Practical Application Study For Food Safety Risk Mitigation In A Nut Processing Facility

by

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B.S., University of Nebraska, 2011

A THESIS

Submitted in partial fulfillment of the requirements

for the degree

MASTER OF AGRIBUSINESS

Department of Agricultural Economics

College of Agriculture

KANSAS STATE UNIVERSITY

Manhattan, Kansas

2018

Approved by:

Major Professor
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ABSTRACT

Food processing facilities are faced with many challenges in ensuring that the food supply is safe for consumption. *Listeria monocytogenes* is a food pathogen that has been linked to ready-to-eat foods, including tree nuts. *Listeria monocytogenes* is part of the ubiquitous microorganism genus, *Listeria*. The most likely cause of *Listeria* contamination in food is post-processing contamination. The purpose of this research is to identify and examine possible solutions a nut processing facility might employ to mitigate a food safety risk.

The outcome of this research helps to establish the most financially viable method a processing facility may implement to address and mitigate an established risk given defined premise construction and constraints. The research objective is to identify a solution, implement a course of action, and establish safeguards to prevent recurrence of the issue.

Factoring in facility specific variables as well as industry data and relevant analyses, the research conducted concludes with recommended actions for the facility to make, including a combination of structural design changes coupled with extensive chemical sanitation techniques.

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ACKNOWLEDGMENTS

I would like to express my sincere gratitude and appreciation to my family and friends for all their love and support during this program. I especially want to thank my husband, Derrick, for his patience, encouragement, and love while I completed the Masters of Agribusiness Program. While we faced many life changes and challenges, and experienced professional and personal highs and lows, his support and inspiration has been unwavering. I would not have been able to realize this dream without him.

A huge thank you to Leslie Primo and Oscar Salas for all the long hours, thoughtful discussions, explanations, and overall support. Thank you for taking time at night, on weekends, and even over Easter to investigate the issue and try new solutions with me. I honestly couldn’t have completed this without both of you and I am eternally grateful that we make such a great team.

I would also like to thank my fellow MAB Class of 2018 colleagues for providing the best relief, understanding, and support throughout this entire process. I wouldn’t be where I am without you guys. Essentially, I would like to thank you for the laughter, learnings, and of course introducing me to Nancy.

Finally, I would also like to express my gratitude to my major professor, Dr. Keith Harris, and Deborah Kohl for challenging me to think in an objective manner and to see problems through fully before jumping to solutions. Thank you both for providing exceptional patience and guidance while helping me meet my personal and professional goals and for being so extraordinarily supportive of me personally and professionally.

CHAPTER I: INTRODUCTION

Archer Daniels Midland, one of the world's largest agricultural processors and food ingredient providers, (Archer Daniels Midland Company 2018) was founded in 1902 as Daniels Linseed Co. in Minneapolis, MN. The company expanded rapidly to include soybeans and flour milling and became Archer Daniels Midland Company, commonly known as ADM, in 1923 (Archer Daniels Midland Company 2018). Today, ADM has nearly 32,000 employees located around the world and sales of $62.39B in 2017 (Forbes Media LLC 2017).

The structure of ADM consists of four primary business segments that embody the company's vision to connect the "harvest to the home" by making products for food, animal feed, industry, and energy (Archer Daniels Midland Company 2018). The four business segments are Corn Processing, Oilseeds Processing, WILD Flavors and Specialty Ingredients, and Agricultural Services.

Agricultural Services is the largest business segment of ADM. It consists of an extensive global grain elevator network, a transportation network of infrastructure and routes, and port operations. These all function to buy, store, clean, and transport agricultural commodities such as oilseeds, corn, wheat, milo, oats, rice, and barley. Agriculture Services resells these commodities primarily as value-added products including food and animal feed ingredients, or as raw materials for the agricultural processing industry. The Agricultural Services business segment also includes the flour milling (Archer Daniels Midland Company 2018). Agricultural Services accounts for 45% of ADM total revenue (Nisser 2018). Included in the Agricultural Services is the Golden Peanut and Tree Nuts company.

Golden Peanut and Tree Nuts was formed as a joint venture between ADM and Gold Kist Peanuts in 1986 as Golden Peanut (Golden Peanut and Tree Nuts 2018) and quickly grew to become one of the major processors of peanuts. In 2000, Golden Peanut expanded to a global entity by entering into a partnership with Cargill in Argentina. Golden Peanut and all acquisitions were consolidated in 2010, making Golden Peanut a wholly owned subsidiary of ADM. In 2013, Golden Peanut expanded its global footprint by acquiring the assets of P – Farm Agente, one of South Africa's leading peanut processors. In 2014, Golden Peanut became Golden Peanut and Tree Nuts, entering the global tree nut processing industry by acquiring Harrell Nut Company, a pecan sheller and processor (Golden Peanut and Tree Nuts 2018). The final business expansion in 2017 cemented Golden Peanut and Tree Nuts as a player in the ready-to-eat tree nut industry by acquiring three tree nut processing facilities in California from Specialty Commodities Inc. With this acquisition, Golden Peanut and Tree Nuts consisted of 12 processing facilities and 106 peanut buying points. The three California facilities are located in Lodi, Stockton, and Modesto and form the Processing and Distribution Division of Golden Peanut and Tree Nuts.

Golden Peanut and Tree Nuts' processing facility in Lodi, CA is a 36,000 sq. ft. facility located on four acres in the heart of a residential area. Originally constructed in 1949 as a black walnut facility known as the Lodi Nut Company, the final expansion was completed in 2010 when the Lodi Nut Company was purchased by Specialty Commodities Inc. The facility is the largest and offers the most diverse portfolio of the three Processing and Distribution Division facilities. Lodi is capable of steam dry roasting, oil roasting, pasteurizing, dicing, sorting, optical sorting, packaging, and retail packaging a wide array of tree nuts and seeds with two controlled temperature storage warehouses. Products processed include almonds, brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, pistachios, pumpkin seeds, sunflower seeds, and walnuts that are packaged for further food processing or direct to consumer retail.

Table 1.1: Processing and Distribution Division Facility Capabilities

	Lodi	Stockton	Modesto
Products Processed			
Almonds	X	X	X
Brazil Nuts	X	X	
Cashews	X	X	X
Hazelnuts (Filberts)	X	X	
Macadamia Nuts	X	X	
Pecans	X	X	
Pine Nuts	X		
Pistachios	X	X	
Pumpkin Seeds	X		X
Sunflower Seeds	X		
Walnuts	X	X	
Process Capabilities			
Hand Sorting	X	X	X
Optical Sorting	X		X
Validated Steam Dry Roasting	X		
Validated Dry Roasting	X		X
Dry Roasting	X	X	X
Validated Oil Roasting	X		
Oil Roasting	X	X	
Steam Pasteurization	X		X
Dicing	X	X	X
Butter Line		X	
Retail Canning	X		
Retail Jar Line	X		
Retail Pouching	X		X
2017 Pounds Processed	**33,997,902**	**13,381,075**	**7,413,406**

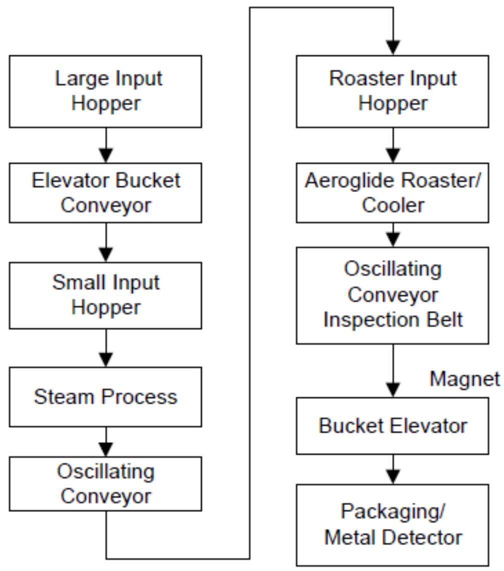
Approved suppliers deliver raw materials in 25 pound cardboard cartons or 2,500 pound flexible intermediate industrial containers (FIBC), commonly referred to as super sacks, and delivered via van trailers. All inbound raw materials are sampled and tested for organoleptic properties, free fatty acids, peroxide value, and aflatoxin prior to processing. Once the product is released for use by the Quality Control Department, it is sorted to remove any broken pieces, shells, or foreign material using either a TOMRA Nimbus™ optical color laser sorting unit, or manual hand sorting. For steam dry roasted products, sorted material is moved into the separate steam room. The steam / dry roaster is comprised of two separate processes; a custom built steamer bed and the Buhler Aeroglide™ dry roaster.

The steamer room, built onto the existing facility in 2010, is physically separated from ready-to-eat areas by enclosed walls. This segregation ensure raw products are kept separate from the ready-to-eat finished products. Raw material enters through a large roll up door to the outside and goes through a hopper into the south end of the custom steamer bed. The product flow into the steamer is controlled by a Syntron® vibratory feeder to ensure the product is evenly distributed (Salas 2018). Culinary steam is produced by a boiler and added to the product at the steamer. The steamer is a custom built covered chamber 12 feet long and 36 inches wide. Steam is distributed in three locations along the bottom east side length in equal distances. The temperature of the steam added to the conveyor is monitored by four thermocouples on the west side of the conveyor. A Honeywell™ RTD temperature controller controls the process and displays the actual and set point temperatures of the product. The process is monitored by an Omega™ continuous chart recorder with a temperature alarm. The belt speed is adjusted by a variable speed controller (Salas 2018). Once product is heated to the correct temperature and time, as designated by product validation parameters, the product exits the steamer and travels east on a conveyor belt through a small opening in the wall separating the steamer from the dry roaster. The product is elevated and enters the dry roaster.

The Buhler Aeroglide™ dry roaster has multiple heat zones and measures 14.8 feet long, approximately 6 feet high, with a belt width of 8.5 inches (Salas 2018). The roaster is divided into two heat zones of equal length. The airflow in zone one is initially directed downward for the first section, then upward for the remainder of the zone. Zone two airflow is identical to zone one. The cooler section is approximately 8.6 feet long and has the option of using ambient air or refrigerated air for cooling. The cooling air is filtered through a pleated filter before being forced through the bottom of the product bed (Salas 2018). A Honeywell™ RTD Temperature Controller allows for changes in set-point temperatures. The temperature controller displays the set-point temperature and the actual temperature for both zones. There are four total product temperature probes; one in zone one and the remaining three in zone two. All probes are set at a product dependent, predetermined height above the belt. The product temperatures are continuously recorded on an Omega™ continuous chart recorder (Salas 2018).

After the product exits the cooler section of the dry roaster, it is carried on an open conveyor belt past a specialty trained operations employee who inspects the product for defects or foreign material. At the end of the inspection belt, the product passes over a rare earth magnet and through a calibrated Thermo Fisher Metal Detector into either a super sack for further processing or into 25 pound nylon bags packed into cardboard boxes for distribution.

Figure 1.1: Steam Dry Roaster Flow Diagram



The steam dry roaster is validated for at least a five log reduction of *Salmonella* for cashews, macadamia nuts, and pumpkin seeds. The validations are performed in accordance with the Almond Board of California's published dry roasting guidelines (Almond Board of California Technical Expert Review Panel (TERP) 2014) whereby *Enterococcus faecium* NRRL B-2354 (*Pediococcus*), a recently accepted surrogate for SE PT 30 under dry and wet heat almond processing conditions, can be used for validation of dry roast processing.

When ADM purchased Specialty Commodities Inc. in 2014, the purchase agreement did not include the buildings used for production, processing, and storage. Instead, the company leases the buildings from the original owners of the Lodi Nut Company, which is set to expire January 31, 2021 (Lease Extension Agreement 2016). The lease agreement is non-negotiable and includes provisions of what the owners are responsible for repairing and how the building is to be maintained (Lease Agreement 2010). Section 7.2 of the leasing agreement stipulates that the owners of the property are responsible for roof repairs, any underground piping or plumbing issues, and any structural repairs needed for the foundation of the building (Lease Agreement 2010). ADM has proposed a plan to build a new building to replace the current Lodi processing facility. Until the new building is finished, Golden Peanut and Tree Nuts must operate within the parameters of the lease agreement. This includes an alterations provision whereby any structural changes made to the building must be pre-approved in writing by n the landlords and restored to original conditions prior to ADM leaving the facility (Lease Agreement 2010). The proposed $3.5M building is scheduled to open in 2021.

1.1 Research Problem

When the steamer room was constructed in 2010, the addition was added to an exterior wall that is constructed of dry wall and wood covered by paneling. Since the construction, *Listeria species (spp)* has been persistent in dry roast side near the wall where the product is conveyed. The findings of *Listeria spp* is dormant during the warm weather but becomes active during the rainy season of December through April.

What stems from this problem is the following research question: What is the most efficient method or methods that the Golden Peanut and Tree Nuts Lodi facility may use to address the persistent strain of *Listeria* while effectively mitigating the problem from recurring?

Listeria is a species of pathogenic bacterium that are short rod-shaped, Gram-positive, non-spore-forming, facultative anaerobes (Wang and Orsi 2013). *Listeria* is a robust organism that can grow from 1ºC to 45ºC, a pH range of 4.4 to 9.4 (Saini 2008) and in salt solutions up to 10% (Wang and Orsi 2013). Ingestion of pathogenic *Listeria monocytogenes* causes listeriosis (Centers for Disease Control and Prevention 2017). The symptoms of listeriosis range from diarrhea and fever to stillbirths and death (Slutsker and Schuchat 1999). As such, the FDA has established a zero-tolerance policy for *Listeria* in foods since 1985 (American Bakers Association; et al n.d.). As part of this policy, any ready-to-eat food where a *Listeria* species detected is deemed adulterated (Federal Food, Drug, and Cosmetic Act 2013). *Listeria* is generally recognized as a ubiquitous environmental pathogen (American Bakers Association; et al n.d.). As such, it is commonly found in water, soil, plant material, and inside processing facilities. The prevalence and virility of *Listeria* in food processing environments is compounded by its ability to form biofilms (Chang, et al. 2012). Biofilms develop when microorganisms colonize on a surface and form a monolayer or multilayer of cells (Kim 1993). Biofilms exhibit distinct characteristics that differ from planktonic cells. Biofilm formation includes initial attachment to a surface, including stainless steel, followed by the formation of micro-colonies and then the maturation into a matrix-encased biofilm (Chang, et al. 2012). One of the means by which a biofilm exhibits different characteristics than planktonic cells is an increased resistance to antimicrobial agents and sanitizers (Mah and O'Toole 2001).

One of the largest sources of contamination in ready-to-eat foods is environmental pathogenic cross-contact in the processing facility (Behling 2010). Environmental pathogens, such as *Listeria* and *Salmonella*, are actively searched for in the Lodi Golden Peanut and Tree Nuts processing facility through a comprehensive Pathogenic Environmental Monitoring Program as required by the Food Safety Modernization Act (Food Safety Modernization Act (FSMA) 2011). The premise of a pathogenic environmental monitoring program is the relationship between microbes in the environment and microbes in product contact surfaces exists and that contamination of product contact surfaces will result in measurable product contamination events (Kornacki 2014). In accordance with the program, swabs are taken on a weekly basis throughout the facility during production. Swabs are taken and categorized by zone in accordance to proximity to the actual product (Grocery Manufacturers Association 2014). Zones are designated 1 through 4 with zone 1 being product contact and zone 4 more remote areas away from production.

Table 1.2: Golden Peanut and Tree Nuts Lodi Pathogenic Environmental Monitoring Program Zone, Test, Critical Limit and Frequency

Location	Tests	Critical Limit	Frequency
Zone 1			
Product Contact Surfaces	ATP	<300	After each full clean
	TPC	1000 cfu / sq. inch	Quarterly
	Coliforms	100 cfu / sq. inch	Quarterly
	E. coli	Negative	Quarterly
	Yeast	100 cfu / sq. inch	Quarterly
	Mold	100 cfu / sq. inch	Quarterly
Zone 2			
Adjacent to zone 1	*Salmonella spp*	Negative	Weekly
	Listeria	Negative	Weekly
Zone 3			
Other surfaces in production area	*Salmonella spp*	Negative	Weekly
	Listeria	Negative	Weekly
Zone 4			
Remote areas not in production	*Salmonella spp*	Negative	Weekly
	Listeria	Negative	Weekly

Deviations from the established critical limits have typically been managed through cleaning and sanitation practices. Cleaning is performed by production employees using chemicals supplied by ChemStation, the facility's industrial chemical solutions provider. The cleaning and sanitizing process begins with employees using ChemStation 10023 Heavy Degreaser to remove particles on equipment. The equipment is scrubbed and scraped clean with designated brushes and utensils and then rinsed free from residue with hot potable water. Adenosine triphosphate (ATP) swabs are taken of each piece of equipment to verify the cleaning practices. ATP in recent years has become a standard method of determining biological cleanliness in the food industry (Powitz 2007). ATP is the primary transfer molecule present in all living organisms and cannot be produced or maintained by other substances (Powitz 2007).

Once the equipment is verified as clean, the equipment is then sanitized with Alpet D-2 sanitizer or Perasan A sanitizer, when sanitizing prior to processing organic products. Floors, walls, and drains are scrubbed clean with Sterilex Ultra Disinfectant Cleaner designed to remove biofilm in the food and health industry (Sterilex 2017). The floors are then rinsed with hot potable water. If a swab returns a “presumptive positive” for *Listeria*, the area is cleaned and sanitized and then treated with O-Zone (Vapex Nano-Radical) to destroy the biofilm. O-Zone is a gas that is a triatomic form of oxygen and has become known as a broad-spectrum biocide against viruses, bacteria, biofilms, and protozoa that are not known to build resistive tolerances to the application since because it disinfects by oxidation processes (Rice, Graham and Lowe 2002). Aqueous ozone is generated with electricity, water, and oxygen. An electronic current is passed through pure oxygen (O_2). Then, the electrical current separates some of the oxygen molecules into two. These oxygen molecules attach onto the remaining O_2 to create ozone (Montag 2017). The ozone is then infused into water and sprayed onto the surface that yielded the presumptive positive result.

In January 2018, the Lodi processing facility became unable to eradicate the strain of *Listeria* found in the dry roast area by the wall coming from the steamer room using the established methods. The primary problem addressed in this research is to determine what actions should be implemented to mitigate the risk of *Listeria* in the processing facility until the current lease agreement expires and a new processing facility is built.

1.2 Research Objectives

The objective of this research is to conduct an analysis to define the best financially viable method(s) of *Listeria* control the Golden Peanut and Tree Nuts processing facility can implement. The specific objectives:

1. Identify and isolate the sources of *Listeria* in the dry roast environment.
2. Identify alternative viable options available to the facility to control the *Listeria* strain and analyze the costs associated with the options.
3. Establish long term controls that will mitigate the risk of *Listeria* until the new building is finished in 2021.

There is not an immediate risk to the products processed or produced by the facility. The Golden Peanut and Tree Nuts Lodi facility has found the presence of the strain on the raw-material side of the process, meaning that all products near where the strain has been found has yet to receive a validated kill step. Many companies do not swab the raw side of the process due to knowing the ubiquitous nature of *Listeria* and that the product is to receive a validated kill step (American Bakers Association; et al n.d.). However, the Golden Peanut and Tree Nuts facility policy is to swab all areas to ensure that the organism is not spread to a point where it could potentially contaminate finished product.

1.3 Significance of the Study

This problem has the potential for widespread and potentially irreversible financial and reputational impacts for Golden Peanut and Tree Nuts as a whole. Multiple cost savings and cost avoidance benefits of mitigating the issue have been identified. The benefits of addressing the issue include:

1.3.1 Cost Savings of Mitigating the Issue

1. The immediate impact is the cost associated with sanitation and the swab testing of the area. Each swab submitted for testing costs $20. After a presumptive positive result is obtained, the facility implements vector swabbing. Vector swabbing is when additional swabs are taken around the initial presumptive positive site in an outward starburst pattern that includes vertical and horizontal surfaces to identify the path of the organism and ultimately to find the source of the contamination (Luce 2018). A minimum of three vector swabs are taken for each presumptive positive result until the facility receives three consecutive days of negative results. Each presumptive positive results in a minimum of $240 in testing. In addition, the increase of chemical usage also adds costs. Prior to conducting vector swabbing, the facility conducts the full cleaning and sanitation process for the area.
2. To perform the O-Zone treatment, the processing line must be shut down. Therefore, the problem has caused facility downtime and delayed production scheduling. The cost of each line is calculated by number of pounds processed. The dry roast department is capable of processing 2,500 pounds per hour. Cleaning impacted areas averages two hours. Factoring in the labor costs, cleaning for after each presumptive positive swab result costs the company $1500.

Table 1.3: Golden Peanut and Tree Nuts Lodi Departmental Cleaning Cost per Presumptive Positive Swab

Department	Labor Cost (per pound)	Overhead Cost (per pound)	Pounds per Hour	Average Swab Cleaning Time	Total Cost
Steam / Dry Roasting	$0.11	$0.19	2500	2 hours	**$1500**
Oil Roasting	$0.19	$0.19	3000	1 hour	**$1140**
Steam Pasteurization	$0.08	$0.19	5400	1 hour	**$1458**
Pasteurized Packaging	$0.11	$0.18	2000	1 hour	**$580**
Dicing	$0.24	$0.21	2500	2 hours	**$2250**
Hand Sorting	$0.15	$0.19	1500	0.5 hours	**$255**
TOMRA Laser Sorter	$0.06	$0.20	3000	0.5 hours	**$390**
Retail Can Line	$0.24	$0.18	2000	1 hour	**$840**
Retail Pouch Line	$0.13	$0.18	1200	1 hour	**$372**
Retail Jar Line	$1.15	$0.18	1500	1 hour	**$1995**

1.3.2 Cost Avoidance of Mitigating the Issue

3. The presence of *Listeria* is a hazard in terms of its tangible (business) and intangible (good-will) impact. Since the Food Safety Modernization Act of 2011, the FDA has the authority to swab facilities and see swabbing results. The FDA also has the authority to issue to the firm's management a 'Form 483', which when observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health. (U.S. Food and Drug Administration 2017). The presence of *Listeria* in the processing facility does not itself constitute a Form 483, but if the FDA determines that the facility failed to take proper steps to mitigate the risk and eradicate the issue, the FDA may deem the situation as a potential food safety risk. While Form 483 does not have costs such as penalties, fines, or fees associated with it, firms are obligated to disclose to customers when asked if the company has received a violation or a Form 483, leading to reputation damage and possible loss of business (Chen 2016).

4. In addition, the FDA has the authority to issue "Warning Letters" that are made public and have the potential to damage a company's goodwill with customers. The tangible costs of a warning letter include fines associated with the findings noted, corrective actions and required implementation. As a publically traded company, ADM would also likely experience a change in stockholder confidence, resulting in a drop in stock price. There are also the intangible and hard to measure costs of an FDA Warning Letter as well. A company's failure to comply with the Code of Federal Regulation (CFR) or Good Manufacturing Practices (GMP) requirements and their inadequacies are made public record by the FDA. In addition, the idea of quantifying a warning letter from the FDA is nearly impossible as each company incurs different expenses and underlying abstract expenses (Rothrauff 2013). These intangible costs include reputation and goodwill damage, customer loss, and employee turnover.
5. Finally, the FDA has the regulatory authority to stop production and ultimately close a process or entire facility if a food safety contamination is identified and has been deemed that it was not properly addressed. The FDA closing a facility, such as the Peanut Corporation of America, would result in total financial loss of customers, production, and assets. Lawsuits regarding the ethicality of the company and safety of products produced would likely occur, as evident by the Peanut Corporation of America. This would consequently result in irreparable reputational damages for Golden Peanut and Tree Nuts, and ultimately ADM.

CHAPTER II: LITERATURE REVIEW

This chapter presents the literature used in consideration as potential methods for the established problem. The chapter is organized into three main sections to provide context and information for an assessment that could be made by the Golden Peanut and Tree Nuts Lodi facility.

2.1 Formation and Prevalence

Listeria is a pervasive and ubiquitous organism that persists and thrives in multiple environments, making it difficult for food processing facilities to control the risk. *Listeria* has been isolated from soil, silage, water, and feces (Ryser and Donnelly 2015). Known to thrive in cool and wet environments, *Listeria* is often found in water samples (U.S. Department of Health & Human Services 2018). While abundant in nature, *Listeria* in processing environments is most commonly found in cool, damp environments including conveyors, floors, and drains (Slade 1992). Drains are susceptible to high populations of *Listeria* (Tompkin, et al. 2010). Due to the organism's pervasiveness, *Listeria* is often re-introduced into food processing facility environments (Tompkin, et al. 2010).

According to the CDC, *Listeria monocytongenes* causes the food borne illness *Listeriosis* which primarily affects pregnant women, older adults, and those with weakened immune systems (Centers for Disease Control and Prevention 2017). Symptoms of *Listeriosis* include septicemia, gastroenteritis, meningitis, miscarriages, stillbirths, and death (Colagiorgi, et al. 2017). After the organism is ingested, *Listeria* multiplies in the human intestinal tract, can cross the intestinal barrier, and enter the bloodstream. Once in the bloodstream, *Listeria* can accumulate in the liver and spleen (Ricci, et al. 2018). While *Listeria* accounts for less than 1% of all foodborne illnesses in the United States, it accounts for 28% of the deaths caused by foodborne illnesses (Pan, Breidt and Kathariou

2006). Consumption of ready-to-eat foods contaminated with *Listeria* is the main cause of *Listeriosis* (Doijad, et al. 2015). There have been multiple documented cases of *Listeria* found in tree nuts and peanuts causing recalls (Yada 2018).

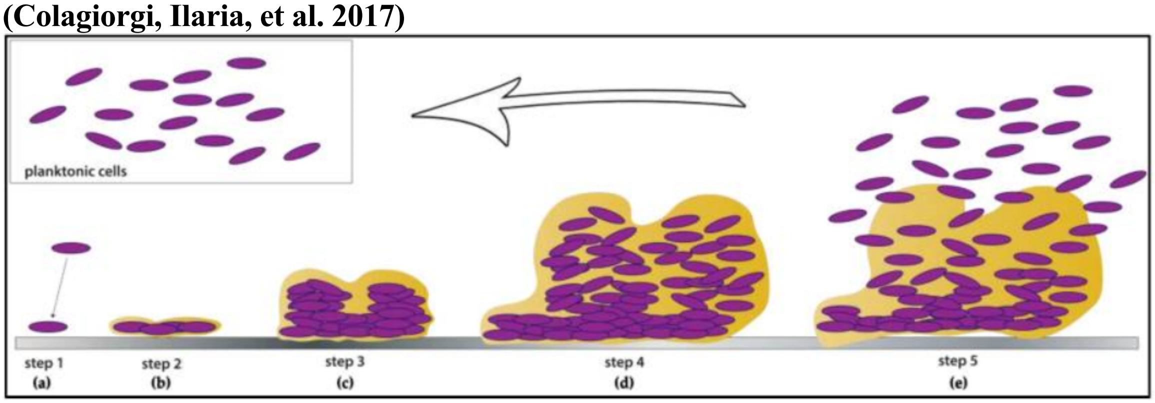
Listeria can grow both aerobically and anaerobically, multiplies in temperatures ranging from 1^{o}-45^{o}C, is acid tolerant, and can grow in water activity of 0.90 (Ryser and Donnelly 2015). In addition, *Listeria* is able to adapt to changing environments and handle osmotic stresses and high salt environments (Ricci, et al. 2018). *Listeria* is able to thrive in food processing environments for extended periods of time including cases of the same strain persisting in a processing environment for more than 10 years (Pan, Breidt and Kathariou 2006).

2.2 Chemical Resistance

Listeria is a highly adaptable bacteria that has been known to exhibit tolerance against standard cleaning chemicals such as quaternary ammonium (Ricci, et al. 2018). Bacteria such as *Listeria* are able to affix themselves onto surfaces including stainless steel (de Oliveira, et al. 2010), and form biofilms. Biofilms are a community embedded in a matrix of extracellular polymeric substances (EPS's) (Colagiorgi, Di Ciccio, et al. 2016). *Listeria* is able to form biofilms that are highly resistant to chemical sanitizers (Moberg and Kornacki 2015). Some biofilms are more than 1,000 times more resistant to destruction and sanitizers than freely suspended cells (J. L. Kornacki 2010). Each biofilm appears to be composed of unique patterns and organisms and dependent on the environment and surface attached, making it so no two biofilms are the same. It has been hypothesized that there are multiple mechanisms that interconnect to form a biofilm's unique makeup and biocide resistance (Mah and O'Toole, Mechanisms of biofilm resistance to antimicrobial agents 2001). Therefore, there are numerous variables that influence biofilm formation and resistance to sanitizers. Some of the variables include the surface that the biofilm is affixed to, the food source of the biofilm, the polysaccharide makeup and matrix composition of the biofilm, and environmental factors such as humidity, temperature, etc. have a profound impact on the biofilm (Colagiorgi, Di Ciccio, et al. 2016).

A *Listeria* biofilm develops in multiple stages illustrated in Figure 2.1. The first stage is when planktonic cells attach to a surface. The cells begin to multiple and form a matrix of extracellular polymeric substances (EPS's) in the second stage (Colagiorgi, Di Ciccio, et al. 2016). The biofilm continues to diversify, and may start to incorporate other organisms in stage three. The fourth stage of *listeria* biofilm formation occurs when the biofilm begins expanding and spreading on the affixed surface. During this stage, the matrix become less compact around the cellular organisms. The final stage of the biofilm development occurs when planktonic cells are released from the matrix.

Figure 2.1: Schematic Representation of Listeria Biofilm Development Stages (Colagiorgi, Ilaria, et al. 2017)



CHAPTER III: EXPLORATORY EVIDENCE AND PROPOSITIONS

This chapter provides exploratory evidence and data used to identify potential sources of the persistent strain of *Listeria* in the dry roasting environment. Three propositions have been identified as part of the problem tracking and exploratory evidence. These propositions include:

Proposition 1 (P_1): Rain Tracked into the Facility. P_1 is based on a presupposition that rain water containing *Listeria* from the outside is brought into the facility by employee movements and traffic patterns.

Proposition 2 (P_2): Water Draining from the Steam Room into the Wall between the Steamer and Dry Roaster. P_2 is was developed based on a presupposition that water used in cleaning the steam room drains towards the wall, providing an environment prime for *Listeria* biofilm formation and growth.

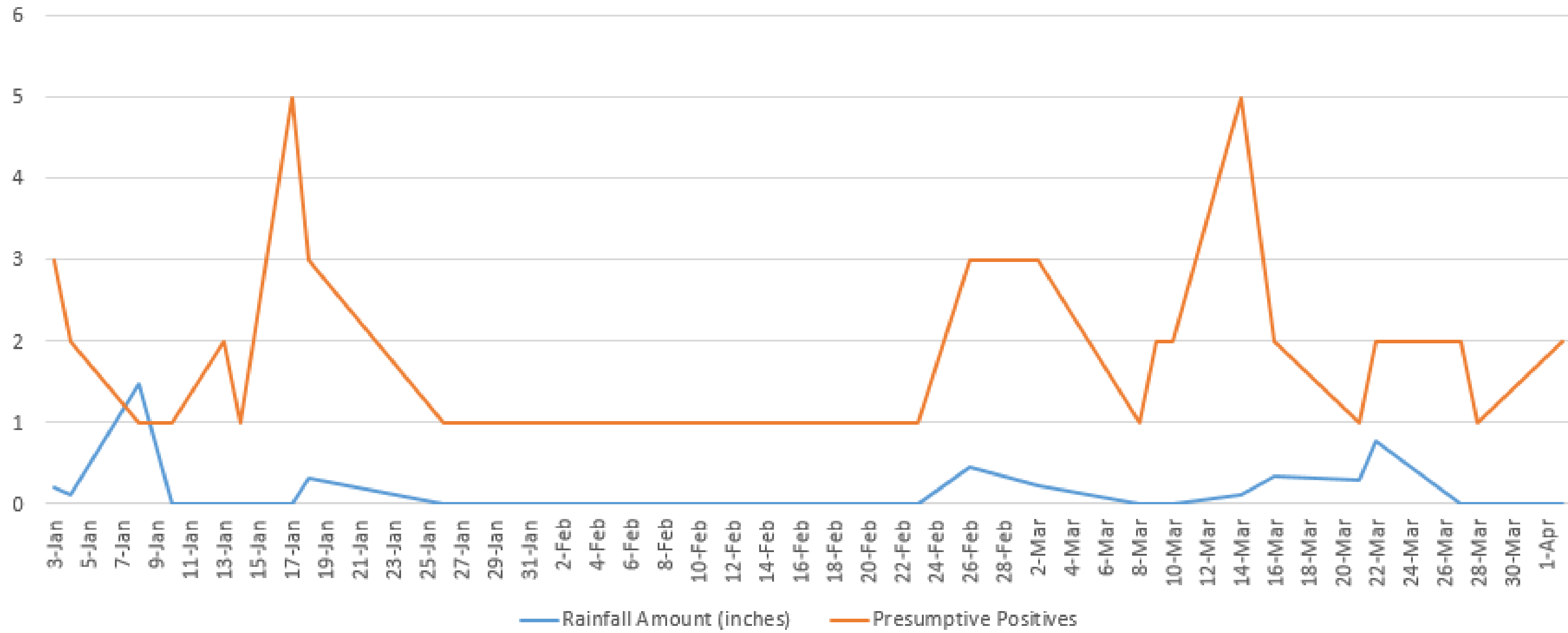
Proposition 3 (P_3): Rain going into the wall between the Steamer and Dry Roaster. P_3 was developed based on a presupposition that rain water is able to get into the wall that separates the steamer room from the dry roasting room, creating an environment for the *Listeria* to grow.

3.1 Exploratory Evidence: Problem Emergence and Perseverance

The initial presumptive positive swabs in the dry roasting areas were taken on January 3, 2018. Prior to January 3, the last swab in the dry roast area that tested as a presumptive positive was found in the drain between the dry roaster and the oil roaster on September 25, 2017. That presumptive came back as negative on September 27, 2017. The initial presumptive positive swabs were routine swabs taken as part of the Pathogenic Environmental Monitoring Program and submitted to an accredited third party laboratory for analysis.

On January 3, 2018, Lodi, CA received 0.21 inches of rain, the first significant measurable rainfall of the season (Lodi Lake Weather 2018). Including that initial rain, Lodi received 9.01 inches of rain from 29 days of rainfall, resulting in 48 presumptive positive swabs in the steam / dry roast area. Of those 48 presumptive positive swabs, 26 were taken on days where it rained and 6 were taken the day after a rainfall. The pattern observed was that when it would rain, the facility would receive presumptive positive swabs in the dry roast area around the wall that separates the steam room and the dry roaster. Figure 3.1 summarizes the data of the presumptive positive swabs taken during the established time period of January 3, 2018 to April 2, 2018 correlated to the amount of rain received.

Figure 3.1: Rainfall Amount and Presumptive Positive Swab Results



Because *Listeria* is known to be ubiquitous (American Bakers Association; et al n.d.), the facility began swabbing items left outside pre and post rain in an effort to identify if the rain water was the source of the *Listeria* in the facility. Items such as pallets, bins, and old equipment were swabbed prior to rain and then after the rain ceased. Three out of twelve swabs returned presumptive positive results post rainfall. Table 3.1 summarizes the results and the areas swabbed.

Table 3.1: Pre and Post Rain Swab Data

Swab Date	Rainfall Accumulation (in)	Area Swabbed	Pre Rain Result	Post Rain Result
01/16/2018	0.02	White Bin Outside	Negative	Negative
01/16/2018	0.02	Pallet	Negative	Negative
01/16/2018	0.02	Grey Ladder	Negative	Negative
01/18/2018	0.32	Grey Ladder	Negative	Presumptive
01/18/2018	0.32	Forklift #4 Tires	Negative	Presumptive
01/18/2018	0.32	Scrap Metal	Negative	Negative
01/22/2018	0.20	Stainless Steel Bin Outside	Negative	Presumptive
01/22/2018	0.20	Shipping Dock Plate	Negative	Negative
01/22/2018	0.20	Pallet Storage Container	Negative	Negative
02/24/2018	0.46	Tires of Bin	Negative	Negative
02/24/2018	0.46	Forklift Post	Negative	Negative
02/24/2018	0.46	Pallet	Negative	Negative

3.2 Exploratory Evidence: Problem Investigation and Tracking

An investigation was launched to understand from where the *Listeria* was coming by using vector swabbing and Indicon Gel. Indicon Gel is a rapid biological hygiene indicator designed by Sterilex that indicates the presence of a biofilm on a surface (Sterilex 2017). Indicon Gel is a blue gel that is sprayed onto a surface. If the gel comes into contact with a biofilm, it will produce white foam/bubbles within two minutes (Food Safety Tech 2017). In an effort to identify the source of the *Listeria* in the area and track the movement of the biofilm through the facility, Indicon Gel was applied to the floors and wall. When applied to the wall that separates the steam room and the dry roast room and the floor along the wall, the Indicon Gel turned white and foam, indicating the presence of a biofilm as demonstrated in Figure 3.2.

Figure 3.2: Indicon Gel Foam Dry Roast Floor Under Cup Elevator Photograph

3.3 Propositions

Based on the presented exploratory evidence, the following three propositions were studied as potential sources of the *Listeria* strain.

3.3.1 Proposition 1 (P_1): Rain Tracked into the Facility

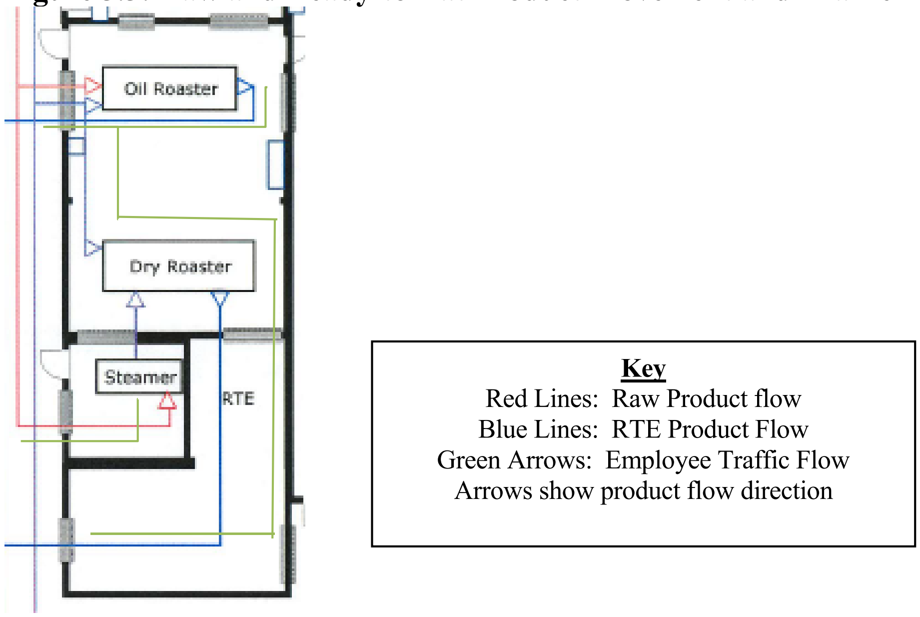
The initial proposition evaluated as that the listeria is being tracked into the facility by employees coming into the dry roast area directly from the outside. As part of the facility's established Good Manufacturing Practices (GMP) program, all employees are required to put on disposable boot covers immediately when entering into the dry roast environment. The door from the outside into the dry roast room has a small corral whereby employees must put on white disposable boot covers over their shoes and wash their hands prior to stepping into the production area. Boot covers were introduced to the facility in April 2017 and have become ingrained in the food safety culture of the facility. Routine inspections are performed by the supervisory team multiple times per shift to ensure employees are adhering to all GMPs and a full audit is performed by the management team monthly. In addition, the floor around the entrance is routinely swabbed as part of the Pathogenic Environmental Monitoring Program. To date, no swabs taken in the area have ever returned positive results. After the issue began in January, the facility increased the amount of swabs taken in the corral area as well as the established traffic patterns to ensure the *Listeria* was not being tracked inside by employee shoes. The results of all the additional swabs were negative, as shown in Table 3.2.

Table 3.2: Dry Roast Foot Traffic Swab Data

Swab Date	Area Swabbed	Swab Result
01/11/2018	Roasting Room – Floor by North Man Door	**Negative**
01/19/2018	Roasting Room – Floor by North Man Door	**Negative**
01/19/2018	Roasting Room – Foot Traffic Pattern	**Negative**
01/26/2018	Roasting Room – Foot Traffic Pattern	**Negative**
01/27/2018	Roasting Room – Floor by North Man Door	**Negative**
01/27/2018	Roasting Room – Foot Traffic Pattern	**Negative**
02/09/2018	Roasting Room – Floor by North Man Door	**Negative**
02/14/2018	Roasting Room – Floor by North Man Door	**Negative**
02/14/2018	Roasting Room – Foot Traffic Pattern	**Negative**
02/22/2018	Roasting Room – Floor by North Man Door	**Negative**
02/26/2018	Roasting Room – Foot Traffic Pattern	**Negative**
03/01/2018	Roasting Room – Floor by North Man Door	**Negative**
03/01/2018	Roasting Room – Foot Traffic Pattern	**Negative**
03/02/2018	Roasting Room – Foot Traffic Pattern	**Negative**
03/16/2018	Roasting Room – Floor by North Man Door	**Negative**

Finally, the area where the presumptive swab results are noted are not high traffic areas for employees. The facility has established traffic patterns as part of the documented Hygienic Zoning Program. These traffic patterns were reviewed as part of the investigation. As shown in Figure 3.3, the traffic patterns of raw and ready-to-eat products and personnel do not cross, meaning that there is no contamination of the ready-to-eat areas with microorganisms from the raw side of the processing. In addition, there is not any traffic flow directly near the transition area from steamer to dry roaster. Due to this evidence, P_1 was rejected.

Figure 3.3: Raw and Ready-to-Eat Product Movement and Traffic Pattern



3.1.2 Proposition 2 (P_2): Water Draining from the Steam Room into the Wall between the Steamer and Dry Roaster

The second proposition (P_2) evaluated is that water from cleaning the steam room was draining into the wall between the steamer and the dry roaster. This action may potentially provide an environment for the *Listeria* strain to prosper. The proposition was evaluated by observing the cleaning practices. The steam room was added to the existing facility in 2010 (Salas 2018), turning the once exterior wall into an interior divider between the steamer room and dry roaster room. The floor is slightly sloped for water to drain away from the wall and towards a drain in the middle of the steam room. The process of cleaning and sanitizing was observed to ensure that water drained properly away from the wall. Cleaning was observed by the Food Safety and Quality Manager on January 19, 2018 and again February 13, 2018. The sanitation practices observed were conducted across multiple shifts, ensuring compliance to the established procedure. The cleaning was all performed in accordance to the established Standard Sanitation Operating Procedure whereby all equipment was properly disassembled. The lower steam bed was cleaned using a ChemStation Foaming Chemical Application System that applies ChemStation 10023 Heavy Degreaser, a patented degreaser consisting of sodium silicate, ethylene glycol monobutyl ether, tetrasodium EDTA, and potassium hydroxide. The walls, including the wall that separates the steam room from the dry roast room were cleaned using the ChemStation 10023 Heavy Degreaser. The foam was allowed to sit on the equipment and walls for 15-30 minutes before being rinsed off with hot water applied by the pressure washer. The floors were swept and mopped using Sterilex. Sterilex is a patented chemical composed of sodium carbonate, potassium carbonate, and tetrasodium ethylenediaminetetraacetate (Sterilex 2017). During this process, all water and chemicals drained away from the wall and towards the drain in the middle of the room. Therefore, this observed evidence effectively dispelled this theory. Figure 3.4 is a checklist of duties the Steam Room Operator is responsible for completing as part of the Standard Sanitation Operating Procedure.

Figure 3.4: Steam Room Standard Sanitation Operating Procedure Checklist

	#	Description of Operation Step	Status	Time
(4) STEAM ROOM OPERATOR	1	Lock out steam room		5
	2	Cover electrical panels & outlets with plastic		10
	3	Remove garbage cans & catch bins		5
	4	Disassemble steam bed		30
	5	Remove infeed chute		5
	6	Disassemble infeed conveyance		5
	7	Clean lower steam bed		140
	8	Clean walls		10
	9	Sweep & mop floor		20
	#	Reinstall steam bed		30
	#	Reinstall feed system & infeed chute		15
	#	Reinstall elevator buckets, sanitize & replace guards		30
	#	Finish prepping for start up		30
	#	Start up machine & warm up		40
	#	Fill line		20

To verify that the cleaning practices are not responsible for the strain of *Listeria*, additional swabs were taken throughout the steam room and along the wall. All swab results taken throughout the research study yielded negative results as shown in Table 3.3.

Table 3.3: Steam Room Swab Data

Swab Date	Area Swabbed	Swab Result
01/04/2018	Steam Room Roll Up Door Entrance to Dry Roast	**Negative**
01/04/2018	Steam Room Ladder	**Negative**
01/04/2018	Steam Room South Wall	**Negative**
01/04/2018	Steam Room Frame of Conveyor	**Negative**
01/04/2018	Steam Room Elevator Frame Work	**Negative**
01/09/2018	Steam Room Floor Under Cup Elevator	**Negative**
01/11/2018	Steam Room Floor at Emergency Exit Door	**Negative**
01/11/2018	Steam Room Floor by Blue Mesh Roll Up Door	**Negative**
01/11/2018	Steam Room Forklift Traffic	**Negative**
01/11/2018	Steam Room Floor at Conveyor Opening into Dry Roasting	**Negative**
01/13/2018	Steam Room Wall by Door	**Negative**
01/18/2018	Steam Room Lift Truck Controls	**Negative**
01/19/2018	Steam Room Forklift Traffic	**Negative**
01/19/2018	Steam Room Floor at Conveyor Opening into Dry Roasting	**Negative**
01/19/2018	Steam Room Drain Cover	**Negative**
01/19/2018	Steam Room Roll Up Door Entrance to Dry Roast	**Negative**
01/26/2018	Steam Room Boot Cover Dispenser	**Negative**
01/27/2018	Steam Room Floor Under Boot Cover Dispenser	**Negative**
01/27/2018	Steam Room Floor Under Steam Bed	**Negative**
01/27/2018	Steam Room Forklift Traffic	**Negative**
01/27/2018	Steam Room Roll Up Door Entrance to Dry Roast	**Negative**
02/02/2018	Steam Room Floor Under Hopper	**Negative**
02/02/2018	Steam Room Lift Truck	**Negative**
02/02/2018	Steam Room Stairs to Platform	**Negative**
02/02/2018	Steam Room Wall on West Side	**Negative**
02/02/2018	Steam Room Post	**Negative**
02/05/2018	Steam Room Roll Up Door on North Side	**Negative**
02/05/2018	Steam Room Cup Elevator Frame	**Negative**
02/05/2018	Steam Room Drain Cover	**Negative**
02/05/2018	Steam Room Top Frame of Steamer	**Negative**
02/09/2018	Steam Room Frame of Hopper Input	**Negative**
02/13/2018	Steam Room Drain Cover	**Negative**
02/14/2018	Steam Room Floor at Emergency Exit Door	**Negative**
02/14/2018	Steam Room Forklift Traffic	**Negative**
02/14/2018	Steam Room Roll Up Door on North Side	**Negative**
02/14/2018	Steam Room Wall on West Side	**Negative**
02/22/2018	Steam Room Floor by Blue Mesh Roll Up Door	**Negative**
02/23/2018	Steam Room Frame of Hopper Input	**Negative**
02/23/2018	Steam Room Floor Under Steam Bed	**Negative**
02/23/2018	Steam Room Grey Metal Trim on West Wall	**Negative**
02/23/2018	Steam Room Frame of Cup Elevator	**Negative**
03/01/2018	Steam Room Roll Up Door on North Side	**Negative**
03/01/2018	Steam Room Frame of Conveyor	**Negative**
03/01/2018	Steam Room Lift Truck	**Negative**
03/01/2018	Steam Room Floor Under Hopper	**Negative**
03/01/2018	Steam Room Floor at Emergency Exit Door	**Negative**
03/06/2018	Steam Room Forklift Tires	**Negative**
03/08/2018	Steam Room Stairs by Cup Elevator Hopper	**Negative**
03/08/2018	Steam Room Roll Up Door on North Side	**Negative**
03/08/2018	Steam Room Frame of Cup Elevator	**Negative**
03/13/2018	Steam Room Roll Up Door on North Side	**Negative**
03/14/2018	Steam Room Floor Under Red Tubs	**Negative**
03/16/2018	Steam Room Floor at Emergency Exit Door	**Negative**

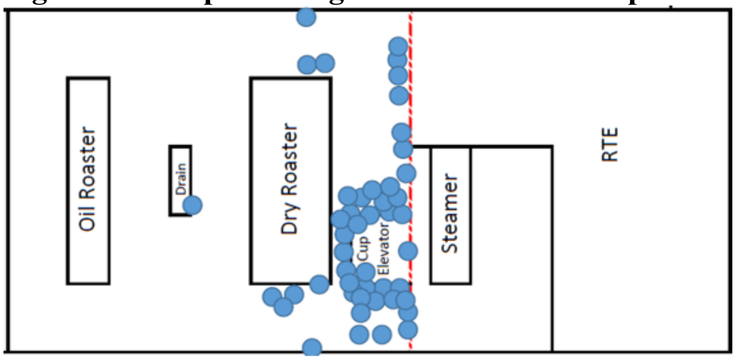
03/16/2018	Steam Room Wall on East Side of Steamer Bed	**Negative**
03/16/2018	Steam Room Forklift Traffic	**Negative**
03/22/2018	Steam Room Floor Under Hopper	**Negative**
03/22/2018	Steam Room Roll Up Door on North Side	**Negative**
03/22/2018	Steam Room Floor at Emergency Exit Door	**Negative**
03/22/2018	Steam Room Floor Under Cup Elevator	**Negative**
03/22/2018	Steam Room Forklift Traffic	**Negative**
03/22/2018	Steam Room Floor Under Red Tubs	**Negative**
03/22/2018	Steam Room Post	**Negative**

Based on the swabbing results and observation that water used for cleaning does not train towards the wall, Proposition 2 (P_2) was rejected.

3.1.3 Proposition 3 (P_3): Rain going into the wall between the Steamer and Dry Roaster

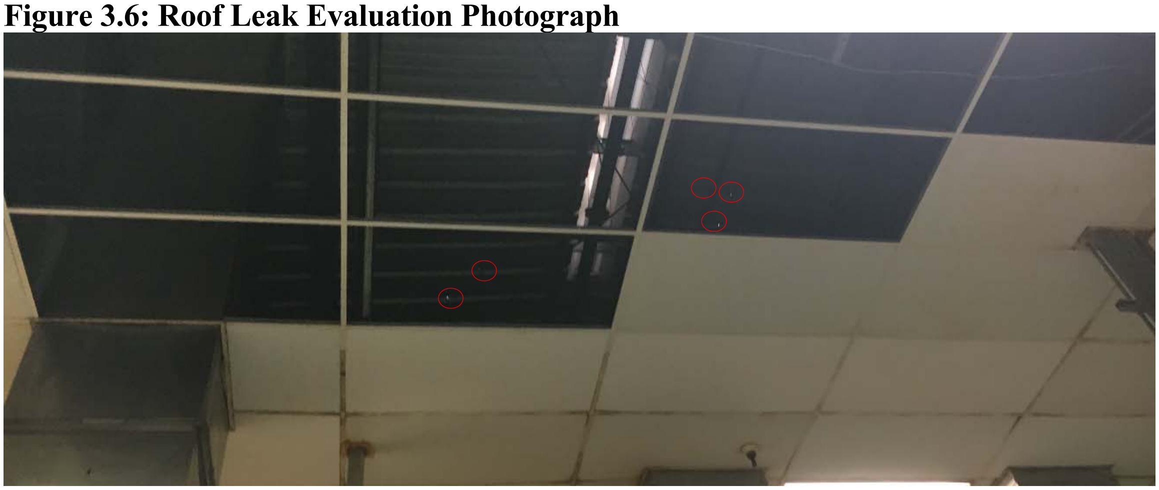
As part of the exploratory investigation, the wall between the steam room and dry roast room was observed while in operation. It was observed on multiple occasions by both the Maintenance Supervisor and Food Safety and Quality Manager that when it was raining, the wall would visibly swell. All swab results were charted and the epicenter of the population seemingly stemmed from where the product is conveyed through the wall and into the dry roaster. Because the wall was originally an exterior facing wall, all water drains towards the drain in the middle of the dry roast room. Figure 3.5 is a visual depiction of each of the presumptive positive swab results received from January 3, 2018 to April 2, 2018. The blue dots indicate areas that returned a presumptive positive result. The red line indicates the wall in question that separates the steamer room from the dry roasting rooms. The cup elevator area is where the product is conveyed through the wall and is elevated into the dry roaster.

Figure 3.5: Map Showing Locations of Presumptive Positive Swab Results



As part of the investigation, the Maintenance Supervisor and Food Safety and Quality Manager removed the drop ceiling tiles to evaluate how the rain was entering into the wall and the processing area. The tin roof was noted to have multiple areas where daylight could be seen, indicating that rain water could enter through the roof and run into the wall between the steam room and dry roast area as noted in Figure 3.6. Evidence of water damage and tracks were observed where rain water was seeping into the wall in question.

Figure 3.6: Roof Leak Evaluation Photograph



Based on the empirical evidence of the presumptive positive swab analyses, visual evidence of the roof disrepair, the exploratory evidence that the rain may carry *Listeria*, and extensive literature supporting that *Listeria* is known to thrive in cool damp environments (American Bakers Association; et al n.d.), P_3 was accepted.

CHAPTER IV: ANALYSIS AND SOLUTIONS

This chapter presents potential mitigation solutions and analyzes the financial costs of the proposed solutions. These approaches are based on the determined source from the exploratory evidence and propositions. This chapter presents the financial and technical data for the Golden Peanut and Tree Nuts Lodi facility to assess the options for mitigating the risk. Two potential mitigation strategies were analyzed: Structural Evaluation of the wall, roof, and floors as well as a Chemical Analysis of proposed chemicals and combinations that could potentially effectively mitigate the risk.

4.1 Structural Evaluation

Once the investigation yielded that the most likely root cause of the presumptive positive swabs originated from the wall separating the steam room and the dry roast room, potential solutions were developed for controlling the strain. Multiple structural options were evaluated.

4.1.1 Wall Demolition and Reconstruction

The first structural option explored was to remove the wall and replace it. *Listeria* is known to become established in damaged floors and walls (Rees and Dodd 2016). It is believed, based on the quantifiable swab data, that the inside of the wall is a harborage point whereby *Listeria* bacteria is growing without means to eradicate it. The wall was originally constructed in 1959 when the facility added roasting capability to the existing shelling operation. The wall was originally an external wall and constructed of dry wall over wood 2 inches by 6 inches (Salas 2018). Washable fiberglass reinforced plastic (FRP) panels that extend 15 feed high on the wall and the drop ceiling were installed in 2010 when the steam room was added.

Two separate contractors were identified and approached about demolishing the existing wall, and furnishing and installing five eighth inch sheetrock and fire tape wall with fiberglass reinforced plastic (FRP) panels to be applied to the full height and length of the wall with stainless steel base angles. The first contractor, Douglas J. Faszer Construction INC, estimated that the work would take at least two weeks and would cost $29,000 (Proposal and Contract for Demolition and Construction 2018). The second contractor, Commercial Specialty INC, also estimated that the work would take two weeks to complete and would cost $29,245 (Commercial Specialty Acoustical Ceilings and Framing Proposal 2018).

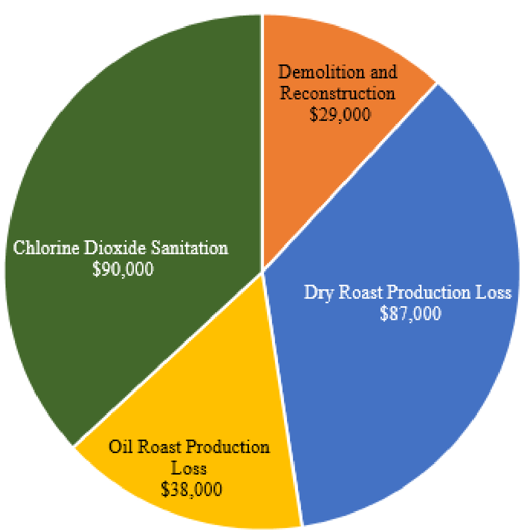
To complete the wall demolition and new construction, both dry roast and oil roast production lines would have to cease production for at least two weeks since these two production lines share the same room where the wall is located. This would lead to sales losses totaling around $87,000 for dry roasting and $38,000 for oil roasting. In addition, the dry roast line employs nine employees on all three shifts while the oil roaster employs six employees on all three shifts. This project would require 45 employees to work in other departments or be furloughed for two weeks.

Table 4.1: Cost Analysis of Wall Demolition and Reconstruction

Department	Labor Cost (per pound)	Overhead Cost (per pound)	Average Pounds per Two Weeks	Employees per Line per Shift	Estimated Sales Loss
Steam / Dry Roasting	$0.11	$0.19	290,000	9	**$87,000**
Oil Roasting	**$0.19**	**$0.19**	**100,000**	**6**	**$38,000**

ChemStation, the chemical supplier for the facility, was contacted about precautionary sanitation steps and best practices that would need to be taken during the demolition and reconstruction of the wall. The representative inspected the area and discussed shared concerns with the demolition of the wall. The inside of the wall is not able to be evaluated without construction and there are concerns of opening the wall and spreading listeria throughout other areas of the processing room and facility (Cervantes 2018). Both the facility and ChemStation noted concerns with other potential issues that may be unearthed if the wall were to be removed including mold issues, other pathogens, and spreading of the resident biofilm. ChemStation recommended the use of chlorine dioxide to fumigate the entire area after completion of the project to ensure the processing equipment is properly sanitized after the reconstruction (Cervantes 2018). The cost associated with performing the chlorine dioxide fumigation is estimated at $90,000 for fumigating the steam room, dry roast and oil roast room, and Dry Roast Ready-to-Eat room and all potentially impacted equipment. The projected cost for the wall demolition and reconstruction is estimated to total $119,000 with an estimated $125,000 in production loss. The projected cost for the demolition and reconstruction of the wall totals $244,000 for the project.

Figure 4.1: Distribution of Projected Cost Analysis for Wall Demolition and Reconstruction Project



4.1.2 Roof Repair and Replacement

The second structural option evaluated was to repair and/or replace the roof. As stipulated in section 7.2 of the Leasing Agreement (Lease Agreement 2010) entitled Landlord's Maintenance Obligations, the owners of the property, Kelley and Virgil Seuss, are responsible for keeping the roof, foundation, exterior walls, and other structural elements of the Premises in good order and condition and in compliance with all applicable laws. In the event that the Premises should become in need of repairs required to be made by the Landlord, the Tenant shall give prompt written notice to the Landlord. The Landlord shall complete all repairs required at its sole cost and without reimbursement from the Tenant.

Written notice was given to the Landlord of the property on February 16, 2018. The noticed outlined the problem in detail and described the need to repair and replace sections of the damaged roof. Estimates were given by Commercial Specialty whereby repairing sections and replacing the roof directly over the wall would take four days of work and require both the steam dry roasting and oil roasting departments to cease production for a minimum of two days if half of the work was to be performed on a weekend. The Steam Dry Roasting line processes 48,000 pounds per day on average, while the Oil Roasting line is capable of processing 60,000 pounds per day on average. Losing two days of production would result in $74,400 in projected dry roasting and oil roasting product sales lost for the roof repair project.

Table 4.2: Cost Analysis of Roof Repair and Replacement

Department	Labor Cost (per pound)	Overhead Cost (per pound)	Average Pounds Day	Employees per Line per Shift	Estimated Sales Loss / Day
Steam / Dry Roasting	$0.11	$0.19	48,000	9	**$14,400**
Oil Roasting	**$0.19**	**$0.19**	**60,000**	**6**	**$22,800**

The Landlord responded that the Tenants, Golden Peanut and Tree Nuts, caused the damage to the roof by having maintenance go on the roof and check the air filters every month, and therefore refused to comply with the request.

Golden Peanut and Tree Nuts rented a boom lift to evaluate the roof damage on April 7, 2018. Structural deficiencies, damages, and pooling water were noted along the edge where the roof extended over the wall that separates the steam room from the dry roast area as depicted in Figure 4.2.

Figure 4.2: Roof Structural Deficiencies and Damages Photograph

4.1.3 Wall/Floor Junction Seal

The final structural option evaluated was to seal the floor wall junctions along the wall that separates the steam room from the dry roast room with stainless steel paneling.

The junctions are currently treated concrete that meets the fiberglass reinforced plastic (FRP) panels. In conjunction with sealing the floor/wall junctions, sealing the concrete cracks near the wall was evaluated as well. Concrete is porous and it is believed that the *Listeria* biofilm has spread into the concrete with the abundance of rain.

The work can be performed in-house by the trained maintenance staff but the epoxy used to bind and seal the area requires two days. The work would require weekend staffing and overtime associated with staffing. Two technicians would be required to work eight hours on Saturday at time-and-a-half overtime pay. The project will also require the technicians to work eight hours on Sunday, receiving double-time pay. The base rate of technician one is $20.54, while the base rate for technician two is $14.68. Resulting in the project costing $985.84 in overtime pay (Table 4.3). All parts and tools required to complete the project are kept in stock as part of the preventive maintenance program and are readily available. Those costs were not factored into the project since they are negligible.

Table 4.3: Cost Analysis of Floor / Wall Junction Repair

Personnel	Labor Cost (Base Rate)	Labor Cost (Saturday Overtime)	Labor Cost (Sunday Overtime)	Saturday Hours	Sunday Hours	Total Cost
Maintenance Technician 1	$20.54	$30.81	$41.08	8	8	**$575.12**
Maintenance Technician 2	$14.68	$21.98	$29.36	8	8	**$410.72**
						$985.84

4.2 Chemical Analysis

As an alternative approach to mitigating the problem, chemical solutions were reviewed. Due to the pervasiveness and longevity of the strain, the facility analyzed multiple potential chemical solutions and combinations.

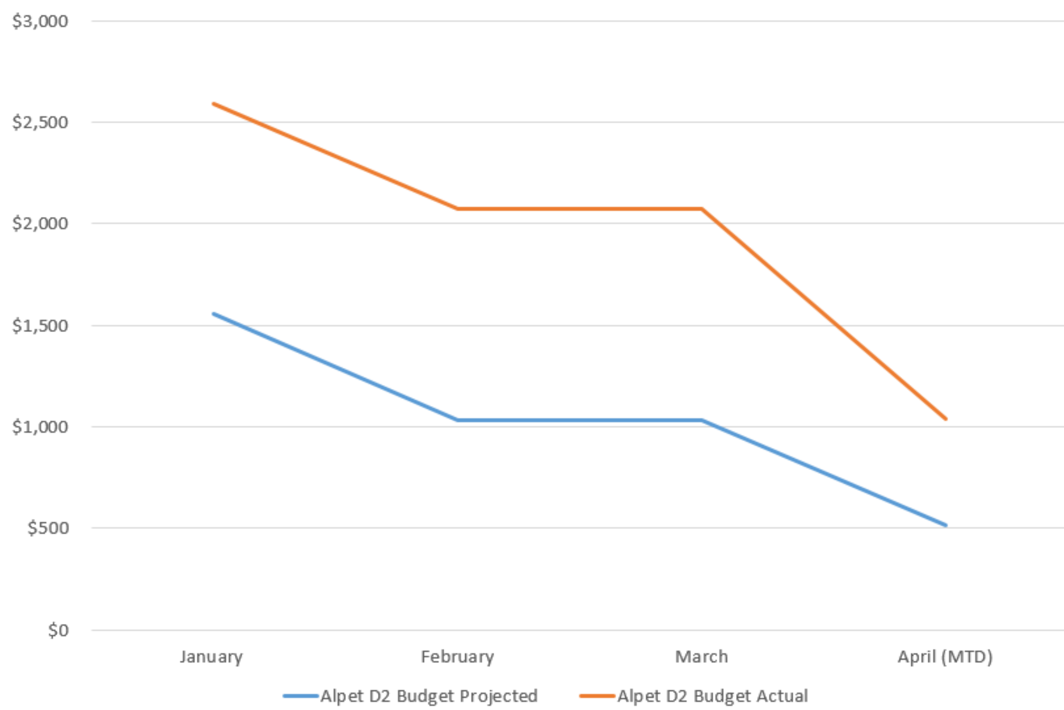
Normal cleaning and sanitizing functions performed by the facility includes scraping all equipment free from debris, using a ChemStation Foaming Chemical Application System with ChemStation 10023 Heavy Degreaser, a patented degreaser consisting of sodium silicate, ethylene glycol monobutyl ether, tetrasodium EDTA, and potassium hydroxide. The areas to be cleaned are foamed with the degreaser. The foam is allowed to set for 15-30 minutes, and then the areas are scrubbed clean with designated brushes. Hot water is applied via pressure washers to remove the 10023 Heavy Degreaser foam. The areas are dried and then sanitizer is applied. Two sanitizers are used by the facility. The most common sanitizer used is Alpet-D2 which is 55-65% isopropyl alcohol and quaternary ammonia solution designed to be highly-evaporative and fast acting that does not require to be rinsed off the equipment after application (Best Sanitizers INC 2018). Prior to processing organic product, Perasan A sanitizer, which is composed of hydrogen peroxide, acetic acid, and peroxyacetic acid, is applied. The drains and floors are also treated with Sterilex. Sterilex is a patented chemical composed of sodium carbonate, potassium carbonate, and tetrasodium ethylenediaminetetraacetate.

Because the establish practices were unable to contest the persistent strain, new chemical options and combinations were explored. Sanitizers containing quaternary ammonium compounds (QACs), peroxyacetic acid, or chlorine have been effective in controlling *Listeria* in various situations (U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition 2017).

4.2.1 Quaternary Ammonium Compounds (QACs)

Quaternary Ammonium Compounds (QACs) are widely used to control bacterial growth in domestic and industrial settings. QACs are biocides used to control broad-spectrum microbial activity (McBain, et al. 2004). However, studies have shown that QACs leave a residual germicidal effect on surfaces (Tompkin, et al. 2010) and have been linked to the emergence of antibiotic resistance strains (McBain, et al. 2004). Therefore, since the facility processes Ready-to-Eat products and is a certified organic processor, the decision was made to not explore QAC chemicals that are more potent than the Alpet-D2 sanitizer already in use. Alpet-D2 is stored onsite in a 50 gallon drum. The drum typically is refilled on a bi-weekly basis for $517.45. While addressing the established problem, the use of Alpet-D2 increased so the drum had to be refilled on a weekly basis, resulting in an increase spending of $4,139.60. Figure 4.3 provides a depiction of the financial increase in refilling the Alpet-D2 from once every other week to every week.

Figure 4.3: Alpet-D2 2018 Projected Budgetary Spending vs. Actual Spending



4.2.2 Peroxyacetic Acid

Peroxyacetic acid, commonly called peracetic acid, is a mixture comprised of equal parts acetic acid and hydrogen peroxide that creates a highly effective biocide that quickly reacts when applied and breaks down into harmless chemicals of acetic acid, oxygen, and water (Warburton 2014). Peroxyacetic acid in high concentrations produces a potent vinegar-like smell that can be irritating to those exposed. OSHA has not yet established exposure limits to the chemical, but the EPA has issued guidelines for acute exposure that are intended for one-time exposure and not repetitive exposure (Warburton 2014). Currently, the facility utilizes Perasan A sanitizer that contains low levels (5.0-5.9%) of peroxyacetic acid. During the investigation, ChemStation offered a new chemical, Reflex, which contains higher concentrations of peroxyacetic acid. Reflex is comprised of hydrogen peroxide, acetic acid, sulfuric acid, nitric acid, and peroxyacetic acid. The peroxyacetic acid represents 5.5-6.5% of the concentration. Reflex is received pre-diluted from ChemStation in five gallon dispensers. Each dispenser costs $65.60. Based on the history of use, the dispensers are projected to be refilled once every two weeks. The total annual projected cost of using Reflex to mitigate the issue is $1705.60.

4.2.3 Chlorine

Chlorine, chemically named sodium hypochlorite, is also a widely used sanitizer in the food industry. Chlorine disinfects areas by denaturing proteins in the microorganism. However, *Listeria* strains and biofilms have been known to become resistant to chlorine applications (Folsom and Frank 2006). The facility began using a 10% chlorine solution on the affected floors, walls, and equipment by diluting Multi-Chlor, a 12.5% sodium hypochlorite solution. Mulit-Chlor is received in 121 oz. containers and costs $25.10 for three containers. It is estimated that the containers would need to be replaced every two weeks, resulting in a total annual cost projection of $652.60.

CHAPTER V: RESULTS AND RECOMMENDATIONS

The results from the propositions and proposed mitigation tactics analyzed are presented in this chapter. First, the results of the propositions are examined. Then, the results from the proposed solutions are presented, beginning with the structural evaluations followed by the results of the chemical analyses. Finally recommendations are made based on the established problem and operating parameters, including the lease and time frame for leaving the property, to establish the most financially viable solutions for the facility.

5.1 Proposition Results

The first objective of this research is to identify and isolate the source of the *Listeria* in the dry roasting environment. Based on the literature review and exploratory data, three propositions were identified as potential sources of strain.

Proposition 1 (P_1): Rain Tracked into the Facility. P_1 evaluated was based on a presupposition that rain water containing *Listeria* from the outside was being brought into the facility by employee movements and traffic patterns. High foot traffic areas and the floor by the doors into the dry roasting room were all swabbed to find *Listeria*. All the swab analyses returned negative results. In addition, traffic patterns were observed and found the areas where the strain persisted were very low traffic areas. Finally, the strict GMP program of the facility includes that employees wear disposable boot covers in the processing area. No infractions of the GMPs have been noted. Based on all of the evidence, P_1 was rejected.

Proposition 2 (P_2): Water Draining from the Steam Room into the Wall between the Steamer and Dry Roaster. P_2 is was developed based on a presupposition that water used in cleaning the steam room drained towards the wall, providing an environment prime for *Listeria* biofilm formation and growth. The cleaning practices were verified by the Food Safety and Quality Manager to ensure the established SSOPs were being followed. In addition, the draining of water used for cleaning was observed to drain away from the wall in question. Finally, additional swabs were taken in the steam room in an effort to ensure that the cleaning practices were not the underlying root cause of the persistent strain. All of the swab results returned as negative. Therefore, based on the observations and swab data, P_2 was rejected.

Proposition 3 (P_3): Rain going into the wall between the Steamer and Dry Roaster. P_3 was developed based on a presupposition that rain water is able to get into the wall that separates the steamer room from the dry roasting room, creating an environment for the *Listeria* to grow. The investigation found that the epicenter of all the presumptive positive swab results is the area where product is conveyed through the wall. The drop ceiling tiles were removed and visible daylight as well as water damage and water tracks were observed running into the wall. Based on the literature review and empirical evidence, P_3 was not rejected.

5.2 Structural Evaluation Results

The cost analysis of the structural evaluation yielded that to effectively remove the wall from which the *Listeria* is festering, the facility would have to cease production of the steam and/or dry roaster and oil roaster for two weeks. The process is estimated to cost $244,000. This option also presents unquantifiable risk whereby the demolition of the wall may yield further microbial issues and contamination by spreading the population to equipment and throughout the facility.

Currently, the landlords are refusing to address the request to repair or replace the roof, as stipulated in the Leasing Agreement section 7.2 (Lease Agreement 2010). Roof inspections found that there are multiple holes, damages, and deficiencies that are beyond the tenant's ability to repair under the current Lease Agreement. The roof allowing rain water to seep into the wall is the true root cause of the problem, as yielded by the exploratory evidence and source proposition investigation performed.

The final structural option evaluated was to seal the floor / wall junctions that are currently concrete with epoxy and stainless steel and in conjunction, seal the cracks in the porous concrete floors. The use of Indicon Gel indicated that these junctions and the cracks in the concrete have the presence of biofilm. The cracks and junctions are hard to clean using traditional methods.

5.3 Chemical Analysis Results

Several chemical options were evaluated. The facility chose not to evaluate new QACs based on risk to ready-to-eat products. A new peroxyacetic acid concentration, Reflex, was recommended by chemical supplier ChemStation. Preliminary use found that when Reflex was employed, the vector swabs would return negative and there would not be any presence of biofilm indicated by Indicon Gel. However, after the facility received more rain, the strain would be found again in the areas that had been treated.

Multi-Chlor sodium hypochlorite chlorine was also utilized in the chemical analysis. Preliminary results did not find a change in the resident population when the Multi-Chlor was employed in conjunction with the sanitation standard operating procedures. The results were not entirely unexpected since research yielded that *Listeria* biofilms are known to become resistant to sodium hypochlorite (Norwood and A. 2000).

Studies were evaluated where a combination of multiple chemicals were used to eliminate *Listeria* population. The facility coupled sodium hypochlorite chlorine with peroxyacetic acid (Neo, et al. 2013). Results were similar to the use of peroxyacetic acid, Reflex, alone whereby the process would eliminate the population but the population would return once the facility received more rain.

A final study was evaluated where a multi-step approach was taken to eliminate the presence of a *Listeria* biofilm. The facility cleaned the affected area per established SSOP, then scrubbed with a 10% chlorine solution, treated with aqueous O-Zone (Vapex Nano-Radical), and employed a 3% solution of hydrogen peroxide (Elimination of Listeria monocytogenes biofilms by ozone 2005). The process was found to be very successful in treating areas that the biofilm had migrated to, but the issue persisted in the Dry Roast Floor Under Cup Elevator and the Dry Roast Cup Elevator Frame, where the biofilm had been very deep-rooted since the initial presumptive positive.

The facility developed new procedures whereby the areas are foamed and scrubbed with 10023 Heavy Degreaser, rinsed with hot water via the pressure washer, visually inspected for residue or food particles, scrubbed with a 10% chlorine bleach solution, treated with aqueous O-Zone (Vapex Nano-Radical), sanitized with Alpet-D2, treated with isopropyl alcohol, sanitized with hydrogen peroxide, and finally sanitized with Reflex. Since the employment of this procedure, the areas treated have yielded negative results, even after the facility received more rain. The annual cost of implementing the new procedure is projected to be $2900 as shown in Table 5.1. The total cost of the chemical procedure until the new facility is built is $8,700.

Table 5.1: Annual Cost Analysis of Chemical Procedure

Chemical	Cost of Chemical	Projected Annual Refills	Total Cost
Chlorine Solution	$25.10	26	**$652.60**
Isopropyl Alcohol	$10.40	26	**$270.90**
Hydrogen Peroxide	$10.40	26	**$270.90**
Reflex	$65.60	26	**$1705.60**
			$2900.00

5.4 Recommendations

Based on the investigations and analyses, several recommendations can be made as to how the facility should mitigate the risk until the new facility is built. The first recommendation is that ADM Golden Peanut and Tree Nuts work with the landlord to address the roof leaks since the proposition of rain leaking into the wall has been identified as the probable true root cause of the problem. Eliminating the rain from entering into the wall will eliminate the environment inside the wall that has become conducive to a robust *Listeria* population.

It is also recommended that the facility take measures outlined to address the floor / wall junctions and cracks in the porous concrete. As indicated by both vector swabbing and Indicon Gel use, these areas have fostered the development of the biofilm. Because these areas are hard to clean and properly disinfect with traditional methods, changing the structure and design of these areas is recommended so that they may be properly sanitized and eliminate the harborage point of the biofilm.

Finally, it is recommended that the facility employ multiple chemical sanitation techniques to address and mitigate the problem. As multiple studies have concluded, *Listeria* is able to adapt and become resistant to chemical usage (U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition 2017). Therefore, it is recommended that the facility employ multiple procedures and change sanitizers routinely to avoid the biofilm becoming resistant and as robust as the population outlined in the problem. Using chemicals such as chlorine, quaternary ammonium compounds (QACs), peroxyacetic acid, hydrogen peroxide, iodine, isopropyl alcohol, and aqueous Ozone in various combinations is recommended to prevent the *Listeria* biofilm from re-establishing and resisting efforts.

The potential total costs for the recommendations are $83,685.84 to mitigate the problem for three years until the new facility is built in 2021 (Table 5.2).

Table 5.2: Potential Total Cost of Recommendations

Recommendation	Cost
Roof Repair	$74,000
Floor / Wall Junction Repair	$985.84
Chemical Procedures	$8,700
	$83,685.84

CHAPTER VI: CONCLUSION

This analysis was conducted to provide solutions to the established research question of what the most financially viable solution the Golden Peanut and Tree Nuts Lodi Facility can employ to address the persistent *Listeria* strain while effectively mitigating the problem from recurring until the new building can be built. The facility is challenged to mitigate contamination of ready-to-eat tree nuts in the current operating space given the confines of the established leasing agreement.

Three primary objectives were outlined for the research to address. The first objective was to identify and isolate the source of the *Listeria* in the dry roast room. Three propositions were developed in order to identify the source of the *Listeria.* Through research and analysis conducted by vector swabbing and the use of Indicon Gel, it was determined that the epicenter of the *Listeria* resident population to be the wall between the steam room and the dry roast room. The wall was originally an exterior wall and therefore the floors slope to drain away from the wall, as evident of the tracking of the *Listeria* through the facility Pathogenic Environmental Monitoring Program, dispelling P_2. The roof was examined as part of the investigation and found that there are multiple cracks, holes, and deficiencies in the roof that enable rain water to enter into the facility and run into the wall, P_3.

The second objective outlined was to identify immediate actions to implement in order to mitigate the problem. Immediate actions taken included chemical analysis and combinations to eradicate the resident population. A new procedure has been developed and documented whereby the areas are foamed and scrubbed with 10023 Heavy Degreaser, rinsed with hot water, visually inspected, scrubbed with a 10% chlorine bleach solution, treated with aqueous O-Zone (Vapex Nano-Radical), sanitized with Alpet D2, treated with isopropyl alcohol, sanitized with hydrogen peroxide, and finally sanitized with Reflex. The new process has eradicated the presence of biofilm and *Listeria* in the areas treated.

The third and final objective of the research conducted was to establish financially viable long term controls that will mitigate the risk until the new building is finished in 2021. The structural analysis yielded that demolishing the existing dry wall and wood wall and reconstructing it would cost an estimated $244,000. The demolition project would cost two weeks of production and the re-assignment or furlough of employees during the downtime. In addition, the proposed roof repair solution would result in a minimum of two days of production loss. Whereas the chemical usage outlined in the chemical analysis was much more financially viable and did not result in extended periods of downtime and lost production.

Due to the limited time the facility must continue to operate in the current premises, it is concluded that the most financially viable method to mitigate the current risk is a combination of structural repairs and chemical control. The floor and/or wall junctions and cracks in concrete have been identified as structures where the *Listeria* biofilm is able to thrive. Changing the structural design to eliminate these points through the use of epoxy and stainless steel will allow these areas to be cleaned and sanitized effectively and reduce the ability of *Listeria* to form biofilms on the surfaces. In addition, the facility should utilize multiple sanitation methods and chemicals to ensure the biofilm does not become resistant to efforts. Multiple chemicals have been identified as part of the analysis as potential chemicals to be used. The sanitation process should be updated routinely to ensure that the areas are being properly sanitized and preventing *Listeria* biofilm development.

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