 Guidelines for Initial IFT Approval of Undergraduate Food Science and Food Technology Programs.* Retrieved from IFT Undergraduate Program Approval: https://www.ift.org/-/media/community/educators-herb/2018herbguidelinesforinitialiftapproval1.pdf?la=en&hash=559ED853B136E7DD47C812C14B478DE32B4CBEF5

ILSI. (1999). *Validation and Verification of HACCP.* Belgium: International Life Sciences Institute Europe.

ISO. (2018). Risk Management - Guidelines. *2nd*.

Jennings, W. G. (1965). Theory and Practice of Hard-Surface Cleaning. *Advances in Food Research, 14*, 325-458.

Jideani, A. I., Anyasi, T. A., Mchau, G. R., Udoro, E. O., & Onipe, O. O. (2017). Processing and Preservation of Fresh-Cut Fruit and Vegetable Products. *IntechoOpen*. doi:10.5772/intechopen.69763

Keller, S. (2006). Effect of Quality Sorting and Culling on the Microbiological Quality of Fresh Produce. In G. M. Sapers, J. R. Gorny, & A. E. Yousef (Eds.), *Microbiology of Fruits and Vegetables.* Taylor & Francis.

Kornacki, J. L. (2010). *Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment.* Springer. doi:10.1007/978-1-4419-5518-0

Kornacki, J. L., Gurtler, J. B., & Stawick, B. A. (2015). Enterobacteriaceae, Coliforms, and Escherichia coli as Quality and Safety Indicators. In Y. Salfinger, & M. L. Tortorello (Eds.), *Compendium of Methods for the Microbiologal Examination of Foods* (5th ed.). APHA.

Kozak, G. K., MacDonald, D., Landry, L., & Farber, J. M. (2013). Foodborne Outbreaks in Canada Linked to Produce: 2001 through 2009. *Journal of Food Protection, 76*(1), 173-183. doi:10.4315/0362-028X.JFP-12-126

Krueger, H., Koot, J., & Andres, E. (2017). The Economic Benefits of Fruits and Vegetable Consumption in Canada. *Canadian Journal of Public Health, 108*(2), 152 - 161. doi:10.17269/CJPH.108.5721

Kubiak, T. M., & Benbow, D. W. (2009). *The Certified Six Sigma Black Belt Handbook* (2nd ed.). American Society for Quality.

Lachance, P. A. (1997). How HACCP Started. *Food Technology, 51*, 35.

Lean Manufacturing and Six Sigma Definitions. (n.d.). Retrieved October 25, 2019, from https://goleansixsigma.com/glossary/

Lean Six Sigma Dictionary. (n.d.). Retrieved Sep 11, 2019, from https://www.isixsigma.com/dictionary/

Lean Six Sigma Glossary. (n.d.). Retrieved Sept 11, 2019, from https://goleansixsigma.com/glossary/

Leighton, P. (2016). Mass Salmonella Poisoning by the Peanut Corporation of America: State-Corporate Crime Involving Food Safety. *Critical Criminology, 24*, 75-91. doi:10.1007/s10612-015-9284-5

Lewis, J., Corriveau, A., & Usborne, W. R. (2013). *Independent Review of XL Foods Inc. Beef Recall 2012.* Government of Canada. Retrieved Sep 16, 2013, from http://www.foodsafety.gc.ca/english/xl_reprt-rapprte.asp#a

Liao, C., & Fett, W. F. (2001). Analysis of Native Microflora and Selection of Strains Antagonistic to Human Pathogens on Fresh Produce. *Journal of Food Protection, 64*(8), 1110-1115.

Lim, S. A., Antony, J., & Albliwi, S. (2014). Statistical Process Control (SPC) in the Food Industry - A systematic Review and Future Research Agenda. *Trends in Food Science & Technology, 37*(2), 137 - 151. doi:10.1016/j.tifs.2014.03.010

Lopez-Galvez, F., Allende, A., Selma, M. V., & Gil, M. I. (2009). Prevention of Escherichia coli Cross-Contamination by Different Commercial Sanitizers during Washing of Fresh-Cut Lettuce. *International Journal of Food Microbiology, 133*, 167-171.

Loss, C. R., & Hotchkiss, J. H. (2001). Inhibition of Microbial Growth by Low-Pressure and Ambient Pressure Gases. In V. K. Juneja, & J. N. Sofos (Eds.), *Control of Foodborne Microorganisms* (pp. 245-280). CRC Press.

Lund, B. M. (2019). Provision of Microbiologically Safe Food for Vulnerable People in Hospitals, Care Homes, and in the Community. *Food Control, 96*, 535-547. doi:10.1016/j.foodcont.2018.09.032

Lynch, M. F., Tauxe, R. E., & Hedberg, C. W. (2009). Review Article. The Growing Burden of Foodborne Outbreaks due to Contaminated Fresh Produce: Risks and Opportunities. *Epidemiology & Infection, 137*, 307-315. doi:10/1017/S0950268808001969

Lyytikainen, O., Autio, T., Maijala, R., Ruutu, P., Honkanen-Buzalski, T., Miettinen, M., . . . Siitonen, A. (1999). An Outbreak of Listeria Monocytogenes Serotype 3a Infections from Butter in Finland. *Journal of Infectious Diseases, 181*(5), 1838-1841.

Ma, L., Zhang, G., Gerner-Smidt, P., Mantripragada, V., Ezeoke, I., & Doyle, M. P. (2009). Thermal Inactiviatin of Salmonella in Peanut Butter. *Journal of Food Protection, 72*(8), 1596-1601.

Maatta, J., Lehto, M., Kuisma, R., Kymalainen, H., & Maki, M. (2013). Microbiological Quality of Fresh-Cut Carrots and Process Waters. *Journal of Food Protection, 76*(7), 1240-1244. doi:10.4315/0362-028X.JFP-12-550

Manning, L., & Soon, J. M. (2013). Mechanisms for Assessing Food Safety Risk. *British Food Journal, 115*(3), 460-484.

Marriott, N. G., & Gravani, R. B. (2006). *Principles of Food Sanitation.* Springer US. doi:10.1007/b106753

Marriott, N. G., Schilling, M. W., & Gravani, R. B. (2018). Dairy Processing Plant Sanitation. In N. G. Marriott, M. W. Schilling, & R. B. Gravani, *Principles of Food Sanitation* (6th ed.). Springer International Publishing. doi:10.1007/978-3-319-67166-6_16

Marriott, N. G., Schilling, M. W., & Gravani, R. B. (2018). Sanitation Equipment. In N. G. Marriott, M. W. Schilling, & R. B. Gravani, *Principles of Food Sanitation* (6th ed.). Springer US. doi:10.1007/978-3-319-67166-6_9

Merriam-Webster Online. (n.d.). Retrieved Sept 11, 2019, from https://www.merriam-webster.com/dictionary/cross-contamination

Murray, K., Wu, F., Shi, J., Xue, S. J., & Warriner, K. (2017). Challenges in the Microbiological Food Safety of Fresh Produce: Limitations of Post-Harvest Washing and the Need for Alternative Interventions. *Food Quality and Safety, 1*(4), 289-301. doi:10.1093/fqsafe/fyx027

NACMCF. (1989). HACCP Principles for Food Production. Ad hoc HACCP Working Group. In M. Pierson, & D. Corlett (Eds.), *HACCP: Principles and Applications.* New York: Chapman and Hall.

NACMCF. (1998). Hazard Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection, 61*(9), 1246-1259.

NASA. (1963). *Reliability Program Provisions for Space System Contractors.* NASA Reliability Publication, Washington DC: US Government Printing Office.

NASA. (1966). *Procedure for Failure Mode, Effects, and Criticality Analysis (FMECA).* Washington, D.C.: NASA.

NICD. (2018, July 4). *Listeria Outbreak Situation Report.* Retrieved July 13, 2018, from NICD: http://www.nicd.ac.za/index.php/listeriosis-outbreak-situation-report-_4july2018/

NIST/SEMATECH. (2013). Runs Test for Detecting Non-randomness. In *Engineering Statistics.* Retrieved Aug 10, 2019, from https://www.itl.nist.gov/div898/handbook/eda/section3/eda35d.htm

Nunez, J., Hartz, T., Suslow, T., McGiffen, M., & Natwick, E. T. (2008). *Carrot Production in Californa.* UC Vegetable Rsearch & Information Center. Retrieved May 15, 2019, from U of California Agriculture and Natural Resources: https://anrcatalog.ucanr.edu/pdf/7226.pdf

OMAFRA. (2006). *Foods of Plant Origin. Cleaning and Sanitation Guidebook.* Retrieved Apr 01, 2015, from Foods of Plant Origin - Inspection Programs: http://www.omafra.gov.on.ca/english/food/inspection/fs_food_plant.htm#fresh

Ozilgen, S., & Ozisgen, M. (2017). General Template for the FMEA Applications in Primary Food Processing. *Advances in Biochemical Engineering/Biotechnology, 161*, 29-29. doi:10.1007/10_2016_52

Ozilgen, S., Bucak, S., & Ozilgen, M. (2013). Improvement of the Safety of the Red Pepper Spice with FMEA and Post Processing EWMA Quality Control Charts. *Journal of Food Science and Technology, 50*(3), 466-476. doi:10.1007/s13197-011-0371-7

Painter, J. A., Hoekstra, R. M., Ayers, T., Tauxe, R. V., Braden, C. R., Angulo, F. J., & Griffen, P. M. (2013). Attribution of Foodborne Illnesses, Hospitalization, and Deaths to Food Commodities by using Outbreak Data, United States, 1998-2008. *Emerging Infectious Diseases, 19*(3), 407-415. doi:http://dx.doi.org/10.3201/3id1903.111866

Perla, R. J., Provost, L. P., & Murray, S. K. (2011). The Run Chart: A Simple Analytical Tool for Learning from Variation in Healthcare Processes. *BMJ Quality & Safety, 20*, 46-51. doi:10.1136/bmjqs.2009.037895

Petran, R. L., Grieme, L. E., & Foong-Cunningham, S. (2015). Culture Methods for Enumeration of Microoganisms. In Y. Salfinger, & M. Tortorello (Eds.), *Compendium of Methods for the Microbiological Examination of Foods* (5th ed., pp. 75-87). APHA Press.

PHAC. (2019, Jan 11). *Public Health Notice - Outbreak of E. coli infections linked to romaine lettuce*. Retrieved Aug 16, 2019, from https://www.canada.ca/en/public-health/services/public-health-notices/2018/outbreak-ecoli-infections-linked-romaine-lettuce.html

Powell, M. R. (2016). Trends in Reported Foodborne Illness in the United States; 1996 - 2013. *Risk Analysis, 36*(8). doi:10.1111/risa.12530

(1980). *Procedures for Performing a Failure Mode, Effects and Criticality Analysis.*

Redemann, R. (2005, April/May). Sanitation. Basic Elements of Effective Food Plant Cleaning and Sanitizing. *Food Safety Magazine*.

Ross, T., & McMeekin, T. A. (2009). Risk Assessment and Pathogen Management. In C. d. Blackburn, & P. J. McClure (Eds.), *Foodborne Pathogens* (2nd ed.). Woodhead Publishing.

Ross, T., & Sumner, J. (2002). A Simple, Spreadsheet-based, Food Safety Risk Assessment Tool. *Internationals Journal of Food Microbiology, 77*(1-2), 39-53. Retrieved Aug 2, 2019, from https://www.cbpremium.org/RiskRanger

Ross-Nazzal, J. (2007). "From Farm to Fork": How Space Food Standards Impacted the Food Industry and Changed Food Safety Standards. In R. D. S J Dick, *Societal Impact of Space Flight* (pp. 219-236). NASA. Office of External Relations. History Division.

Ryser, E. T., & Schuman, J. D. (2015). Mesophilic Aerobic Plate Count. In Y. Salfinger, & M. L. Tortorello (Eds.), *Compendium of Methods for the Microbiological Examintation of Foods* (5th ed.). APHA.

Sapers, G. M. (2001). Efficacy of Washing and Sanitizing Methods for Disinfection of Fresh Fruit and Vegetable Products. *Food Technology and Biotechnology, 39*(4), 305-311.

Saskatchewan Government. (2019, June 11). *Carrot Production*. Retrieved July 13, 2019, from Business and Industry: https://www.saskatchewan.ca/business/agriculture-natural-resources-and-industry/agribusiness-farmers-and-ranchers/crops-and-irrigation/horticultural-crops/vegetables/carrot-production

Scallon, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M., Roy, S. L., . . . Griffin, P. M. (2011). Foodborne Illnes Acquired in the United States - Major Pathogens. *Emerging Infectious Diseases, 17*(1), 7-15.

Schilling, M. F. (2012). The Surprising Predictablity of Long Runs. *Mathematics Magazine, 85*(2), 141-149. Retrieved Aug 25, 2019, from http://www.jstor.org/stable/10.4169/math.mag.85.2.141 .

Scott, B. S., Wilcock, A. E., & Kanetkar, V. (2009). A Survey of Structured Continuous Improvement Programs in the Canadian Food Sector. *Food Control, 20*(3), 209-217. doi:10.1016/j.foodcont.2008.04.008

Seo, K. H., & Frank, J. F. (1999). Attachment of Escherichia coli O157:H7 to Lettuce Leaf Suface and Bacterial Viablity in Response to Chlorine Treatment as Demonstrated by Using Confocal Scanning Laser Microscopy. *Journal of Food Protection, 62*(1), 3-9.

Siddiqui, M. W. (2018). *Postharvest Disinfection of Fruits and Vegetables.* Academic Press. doi:10.1016/B978-0-12-812698-1.09988-X

Six Sigma Academy. (2002). *Black Belt Memory Jogger.* GOAL/QPC.

Slade, P. J. (2002). Verification of Effective Sanitation Control Strategies. *Food Safety Magazine*, 24-43.

Snee, R. D. (2010). Lean Six Sigma - Getting Better All the Time. *International Journal of Lean Six Sigma, 1*(1), 9 - 29. doi:10.1108/20401461011033130

Sperber, W. H. (2001). Hazard Identification: from a Quantitative to a Qualitative Approach. *Food Control, 12*, 223-228.

Sperber, W. H., Moorman, M. A., & Freier, T. A. (2015). Cultural Methods for the Enrishment and Isolation of Microorganisms. In Y. Salfinger, & M. Tortorello (Eds.), *Compendium of Methods for the Microbiological Examination of Foods* (5th ed., pp. 67-73). APHA Press.

Tague, N. R. (2005). *The Quality Toolbox* (2nd ed.). American Society for Quality.

Takeuchi, K., Matute, C. M., Hassan , A. N., & Frank, J. F. (2000). Comparison of the Attachment of Escherichia coli O157:H7, Listeria monocytogenes, Salmonella Typhimurium, and Pseudomanas Fluorescens to Lettuce Leaves. *Journal of Food Protection, 63*(10), 1433-1437.

Taleb, N. N. (2007). *The Black Swan. The Impact of the Highly Improbable.* New York: Random House.

Tarver, T. (2009). Biofilms. A Threat to Food Safety. *Food Technology Magazine, 63*(2), pp. 46-52.

Taylor, T. M., Sofos, J. N., Bodnaruk, P., & Acuff, G. R. (2015). Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis. In Y. Salfinger, & M. Tortorello, *Compendium of Methods for the Microbiological Examination of Foods* (5th ed.). APHA.

Tompkin, R. B. (2004). Environmental Sampling - A Tool to Verify the Effectiveness of Preventive Hygiene Measures. *Metteilungen aus Lebensmitteluntesuchung und Hygiene, 95*, pp. 45-51.

Tournas, V. H. (2008). Spoilage of Vegetable Crops by Bacteria and Fungi and Related Health Hazards. *Critical Reviews in Microbiology, 31*(1), 33-44. doi:10.1080/10408410590886024

UFPA. (2014). *Microbiological Testing of Fresh Produce. A White Paper on Considerations in Developing and Using Microbiological Sampling and Testing Procedures if Used as Part of a Food Safety Program for Fresh Fruit and Vegetable Products.* United Fresh Food Safety & Technology Council. Retrieved from https://www.unitedfresh.org/content/uploads/2014/07/FST_MicroWhite-Paper.pdf

USDA. (2011). *Microbiological Data Program. Progress Update and 2009 Data Summary.* United States Department of Agriculture. Retrieved May 15, 2019, from https://www.ams.usda.gov/sites/default/files/media/MDP%20Progress%20Update%20and%202009%20Data.pdf

USDA FSIS. (2011). *Arkansas Firm Recalls Ground Turkey Products Due to Possible Salmonella Contamination.* Recall Notice. Retrieved July 20, 2019, from https://www.fsis.usda.gov/wps/wcm/connect/fsis-archives-content/internet/main/topics/recalls-and-public-health-alerts/recall-case-archive/archives/ct_index114a

Van Tassell, J. A., Martin, N. H., Murphy, S. C., Wiedmann, M., Boor, K. J., & Ivy, R. A. (2012). Evaluation of Verious Selective Media for the Detection of Pseudomonas species in Pasteurized Milk. *Journal of Dairy Science, 95*(3), 1568-1574. doi:doi.org/10.3168/jds.2011-4958

Varzakas, T. H. (2011). Application of ISO22000, Failure Mode, and Effect Analysis (FMEA) Cause and Effect Diagrams and Pareto in Conjunction with HACCP and Risk Assessment for

Processing of Pastry Products. *Critical Reviews in Food Science and Nutrition, 51*(8), 762-782. doi:dx.doi.org/10.1080/10408391003799970

Varzakas, T. H., & Arvanitoyannis, I. S. (2009). Application of Failure Mode and Effect Analysis and Cause and Effect Analysis on Processing of Ready to Eat Vegetables – Part II. *International Journal of Food Science and Technology, 44*, 932-939. doi:10.1111/j.1365-2621.2007.01682.x

Varzakas, T. H., & Arvanitoyannis, I. S. (2011). Application of Failure Mode and Effect Analysis (FMEA), Cause and Effect Analysis, and Pareto Diagram in Conjunction with HACCP to a Corn Curl Manufacturing Plant. *Critical Reviews in Food Science and Nutrition, 47*, 363-387. Retrieved from 10.1080/10408390600781316

Wallace, C. A., & Powell, S. C. (2005). Post-Training Assessment of HACCP Knowledge: Its use as a Predictor of Effective HACCP Development, Implementation and Maintenance in Food Manufacturing. *British Food Journal, 107*(10), 743-759. doi:10.1108/00070700510623522

Wallace, C. A., Holyoak, L., Powell, S. C., & Dykes, F. C. (2014). HACCP - The Difficulty with Hazard Analysis. *Food Control, 35*, 233-240.

Weatherill, S. (2009). *Report of the Independent Investigator into the 2008 Listeriosis Outbreak.* Agriculture and Agri-food Canada. Retrieved Mar 18, 2015, from http://epe.lac-bac.gc.ca/100/200/301/aafc-aac/report_independent_listeriosis-ef/A22-508-2009E.pdf

Wehr, H. M., & Frank, J. F. (Eds.). (2012). *Standard Methods for the Examination of Dairy Products* (17th ed.). APHA.

Wheeler, D. J. (2011, Jun 27). Problems with Risk Priority Numbers. *Quality Digest, 13*(18). Retrieved Aug 4, 2019, from https://www.qualitydigest.com/inside/quality-insider-article/problems-risk-priority-numbers.html

WHO. (2015, Apr 7). *Food Safety: What You Should Know*. Retrieved Sep 12, 2019, from http://www.searo.who.int/entity/world_health_day/2015/whd-what-you-should-know/en/

Wittenberger, K., & Dohlman, E. (2010). *Peanut Outlook. Impacts of the 2008-09 Foordorne Illness Outbreak Linked to Salmonella in Peanuts.* USDA. Retrieved Aug 10, 2019, from https://www.ers.usda.gov/publications/pub-details/?pubid=37836

Zagory, D. (1999). Effects of Post-Processing Handling and Packaging on Microbial Populations. *Postharvest Biology and Technology, 15*, 313-321.

Appendix A. Logic underlying the severity, occurrence and detection ratings in the FMEA

The severity and occurrence ratings were determined by matching the results of the RALR and site observations with the criteria listed in Table 1 of the Literature Review.

Severity

The severity of the failure mode "contamination with pathogens" and "growth of pathogens" was rated as a 10, the highest rating, because if this failure mode occurs, the results are catastrophic because consumers may become ill and possibly die (Scallon, et al., 2011) without warning because the food does not usually show signs of being contaminated (WHO, 2015).

Occurrence

Receiving

The likelihood that incoming produce contains pathogens at levels high enough to cause foodborne illness was examined in detail in the RALR because there are no processing steps in a fresh-cut produce processing plant that will reliably reduce pathogens to levels that are safe to consume if heavily contaminated carrots are purchased and received by the site (ICMSF, 2011).

A review of literature examining the likelihood of produce containing enough pathogens to cause a foodborne outbreak indicates that foodborne outbreaks have been increasingly attributed to produce over the last several decades. In the 1970s, less than 1% of all reported outbreaks were linked to produce (Lynch, Tauxe, & Hedberg, 2009). Then from 1998 – 2008, the Centre for Disease Control (CDC) reported that, in the US, produce accounted for 46% of illnesses with 22% of these illnesses being associated with leafy vegetables, more than any other commodity (Painter, et al., 2013). Between 2004 and 2013, the Center for Science in the Public Interest (CSPI) (CSPI, 2015) determined that, in the US, produce was responsible for the most

solved foodborne outbreaks and associated illnesses at 19% and 24% respectively. In Canada there were 27 produce-related outbreaks from 2001 – 2009 causing an estimated 1,549 illnesses (Kozak, MacDonald, Landry, & Farber, 2013). Between 2000 and 2007, carrots were associated with 18 outbreaks and 405 related illness in the US (Erickson, 2010). In 2008, the FAO/WHO (2008) ranked produce into three levels of priority based on their association with foodborne illness: priority 1 – Leafy vegetables including herbs, priority 2 berries, green onions, melons, sprouted sees, tomatoes, and priority 3 - carrots, cucumbers, almonds, baby corn, sesame seeds, onions and garlic, mango, paw paw, celery and maimai.

Norovirus is responsible for the most outbreaks and *Salmonella* is responsible for the second most outbreaks in the US and European Union (Callejon, et al., 2015). In the US it was estimated that from 1998-2008, Norovirus caused half of the produce-related foodborne outbreaks (Painter, et al., 2013).

An examination of the prevalence of pathogens in produce indicated that Norovirus was found in 28.2% and 5.3% of leafy green samples in Canada (Baert, et al., 2011) and the United Kingdom (Cook, Williams, & D'Agostino, 2019), respectively. Two Canadian studies detected *Salmonella* in two out of 1856 samples tested for a contamination rate of 0.1% (Arthur, Jones, Fabri, & Odumeru, 2007) (Bohaychuk, et al., 2009). The CFIA performed a large survey of domestic and imported fruits and vegetables from 2009 – 2013 in which the pathogen prevalence rate was 0.1% (16/12073) in leafy vegetables, 0.08% (5/6032) in leafy herbs, 0% (0/4837) in tomatoes, 0.03% (1/3381) in green onions, 0.1% (4/3230) in cantaloupes and 0% (0/1176) in berries (Denis, Zhang, Leroux, Trudel, & Bietlot, 2016). In 2009, the USDA's study of domestic and imported produce detected *Salmonella* in 0.2% of 16, 866 samples and pathogenic *E. coli* in 0.2% of 15,354 samples (USDA, 2011).

A Canadian study examining the actual numbers of pathogens in leafy vegetables, whose results were included in the Canadian survey described above, found that the 4 out of 4250 leafy green samples that had generic *E. coli* counts were all below the unsatisfactory threshold of 1000 cfu/g while the 3 out of 1850 fresh-cut leafy vegetable samples that were positive for *L. monocytogenes* were below 100 CFU/g, a level "generally considered to pose very little risk in this type of food" (CFIA, 2014a). It should be noted however, that most pathogen detection methods include an enrichment step whose purpose is to amplify the low initial numbers that may be present and to recover injured microorganisms (Sperber, Moorman, & Freier, 2015) so leaving this step out so as to enumerate the microorganisms may lead to false negatives.

While this information seems to indicate that occurrence of pathogens in incoming produce sufficient to cause illness may occur with some frequency, the Center for Science in the Public Interest (CSPI) presented information indicating a different view point. They considered that for the relative rate of illness adjusted for consumption, fruit and vegetables are still among the safest foods to eat while seafood is the most hazardous food followed by poultry as illustrated in Figure 27 (CSPI, 2015). It should also be noted that between 1990 and 2005, the CSPI estimated that 63% of produce-related outbreaks originated in restaurants and private homes leaving produce producers and processors responsible for just the remaining 37% (CSPI, 2009). In addition, the researchers performing the CFIA study summarized above, stated that "the contamination of fresh fruits and vegetables with bacteria at levels representing a risk to public health is rare in the Canadian marketplace" (Denis, Zhang, Leroux, Trudel, & Bietlot, 2016).

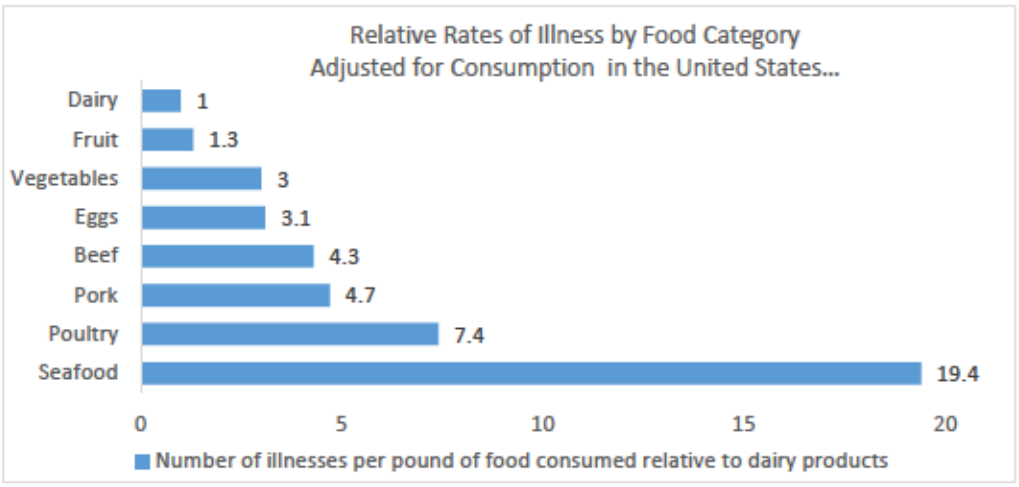


Figure 27. Relative Rates of Illness by Food Category Adjusted for Consumption in the United States - 2004-2013.
Adapted from "Outbreak Alert! 2015, ", by N. Fischer, A. Bourne, and D. Plunkett, 2015, CSPI.

These results are supported by an examination of produce consumption in Canada as compared to the number of foodborne outbreaks. Canadians consume an average of 4.38 servings of produce per day which equals 0.35 kg/day assuming each serving is 80 grams (Krueger, Koot, & Andres, 2017). This translates to 4.5×10^9 kg of produce[22] being consumed each year in Canada. Looking more specifically at fresh-cut produce which is not cooked or washed before consumption, if it is assumed that at least one serving per week is an RTE prepackaged salad, (likely a conservative assumption given that sales of prepared salads increased by 5% in Canada in 2016 over sales in 2015 (Gain Report, 2016)), this would mean that at least 1.5×10^8 kg of RTE prepackaged salad is consumed by Canadians each year.

Given this amount of produce consumption each year, it is notable that just 27 produce-related outbreaks were reported in Canada between 2001 – 2009 causing an estimated reported 1,549 illnesses (Kozak, MacDonald, Landry, & Farber, 2013). Therefore the likelihood of produce containing microbial contamination at levels high enough to cause illness is extremely rare.

[22] Assuming 35,000,000 Canadians **Invalid source specified.**

In 2008 the FAO/WHO published a report providing recommendations for mitigating the biological risks associated with leafy greens and herbs[23] which should, if implemented, enable each participant in the produce supply chain to meet Performance Objectives (POs) that ensure the Food Safety Objective (FSO) is met as described by the ICMSF conceptual equation described in Figure 10: $H_o - \Sigma R + \Sigma I \leq$ FSO or PO. This report indicates that the likelihood of pathogens will be minimized if all participants in the produce supply chain follow Good Agricultural Practices (GAP) or Good Manufacturing Practices (GMP), as appropriate, using a HACCP-based approach (FAO/WHO, 2008). Participants include producers who grow and harvest the produce, packing houses, processors and storage facilities. If each entity properly performs their processes such that they achieve the needed reduction in pathogens (ΣR) while minimizing their increase (ΣI), then, as illustrated in Figure 10, the next entity's raw materials will receive raw materials with an appropriate H_o value thus ensuring the FSO is met by the time the produce is being consumed.

Recommendations for both primary production and processing are provided by the FAO/WHO. The primary production recommendations cover the requirements for controlling: management of the farming environment, soil amendments and fertilizers, water, harvesting, field packing and packing houses while the processing recommendations cover the requirements for controlling: primary preparation, further processing, packaging and chilled storage. The ICMSF also stated that prevention of contamination is key because subsequent removal of contamination cannot be reliably achieved (ICMSF, 2018) (ICMSF, 2011). Maintaining the cold chain is also important because pathogens like *E. coli* O157:H7 do not grow at temperatures ≤8°C from data reviewed by (Delaquis, Bach, & Dinu, 2007).

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[23] While this report focused on leafy greens and herbs because of their higher association with foodborne outbreaks than other produce, the guidelines for mitigating biological hazards are appropriate for the primary production and processing of all produce.

The site, therefore, strives to meet the PO for fresh-cut carrot processing by purchasing carrots with an appropriate H_0 from producers and processors that have been qualified and audited to the FAO/WHO recommendations by an organization specializing in produce safety. The Receiver ensured the carrots have been purchased from an approved supplier and the carrots and the truck met a set of food safety and quality criteria before accepting the load.

The assigned occurrence rating for pathogen contamination of incoming carrots at Receiving was therefore a 2 because the information contained in this section of the report suggests that the likelihood of occurrence of pathogens occurring at a level sufficient to cause illness in a customer is extremely rare because the site purchased carrots from approved suppliers.

This low occurrence rating for pathogen contamination at *receiving* means that the occurrence ratings at subsequent process steps will also be low if the site ensures that all control measures are being followed thus maximizing ΣR and minimizing ΣI.

Pathogen contamination because carrots cannot be purchased because the normal supply chain has been interrupted because of an extraordinary event was assigned a 4 because the site would not be purchasing from known and qualified suppliers that have demonstrated compliance to the FAO/WHO recommendations for producing and processing produce.

The assigned occurrence rating for pathogen growth at *receiving* because of temperature abuse during shipping was a 2 because all trucking companies have been approved through the SQA program and were required to properly service their trucks and keep the reefers on throughout the trip.

Storing

The warehouse temperature of the stored carrots was maintained at ≤4°C which is the primary method by which microorganisms are controlled after produce has been harvested

(ICMSF, 2011). Each load of carrots were processed within 2 and 10 days of receiving which is suitable because intact carrots have a much longer shelf life than fresh-cut produce (ICMSF, 2011). The carrots were stored together in designated areas of the cooler and the forklift drivers were trained in these warehouse procedures.

The assigned ratings for the three potential causes of failure at *storing* were therefore assigned 2 because this evaluation indicates the likelihood of occurrence is extremely rare.

Peeling

A study by Garg et al. in 1990 indicated that peeling can reduce mean aerobic microbial populations by more than 2 logs which means that pathogens associated with the peel would also be removed so the occurrence rating could potentially be reduced to a 1. However, while the peeler was specifically designed to peel carrots and was relatively easy to set it up for proper peeling, it sometimes goes out of adjustment so the occurrence rating for the peeler leaving peel on the carrot was assigned a 2, the same value assigned for receiving.

The operators examined every carrot before it is placed on the line, so it was unlikely that sub-standard carrots will be processed; the occurrence rating for this cause was therefore assigned a 2.

The likelihood that the sanitation program was not effectively removing pathogens from the peeler was rated a 2 because the site operated a full sanitation shift with designated, trained workers.

The occurrence rating for pathogens being introduced through improper employee handling or hygiene practices was also assigned a 2 because employees wore company-supplied gear and were trained to follow good hygiene and handling practices.

Washing

During washing, the microbial load, including pathogens, will be reduced by 1 -2 logs (Sapers, 2001) (ICMSF, 2011) or 2-3 logs (Gil, Selma, Lopez-Galvez, & Allende, 2009) depending on the type of produce, type and concentration of sanitizer, exposure time, type of washing, the type of microorganisms and whether or not they preferentially attach to intact plant surfaces or to more inaccessible areas below the surface of stomata or cut edges (Seo & Frank, 1999) (Takeuchi, Matute, Hassan , & Frank, 2000). While water can achieve a similar reduction in microorganisms with or without sanitizers, the sanitizers are needed to kill the pathogens that are now suspended in the water thereby preventing cross-contamination of these pathogens back onto the produce (Allende, Selma, Lopez-Galvez, Villaescusa, & Gil, 2008) (FDA, 2008) (Gil, Selma, Lopez-Galvez, & Allende, 2009). Research by Lopez-Galvez (2009) also indicates that a 500 mg/L (500 ppm) (equivalent to 70 ppm of PAA) of a PAA/HA sanitizer reduced 3 and 5 logs of *E. coli* to undetectable levels on fresh-cut lettuce. This research indicated the importance of washing fresh-cut produce in a sanitizer solution to further reduce the low levels of pathogens that can occasionally occur in produce. It is also important to manage washing because water can be a direct source of contamination or the means by which the contamination is spread (FDA, 2008)

The site has set up the production line to ensure all carrots were conveyed through the washer for a set dwell time so the occurrence rating for pathogens being present because the carrots were not washed was assigned a rating of 1.

Operators set up the carrot washer with a prescribed amount of PAA and water each day after which more PAA is added at regular intervals throughout the day. The occurrence rating for not have enough PAA in the water was a 2 because there were written procedures in place and the operators were trained to this procedure.

The occurrence rating for there still being enough pathogens to cause illness on the carrots after washing because the initial contamination level was very high or because they are inaccessible is a 1. This is based on the original occurrence rating of 2 at receiving because the RALR indicated that the likelihood of pathogens on incoming produce at levels high enough to cause illness was extremely rare. If it is assumed that washing will render some of these contaminated loads safe to eat as also indicated in the RALR, then the occurrence rating drops to a 1.

The occurrence of pathogens at washing being related to contamination from unsanitary equipment was rated as 2 because there was a full sanitation program in place.

Shredding

The occurrence of pathogens at *shredding* was related to contamination from unsanitary equipment and improper employee hygiene and handling practices. These ratings are a 2 because there was a sanitation program and employee training program in place.

Transferring/Waiting

The occurrence of pathogens at shredding is related to contamination from unsanitary equipment, unsanitary mesh bags and improper employee hygiene and handling practices. The assigned ratings were 2 because there was a sanitation program and employee training program in place.

There is also a failure mode associate with pathogen growth at this step of the process if the shredded carrots wait too long to be packaged. While the refrigerated production floor slows down bacterial growth, the carrot plant tissues that are now damaged by shredding is a good substrate for the growth of microorganisms (Zagory, 1999). Occurrence was rated as a 2 because the transfer buckets were placed in a prescribed order in a designated area on a refrigerated processing floor so they were not sitting for long periods of time before packaging.

Packaging

The occurrence of pathogens at washing being related to contamination because of improper employee hygiene and handling practices and from unsanitary equipment were rated as 2 because there was a full employee training program and sanitation program in place.

Pathogen contamination because of poor sealing was given an occurrence rating of 3 because, while the sealer was regularly serviced as part of the preventive maintenance program, every few days the sealer failed to produce a complete seal on the package.

The occurrence rating for applying an incorrect or illegible best before date was given a 2 because there was a process in place for ensuring the correct best before date was applied to the coding machine by Quality every day before start-up.

Detection

The Detection ratings for the six process steps being examined on a fresh-cut carrot processing line were determined by matching the site's methods for detecting the hazard with the detection criteria in Table 1 of the Literature Review.

Receiving

The detection of pathogens sufficient to cause illness in customers was given a 10 because there was no program in place to make this assessment at Receiving; because, as the ICMSF states, "the perishable nature of fresh and fresh-cut vegetables and the low frequency of contamination of the products with human pathogens makes the use of routine microbiological testing as a means of separating safe and unsafe product impractical" (ICMSF, 2011).

The rating for detecting whether or not the load was temperature abused was assigned a 2 because the receiver checked the temperature of the incoming load and the reefers had a data logger for recording the temperatures throughout the trip.

Storing

Detection of time/temperature abuse was a 2 because the refrigerated warehouse was continually monitored and alarmed with notification of the maintenance department.

The rating for detecting time/temperature abuse because FIFO was not followed and for detecting whether or not there was cross-contact of carrots with other produce was a 6 because Quality performs daily checks to ensure warehouse procedures are being followed.

Peeling

The failure modes of pathogen contamination because of faulty peeling and not grading out sub-standard carrots was assigned a detection rating of "3" because operators examined each carrot and graded out unpeeled carrots when they manually transfer the washed, peeled carrots to crates.

Pathogen contamination because of unsanitary equipment was assigned a detection rating of 7 because the sanitation checks, pre-operational inspections and environmental swabs, were performed after sanitation is complete.

The detection rating for improper hygiene and/or handling practices was rated as 4 because lead hands monitor the production floor to ensure all personnel were properly garbed and followed correct procedures for sanitizing gloves and handling produce. The glove dip stations and soap usage were also monitored.

Washing

The detection rating for carrots not being washed was a 1 because all the carrots were conveyed through a washer set for a dwell time of one minute. The dwell time was confirmed daily.

The failure mode or hazard of insufficient concentration of PAA was rated a 4 because operators regularly checked the concentration of PAA and Quality verified that the checks were being properly performed at the required intervals.

The detection of pathogens sufficient to cause illness in customers was a 10 because there was no program in place to make this assessment at washing.

Pathogen contamination because of unsanitary equipment was assigned a detection rating of 7 because the sanitation checks, pre-operational inspections and environmental swabs, were performed after sanitation is complete.

Shredding

Pathogen contamination because of unsanitary equipment was assigned a detection rating of 7 because the sanitation checks, pre-operational inspections and environmental swabs, were performed after sanitation is complete.

The detection rating for improper hygiene and/or handling practices was rated as 4 because lead hands monitored the production floor to ensure all personnel were properly garbed and following correct procedures for sanitizing gloves and handling produce. The glove dip stations and soap usage were also monitored.

Transferring/Waiting

Pathogen contamination because of unsanitary transfer buckets was assigned a detection rating of 7 because the sanitation checks, pre-operational inspections and environmental swabs, were performed after sanitation is complete.

The detection rating for contaminated mesh bags is a 4 because they were washed by trained people using a validated washing procedure. They were also sanitized in monitored dips to ensure they are at the correct concentration.

The detection rating for improper hygiene and/or handling practices was rated as 4 because lead hands monitored the production floor to ensure all personnel were properly garbed and following correct procedures for sanitizing gloves and handling produce. The glove dip stations and soap usage were also monitored.

The detection rating for understanding whether or not FIFO was being followed for carrots waiting for packaging was a 10 because there were no obvious visual clues that indicate whether or not FIFO was being followed.

Detection of time/temperature abuse was given a 2 because the refrigerated production floor was continually monitored and alarmed with notification of the maintenance department.

Packaging

The detection rating for improper hygiene and/or handling practices was rated as 4 because lead hands monitored the production floor to ensure all personnel were properly garbed and following correct procedures for sanitizing gloves and handling produce. The glove dip stations and soap usage were also monitored.

Pathogen contamination because of unsanitary packaging tables was assigned a detection rating of 7 because the sanitation checks, pre-operational inspections and environmental swabs, were performed after sanitation is complete.

Pathogen contamination of the carrots because the sealer did not properly seal the package was assigned a detection rating of 2 because every bag was inspected by the operator and Quality periodically checked the packaging operation throughout the day.

Pathogen growth because of an incorrect or illegible best before date was rated as 2 because the operators observed the legibility of the best before date as they applied the date and Quality periodically checked the packaging operation throughout the day.

Appendix B. Logic underlying hazard significance in the SFCR HA

Receiving

Information provided in Appendix A under "Receiving" in "Occurrence" indicate that the likelihood of biological hazards at levels significant enough to cause illness in consumers is extremely rare if the produce supply chain practices GAPs and GMPs using a HACCP approach. The hazard that pathogens may be present in carrots at receiving was therefore not considered significant because the site has two preventive control programs in place to ensure suppliers meet these requirements; the Supplier Quality Assurance program and the receiving program.

The hazard that pathogens may be present because the usual supply chain is not available was considered significant because the site is not purchasing from known and qualified suppliers that have demonstrated compliance to the FAO/WHO recommendations for producing and processing produce.

Storing

The hazards associated with storing was not significant because the hazards associated with temperature control, FIFO and product locations were managed through the equipment and the warehouse preventive control programs.

Peeling

The hazards associated with faulty peeling and not properly grading out substandard carrots was insignificant because they were controlled through the equipment maintenance and employee training preventive control programs along with a line speed that facilitated grading out improperly peeled carrots.

The unsanitary equipment and improper employee hygiene and handling associated hazards were insignificant because they were managed through the sanitation and employee training preventive control programs.

Washing

The likelihood of pathogen contamination remaining on the carrots because they were not washed was low because the carrot processing line was designed to convey all the carrots through the wash water hence this hazard was insignificant.

Ensuring the water contains enough PAA sanitizer was considered significant because, if the sanitizer concentration is too low, the pathogens that were being removed from the produce will not be killed and viable organisms will be cross-contaminated back onto the carrots as explained in the FMEA "Washing" description. It was therefore important to ensure the PAA concentration is at the correct concentration at all times.

The hazards associated with an excessively high load of pathogens or inaccessible pathogens such that washing would not effectively reduce their numbers was considered low because the RALR indicated that this level of pathogen contamination is an extremely rare occurrence if produce is purchased from suppliers that have HACCP programs in place as described above in "Receiving". This hazard was therefore not significant.

The hazard associated with unsanitary equipment was insignificant because it was managed through the sanitation preventive control program.

Shredding

The unsanitary equipment and improper employee hygiene and handling associated hazards were insignificant because they were managed through the sanitation and employee training preventive control programs.

Transferring/Waiting

The hazards associated with unsanitary equipment, unsanitary mesh bags and improper employee hygiene and handling were insignificant because they were managed through the sanitation and employee training preventive control programs.

The hazard that pathogens may grow if the transfer bins containing the shredded carrots, or WIP, sit for an extended time because FIFO was not followed was considered insignificant because employees were trained to place the transfer bins in a prescribed area and order and to follow FIFO when moving these bins to the packaging area.

The temperature control hazard was not significant because refrigeration of the production floor was managed through the equipment preventive control program.

Packaging

The improper employee hygiene and handling and unsanitary equipment associated hazards were insignificant because they were managed through the employee training and sanitation preventive control programs.

Pathogen contamination because of an improperly sealed package was insignificant because the sealer was maintained through the equipment preventive control program, the seal on every bag was inspected by the operator and Quality periodically checked the packaging operation. The operator was trained to perform this function through the employee training preventive control program.

Pathogen growth because of an incorrect best before date or illegible date was insignificant because Quality ensured the dating machine was coded with the correct date. The operators were also trained to ensure the date was applied to each package and was legible through the employee training preventive control program.

Appendix C. Fresh-cut produce plant sanitation program defect opportunity checklist (DOC) examining three runs of a sanitation process.

Defect Category	Step	Best Practices	Defect Opportunity	Run 1			Run 2			Run 3		
				R1	R2	R3	R1	R2	R3	R1	R2	R3
Time-Related	1	Dry pickup of scrap, product or input spills during processing and end of shift to prevent unsanitary processing conditions and to save the sanitation shift time and effort.	*No or incomplete dry pick of product spills during processing and end of production shift.*	1	1	1	1	0	0	1	0	1
Time-Related	2	Remove raw materials, WIP, and packaging from area at end of production shift.	*Items not physically removed or adequately covered in room by production shifts.*	1	1	1	1	0	1	1	1	1
Time-Related		Do not place raw materials for next day's production onto production floor before cleaning is finished.	*Materials placed on production floor before cleaning is complete.*	0	1	0	0	1	0	0	1	0
	3	Cover electrical equipment that may be damaged by water.	*Items not covered.*	0	0	0	0	0	0	0	0	0
	4	Lock out/tag out equipment as needed.	*Equipment not locked out when needed.*	0	0	0	0	0	0	0	0	0
Time-Related	5	Physically remove as much soil as possible using brooms, shovels, squeegees, etc. before four step sanitation process begins.	*Gross food residue not removed from equipment and surrounding area (floor) before four step sanitation begins.*	1	1	1	1	1	1	1	1	0
Time-Related	6	Perform entire sanitation procedure on walls, floors and equipment.	*Walls, floors and equipment not completely cleaned and sanitized.*	1	1	1	1	1	1	1	1	1
	7	Rinse										

Defect Category	Step	Best Practices	Defect Opportunity	Run 1			Run 2			Run 3		
				R1	R2	R3	R1	R2	R3	R1	R2	R3
		Rinse equipment and walls from top to bottom.	*Not rinsed from top to bottom.*	0	0	0	0	0	0	0	0	0
		Use lowest effective water pressure.	*Using high-pressure hoses for cleaning off equipment.*	0	0	0	0	0	0	0	0	0
	8	**Disassemble equipment as needed.**	*Equipment not disassembled as needed.*	0	0	0	0	0	0	0	0	0
			Equipment not properly disassembled.	0	0	0	0	0	0	0	0	0
Incorrect Procedure	**9**	**Place small items such as equipment parts, cutting boards and knives in designated areas for cleaning.**	*Small items not placed in designated areas for cleaning.*	0	0	1	0	0	1	1	0	0
	10	**Wash equipment and disassembled parts with cleaning agent.**										
		Use correct concentration	*Incorrect concentration or no cleaner.*	0	0	0	0	0	0	0	0	0
		Use correct cleaner	*Incorrect cleaner*	0	0	0	0	0	0	0	0	0
Worker Safety		Wear safety gear - gloves, apron, goggles	*Safety gear not worn when making and applying solution.*	1	1	1	1	1	1	0	0	0
Worker Safety		Use properly labelled foamer	*Not properly labelled.*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
Worker Safety		Use labelled containers for transferring chemicals	*Transfer containers not properly labelled.*	1/3	1/3	1/3	1/3	1/3	1/3	0	0	0
Worker Safety		Use properly labelled chemical containers	*Chemical containers not properly labelled.*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
		Apply to food contact surfaces	*Not applied to all equipment food contact surfaces.*	0	0	0	0	0	0	0	0	0
		Clean small parts	*Parts not cleaned.*	0	0	0	0	0	0	0	0	0

Defect Category	Step	Best Practices	Defect Opportunity	Run 1			Run 2			Run 3		
				R1	R2	R3	R1	R2	R3	R1	R2	R3
Time-Related		Clean all produce transfer conveyances including crates, baskets, and transfer bins	*Full sanitation procedure not applied to all transfer conveyances.*	1	1	1	1	1	1	1	1	1
Time-Related		Apply foam cleaner to undersurfaces	*Not applied to undersurfaces.*	1	1	1	1	1	1	1	1	1
		Apply for appropriate amount of time	*Not applied for correct amount of time.*	0	0	0	0	0	0	0	0	0
Incorrect Procedure		Apply foam cleaner from bottom to top	*Not applied from bottom to top.*	1	1	1	1	1	1	1	1	1
	11	**Scrub as needed**										
		Use designated colour-coded cleaning aids	*Equipment not cleaned using designated cleaning aids.*	0	0	0	0	0	0	0	0	0
Incorrect Procedure			*Colour-coded cleaning aids not in correct room.*	1	0	0	0	1	0	0	1	0
		Use clean, sanitized, non-abrasive brushes or nylon scouring pads	*Cleaning aids not clean and sanitized before use.*	0	0	0	0	0	0	0	0	0
		Run conveyors or equipment at slow speeds to assist with cleaning	*Equipment not run at low speeds to aid cleaning.*	0	0	0	0	0	0	0	0	0
	12	**Rinse equipment**										
		Rinse equipment from top to bottom	*Equipment not rinsed from top to bottom.*	0	0	0	0	0	0	0	0	0
Time-Related	**13**	**Inspect (monitor) equipment before sanitizing**	*Equipment not inspected before sanitizing.*	1	1	1	0	1	1	1	1	1
	14	**Sanitize**										
		Correct sanitizer	*No sanitizer or incorrect sanitizer.*	0	0	0	0	0	0	0	0	0
Incorrect Procedure		Correct sanitizer concentration	*Incorrect sanitizer concentration.*	0	1	0	0	1	1	1	1	1
		Correct amount of time	*Incorrect time.*	0	0	0	0	0	0	0	0	0
Time-Related		Sanitize equipment starting with support structures and working upward	*Not applied from the bottom upward.*	1	1	1	1	1	1	1	1	1

Defect Category	Step	Best Practices	Defect Opportunity	Run 1			Run 2			Run 3		
				R1	R2	R3	R1	R2	R3	R1	R2	R3
	15	**Documentation**										
		Sanitation Documentation filled in correctly	Documentation not filled in correctly.	0	0	0	0	0	0	0	0	0
	16	**Standard Operation Procedures**										
SOPs		SOPs match Best Practices	*SOPs do not match sanitation best practices.*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
SOPs		SOPs are complete and up-to-date	*SOP are incomplete and not up-to-date.*	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3	1/3
			Totals	**12 2/3**	**13 2/3**	**12 2/3**	**10 2/3**	**12 2/3**	**12 2/3**	**12 1/3**	**12 1/3**	**10 1/3**
			Total Defects	**39**			**36**			**35**		
			% Defects	**39%**			**36%**			**35%**		