2021

Evaluating Compliance with the Produce Safety Rule and Managing Mycotoxins

Yvette May Molajo
Walden University

Walden University

College of Social and Behavioral Sciences

This is to certify that the doctoral dissertation by

Yvette Molajo

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Marcia A. Kessack, Committee Chairperson,
Public Policy and Administration Faculty

Dr. Asghar Zomorrodian, Committee Member,
Public Policy and Administration Faculty

Dr. Meena Clowes, University Reviewer,
Public Policy and Administration Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2021

Abstract

Evaluating Compliance with the Produce Safety Rule and Managing Mycotoxins

by

Yvette Molajo

MA, Walden University, 2020

MPA, Nova Southeastern University, 2014

BS, University of Maryland, College Park, 2012

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Policy and Administration

Walden University

August 2021

Abstract

Foodborne diseases are the cause of many illnesses that occur from foods that contain mycotoxins. Mycotoxins are produced from fungi and are environmental and carcinogenic agents that contaminate agricultural foods during preharvest and postharvest conditions. While researchers have conducted many studies on mycotoxin occurrence and production, there is a significant gap in the current literature regarding which environmental factors could put farmers' ability to remain in compliance with the Food Safety Modernization Act's *Produce Safety Rule* at risk. Therefore, the purpose of this quantitative study was to investigate which environmental factors could put farmers' ability to remain in compliance with the Food Safety Modernization Act's *Produce Safety Rule* at risk. The theoretical approach was the organizational economics theory with an emphasis on transaction cost economics. Secondary data consisted of 813 fumonisin toxin level survey from the Illinois Department of Agriculture and 4,020 temperature data from the National Oceanic and Atmospheric Administration collected between 2013 and 2018 were used in the analysis. Pearson correlations showed a significant negative relationship between fumonisin and temperature ($p < .01$). Linear regression analysis showed a significant statistical relationship between temperature and fumonisin ($p < .05$). There was also an association between temperature and wind that increase vomitoxin levels. The findings of this study showed the need to evaluate the Food Safety Modernization Act's *Produce Safety Rule* to include compliance in the prevention of mycotoxins. The results of the study can influence positive social change that may bolster food safety regulations associated with risks of mycotoxin contamination in foods.

Evaluating Compliance with the Produce Safety Rule and Managing Mycotoxins

Yvette Molajo

MA, Walden University, 2020

MPA, Nova Southeastern University, 2014

BS, University of Maryland, College Park, 2012

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Policy and Administration

Walden University

August 2021

Dedication

To my great-grandparents Agatha and Samuel Harrison, Amanda, and William Prince. My grand-parents John and Johanna Harrison, my ancestors. My parents Louise and Leslie. My brothers Oneal and Lennon. To my nieces and nephews, Olivia, Sophia, Samanda-Blueu, Bryan, Charlie, Lenny, and Leslie. Know that you can do all things through Christ who gives strength. I love you.

Acknowledgements

My heartfelt gratitude to Dr. Marti Kessack, thank you for all your support and guidance throughout my dissertation journey. Your kind words of encouragement meant a lot. I would also use the opportunity to thank Dr. Karen Shafer for serving as my chair and for professional guidance to completion. Thank you Dr. Asghar Zomorrodian, my committee member for your patience and insight and for providing valuable feedback and to my URR, Dr. Meena Clowes thank you. Thanks to the dedicated staff, advisors, and faculty at Walden. I would like to acknowledge all those who started the journey with me and have made a valuable contribution, to make this day possible. Thank you.

My deepest appreciation to James and Martin and all my friends who contributed to my success. Mo, thanks for your insightful and valuable feedback. Juvencio for technical and computer support thank you. Allan, Una, Pauline, Cliff, Larry, Ciprien and Aston, thank you. My best friend Henry, thank you for believing in me and supporting me. My fellow cohorts and my friend Henrietta you are a gem. Thanks to all my editors, my pastors and prayer partners. Thank you to everyone who made this journey possible. I am forever grateful, thank you. Special thanks to my family for motivating me and encouraging me to be a high achiever. Most importantly, thanks to my Maker I could only do it because of you.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Foodborne diseases are challenging for public health worldwide. The Centers for Disease Control and Prevention (CDC) has identified about 250 foodborne diseases that are infectious and harmful (CDC, 2017b). Each year, about 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and about 3,000 deaths occur annually from eating contaminated foods (CDC, 2017a). Researchers have estimated the annual burden of foodborne pathogens to cost between 14 billion and 36 billion dollars (Astill et al., 2019). Similarly, the United States Department of Agriculture (USDA) estimated that foodborne illnesses cost more than 15.6 billion dollars each year (CDC, 2018). The global incidence of foodborne diseases is difficult to estimate because many cases of foodborne diseases are often not reported or under reported (Agyei-Baffour et al., 2013; Rehber, 2012). In the United States, those experiencing a foodborne illness are most often young children under the age of four and adults over 50 years of age (Government of District of Columbia Department of Health, 2016). Foodborne diseases have serious complications for these vulnerable populations, as well as those with a compromised immune system (Government of District of Columbia Department of Health, 2016).

The World Health Organization (WHO, 2018) reported that foodborne diseases are caused by bacteria, viruses, parasites, harmful toxins, and chemical contaminants. Food contamination refers to foods that are spoiled and tainted because of microorganisms, such as bacteria, parasites, or toxic substances, that make foods unfit for consumption (Hussain, 2016). These contaminants have several routes through the food chain, from the farm to consumption, that are risks for foodborne illnesses (Nychas et al., 2016). With increased urbanization and globalization, food commodities may be exposed to various microbial, chemical, and physical hazards that can risk the consumption of contaminated foods (Nychas et al., 2016). Food safety is a major challenge threatened by various contaminants that can originate from environmental factors (Oskarsson, 2012). These microbial toxins can enter the food chain either directly or indirectly from agricultural commodities.

Mycotoxins are the number one threat to feed and food regarding chronic toxicity (Oskarsson, 2012). Mycotoxins are fungi that cause toxic and carcinogenic outcomes in humans and animals (Raiola et al., 2015; Wu et al., 2014). Those that have a significant impact on human and animal health are *aflatoxins, fumonisins*, and *tricothecenes*, which are from the genera *Aspergillus, Penicillium,* and *Fusarium* (Kosicki et al., 2016; Wu et al., 2014). The contamination of foods by toxins and mycotoxins poses serious implications for human health and a significant issue for global trade (Sheikh-Ali et al., 2014).

According to the CDC (2017), mycotoxins affect up to 25% of the world’s grain supply and all bioterrorism threat agents. Several studies have indicated different types of mycotoxins could contaminate many agricultural crops (Bryden, 2011; Milicevic et al., 2015; Nielsen et al., 2014). Xu et al. (2019) reported mycotoxin infestations cause head blight in cereal and ear rot in corn that leads to significant crop damage, lowers quality of foods and feeds, and decreases the nutritional content of foods and feedstuff. In the United States, mycotoxins pose a heavy economic threat to the corn industry and cost the United States about one billion dollars annually (USDA, 2018). Aflatoxins are the most problematic for agriculture in the United States and the most toxic and carcinogenic of the known mycotoxins (Mitchell et al., 2016). *Fusarium Head Blight* (FHB), the most devastating fungal disease, has been responsible for significant loss in damage to wheat and cereal crops worldwide (Cendoya et al., 2018; Xu et al., 2019). A review of the literature resources revealed that extensive research has been conducted on mycotoxin occurrence and production.

However, there was a paucity of research on how to investigate which factors could put farmers' ability to remain in compliance with the Food Safety Modernization Act's (FSMA) *Produce Safety Rule* at risk of environmental conditions, like temperature, wind speed and precipitation, in managing mycotoxins for regulatory oversight in the state of Illinois between 2013 and 2018. This study may lead to positive social change by enhancing regulatory policies that safeguard human health through enforcement and compliance of food safety management practices for mycotoxins.

The enactment of the FSMA gave the Food and Drug Administration (FDA) authority to regulate the growing, harvesting, packing, and holding of fresh fruits and vegetables, which was a major shift in outbreak response to prevention-based control across the food supply. One of the implementing rules of the FSMA is the *Produce Safety Rule* (*Produce Rule*), intended to reduce foodborne illnesses associated with consumption of fresh produce (Adalja & Litchenberg, 2018).

The FDA was founded in 1862 as part of the Division of Chemistry in the Department of Agriculture (USDA). It is now part of the U.S. Department of Health and Human Services. In 1906, Congress passed two separate acts that charged one branch of government with inspecting meat and the FDA with ensuring the safety of all other foods. As established by the 1906 legislation, the USDA Food Safety and Inspection (FSIS) and the FDA regulate the safety of foods in the United States USDA, 2018a). The FSIS is responsible for regulating meat, poultry, and egg products (Carneiro & Kaneene, 2017; USDA, 2018a). The Federal Grain Inspection Service (FGIS) is an arm of the USDA, which was created by Congress in 1976, to manage national grain inspection which was initially established in 1916 (USDA, n.d.). The FGIS is responsible for facilitating and marketing U.S. grains and related products by establishing standards for quality assessments, regulating handling practices, and managing federal, state, and private laboratories that provide official inspection and verifying services (USDA, n.d.). Under the United States Grain Standards Act (USGSA) and the Agriculture Marketing Act (AMA) of 1946, the FGIS (USDA, n.d.).

- Establishes and maintains official U.S. grain standards for barley, canola, corn, flaxseed, oats, rye, sorghum, soybeans, sunflower seed, triticale, wheat, mixed grain, rice, and pulses.
- Inspects and weighs grain and related products for domestic and export trade.
- Establishes methods and procedures and approves equipment for the official inspection and weighing of grain.
- Supervises the official grain inspection and weighing system. The official system is a network of FGIS field offices and state and private grain inspection and weighing agencies across the nation that the FGIS authorized to provide official inspection and weighing services.

- Provides international services and outreach programs and protects the integrity of the official inspection system and the market at large to ensure markets for grain and related products are fair and transparent (USDA, n.d.).

In this chapter, I covered the background of the study, problem statement, purpose of the study, research questions, hypotheses, theoretical framework, nature of the study, operational definitions of terms, assumptions, scope and delimitations, limitations, and significance of the study.

Background

From October 1997 through October 1998, 16 outbreaks of gastrointestinal illness associated with eating burritos occurred in Florida, Georgia, Illinois, Indiana, Kansas, North Dakota, and Pennsylvania (CDC, 2001). All outbreaks except one occurred in schools, and of the approximately 1,700 persons affected, most were children (CDC, 2001). The data from the 16 outbreaks showed similarities in the symptoms, incubation period, and duration of illness. The Georgia and Florida departments of health reported children from elementary schools. Testing from burrito samples from some of the U.S. outbreaks had acceptable levels of 1 ppm recommended by the FDA (CDC, 2001).

Outbreaks with similar symptoms and incubation periods have occurred in China and India, where illness has been linked to consumption of products made with grains contaminated with fungi. These fungi produced heat-stable tricothecene mycotoxins called vomitoxin. In China, 35 outbreaks affecting 7,818 persons during 1961 to 1985 were attributed to consumption of foods made with moldy grains (CDC, 2001). Corn and wheat samples collected during the two outbreaks had higher levels of deoxynivalenol

(DON). In India in 1987, 97 persons consumed wheat products following heavy rains. DON and other tricothecene mycotoxins were detected in the wheat products.

Aspergillus flavus and *Aspergillus parasiticus*, common foodborne fungi, produce aflatoxin, which colonizes crops in tropical and subtropical regions worldwide. These fungi can produce aflatoxin in storage, transportation, and food processing. *Aflatoxin* B_1 is the most toxic and potent naturally occurring chemical liver carcinogen known to have greater risk than other the other aflatoxins (Alim et al., 2018; Kosicki et al., 2016; Ruyck et al., 2015; Womack et al., 2013). Acute aflatoxicosis causing gastrointestinal illness and deaths results from high aflatoxin doses (Wu & Guclu, 2012). In recent years, hundreds of aflatoxicosis cases in Africa have resulted from contamination of maize (Wu & Guclu, 2012; Mwalwayo & Thole, 2016). Due to high consumption of maize and the susceptibility to aflatoxin contamination worldwide, over 100 nations have set regulatory limits on allowable levels in human foods and animal feeds (Cheli et al., 2014; Marin et al., 2013; Womack et al., 2013; Wu & Guclu, 2012). With food trade throughout the world, food safety is a responsibility shared by both developed and developing countries. Foodborne diseases negatively impact the economy due to costs associated with foodborne outbreaks (King et al., 2017).

The United States is the largest contributor of corn to agriculture and trade, providing more than half the world’s supply of corn (Mitchell et al., 2017). Field corn accounts for over 87 million acres of land harvested in the United States and contributes about 75 billion dollars to the U.S. economy and 95% of the total U.S. feed and grain production (Mitchell et al., 2017). Mycotoxins pose a significant threat to the corn industry, with aflatoxin being the greatest concern. The market losses due to aflatoxin in corn are likely to increase within the next decade in the Corn Belt states in the United States due to climate change (Mitchell et al., 2017). Agyekum and Jolly (2017) found that aflatoxin contamination in food is a significant policy issue for food industries worldwide. Currently there is a lack of data on mycotoxin occurrence state by state in the United States and the resulting economic impact (Mitchell et al., 2017).

During the 1990s, the increased numbers and severity of food-poisoning outbreaks raised consumer awareness of the need for food safety and protection from foodborne diseases (Koutsoumanis & Aspridou, 2016). The evidence suggested to regulatory authorities and the food industry that approaches to food safety that rely heavily on regulatory inspection and sampling cannot adequately ensure consumers' protection (Koutsoumanis & Aspridou, 2016). The increased threat to food safety led the FDA in 2011 to create the FSMA to reform the U.S. food safety system, which shifted the focus of regulators from response to prevention of foodborne diseases (National Environmental Health Association [NEHA], 2018). The World Trade Organization (WTO) suggested risk assessment for the basis of food safety and appropriate levels of protection by member countries (Koutsoumanis & Aspridou, 2016). The European Commission followed with Regulation (EC) 178/2002 to use a science-based risk analysis framework for food safety (Cheli et al., 2014). In 2003, the Codex Alimentarius Commission adopted Principles for Food Safety and Risk Analysis to be used in the Codex framework (Koutsoumanis & Aspridou, 2016).

Governments establish food safety policies to put in place a system of controls and cooperative aim that ensures food safety goals are met (Khalid, 2016; Wengle, 2016). Food safety should be a shared responsibility of different stakeholders participating in the food trade. The idea of food safety control is that operators among the food chain must demonstrate to regulatory authorities that their operations follow national standards (Khalid, 2016). The increased threat to food safety provoked various institutional reforms. The current food safety climate relies heavily on audits, regulatory inspections, sampling, and all operators along the food chain.

Research has shown that mycotoxin contamination is an ongoing global concern, because of the unpredictable and unavoidable nature of the contaminant (Alshannaq & Yu, 2017). Regulations on mycotoxin contamination in developed countries are more stringent to ensure protection, but in developing countries, regulations can be poor or lack surveillance. Mycotoxin contamination can occur indirectly or directly (Bezerra da Rocha et al, 2014; Cheli et al., 2014; Marín et al., 2013). Indirect contamination can occur when foods that were previously contaminated by fungal toxin and eliminated, but the mycotoxin remains in the final products. For direct contamination, the food becomes infected by a toxigenic fungus and subsequently forms mycotoxins that are detrimental to human and animal health (Bezerra da Rocha et al., 2014). The failure to prevent fungal growth and toxin production during preharvest and postharvest creates health challenges for the consumer and results in economic losses and loss of quality (Lee & Ryu, 2015).

A review of the FGIS’s Mycotoxin Handbook provided the background information on sample preparation to determine mycotoxins (*aflatoxin*, *deoxynivalenol*, *fumonisin*) in grain and processed commodity products, compliance with safety, environmental regulations in testing process and certification of results, and the predictor variables for environmental conditions for grain storage (USDA, 2015).

Problem Statement

Foodborne diseases pose a serious threat to human health (Demaegdt et al., 2016). Mycotoxin contamination and other naturally occurring toxins account for many foodborne illnesses. Mycotoxins are toxigenic fungi that contaminate many of the most consumed foods and feeds worldwide (Peng et al., 2018). The occurrence of mycotoxins in humans is a result of skin contact, inhalation, or consumption of contaminated agricultural products or metabolite products in foods from animals, such as milk and eggs (Capriotti et al., 2012). Mycotoxin contamination is a problem for both developed and developing countries (Trucksess & Diaz-Amigo, 2013). There are potential risks of mycotoxin contamination in grain foods and human susceptibility to diseases due to infestation and occurrence.

Mycotoxin contamination is a global food safety problem that can cause ill health in humans, raise concerns for public health, and threaten food security (Trucksess & Diaz-Amigo, 2013). Mycotoxins are potentially carcinogenic and carry the risk of causing cancer and other adverse health effects, which could be a further challenge for public health (Capriotti et al., 2012). Aflatoxins are the most toxic of all mycotoxins, with significant economic burden in the United States and Europe (Womack et al., 2013). The level of aflatoxin in the United States’ food supply is generally low, but from 2004 to 2013 there were 18 reports of food and feed contamination due to aflatoxins (Mitchell et al., 2017). Annual losses in the U.S. corn industry from aflatoxin, range from 52.1 million dollars to 1.68 billion dollars. Also, mycotoxins are the main hazard attributed to EU border rejection for foods and feed, according to the Rapid Alert System for Food and Feeds (Alshannaq & Yu, 2017). In Asian and African countries, aflatoxins contribute to hundreds of cases of heptacellular carcinoma each year (Alshannaq & Yu, 2017). Given that mycotoxin is a toxin in foods and feeds, the food industry and agribusinesses have put considerable effort into implementing and improving food safety management systems. In the last few years, the Codex Alimentarius hygiene code of practice became a worldwide reference (Kussaga et al., 2014). Food sourced and transported all over the world, and produced under different codes of practice, creates more possibilities for food safety hazards (Kussaga et al., 2014).

A review of the literature revealed that extensive research has been conducted on mycotoxin occurrence and production. However, there is a paucity of research on how to investigate which factors could put farmers' ability to remain in compliance with the FSMA's *Produce Safety Rule* at risk of environmental conditions, like temperature, wind speed, and precipitation, in managing mycotoxins in Illinois between 2013 and 2018. It is important to note that food safety issues are widespread and influence consumers' behaviors (Adinolfi et al., 2016). Several types of hazards can contribute to a foodborne illness, which means preventative measures may require legislation and harmonization (Odeyemi, 2016). This quantitative study may contribute to the broader debate by building a higher standard for food safety policies that define rules and controls aimed at mycotoxin prevention.

Purpose of the Study

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the FSMA's *Produce Safety Rule* at risk of environmental conditions, like temperature, wind speed, and precipitation, in managing mycotoxins in of Illinois between 2013 and 2018.

Research Questions and Hypotheses

In a quantitative study, the research questions and hypotheses are significant for making inquiries (Creswell, 2009). The quantitative research questions inquire about the relationship among variables, whereas the hypotheses are important for making predictions about expected relationships among variables that are not empirically tested (Berman & Wang, 2012; Creswell, 2009). In this quantitative research, I was interested in investigating what factors could put farmers' ability to remain in compliance with the FSMA's *Produce Safety Rule* at risk in managing mycotoxins in Illinois between 2013 and 2018 for regulatory oversight of the USDA. Therefore, I designed the following research questions to examine the statistically significant relationship, if any, between measuring compliance at the level of three toxins (*aflatoxin*, *fumonisin*, and *vomitoxin*) and environmental conditions (temperature, wind speed, and precipitation) and managing mycotoxins in Illinois between 2013 and 2018.

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

$H_0$1: There is no relationship between environmental factors and toxin level.

H_a1: There is a relationship between environmental factors and toxin level.

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

> $H_0$2: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.
>
> H_a2: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

> $H_0$3: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.
>
> H_a3: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

Operational Variables

Environmental conditions: Independent variables (IVs): Temperature, wind speed, and precipitation.

Toxicity levels: Dependent variables (DVs): Measuring compliance at the level of three toxins: aflatoxin, fumonisin, and vomitoxin.

Theoretical Foundation

The theoretical foundation of this quantitative study was the transaction cost economics approach (TCE) from Williamson's (1981) organizational economics theory (OET). Williamson argued that, under the TCE, the transaction is the basic unit of analysis and held that an understanding of transaction cost economizing is central to the study of organizations. In applying this approach, Williamson required that a transaction be dimensional and descriptive of alternative governance structures. The approach applies to efficient boundaries, as between firms and markets, and to the organization of internal transactions, including employee or contractual relations. Williamson's proposition was that the firm is a production of functions to which a profit maximizes objection and is less illuminating, as with economics the realization of the neoclassical theory of the firm is self-limiting.

The key points of the TCE to other approaches are (a) microanalytic, (b) self-conscious about behavioral assumptions, (c) introduces and develops the economic importance of asset specificity (d) relies on more comparative institutional analysis, (e) regards the business firm as a governance structure rather than a production function, (f) places greater weight on the ex post institutions of contract, with special emphasis on private ordering (as compared to court ordering), and (g) works out of a combined law, economics, and organization perspective (Williamson, 1981).

The origins of the TCE are grounded in seminal contributions in law, economics, and organization from the 1930s. Commons (1934) and Coase (1937) were the leading theorists on economic contributions. Llewellyn (1931) added key legal insights, and

Barnard (1938) offered an organization theory perspective. Commons argued that the transaction was and should be the basic unit of analysis. Adopting a contractual point of view, attention was focused on the importance of crafting institutions that serve to harmonize trading between parties with otherwise adversarial interests. Coase also adopted a microanalytical perspective and insisted that the study of firms and markets proceed comparatively, with emphasis on transaction cost economizing. Llewellyn argued that the study of contracts should focus less on legal rules than on the purposes to be served. More attention to private ordering (efforts by the parties to align their own affairs and devise mechanisms to resolve differences with correspondingly less weight being assigned to legal centralism (dispute resolution under the legal rules evolved by the courts and adopted by the state). Barnard asserted that the powers and limits of internal organization should be brought more self-consciously to the front (Williamson, 1981). I will cover the TEC in more detail in Chapter 2.

Nature of the Study

In this quantitative study, I used secondary data obtained from the Illinois Department of Agriculture and the National Oceanic and Atmospheric Administration (NOAA). The data included survey reports from 2013 to 2018 and local climatological data between 2013 and 2018 in the state of Illinois. I analyzed the data using IBM’s SPSS software Version 26 and performed the statistical analysis using linear regression to examine the relationship between the dependent variable, compliance with the *Produce Safety Rule*. I measured compliance at the level of three toxins (aflatoxin, fumonisin, and vomitoxin) and three independent variables (temperature, wind speed, and precipitation). The analyses used a significance level of $\alpha = 0.5$ and a statistical power of 0.95.

Definitions of Terms

Aflatoxins: Fungal toxins that commonly contaminate maize and other types of crops during production, harvest, processing, or storage (CDC, 2012).

Code of Federal Regulations: The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration (FDA, 2018a).

Common Foodborne Molds: Microscopic fungi that live on animal and plant matter and include *Aspergillus, Fusarium,* and *Penicillium* (USDA, 2013).

Contaminants: Substances that have not been intentionally added to food.

Control: (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met (FDA, 2017a).

Epidemiologic Triangle Model: The traditional model for infectious disease. The triad consists of an external agent, a susceptible host, and an environment that brings the host and agent together. In this model, disease results from the interaction between the agent and the susceptible host in an environment that supports transmission of the agent from a source to that host (CDC, 2012).

Epidemiology: Is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Various methods can be used to carry out epidemiological investigations. Surveillance and descriptive studies can be used to study distribution; analytical studies are used to study determinants (WHO, 2018).

Food Contaminants: Food contaminants are any harmful substances unintentionally added to food, which may be chemicals from natural sources, environmental pollution, or food processing (Center for Food Safety, 2018).

Food Defense: The protection of food products from contamination or adulteration intended to cause public health harm or economic disruption (USDA, 2018).

Foodborne Diseases: Foodborne diseases encompass a wide spectrum of illnesses and are a growing public health problem worldwide. They are the result of ingestion of foodstuffs contaminated with microorganisms or chemicals. The contamination of food may occur at any stage in the process, from food production to consumption ("farm to fork"), and can result from environmental contamination, including pollution of water, soil, or air (WHO, 2018).

Foodborne Illness: Foodborne illnesses are usually infectious or toxic in nature and caused by bacteria, viruses, parasites, or chemical substances entering the body through contaminated food or water (WHO, 2018).

Food Industry: This includes primary, manufacturing, and processing industries as well as establishments involved in the food chain (Motarjemi, 2014).

Food Law: Food law generally applies to legislation that regulates the production, trade, and handling of food and hence covers the regulation of food control, food safety, and relevant aspects of food trade. Food law includes minimum quality requirements to ensure the foods produced are unadulterated and are not subjected to any fraudulent practices intended to deceive the consumer. In addition, food law covers the total chain, beginning with provisions for animal feed, on-farm controls, and early processing through to final distribution and use by the consumer (Food and Agriculture Organization of the United Nations [FAO], 2018).

Food Safety: Food safety refers to handling, preparing, and storing food in a way designed to best reduce the risk to individuals of becoming sick from foodborne illnesses (Australian Institute of Food Safety, 2016).

Food Security: Food security exists when all people always have physical, social, and economic access to sufficient, safe, and nutritious food that meets their dietary needs and food preferences for an active and healthy life (FAO, 2018).

Fumonisins: Naturally occurring toxins produced by several species of *Fusarium* fungi (molds). There are different known types of *fumonisin*, but *fumonisins B*1, *B*2, and *B*3 (also named FB1, FB2, and FB3) are the major forms found in food. *Fumonisins* were first recognized in 1988 (WHO, 2018).

Fusarium: Fungi that are common to the soil and produce a range of different toxins, including trichothecenes such as deoxynivalenol (DON), nivalenol (NIV), and T-2 and HT-2 toxins, as well as zearalenone (ZEN) and fumonisins (WHO, 2018).

Fungal Diseases: Diseases often caused by fungi that are common in the environment (CDC, 2015).

Hazard Analysis Critical Control Point HACCP: A management system that addresses food safety through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling to manufacturing, distribution, and consumption of the finished product (FDA, 2018).

Natural Toxins: Toxic compounds that living organisms naturally produce. These toxins are not harmful to the organisms themselves, but they may be toxic to other creatures, including humans, when eaten (WHO, 2018c).

Preharvest: Preharvest occurs while a product is in the field, during growth, or awaiting harvest (FDA, 2018c).

Postharvest: Postharvest occurs after harvest, field holding of the harvested crop prior to transportation, processing, and storage (FDA, 2018c).

Public Health: According to the American Public Health Association (APHA, 2016), public health promotes and protects the health of people and communities from diseases.

Produce Safety Rule: A FDA-implemented rule intended to reduce health risks associated with foodborne illness associated with consumption of fresh produce (FDA, ctation).

Surveillance: Surveillance is the regular collection of health information in terms of health indicators, the routine analysis of indicators over time, place, and between population groups, and the sharing of available scientific knowledge as well as the regular dissemination of results (WHO, 2018).

Assumptions

The secondary data used in the study were collected by the Illinois Department of Agriculture and the NOAA. I assumed that the data obtained from these government agencies were complete, correct, and accurate. For the statistical test, I used a linear regression to test the significance of the relationship, if any, between the dependent variable, compliance with the *Produce Safety Rule*, and the independent variables (temperature, wind speed, and precipitation), as discussed in Chapter 3.

Scope and Delimitations

Scope of the Study

The scope of this quantitative study was to examine the statistical relationship, if any, between the dependent variable, compliance with the *Produce Safety Rule*, and the independent variables (temperature, wind speed and precipitation in managing mycotoxins in Illinois between 2013 and 2018. This study only encompasses mycotoxins with significant risk of contamination: *aflatoxins*, *vomitoxin* (also known as *deoxynivalenol* (DON)), and *fumonisins*.

Delimitations

The data used in the study were limited to survey reports of the major mycotoxins (*aflatoxins*, *fumonisins*, and *vomitoxin*) that are of importance to public health policy, including food safety, food security, and economic implications. Also included in the study was local climatological data from Illinois. For the purposes of this study, I only analyzed the data between 2013 and 2018 on these mycotoxins (*aflatoxins, fumonisins*, and *vomitoxin*) that are of significant risk to agricultural grain products or risk of contamination. The Codex Alimentarius Commission (CAC) was founded in 1963 by the Food and Agriculture Organization (FAO) and the WHO to develop guidelines, standards, and other documents to protect the health of consumers and ensure fair practices in food trade (Ankul et al., 2013). Reports on data of allowable and toxicity levels will be limited to the major mycotoxins in this study.

Limitations

The limitation of this study was based on the use of secondary data collected by someone else other than me. The data were collected by the Illinois Department of Agriculture and the NOAA. Using secondary data introduces a great chance of inaccuracies during reporting, collection, or analysis (O'Sullivan et al., 2008). Human error can also play a significant role in data collection and dissemination. There may be lack of reports on regulatory practices, such as allowable or reduce levels on contamination. I took into consideration the lack of health reports, inventory, and inspection reports and the unavailability of data. I limited my study to the significance of mycotoxins (*aflatoxins*, *fumonisins*, and *vomitoxin*) and temperature, precipitation and wind speed.

Significance of the Study

Mycotoxins are fungal toxins that contaminate foods and have adverse health impacts for consumers worldwide (Antonissen et al., 2014; Ferre, 2016). Researchers have identified several mycotoxins that pose significant health risks, such as aflatoxins, fumonisins, ochratoxins, zearalenone, and trichothecenes. This study focused on aflatoxins, fumonisins, and vomitoxin. Mycotoxins have the potential, even at low concentrations, to cause ill health that could lead to foodborne diseases (Bezerra da Rocha et al., 2014; Luo et al., 2018). Agricultural contamination can become an economic burden for both developed and developing countries (Afsah-Hejri et al., 2013;

Patriarca, et al., 2017). Vulnerable populations are most likely to be at risk of food insecurity. While developed countries have regulatory procedures in place to protect their consumers, poorer countries may lack surveillance or have limited regulatory controls (Stoev, 2013; King et al., 2017). Food safety is a major issue for both the developed and developing world, and there is a critical need for collaboration and shared responsibility to protect consumers from mycotoxin contamination and prevent foodborne illnesses.

Repeated exposure to mycotoxins can cause foodborne diseases (Rajkovic, 2014). In developing countries, mycotoxins enter the human food chain during preharvest and postharvest periods because of the dearth of sanitized storage facilities (Mwalwayo & Thole, 2016). This research helps to fill the gap in the modalities of management practices on mycotoxin enforcement strategies for regulatory oversight and provide a broader policy narrative for responsive governance. The study's potential for positive social change includes creating an enabling environment to bolster global food safety and security and, therefore, protect public health.

Summary

Mycotoxins are environmental contaminants that are of global importance to human and animal health. They have been a growing concern for over 30 years (Moy et al., 2014). Mycotoxin contaminations in foods can threaten security, safety, and the economy. Consumption of foods that contain foodborne mycotoxins can have long-term health consequences, including severe liver damage and immune deficiency (WHO, 2018a). The effects of mycotoxins depend largely on exposure, ingestion, and toxic synergies that may complicate issues if various mycotoxins were ingested simultaneously. These are known carcinogenic agents produced from fungi that threaten food security and cause adverse health effects to humans and animals. The occurrence and distribution of mycotoxins in foods are important to understand to determine the level of exposure to humans and explain the causes of some chronic diseases. Mycotoxins have a variety of adverse health effects and have been implicated in causing diseases in humans (Alberts et al., 2017). Even when inhaled or ingested in small amounts, mycotoxins are toxic and pose significant risks to public health. The toxins that are a real threat to food safety are from the genera *aspergillus*, *penicillium* and *fusarium* (Abrunhosa et al., 2016). Grain foods are especially susceptible to mycotoxin infestation, which can enter human food chains directly and indirectly. There are over 400 known mycotoxins, but those that are important to food safety and the health of humans are aflatoxins, fumonisins, and tricothecenes (Abrunhosa et al., 2016).

This chapter included the introduction, background, problem statement, purpose of the study, research questions and hypotheses, theoretical framework for the study, nature of the study, definitions, assumptions, scope and delimitations, limitations, and significance of the study. Chapter 2 details the literature search strategy, theoretical foundation, and the literature review relevant to the study. Chapter 3 describes the research design and rationale, methodology, population, sampling and sampling procedures, data collection and analysis, and ethical considerations. In Chapter 4, I described the results of the study. Lastly, in Chapter 5, I draw conclusions, make recommendations for future research, and describes the implications for positive social change.

Chapter 2: Literature Review

Introduction

In this chapter, I present the literature review on regulatory regimes of food safety policies on mycotoxin occurrence in foods and feeds, compliance with the *Produce Safety Rule* on mycotoxins, and the implications for food safety of managing hazards that contribute to microbiological food outbreaks caused by mycotoxins. I also reviewed past studies within the last decade that are relevant to current food safety policies within the United States and around the world. After reviewing the studies, I selected the most pertinent available information about the relationship between the variables in this study. The theoretical framework used in the study is the TCE approach.

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018. Mycotoxins are the number one threat to feed and food contaminants regarding chronic toxicity (Oskarsson, 2012). Mycotoxins are chemical substances produced by molds and are natural contaminants found in agricultural products and feeds, which causes problems for food safety, food security, and trade worldwide (Mwalwayo & Thole, 2016; Peng et al., 2018). Mycotoxins are produced from filamentous fungi and are naturally occurring and practically unavoidable. These microbial toxins can enter the food chain either directly or indirectly from agricultural commodities (Omotayo et al., 2019). The presence of mycotoxins in foods is a global concern and a considerable threat to the agricultural industry. Mycotoxicosis, the disease caused by exposure to mycotoxins, is potentially lethal and can affect different organs of the human body. In addition to posing a health hazard, the occurrence of mycotoxins in foods is a major economic issue and costs the United States approximately 932 million dollars annually and 46 million dollars in regulatory enforcement and other control measures (Winter & Pereg, 2019).

Literature Search Strategy

For this literature search, I reviewed the following organizations' websites: the USDA, the FGIS, the Federal Grain Inspection Packers and Stockyards, the FDA, the CDC, the Department of Health and Human Services, the Canadian Food Safety Agency, the European Food Safety Agency (EFSA), the District of Columbia (DC) Department of Health Food Safety and Hygiene Inspection Services, the General Accounting Office (GAO), the NOAA, the World Bank, the WHO, and the FAO. I examined several peer-reviewed articles, academic journals, books, surveys, and periodicals that are relevant to this research.

To find sources for this literature review, I searched several databases: Science Direct, Academic Search Complete, Agricola, ProQuest Dissertations and Theses, AGRIS, Agricultural and Environmental Science, Google Scholar, PubMed.gov, MEDLINE, AgNIC, and Public Administration. I also accessed literature from several libraries, including the University of Maryland at College Park, the Nova Southeastern University, the Library of Congress, the USDA National Agricultural Library, Montgomery College, and Walden University. I conducted additional searches based upon articles' citations, which yielded further sources.

The key search words included *food safety*, *food safety regulations*, *food safety management*, *food hazards*, *food contaminants*, *mycotoxins*, *mycotoxin occurrence in grains*, *mycotoxins and food safety*, *mycotoxins and regulatory practices*, *mycotoxins and food security*, *mycotoxin contamination*, *mycotoxins in the United States*, *foodborne illness*, *foodborne diseases*, *Produce Safety Rule*, *enforcement and food safety*, *compliance and regulatory policy*, *HACCP and food policy*, *organization economics theory*, *transaction cost economics approach*, *agricultural economics*, *regulatory system of food safety management*, *mycotoxins and trade*, and *mycotoxins and economics*.

Theoretical Framework

The industrialization of food production in the 20th century has dramatically changed perceptions and behaviors related to food. The revolution of the food industry resulted in significant benefits to consumers, a growing human population, and unwanted foodborne risks (National Research Council, 2010). As markets become more global and complex, so does the economic practice and experience that governments need to regulate (Wengle, 2016). The food processing sector is a regulatory sphere in which economic practice is extremely diverse and dynamic, while also subjected to public sector regulation (Wengle, 2016). To analyze the relationship between managing food safety in the food supply chain and transaction costs, it is important to understand the concept of institutional structures that are central to governance (Bavorová et al., 2014; Cheli et al., 2014;). The term governance derives from the Latin word *gubernare*, which means to steer and linked to the concept of institutions (Von Braun & Birner, 2017).

For this quantitative study, the TCE theory (Williamson, 1981) helped to explain collaboration of organizational structures that foster and promote awareness to strengthen food safety policies on mycotoxins. The TCE approach (Williamson, 1981) explains the emergence of organizations and the levels in which costs exist with uncertainties, asymmetric information, bounded rationalities, and barriers. The approach involves the structure of organizations in relation to transaction costs, agency theory, property rights, and the economics of the organization (Shafritz et al., 2016). Williamson (1981) argued that the TCE approach regarded the transaction cost as the basic unit of analysis and held an understanding of the transaction cost of economizing that is central to the study of organizations. The OET focuses on three aspects of the economic way of thinking: equilibrium analysis, transaction costs, and the concept of the organization. Equilibrium analysis focuses on the behavioral relationships between organizations. The transaction unit of analysis addresses the levels of exchange among organizations, groups, and environments.

Commons (1934) advanced the proposition that the transaction is the basic unit of economic analysis in recognizing governance structures as means to mediate the exchange of goods and services between technologically separable entities. Assessing the capacities of different structures to harmonize relations between parties, Cook and Barry (2004) argued that Williamson's TCE approach holds that (a) organizational economics presupposes that institution matter; (b) susceptible to analysis; (c) differs and not hostile; and (d) is an interdisciplinary combination of law, economics, and organization in which economics is first among equals. Barney posited that organization is bound by two commonalities that include the role in organizational structures and functions and the relationship between competition and organizations (Cook & Barry, 2004).

Shafritz et al. (2016) argued that the TCE approach (Williamson, 1981) is a management theory that is concerned with organizational structures central to governance. It is therefore used to analyze the relationship between food safety management practices and governance mechanisms within the agri-food supply chain (Abebe et al., 2017). As proposed by Commons (1934), the OET incorporated a transaction cost approach as one of its antecedents, which explained the emergence of organizations and the levels in which costs exist with uncertainties, asymmetric information, bounded rationalities, and barriers (Shafritz et al., 2016).

The OET describes the exchange of goods and services as structured by governance in harmonization or sequentially changing events due to its economics. The OET provides a foundation for us to understand the challenges to food safety that are emerging daily. To manage food safety, it is important to identify which foods or pathogens can lead to foodborne illnesses that impact human health. The OET structure of organization concerns transaction cost economics, agency theory, and property rights theory (Cook & Barry, 2004; Shafritz et al., 2016).

The TCE approach to the OET proposed by Commons (1934) (Shafritz et al., 2016) differs from the neoclassical theories of the firm (Cook & Barry, 2004). The OET theorists argued that there are behavioral assumptions in the emergence of organizations and the levels in which costs exist with uncertainties, asymmetric information, bounded rationalities, and barriers (Shafritz et al., 2016). The transaction unit of analysis addresses the levels of exchange among organizations, groups, and environments. The OET describes the exchange of goods and services structured by governance in harmonization or sequentially changing events due to its economics and for us to understand the challenges of property rights, which are costly to enforce. The emphasis is placed on economizing rather than refinement and to provide reasonable alternatives (Cook & Barry, 2004). The TCE presents the argument that economizing on transaction costs is mainly responsible for the choice of one form of organization over the other.

Governance mechanisms are institutions that affect economies of exchange by influencing transaction costs and coordination (Cook & Barry, 2004). Hazards and food quality threats may arise at all levels of the food system which may be concerning for consumers and policy makers. It is important to facilitate exchanges that relate to production and the parameters set by regulatory agencies to enforce compliance (Abebe et al., 2017) and controls for food safety (Wever et al., 2010) in managing mycotoxins.

Jie-hong et al., (2015) tested the transaction cost economics approach (TCE) to explain the relationship between food safety controls and different governance structures in China’s fruit and vegetable industry. To test the transaction cost economics theory approach Jie-hong et al., (2015) examined 1,460 food safety incidents in China, where production was the most critical stage of transmission. Individual and small-scale farmers were not able to afford costs associated with food safety controls. Adoption of food safety is associated with various factors including (private based) firms characteristics and (public based) regulations and governmental support. Firms in this instance refer to governance structure and variance in food safety control practices Jie-hong et al., (2015).

Wever, et al., (2010) tested the TCE to explore the relationship between quality management systems and interfirm governance structures in meat supply chains. Governance structures refer to the manner which transactions are organized within a chain (Wever et al., 2010). The TCE theory is mostly associated with Williamson (1981) in analyzing governance structures choices. In the TCE governance structures are based on the extent to which actors coordinate or control various phases of the production process. The challenges to food safety system are strongly linked to how food supply chains are organized. The agri-food industry firms are restructuring their production processes and distribution systems by transforming their contractual relationships.

Abebe et al., (2017) tested the Transaction Cost Economics approach to examine governance structures and food safety management systems to detect potential food safety hazard. According a TCE framework different governance structures emerge to economize on transaction costs, which are caused by the characteristics of transaction and human behavior. Williamson argued that the TCE referred to private mechanisms in which transactions (economic exchanges) are coordinated within a supply chain. Governance structures range from market based where coordination relies on price to hierarchy where coordination depends on administrative control.

Foodborne Illnesses, Outbreaks, and Costs

The WHO estimated that each year as many as 600 million people worldwide will fall ill from consumption of contaminated foods (Hussain, 2016; King et. al, 2017). Keener et al. (2013) revealed that the total societal cost of foodborne illnesses in the United States could be about 152 billion dollars per year. The prevention of foodborne illnesses will improve public health, reduce medical costs, and avoid disruptions to food systems caused by outbreaks and large-scale product recalls. Foodborne disease outbreaks caused by imported foods appeared to rise in 2009 and 2010, with nearly half of the outbreaks associated with imported products that implicated foods from areas where there were no previous outbreaks (Keener et al., 2013). The CDC Foodborne Disease Outbreak Surveillance reported that, from 2005 to 2010, foods that were imported to the United States from 15 countries caused 39 outbreaks and 2,348 illnesses, with nearly 45% of food causing outbreaks coming from Asia (Keener et al., 2013). In a similar study, Djekic et al. (2016) found that consumption of food contaminated with foodborne microorganisms and toxins produced by the microorganism may lead to death, illness, and hospitalization.

Odeyemi (2016) revealed there are currently more than 2 million deaths that occur every year in developing countries due to foodborne diseases. More than 250 sources of foodborne diseases have been identified. With the increase of foodborne infectious diseases, various countries have imposed several food safety regulations. The global emergence and reemergence of foodborne pathogens have made food safety a concern for public health (Odeyemi, 2016). In developing countries, most foodborne outbreaks have been underreported or underestimated. For example, Nigeria has a reported case of 90,000 foodborne diseases with a population of over a 170 million people. Hussain (2016) found that the highest number of outbreaks were attributed to produce in the United States in 2002 to 2011. Outbreaks of *E. coli* O157:H7, *Cryptosporidium*, and *Listeria monocytogenes* in the European Union and *Salmonella* in Australia (2016).

The GAO (2017) found that multistate foodborne illness outbreaks have increased, despite making up a small portion of total outbreaks affecting a greater number of people. The safety and quality of the United States food supply is governed by a complex system that results from at least 30 laws and 15 different agencies. The CDC reported that many who get sick from a foodborne illness will recover without lasting effects, but some individuals may suffer long-term health consequences, including chronic arthritis, kidney failures, and nerve damage. The GAO revealed that each year in the United States an estimated 1.3 million people is affected by an infection with the foodborne pathogen *Campylobacter*. Approximately one in 1,000 develop Guillain-Barre syndrome, a disorder in which a person's immune system attacks the body's own nerves. Exposure to *E. coli*, *Salmonella,* and other foodborne pathogens carries a long-term risk of developing Crohn's disease, a chronic inflammatory bowel disease. The GAO found that, in 2015, data from the USDA and the Economic Research Service (ERS) indicated that the most common foodborne pathogens together impose an economic burden related to foodborne illnesses, hospitalization, and deaths in the United States of over 15.5 billion dollars annually. The FDA (2015) estimated health costs associated with foodborne illness at about 36 billion dollars annually, and foodborne illness outbreaks can impose additional high costs in food recalls. The CDC's (2015) annual report stated that foodborne diseases from known pathogens are estimated to cause about 9.4 million illnesses each year in the United States (GAO, 2017).

The expansion of food trade throughout the world has seen multiple nations set food safety standards for the maximum tolerance level of certain contaminants in food to protect public health (Wu & Guclu, 2012). King et al. (2017) found that food safety is a shared concern for both developed and developing countries where foodborne diseases negatively impact the economy, trade, and industries.

The Produce Safety Rule and Compliance

Boer and Bast (2018) claimed that it is impossible to ensure that food will not pose serious risk to any consumer. Therefore, in 1993, the Organization for Economic Co-Operation and Development (OCED) established and developed policies regarding food safety as a reasonable certainty that no harm will result from intended uses. The OCED recognized that foods may contain certain toxins but can be considered safe based on controls put in place by management practices (Boer & Bast, 2018). In 1997, Regulation (EC) No 258/97, known as the Novel Food Regulation (NFR), was adopted to harmonize national procedures for bringing new products or ingredients intended for consumption to the European market (Boer & Bast, 2018). The harmonization of legislation throughout the European Union was to ensure that products are safe for human consumption (Boer & Bast, 2018). The use of hazard analysis critical control point (HACCP) does not work in a vacuum to protect consumers, but rather within a system that must be carefully planned and designed. Many countries have enshrined the HACCP approach into legislation, including the European countries’ Regulation on Hygiene of foodstuffs (EC No. 852/2004), the United States’ FSMA, and the Safe Foods for Canadians Act. This approach may mean strengthening through enforcement, but only if the authorities charged with enforcement have the necessary resources, skills, and expertise (Wallace, 2014a).

Adalja and Lichtenberg (2018) revealed that, in the mid-2000s, supermarket chains, commodity group organizations, and other entities had been privately instituting standards for food quality and safety due to foodborne outbreaks in the preceding decade. Those voluntary efforts were inadequate to provide safety measures. In January of 2011, Congress signed the FSMA into law. The *Produce Safety Rule* was first proposed in January 2013 and was officially known as the *Standards for Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. The rule was finalized in November of 2015 and became effective in January 2016 (Adalja & Lichtenberg, 2018; Astill et al., 2019). The FSMA's *Produce Safety Rule* required operational changes to meet standards, including integrated agricultural systems, livestock grazing practices, and sanitation that could be costly for compliance (Adalja & Lichtenberg, 2018). In a similar study, Astill et al. (2019) found that outbreaks in produce seriously impact public health; such outbreaks increased in the mid-1990s for both domestic and imported produce, which led to calls for federal regulations.

The structure of food safety remains a key public health policy challenge in both developed and developing countries (Lamuka, 2014). Most food safety challenges facing developing countries can be attributed to the management systems' inability to detect risks and identify appropriate strategies for collaborative management of food safety (Lamuka, 2014). Despite safe food supply in developed countries, consumers' perception of food safety continues to be problematic because of the ways that food businesses manage food safety. Food companies and agri-businesses must give considerable thought to managing food systems for effective public policy (Kussaga et al., 2014).

The enactment of the FSMA gave the FDA the authority to regulate the growing, harvesting, packing, and holding of fresh fruits and vegetables and represents a major shift in the firm’s approach from outbreak response to prevention-based control across the food supply (FDA, 2018). Fruits and vegetables accounted for 46% of foodborne illness outbreaks during the period of 1998 to 2008, a bigger portion than any other food category (Adalja & Lichtenberg, 2018). As one of the implementing rules of the FSMA, the FDA created the *Produce Safety Rule* to reduce health risks associated with foodborne illness from the consumption of fresh produce.

The *Produce Safety Rule* became effective in January 2016 and requires operational changes to meet standards that could be costly, disproportionately so for small farms (Adalja & Lichtenberg, 2018; FDA, 2018). To test the *Produce Safety Rule*, Adalja and Lichtenberg (2018) examined food safety practices with small farm sizes and reported the expenditures. They then explored policy implications of the exemption to the “*Rule”* through simulation of changes for farm revenue and costs of compliance. The investigation revealed that the costs of compliance with the *Produce Safety Rule* were not size neutral but had negative impacts for profitability for small farmers.

Hazard Analysis Critical Control Point

HACCP is a food safety management system used to promote, assure, and control food safety (Kussaga et al., 2014; Nychas et al., 2016). The HACCP system also refers to a transnational governance regime that uses a preventative approach to food safety management to control health hazards from growing, harvesting, processing, manufacturing, distributing, and consumption of foods (Agyei-Baffour et al., 2013;

Lamuka, 2014; Wengle, 2016). Many countries have legislatively enacted HACCP to use at all stages of the food chain (Agyei-Baffour et al., 2013; Wallace, 2014). The United States National Aeronautics and Space Administration (NASA), the U.S. Army Natick Laboratories, and Pillsbury collaborated to develop HACCP to protect astronauts from getting foodborne illnesses while in space (Wallace, 2014).

The HACCP system uses a preventative approach to food safety management and emphasizes risk mitigation to ensure foods are safe for consumption (Baker et al., 2014). Several studies have indicated inadequacies in some food safety management systems and deficiencies in hygienic, sanitation, and production practices (Kirezieva et al., 2013). HACCP based principles will help to understand the basic tenets of organizational measures to ensure safety measures and food control of microbiological principles.

Food production and consumption are parts of a complex food system, and many factors can contribute to the occurrence or control of foodborne diseases. Hazards can be biological, chemical, or physical. HACCP is designed to address food safety hazards from all angles of the food chain, from preharvest to postharvest to consumption, with the main goal of producing safe foods (FDA, 2017b). Wengle (2016) revealed food safety regulations are central mechanism in the food system, the process, effects, and politics.

Principles of HACCP

The HACCP system is based on seven principles designed to address food safety through analysis and control of biological, chemical, and physical hazards (FDA, 2017d). These principles have been universally accepted by regulatory agencies and food and trade industries (FDA, 2017c):

-Principle 1: Conduct a hazard analysis.

-Principle 2: Determine the critical control points (CCPs).

-Principle 3: Establish critical limits.

-Principle 4: Establish monitoring procedures.

-Principle 5: Establish corrective actions.

-Principle 6: Establish verification procedures.

-Principle 7: Establish record-keeping and documentation procedures.

For the past decade, food safety management has focused on animals and animal products, but risks of increased foodborne outbreaks have been linked to fresh produce, especially fruits and vegetables consumed raw (Kirezieva et al., 2013). Elimination of all contamination is impossible. Production, processing, and trade occur in different kinds of climates around the world under different regulatory guidelines and cultural conditions and within different industrialized food systems involving various actors from small and large supply chains. In the last decade, the issue of food safety has received increased attention due to several food safety scandals that raised public concern. In the United States, there have been several foodborne outbreaks of *Escherichia coli*. A globalized food trade, extensive production, and complex supply chain have contributed to an increase in microbiological food outbreaks that focus on developing food safety policy in strengthening management of foodborne hazards (Adinolfi et al., 2016).

Each year millions of people in the United States get sick from foodborne infections and intoxications from the consumption of contaminated foods (DC Department of Health, 2018). The CDC (2018) reported that 17% of people living in the

United States get sick from a foodborne illness. When a foodborne disease outbreak is detected, public health and regulatory officials work in collaboration to collect epidemiological, traceback, and food and environmental testing data to find the source of the outbreak (CDC, 2018). The contamination of foods can occur at any stage of the food chain, resulting in people becoming infected with a foodborne illness that is significantly costly (CDC, 2018).

With increased urbanization and globalization, food commodities may be exposed to various microbial, chemical, and physical hazards, which increases the risk of consumption of contaminated foods (Nychas et al., 2016). In densely populated areas, foodborne illnesses can affect large groups of people, which can result in outbreaks and hospitalizations. According to the WHO (2018a) and Lake et al. (2017), foodborne illnesses are usually infectious or toxic and can result from bacteria, viruses, parasites, and chemical hazards that enter the body through contaminated food and water. According to the CDC (2018), most of these hazards are undetected or underreported at the time of purchase or consumption.

Food Safety, Compliance, and Enforcement Regulation

The food industry is a billion-dollar system that incorporates several stakeholders from trade and agriculture as well as regulatory, health, private, and public sectors. Most importantly, it also includes its end users, the consumers. Snyder (2015) found that food safety regulation traces back to multiple sites of governance. Regulatory oversight in the United States food safety system has undergone major changes within the last decade. The growing importance of the United States food production in both foreign and domestic trade has made it one of the major drivers for economic development. The identification of food safety as a national priority gave rise to organizational change and the modernization of the food safety legislative framework with the creation of the FDA, the Food Protection Plan of 2007, and the FSMA of 201l. The Food Protection Plan serves to protect the nation's food supply from both unintentional contamination and deliberate attack. The FSMA is the most sweeping reform of food safety authority in more than 70 years, giving the FDA authorities an enhanced mandate to protect consumers and public health (FDA, 2018). Fruits and vegetables accounted for 46% foodborne outbreaks during the period between 1998 and 2008, which led to the creation of the *Produce Safety Rule* in 2016 to reduce health risks from foodborne illness from consumption of fresh produce (Adalja & Lichtenberg, 2018).

In the past decade, food safety has received increased scrutiny with regards to regulation, the food supply chain, and international trade (Bavorová et al., 2014; Carneiro & Kaneene, 2017). Wengle (2016) revealed that food safety regulations are central regulatory mechanisms within the food system. Unnevehr (2015) found the emergence of stringent food safety standards is a result of growth in trade, hazard and epidemiology and regulatory oversight in industrialized countries. In the same study, Unnevehr (2015) found that, despite food safety regulation in high income countries dating back to the 20th century, reforms since the 1990s reflect better scientific understandings of foodborne risks. Wu and Guclu (2012) found that many countries have set food safety standards for the maximum tolerance level of certain contaminants for the purpose of protecting public health.

Many countries have established legislation for regulating toxins and mycotoxins with guidance levels. Kovalsky et al. (2016) revealed there are emerging mycotoxins that have no regulation to date. Fietz et al. (2018) found that decisions on whether to comply with regulations are determined by benefits and costs. The European Union maximum allowable level varies with commodity and the degree of processing. Currently, over 5 billion people are at risk from aflatoxin, a common foodborne fungus that colonizes crops. In industrialized nations, the contamination of aflatoxin in foods is primarily more economic than for health burdens.

The European Union regulation on aflatoxin costs Africa 670 million dollars each year in export (Wu & Guclu, 2012). The loss of millions of dollars in the United States annually is associated more with market losses than health effects due to enforcement of aflatoxin standards that have largely eliminated exposure in foods. In comparison to developing countries that lack resources and infrastructure to monitor and control aflatoxin. Typically, the highest exposures are in sub-Saharan African and Asian countries. Food safety regulation can take on various forms as enforcement agencies have different degrees of uniformed standards. To fully understand the impact of food safety regulation is to evaluate the process of compliance (Henson & Heasman, 1998). The food service industries are made up of facilities that serve prepared food for immediate consumption by consumers. In 2016, the United States food service industry had projected sales of 783 billion dollars; commercial food service establishments were responsible for these sales (Harris et al., 2017).

Agyekum and Jolly (2017) revealed that, in recognition of the health risks posed by aflatoxins, the World Trade Organization (WTO) Sanitary and Phytosanitary Standards (SPS) agreement allows member countries to set their own standards to protect consumers, a policy known as the Precautionary Principle. Since 1998, food standards in industrialized nations have evolved, with the European Commission announcing new aflatoxin regulations of imported foods. However, setting appropriate levels for aflatoxin in foods, especially peanuts, has been a controversial policy (Agyekum & Jolly, 2017).

Food Safety and Mycotoxins

There are more than 250 known foodborne diseases caused by bacteria, viruses, parasites, and chemical contaminants that enter the body through contaminated food and water (CDC, 2017b). According to the CDC, 1 in 6 Americans get sick from foodborne illness. Of most concern are chemical contaminants, such as mycotoxins, which occur naturally and are detrimental to the health of humans. Mycotoxins are environmental toxins found on grains produced by molds that can affect corn and wheat cereals. Unsafe and contaminated foods are one of the leading causes of death and illness, which makes food safety and foodborne diseases a concern for public health (Rehber, 2012).

Marroquín-Cardona et al. (2014) revealed that an estimated 200,000 people are added to the global food demand daily, and by 2050 the world population will exceed 9 billion. Population growth places additional importance on making foods for humans safe for consumption, and both developed and developing countries are at risks. Studies have indicated that the global incidence of foodborne diseases is difficult to estimate. The WHO (2017) and FAO (2018) have concluded that foodborne illness is a global health problem. In a similar study, Klingelhöfer et al. (2018) reported that foodborne diseases remain a significant challenge, and the WHO estimated that about 600 million people are affected by foodborne illnesses each year, which is important context for promoting global food safety.

The contamination of mycotoxins in various crops has implications for human and animal health as well as economic loss to the feed and food industry. Cheli, Pinotti, et al. (2013) and Patriarca and Pinto (2017) revealed that the FAO estimated that 25% of the world's annual crop production is contaminated with mycotoxins, which resulted in an estimated 1 billion metric tons of food and feed loss. The total costs of mycotoxin contamination can reduce yields in crop growth, production, and animal productivity and increase health and risk management costs (Patriarca & Pinto, 2017).

In their study, Mwalwayo and Thole (2016) found that farming households in Malawi, a country in southern Africa, operate below subsistence and low productivity of maize, their main food for consumption and trade. With the results of poor food quality due to mycotoxin contamination, this population is at serious risk of ill health, food insecurity, and gross domestic loss. Several epidemiological studies have reported the incidences of foodborne diseases due to mycotoxin contamination in grain foods. Other studies have revealed lack of awareness and understanding of mycotoxin contamination on food safety and human health.

In a similar study, Unnevehr (2015) found that food hazards can lead to acute and chronic illnesses and reduce food availability for insecure populations. Unnevehr stated that food safety has received increased attention and is an important public health issue in developing countries. Moretti et al. (2019) indicated that, among the emerging issues of food safety, is the increase of plant diseases that are associated with fungal toxins, which synthesize mycotoxins, which is a major problem for human and animal health worldwide. Mycotoxins are the most prevalent food-related health risk in field crops; they affect cereals, the most consumed worldwide food staple for humanity (Moretti et al., 2019).

According to Stoev (2013), food safety and protecting humans from foodborne diseases due to mycotoxin contamination are significant challenges, especially in developing countries. Although developed countries may have well designed infrastructure in place, foods for domestic consumption must have various methods of control to ensure foods are safe at all levels of the food chain.

Lee and Ryu (2015) revealed that aflatoxins, ochratoxins, fumonisins, trichothecenes, and zearalenone are most important to food safety and public health due to worldwide occurrence and toxicity. Several epidemiological studies have indicated that consuming aflatoxin through foods is associated with liver cancer, immune suppression, and stunted growth in children (Marín et al., 2013; Marroquín-Cardona et al., 2014). Pitt et al. (2013) reported in a similar study that aflatoxins are the most important because they are a potent liver carcinogen, have severe health effects on humans, are produced by several species of *Aspergillus*, and are significant because production is both before harvest and postharvest conditions.

The risk of foodborne diseases can occur due to exposure to a microbial toxin. The WHO (2018) revealed foodborne mycotoxins can cause severe illnesses that have long-term health effects, such as cancer and immune deficiency. Foodborne diseases negatively impact countries’ economies, trade, and industries and threaten global food safety and food security (King et al., 2017). Food safety is often compromised by the presence of mycotoxins in grain foods, which is a global problem in both developed and developing countries (Kussaga et al., 2014).

Classification of Mycotoxins and Human Health

Many studies have revealed that the occurrence of mycotoxins in human foods and feed is worldwide. In the last decade, Europe has increased the number of regulated mycotoxins to protect human and animal health (De Saegar et al., 2016). Mycotoxins are chemicals produced from filamentous fungi that cause adverse health effects in humans and animals (Lee & Ryu, 2015). Those from the genera *Aspergillus*, *Penicillium,* and *Fusarium* are of great concern in crop production, processing, storage, and reduction of competitiveness in agricultural commodities (Udomkun et al., 2017). Despite the identification of many mycotoxins, aflatoxins, fumonisins, ochratoxins, tricothecenes, and zearealenone are toxicologically recognized due to worldwide prevalence in agricultural commodities and to the threat they pose to food safety. Mycotoxins are a public health concern because, even at low level contamination, exposure can cause serious health problems. The significance of this problem is that toxigenic species of mycotoxins can cause synergistic effects to produce other mycotoxins, which are potentially dangerous to human health. Populations with little or no regulatory enforcement or primary strategies to reduce risk of mycotoxin contamination are at risk of significant health threats.

All humans are at risk for mycotoxin exposure via ingestion of contaminated foods, so mycotoxins are a significant threat to food security and food safety. Sobral et al. (2018) revealed in a study that human exposure to mycotoxins can occur gastrointestinally via ingestion of contaminated food and beverages and through respiratory transmission; through inhalation, mucous and cutaneous compounded with gaps in knowledge and awareness of mycotoxins.

Aflatoxins

Aflatoxins are produced by the *Aspergillus* species and are the most poisonous of mycotoxins (Abrunhosa et al., 2016). Hot, humid conditions and pest damage during plant growth or storage can favor the growth of aflatoxins (Canadian Food Inspection Agency [CFIA], n.d.). There are significant health risks and economic impacts from agricultural crops frequently affected by *Aspergillus* species; susceptible crops include cereals, oilseeds, spices, and nuts. Cereals include corn, sorghum, wheat, and rice. Oilseeds include soybean and peanuts. Spices include black pepper, turmeric, and ginger. Nuts include tree nuts, such as pistachios and walnuts. The toxins can also be found in the milk of farm animals that have eaten contaminated feed. Aflatoxins in large doses can lead to life-threatening acute poisoning and cause cancer as well as damage to the liver and DNA (WHO, 2018; Abrunhosa et al., 2016).

Aflatoxins are hepatocarcinogenic toxins. The disease they cause was known as Turkey-X disease due to a major outbreak in England and Turkey in the 1960s, which resulted in 100,000 deaths (Anukul et al., 2013). In a similar study, Womack et al. (2013) found that aflatoxins are highly toxic and mainly produced from the strains *Aspergillus* *flavus* and *Aspergillus parasiticus*. Despite showing stability in most conditions during growth, harvest, processing and storage, aflatoxins can accumulate to dangerous levels. Mwalwayo and Thole (2016) discussed in their study that mycotoxicosis in sub-Saharan Africa is mainly caused by aflatoxin ingestion, and about 250,00 hepatocellular carcinoma related deaths occur annually. The same study conducted by Mwalwayo and Thole (2016) revealed that maize is one of the most important food staples; it is grown by 97% of farming households, accounts for 60% food consumption, and contributes to the diets of about 80% of the population.

Alberts et al. (2017) found vulnerable populations are at risk of ill health after consuming poor quality grains contaminated by mycotoxins. The International Agency for Research on Cancer (IARC) has classified aflatoxins as a carcinogen to humans that causes heptacellular carcinoma, and aflatoxicoses often lead to death after exposure (Moretti et al., 2019). Aflatoxins are a significant threat to human health and are carcinogens associated with the hepatitis B virus that are responsible for large numbers of deaths annually, especially in tropical countries (Adeyeye & Yildiz, 2016). The CFIA (n.d.) revealed that short-term exposure to high levels of aflatoxins can cause illness in humans, which is characterized by vomiting, abdominal pain, convulsions, coma, and death. Despite finding the illness rare in developed countries, the CFIA (n.d.) indicated chronic and long-term exposure to high levels of aflatoxins is linked to several human health effects, including increased risk of developing liver cancer.

Aflatoxins are found in various foods and feed and are known to be associated with various diseases, such as aflatoxicoses in livestock, domesticated animals, and humans around the world. Sheikh-Ali et al. (2014) found that several outbreaks of aflatoxicoses were investigated in Kenya and impaired child growth in Benin because of post-weaning exposure to aflatoxins. In developing countries, exposure to aflatoxins leads to overall health disorders and low life expectancy due to food insecurity, poverty, and malnutrition (Klingelhöfer, 2018; Sheik-Ali et al, 2014). Aflatoxins remain a global challenge to protect human health from foodborne diseases.

Several countries have proposed or instated regulations for aflatoxins due to the health hazards posed to humans through consumption or exposure. Aflatoxins present the greatest threat to the United States food supply, and from 2004 to 2013 there were 18 reports of food and feed recall from contamination (Mitchell et al., 2016). The FDA has limits of 20 ppb of total aflatoxins in meals and feed and 0.5 ppb in milk (Umesha et al., 2017), since even in small quantities they can cause severe toxicity very damaging to humans.

Fumonisins

Fumonisins (FBs) are produced from the *Fusarium* genus, *Fusarium verticillioides*, *F. proliferatum*, and *A. niger*. Like aflatoxins, fumonisins cause diseases and are an ongoing problem for food safety. *Fusarium* is the largest fungal form and the most prevalent toxin-producing fungi found in America, Europe, and Asia; it is commonly found in agricultural grains and cereal (Escrivá et al., 2015).

Fumonisins were discovered in 1988 in South Africa following an outbreak of equine encephalomalacia; then, in 1989 and 1990, there were fatal outbreaks of equine leukomalacia, porcine prenatal and neonatal mortality, and pulmonary edema in the

United States (Anukul et al., 2013). Wu et al. (2014) found fumonisins are associated with esophageal cancer and neural tube defects. In a similar study, Mwalwayo and Thole (2016) reported that the International Agency Research in Carcinogenics classified fumonisins as a 2B compound probably carcinogenic for humans. Fumonisins' contamination of many agricultural products, especially maize, has been associated with several human and animal diseases. Pathogenic effects stemming from ingestion of fumonisins include abdominal pain and diarrhea, leukoencephalomalacia, pulmonary edema, and elevated risk of esophageal cancer (Luo et al., 2018; Mwalwayo & Thole, 2016).

In their study, Bezerra da Rocha et al. (2014) found that, in regions of southern Africa, China, and northern Italy, corn grains had been associated with several cases of esophageal cancer. The same researchers found fumonisins in corn sold in supermarkets in Charleston, South Carolina in the United States among African Americans with the highest incidence of esophageal cancer. In a similar study, Cendoya et al. (2018) found that fumonisins have major impacts on human health, welfare, and productivity.

Several studies have indicated fumonisin consumption and exposure stunts growth in children. The Joint FAO/WHO Expert on Committee on Food Additives (JEFCA) has determined a provisional maximum tolerable daily intake of 2mg/kg per body weight (Cendoya et al., 2018). The European Union set limits for human consumption of fumonisins in cereal-based foods in 2007 but did not establish limits for wheat and wheat-based foods. There have been several studies on fumonisins in human populations in Latin America and other countries where occurrence has been reported (Cerón-Bustamante et al., 2018; Tibola et al., 2015).

Ochratoxin A

Ochratoxin A (OTA) is a fungal toxin produced by several species of *Aspergillus* and *Penicillium* (Kuruc et al., 2015; Nguyen & Ryu, 2014). It is one of the five mycotoxins that are of concern to animal and human health. Ochratoxin A forms during the storage of crops and is known to cause toxic effects in animals that could result in damage to kidneys, fetal development, and the immune system. Ochratoxin A contamination occurs in food commodities, such as cereals and cereal products, coffee beans, dried fruits, beer, and wine (WHO, 2018).

OTA is absorbed from the gastrointestinal tract and binds to plasma proteins. It can cause problems in the renal system. In the United States, infants and young children are at greatest risk from OTA (Mitchell et al., 2017). According to Mitchell et al. (2017), several countries around the world, such as Brazil, Israel, Switzerland, Uruguay, and the European Union countries, have set maximum regulatory limits. Both the United States and Canada have not set regulatory guidelines for OTA. In the Canadian population, especially in the diets of children, wheat-based foods, oats, rice, and raisons are the major contributors of OTA, which is a serious public health concern (Mitchell et al., 2017).

OTA is a carcinogen that can cause urinary tract cancer in humans and comes in three forms: A, B, and C (Adeyeye & Yildiz, 2016). OTA has been included by the International Agency for Research on Cancer in a 2B group classification as a carcinogen to humans. Alim et al. (2018) found that exposure to OTA severely affects the kidneys and is associated with immunotoxicity, neurotoxicity, myelotoxicity, and reproductive toxicity, all of which can lead to both acute and chronic conditions and even death in humans.

Tricothecenes

Tricothecenes (TRC) constitute a group of approximately 150 metabolites produced by fungi of the genera *Fusarium, Myrothecium, Stachybotrys, Trichoderma,* and several others (Bezerra da Rocha et al., 2014). Tricothecenes of the *Fusarium* species are of the greatest threat to human and animal health because of their widespread occurrence in cereal crops (USDA, 2018). Despite the identification of several tricothecenes, few occur naturally. Dexoynivalenol (DON), nivalenol (NIV), toxin T2, Toxin HT2, and diacetoxyscirpenol (DAS) are the tricothecenes that are most relevant to food safety and agriculture in the United States (Abrunhosa et al., 2016; USDA, 2018).

DON is the class of mycotoxin mostly found in grain foods, such as wheat, oat, rye, and corn. DON contamination is a significant problem in the United States Midwest, Canada, Europe, and Asia (USDA, 2018). TRC can be acutely toxic to humans when ingested, causing rapid irritation to the skin or intestinal mucosa, leading to diarrhea. Reported chronic effects in animals include suppression of the immune system. Cherkani-Hassani et al. (2016) found that *tricothecenes A* have been associated with fatal and chronic toxicosis and *tricothecenes B* with acute toxicity in humans. García-Cela et al. (2012) revealed tricothecenes are strong inhibitors of protein synthesis in mammalian cells, causing toxicity in humans and animals.

Tricothecenes are the largest group of toxins that cause vomiting, diarrhea, hemorrhage, kidney damage, and immunosuppression (Luo et al., 2018). In a similar study, Marroquín-Cardona et al. (2014) found that DON can have serious health effects related to anorexia, weight loss, malnutrition, endocrine malfunctions, and immune suppression. DON is resistant to food processing, making it problematic for food security. Contamination of wheat. barley, and other field crops with tricothecenes can compromise food safety, leading to reduction in quality, economic losses, and the fungal disease FHB (Da Luz et al., 2017).

Zearalenone

Zearalenone (ZEN) is produced from several *Fusarium* species and is mainly found in cereal crops, such as maize, barley, oats, wheat, rice, and sorghum, with the highest contamination levels found in maize. ZEN has the widest distribution in the world (Stoev, 2014). Lee and Ryu (2015) revealed that, in European countries, ZEN is mostly found in wheat, rye, and oats; in the United States and Canada, wheat and corn are frequently contaminated.

A study conducted by Marroquín-Cardona et al (2014) indicated that susceptible populations, like the poor, are disproportionately affected by risks of consuming mold-contaminated crops. Mold contamination frequently occurs at the preharvest stage. García-Cela et al. (2012) found that ZEN was implicated in several cases of mycotoxicosis in farm animals and head blight found in wheat, barley, and maize. James and Zikankuba (2018) revealed that ZEN causes reproductive toxicity, disrupting estrous cycles in mammals and inducing cervical cancer in humans. Due to its resemblance to the principal hormone in the human ovary it can bind to estrogen receptors. Relatedly, Luo et al. (2018) found that ZEN is an oestrogenic mycotoxin that affects puberty in girls and is highly toxic.

Environmental Conditions

Mycotoxins are environmental toxins produced by molds that contaminate various agricultural commodities before harvest and postharvest. They often grow on crops, including cereals, nuts, spices, coffee beans, and dried fruits. Of all environmental contaminants, mycotoxins have the greatest consequences for human health and as well as the greatest economic costs. Mycotoxin contamination in various crops affects feed and food safety significantly.

The management of postharvest practices to prevent contamination during storage by maintaining low temperature and humidity conditions to limit fungal growth is important for the agri-food industry (Alshannaq & Yu, 2017; Bezerra da Rocha et al., 2014; De Saeger et al., 2016). Mycotoxins are ubiquitous in nature and can come from certain plant diseases and grains that were improperly stored, leading to mold growth. Fungal toxins grow under certain environmental conditions, especially in warm and humid temperatures. The growth of toxins may start in the field and continue during harvest, storage, processing, and handling (Neme & Mohammed, 2017). Moisture and oxygen content are environmental factors that affect production of aflatoxins. Climate change is increasing the growth of mycotoxins; warmer temperatures facilitate the growth of fungi (Anukul et al., 2013).

Outbreaks of aflatoxin contamination are most severe in tropical and subtropical regions and in temperate climates, like in the United States Midwest. Afsah-Hejri et al. (2013) revealed environmental factors, such as temperature, humidity, water activity, and storage conditions, significantly influence mycotoxin growth. Also, poor harvesting, processing, drying, and transportation practices influence fungal growth. Lahouar et al. (2016) found that climate change has been significant and, depending on geological and climate conditions, fungal species can affect foods and feeds. Mycotoxin contamination of agricultural crops can occur when fungal growth acts as a pathogen on plants and fungal growth on stored crops. Agricultural commodities in tropical and subtropical environments are more susceptible to mycotoxin infestation (Afsah-Hejri et al., 2013; Aldars-García et al., 2016; Lahour et al., 2016). Postharvest conditions pose a threat to food safety because of challenging factors that influence growth of mycotoxins. During preharvest, crops can be contaminated by fungi and insects that infect grains (Aiko & Mehta, 2016). Cultural awareness, attitudes, and behaviors also play a significant role in risk of contamination from mycotoxins because of a lack of knowledge about the effects on human health (Nayak & Watson, 2016).

Economic Burden of Foodborne Diseases

Foodborne disease is a challenge for global health and promoting food safety is vitally important to the health of humans. Foodborne diseases are commonly transmitted through foods, microbial pathogens, and chemical and physical hazards (Lake et al., 2017). Each year, foodborne illnesses affect an estimated 600 million people, according to the WHO. Lake et al. (2017) revealed that the burden of foodborne diseases is very costly and may require a quantitative assessment to allocate resources to develop effective food policies that will improve the health of a population. The issue of comorbidity may compound the risks of foodborne diseases, putting vulnerable populations at greater risk of susceptibility to ill health caused by mycotoxins in foods.

Klingelhöfer et al. (2018) found that globalization and trade of agricultural commodities across borders of both developed and developing countries pose unique challenges to global food safety. Growing urbanization, movement beyond borders, and different processing and handling techniques increase the risks. Outbreaks of foodborne diseases are most prevalent in developing countries due to improper handling and regulatory practices. Several studies have shown diseases of water and foodborne origin are a problem for developing countries and a leading cause of death and illnesses (Alimi & Workneh, 2016). Womack et al. (2014) revealed that the FAO estimated 25% of crops are infested with mycotoxins, which is an economic concern for populations worldwide.

The economic impact of aflatoxin contamination includes cost of preventative and mitigation measures, reduced value in foods and feed, and decreased animal production. Womack et al. (2014) found that the toxicity of aflatoxin costs the United States an estimated 500 million dollars, while the global cost is about one billion dollars. A study by Alshannaq and Yu (2017) showed aflatoxins are the most toxic mycotoxin with significant burden to agriculture. For the United States and European Union countries, economic burden is the primary concern for aflatoxins, whereas, in developing countries in Africa and Asia, aflatoxins contribute largely to cases of heptacellular carcinoma annually. In the same study, Alshannaq and Yu revealed that the United States' corn industry has an estimated loss of 52.1 million dollars to 1.68 billion dollars due to aflatoxin contamination and is also the main hazard for rejection of foods and feeds in the European Union Rapid Alert system for Food and Feed (RASFF).

Mycotoxin is a fungal toxin that occurs naturally and is a serious food safety issue that affects grain products, such as wheat, corn, and barley, in both developed and developing countries. In a case study of street food vendors in Africa and Asia, Alimi and Workneh (2016) revealed that street food vending contributes significantly to the growing economy. Street foods are more prone to mycotoxin contamination in developing countries. Mycotoxins can infest the entire food chain, which increases the threat to food safety. The onus is on food industries to ensure best practices by enforcing regulatory guidelines in trade to safeguard food for consumption. The consequences of foodborne illnesses from mycotoxin contamination have caused serious economic burden. Bryden and Nriagu (2011) conducted a study on natural food chain contaminants and found mycotoxin contamination can occur throughout the food chain, which has severe economic impact. The insidious nature of mycotoxins can make it difficult to estimate incidence and cost.

Several studies have indicated that mycotoxins can be produced in crops and other food commodities both preharvest and postharvest. Cendoya et al. (2018) conducted a study on cereals, including wheat, rice, maize, barley, oats, millet, and rye, which make up a large part of the human diet. The researchers found that cereals are frequently colonized by mycotoxins, particularly *Fusarium* species. This has a major impact on productivity, health, and the economy. A similar study by Alim et al. (2018) revealed that breakfast cereals make up a huge part of the human diet by providing essential macronutrients; they estimated approximately 2592 million tons in production and 2567 million tons in consumption. Gregori et al. (2013) determined that long storage of cereal in silos is a common practice worldwide. Preharvest protection of cereal from fungal infestation is important to prevent economic losses during storage and further contamination during production. *Fusarium*, *Aspergillus* and *Penicillium* spp. are of importance economically.

A study by Escrivá et al. (2015) revealed that *Fusarium* is one of the most important genera of fungi that infects agricultural crops, especially wheat, a commodity grain. This toxin-producing fungus is found commonly in America, Europe, and Asia. Disease from this species is an ongoing problem for agriculture. International trade of agricultural commodities, such as cereal grains, nuts, and peanuts, amounts to many tons each year. These foods can be susceptible to mycotoxin contamination. While developed countries have set regulatory guidelines and enforcement for international trades, some developed countries are at considerable risk of economic loss due to mycotoxins (Adeyeye & Yildiz, 2016).

Traditional and cultural market purchases of agricultural commodities can have long storage times, which creates conditions for mold infestation and subsequent rejection that can result in economic losses and food safety deficiencies (Kussaga et al., 2014; Umesha et al., 2017).

Epidemiology, Surveillance, and Food Safety Organizations

Epidemiology and surveillance are important for monitoring chronic diseases and creating intervention strategies in managing public health. These approaches require collecting data and identifying gaps to provide and support intervention strategies in policy making and affect societal changes (Remington et al., 2016). Epidemiology is an essential discipline of public health. It contributes to promoting health, preventing diseases in an organized society, and assessing health issues at the policy and strategic levels (Gulis & Fujino, 2015).

The Epidemiological Triangle is often used in public health to assess the relationship between an agent, a host, and its environment (Gulis & Fujino, 2015). The agent that causes the disease can be physical, chemical, or biological, the host who harbors the disease and the environment where the diseases are transmitted (Bowman et al., 2012; CDC, n.d.; Gulis & Fujino, 2015). In this quantitative study, the agent mycotoxin was a naturally occurring fungi and a food hazard. The host was humans that are likely to be affected by mycotoxin contamination through food consumption. The environment was settings where the disease is caused due to exposure and consumption of mycotoxins that are associated with different types of cancers (Unnevehr, 2015). The epidemiological model is a tool used for mapping to inform how diseases spread and to control spread through identification and prediction of the greatest risks (Pigott et al., 2015). Epidemiological studies have shown that foodborne diseases may occur when individuals are susceptible to infection from contaminated foods.

State and local authorities usually investigate foodborne disease outbreaks, and there are several agencies that are responsible for monitoring outbreaks. The CDC operates under the Department of Health and Human Services in the United States and is responsible for the protection of the lives of Americans from health, safety, and security threats from home and abroad (CDC, 2017). The FAO is the principal agency of the United Nations; it is a leader on global food safety and quality and works in tangent with the WHO and Codex Alimentarius on various policy issues concerning harmonization of food safety and health (Boutrif, 2014).

Unnevehr (2015) revealed that food safety is an important health issue in developing countries because risks contribute to the burden of illness. Several studies have indicated the importance of mycotoxin hazards through food consumption and their association with liver cancer, stunted growth in children, and immune suppression. The concern of food safety is significant to public health and food security.

Food Security and Policy

Maintaining food supply to feed a population is integral to food security. However, the challenges lie in supplying foods that are safe, nutritious, quality assured, and free from environmental contaminants. Among those contaminants are mycotoxins, which can cause foodborne diseases. Studies have indicated that public policies are formulated at many levels of government and have been key in bringing about public health achievements in the 19th and 20th centuries in areas of clean water and sanitization (Bowman et al., 2012). In the same study, Bowman et al. (2012) indicated that public policy is instrumental in the prevention of and control of chronic diseases and emphasized education, legislation, and regulatory and fiscal measures for population interventions. In a similar study, Mohamad and Khalid (2016) demonstrated that food safety is a shared responsibility.

A study conducted by King et al. (2017) indicated that the global population is expected to reach 9 billion by the year 2050, which will require more food production. The food chain will involve more challenges, and patterns of consumption will change, so food safety will be critical to food security. Bureau and Swinnen (2017) and Díez et al. (2017) revealed that, in recent years, the European Commission (EC) has identified food safety as a top priority with the legislative concept of “farm to fork,” which aims to harmonize food safety programs. “Food security is determined by three key components (a) sufficient food availability, (b) access to this food and (c) quality and utilization of the food in terms of nutrition and cultural perspectives” (Medina et al, 2017). In the same study, Medina et al. (2017) found that concerns about mycotoxins have been the focus of the FAO and WHO because of the significant levels of toxicity that impact food security. Despite strict regulation limits in some parts of the world, many African countries only have regulation for those crops intended for export; often, residents in those countries consume crops that are of poor quality and infested with mycotoxins, a significant health risk to the vulnerable. Adetuniji et al. (2014) found in their study that the safety of foods and feeds for humans and animals should be the top priority in advancing regulation, but, in many parts of Africa, vulnerable populations suffer greatly because of poor diets and unsafe foods.

The research argues that decision making to improve food safety is a global challenge due to the complexity of policy formation. Policy making requires several actors to operate and pushes beyond the border of social, economic, and political dimensions (Smith et al., 2016). There is no one overarching food policy within nations, and vulnerable populations are often marginalized due to lack of resources. Effective food safety policies can target consumer awareness, collaboration and harmonization, and regulation to improve food security by ensuring access to safe, healthy, and affordable foods. The essential approach to the significant global food safety challenge is to promote good governance through desirable policies that increase food security.

Food Law and Inspection Regulation

Almond and Esbester (2018) found that different agencies have long used inspection as a regulatory tool that has shifted over time from state-led control toward more self-regulation. Makofske (2019) reported that regulatory compliance is often promoted by unannounced inspections during which detected violations incur punishment. Inspection regimes promote compliance by establishing a cost for violations. In the same study, Makofske (2019) revealed that inspections spanning from October of 2015 through March of 2018 using open data from the County of Los Angeles that multiple establishments and individual establishments performed significantly worse on days when there was facility’s only inspection. There were 7.75% more violations and 16.2% more major critical violations. The most severe LA County health code violations were detected when there was one of multiple inspections. This suggests these establishments had lower compliance levels than was often detected due to the ability to anticipate inspection timing (Makofske, 2019).

In the District of Columbia, the Food Safety and Hygiene Inspection Services Division (FSHISD) of the Department of Health and Human Services is responsible for the inspection of the city's 6,500 food establishments (Government of the District of Columbia Department of Health, 2018). These establishments include delicatessens, bakeries, grocery stores, retail marine markets, ice cream manufacturers, restaurants, wholesale markets, mobile vendors, hotels, and cottage food establishments (Government of the District of Columbia Department of Health, 2018). The *DC Healthy People 2020* goal on food safety focuses on limiting foodborne illnesses. While this is important, food safety depends largely on food systems in production, processing, storage, transport, and consumption (Government of the district of Columbia Department of Health, 2018).

The FAO (2018) revealed that the key to effective food control is through a legal framework that countries adopt to create food laws and regulations. These laws and regulations can be complex. Over 100 countries have adopted regulations to limit mycotoxins in foods to protect consumers from health risks. The Codex Alimentarius Commission has recommendations on the maximum limits of mycotoxins (Moy et al., 2014). Marín et al. (2013) found many countries have adopted regulations to limit mycotoxin exposure. The FAO estimated about 25% of cereal that is produced worldwide is contaminated with mycotoxins.

Since the 1970s, mycotoxins have been a growing concern as food contaminants (Moy et al, 2014). Several mycotoxins have been identified, with a limited number occurring frequently at significant concentration in foods. Among the mycotoxins that are of food safety and public health importance due to occurrence and toxicity are aflatoxins, ochratoxins, zearalenone, fumonisins, and tricothecenes, particularly deoxynivalenol (Lee & Ryu, 2015). Due to worldwide occurrence and prevalence, chronic exposure may lead to adverse health effects, even at low concentrations in foods. Toxigenic fungi species may produce one or more mycotoxins, and multiple species can produce one of the mycotoxins (Lee & Ryu, 2015).

In several studies conducted in North and South America, Europe, and Asia, tests revealed positive samples of aflatoxins, ochratoxins, zearalenone, fumonisins, and tricothecenes. Mycotoxin formation is challenging to control, and failure to prevent fungal growth and production of toxins, both preharvest and postharvest, will lead to ill health and economic losses. Studies have shown that mycotoxins can appear in the food chain by fungal infection of crops, by direct consumption by humans, and in livestock feed (Marín et al., 2013). Wheat, a frequently consumed food worldwide, has a susceptibility to fungal disease outbreaks, particularly FHB (Tibola et al, 2015). In the United States, the costs of foodborne illness have been widely investigated (Lake et al., 2017). Regulatory efforts focus on risk management and promote food safety objectives to oversee how industries control and implement measures. Many food safety issues are complex, and regulators must innovate guidelines and tools that are effective to manage food safety. To meet food safety objectives (FSO) and to manage mycotoxin levels in foods, international specialists aid in evaluation. The toxicity in significant mycotoxins is set by the JECFA, which advises the EFSA and the US National Toxicology Program (NTP) on permissible toxicity levels in international trade (Pitt et al., 2013).

In a study, Udomkun et al. (2017) revealed that legislation and regulations are constantly evolving issues but are important for addressing mycotoxin contamination in foods and feeds; countries have recognized the significance of establishing limits for human consumption that will reduce healthcare costs and access to market value in international trade. In a similar study, Milicevic et al. (2015) found that mycotoxin regulation and legislation in developing countries could fundamentally protect the populations, reduce economic burdens, advance trade, increase risk management, enforce surveillance, and subsequently improve food security.

Mycotoxin exposure in humans demands a regulatory infrastructure. The European Union has set limits for aflatoxin and aflatoxin B1 in cereal grains at 2 mg/kg, for ochratoxins at 5 mg/kg, for tricothecenes at 500 mg/kg, and for zearalenone at 50 to 100 mg/kg (Escrivá et al., 2015; James & Zikankuba, 2018). In some sub-Saharan African countries, there are set regulations for aflatoxins but for no other major mycotoxins, which is problematic for the health of the population and a public health concern. Lee and Ryu (2015) found that the European Union and Canada have set regulatory guidelines for ochratoxin A, but the United States did not have any guidance on tolerable intakes or levels. Several studies conducted in the United States showed high incidences of ochratoxin A in oats and oat-based breakfast cereals of infants, which is quite concerning for public health. There is a lack of regulatory standards for some of the most significant mycotoxins that can be detrimental to human health. Capriotti et al.

(2011) revealed many countries have established regulatory guidelines for aflatoxins, ochratoxin A, tricothecenes, zearalenone, and fumonisins, but there is difficulty in establishing regulation of maximum limits due to the lack of standardized values among different nations. Legislation is important for harmonization among both developed and developing countries for the health and economy of a nation.

Summary

The purpose of this literature review was to analyze the most current literature relating to mycotoxins, the *Produce Safety Rule,* and their implications for food safety, food security, economic progress, and human health. I grounded the literature review in the TEC approach to the OET. Chapter 3 will present my study's research design, sample, population, and analysis.

Chapter 3: Research Method

Introduction

Mycotoxins are toxic and carcinogenic secondary metabolites produced from fungi that colonize food crops and can occur at any stage of the food chain. The presence of mycotoxins in foods is of global concern because of the threat they pose to food safety, food security, agriculture, trade, and economics (Lee & Ryu, 2015; Umesha et al, 2017). Mycotoxicosis, the disease caused by mycotoxin, is a significant health hazard (Stoev, 2015; Winter & Pereg, 2019; Womack et al., 2014). Managing mycotoxins presents a major challenge to the agri-food industry (Baker et al, 2014). The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018.

McDavid et al. (2013) described the quantitative method of research as one that focuses on measurement and analyzes the relationships among variables. Similarly, Creswell (2009) explained that the quantitative research method looks at the general scope of the research and utilizes a deductive approach to understand the relationship among variables. The quantitative method involves collecting data through surveys or administrative records to provide measurement to understand the problem (Berman & Wang, 2012). The use of quantitative research requires a strong knowledge of the problem, the relationship between variables, and what is being measured. The justification for a quantitative research method versus a qualitative research method is based on the differences found in each study and the relevance of the nature of the study. Qualitative research is based on making assumptions from interpretation or theoretical frameworks to inform a study and give meaning to a social phenomenon (Creswell, 2013).

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018. I used secondary sampling and survey data on mycotoxins from the Illinois Department of Agriculture and the NOAA between the period of 2013 to 2018. The main objective of the study was to establish the significance, if any, of the relationship between compliance with the FSMA's *Produce Safety Rule* in managing mycotoxins in Illinois between 2013 and 2018 and risk factors associated with environmental conditions and toxin levels. In this chapter, I provide information on the research design and rationale, population, sampling method and sampling procedures, data collection procedures, data analysis plan, research questions and hypotheses, and ethical procedures.

Research Design and Rationale

I used a quantitative study design and drew upon secondary sampling and survey data between the period of 2013 to 2018 from the Illinois Department of Agriculture and weather sampling data from the NOAA. The use of secondary data was important for saving time and costs (see Berman & Wang, 2012; Frankfort-Nachmias et al., 2015; O'Sullivan et al., 2008). The variables in this study included the dependent variable

(DV), measuring compliance with the *Produce Safety Rule* at the level of three toxins (aflatoxin, fumonisin and vomitoxin), with the independent variables (IVs) (temperature, wind speed, and precipitation). I chose the research questions, research design, and the methodology based on the unit of analysis in the research (see Frankfort-Nachmias et al., 2015). I used the research questions to examine the relationship among the variables and chose the research design to help understand the outcomes and answers to the research questions (see Berman & Wang, 2012).

For this quantitative study, mycotoxin contamination in various crops has significant implications for feed and food safety. The management of postharvest practices to prevent contamination during storage by obtaining low temperature and humidity conditions to limit fungal growth is significant for the agri-food industry (Alshannaq & Yu, 2017; Bezerra da Rocha et al., 2014; De Saeger et al., 2016). Therefore, I designed the following research questions to explain the statistical significance, if any, relationship between the dependent variable and the independent variables. The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018.

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

$H_0$1: There is no relationship between environmental factors and toxin level.

H_a1: There is a relationship between environmental factors and toxin level.

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

$H_0$2: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

H_a2: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

$H_0$3: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.

H_a3: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

For this study, I used a quantitative research design with three IV’s (temperature, precipitation, and wind speed) with the DV toxin level of three toxins (aflatoxin, fumonisin, and vomitoxin). The main purpose of the study was to investigate which factors could put farmers’ ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018.

Methodology

Population

The Midwest is known for its agricultural farmlands. Illinois has 102 counties and is the largest producer of corn (USDA, 2016). I examined the weather data for the state of Illinois for a pattern of environmental conditions and relevance to the study between 2013 and 2018. The target population for this study was corn and wheat grown in Illinois under the regulatory oversight of the USDA between 2013 and 2018. The information in the study came from the secondary data based on mycotoxin surveys and sampling data and local climatological data from NOAA between 2013 and 2018. The significance level or alpha for this study is 0.05, and the statistical power is 95% or 0.95.

Sampling and Sampling Procedures

I based this quantitative study on secondary sampling and survey data that were available from the Illinois Department of Agriculture and the NOAA between the years 2013 and 2018. The aim of sampling is to select from the population and to generalize. The sample can be a representative sample. Representative samples allow for generalization (see Berman & Wang, 2012). Sampling is about targeting a population for a study. Before selecting a sample, it is important to know when the sample is needed, the selection, and the size of the sample (see Berman & Wang, 2012). I analyzed the secondary data in the study by utilizing IBM's Statistical Package for the Social Science (SPSS) software Version 26.

Procedures for Data Collection

Cereal grains are important agricultural commodities in Illinois. I chose the state based on the significant agricultural farmlands scattered over 102 counties. The mycotoxin survey data is available and accessible to the public on the Illinois Department of Agriculture and the NOAA websites. I received Walden University's Institutional Review Board (IRB) approval on April 8, 2020, to collect the secondary data. The Walden University IRB approval number is 04-08-20-0592764. To collect the secondary data, I accessed the government agencies' websites. The sampling data of the Illinois Department of Agriculture were accessible via that website. However, to receive the same sample data in an Excel format, I submitted a request to the Illinois Department of Agriculture's office. I received the sampling data for wheat and corn collected between 2013 and 2018 via email.

Data Analysis Plan

I analyzed the data using IBM's Statistical Package for the Social Science (SPSS) software Version 26.

Research Question One and First Hypothesis:

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

H_01: There is no relationship between environmental factors and toxin level.

H_A1: There is a relationship between environmental factors and toxin level.

Research Question Two and Second Hypothesis:

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

$H_{0}2$: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

$H_{A}2$: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

Research Question Three and Third Hypothesis:

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

$H_{0}3$: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.

$H_{A}3$: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

Operational Variables

Environmental conditions: Independent variables (IVs): Temperature, wind speed and precipitation.

Toxicity levels: Dependent variable (DV): Measuring compliance at the level of three toxins: Aflatoxin, Fumonisin and Vomitoxin.

To investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed and precipitation) in managing mycotoxins in Illinois between 2013 and 2018, I used the Pearson correlation and linear regression statistical tests. According to (Berman & Wang, 2012; Field, 2013) the Pearson correlation measures association or significance between two continuous variables but does not assume a causal relationship. Linear regression was used to test the significance of the relationship and or the association with the predictor variables (IV's) and the outcome variable (DV) Berman & Wang, 2012; Field, 2013).

Threats to Validity

Measurement validity means that the variables really measure what the researcher says they measure (McDavid et al., 2013). The validity of the measurement can be affected based on the validity of the conclusion after the hypothesis was tested (Frankfort-Nachmias et al., 2015). To establish validity, the existing instrument should be used to draw meaningful inferences from the score of the instrument (Creswell, 2009). The validity of the measures should quantify what the researcher purported and intended to measure (Berman & Wang, 2012; Creswell, 2009). Reliability has to do with whether a measurement result is repeatable, such that the same measurement instrument can repeat the same procedures. To ensure reliability is to measure and repeat the measure to achieve consistency (McDavid et al., 2013). Reliability refers to the extent to which a measuring instrument contains variable errors, meaning errors that appear inconsistent between observed measures with the same measurements and procedures (McDavid et al., 2013). Various factors, such as the research subject, observer difference in opinions, or the conditions under which the observer made the measurements, can cause the instrument of reliability to be poor, or data processing in which data was handled or biased (Weiner, 2007).

I collected the secondary data used for analysis in this study from the Illinois Department of Agriculture and the NOAA. Therefore, assessing the reliability and validity of the instrument was subject to limitation. The Illinois Department of Agriculture and the NOAA are both government agencies. As the sole researcher in this study, I do not share any personal bias and did not participate in the data collection process. However, I deemed the data collected by these agencies, the Illinois Department of Agriculture, and the NOAA, to be accurate.

Ethical Procedures

I took ethical procedures as set out by the Institutional Review Board (IRB) into consideration. I received Walden's University Institutional Review Board (IRB) approval on April 8, 2020, to collect the secondary data. The Walden University IRB approval number is 04-08-20-0592764. To collect the secondary data, I accessed the government agencies websites of the NOAA and Illinois Department of Agriculture. Since the data that I utilized in this study are available to the public on the Illinois Department of Agriculture and the NOAA websites, the study did not use participants and thus did not violate any participants' rights. However, to receive the sampling data collected between 2013 and 2018 in an Excel format, I submitted a request to the Illinois Department of Agriculture's office. The Illinois Department of Agriculture had previously collected the data, which included county, county code by number, date of inspection, and results of mycotoxin detection levels. I obtained consent from the IRB to use data from the identified public agencies.

Summary

In this chapter, I used a quantitative study to investigate how the IV's (temperature, precipitation, and wind speed) and DV toxin levels (aflatoxin, fumonisin, and wind speed) could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk in managing mycotoxins in Illinois between 2013 and 2018. This quantitative study utilized secondary data obtained from the Illinois Department of Agriculture and the NOAA from 2013 to 2018, which was analyzed using Pearson correlation and linear regression. I also present in the chapter the research design, methodology, population, sample and sampling procedures, data for collection process, data analysis plan, threats to validity, and the ethical procedures. In Chapter 4, I will discuss the results of the study.

Chapter 4: Results

Introduction

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018 for regulatory oversight of the USDA.

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

$H_0$1: There is no relationship between environmental factors and toxin level.

H_a1: There is a relationship between environmental factors and toxin level.

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

$H_0$2: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

H_a2: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

H_03: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.

H_a3: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

This chapter includes discussions of the data collection process, descriptive statistics, sample data, data analysis for each research question and hypothesis, testing linear assumptions for regression, the Kolmogorov-Smirnov test for normality, multicollinearity, and a summary of the findings used in the study.

Data Collection

I received Walden University's Institutional Review Board (IRB) approval on April 8, 2020, to collect the secondary data. The Walden University IRB approval number is 04-08-20-0592764. To collect the secondary data, I accessed the government websites of the NOAA and Illinois Department of Agriculture. The sampling data of the Illinois Department of Agriculture were accessible via that website. However, to receive the data in an Excel format, I submitted a request to the Illinois Department of Agriculture's office. I received the sampling data collected between 2013 and 2018 for wheat and corn.

I show the results of the research questions and hypotheses with figures and tables. I performed the statistical tests using IBM Statistical Package Software for the Social Sciences (SPSS) Version 26 and based the tests on a 0.05 significance level ($p < 0.05$) and a statistical power of 0.95 or 95%. The figures and tables below present the results of each research question and hypothesis in this study. I carefully examined and matched each data set with the original raw data files. I combined all time points within each corn, wheat, and temperature file and reformatted and added date variables. I then merged the toxin and weather data to correspond with each other and recorded the variables into numerical values. I converted the PDF files to Excel files and then the Excel files to IBM SPSS Version 26, first double checking the merged files to ensure the integrity of the data before importing them into IBM SPSS Version 26. To answer the research questions and hypotheses, I used correlation and linear regression tests for all the study variables.

Results of the Study

Descriptive Statistics

The tables below show the descriptive statistics for all the study variables. The reported means of the general study variables of the whole sample are shown in Table 1. Aflatoxin (AFL) is measured in parts per billion (ppb) (*n* = 437). For fumonisin (FUM) (*n* =813) and vomitoxin (VOM) (*n* = 987) and are both measured in parts per million (ppm). Table 2 shown for corn, AFL and FUM remain the same and VOM (*n* = 52). Table 3 shown for the wheat, VOM (*n* = 935). Pearson correlation and linear regression were used to investigate the statistical relationship between the dependent variable (DV) toxin levels (AFL, FUM and VOM) and the independent variables (IV's) (temperature, precipitation, and wind speed). See Table 1, Table 2, and Table 3.

Table 1

Descriptive for Study Variables for Whole Sample

Variable	*N*	Min	Max	Mean	Std. Dev	Skew		Kurtosis	
						Stat	Std. Error	Stat	Std. Error
AFL (ppb)	437	0.6	367	6.29	22.17	11.33	0.12	165.62	0.23
FUM (ppm)	813	0.25	36.3	3.04	3.34	3.20	0.09	17.79	0.17
VOM (ppm)	987	0.29	46.5	4.02	4.34	3.09	0.08	16.72	0.16
Temp	4020	42	95	76.29	10.28	-0.73	0.04	0.34	0.08
Precip	3831	0	29	0.98	4.75	5.76	0.04	31.45	0.08
Wind	4155	1.7	22.1	9.23	3.71	0.68	0.04	0.19	0.08

Table 2

Descriptive for Study Variables for Corn Only

Variable	*N*	Min	Max	Mean	Std. Dev	Skew		Kurtosis	
						Stat	Std. Error	Stat	Std. Error
AFL (ppb)	437	0.6	367	6.29	22.17	11.33	0.12	165.62	0.23
FUM (ppm)	813	0.25	36.3	3.04	3.34	3.20	0.09	17.79	0.17
VOM (ppm)	52	0.5	3.7	1.39	0.87	0.92	0.33	0.14	0.65
Temp	2234	42	95	72.04	10.87	-0.35	0.05	-0.27	0.10
Precip	2151	0	29	1.52	6.27	4.20	0.05	15.67	0.11
Wind	2320	1.8	22.1	9.30	3.52	0.89	0.05	1.45	0.10

Table 3

Descriptive for Study Variables for Wheat Only

Variable	*N*	Min	Max	Mean	Std. Dev	Skew		Kurtosis	
						Stat	Std. Error	Stat	Std. Error
AFL (ppb)	0								
FUM (ppm)	0								
VOM (ppm)	935	0.29	46.5	4.17	4.41	3.03	0.08	16.14	0.16
Temp	1786	68	95	81.59	6.29	-0.05	0.06	-1.03	0.12
Precip	1680	0	2	0.28	0.43	2.28	0.06	6.02	0.12
Wind	1835	1.7	15.8	9.14	3.93	0.51	0.06	-0.92	0.11

Assumption of Linear Relationship Between Variables

After carefully examining the datasets and merging each data file, I used Pearson correlation and linear regression tests to analyze the research questions and hypotheses. The Pearson correlation depicts the measure of association between the continuous variables to test the significance and strength of the relationship through linear regression (Berman & Wang, 2012). The linear regression was used to test for the linear relationship assumption between the study variables (temperature, precipitation, and wind speed) and toxin levels of AFL, FUM and VOM.

I used linear regression to test for the linear relationship between maximum temperature, precipitation shown here as the total liquid content (TLC), and wind speed and AFL, FUM, and VOM. The toxin levels of AFL, FUM, and VOM show there was not strong evidence for a linear relationship between maximum temperature, TLC, and wind speed. The examination of the scatterplots revealed there is not strong evidence for a linear relationship between toxin level AFL, FUM and VOM and any of the environmental factors (temperature, TLC, and wind speed). (see Appendix B), (see Appendix C) and (see Appendix D). The plots are close to zero, which means that there is compliance for the *Produce Safety Rule*.

Assumption of Normality

I used a Kolmogorov-Smirnov test for all continuous variables to test for the normality assumption of linear regression. I conducted a Kolmogorov-Smirnov goodness of fit test for all continuous variables to test for the normality assumption of linear regression. The two tests used for normality are the Kolmogorov-Smirnov test with more than 50 observations and the Shapiro-Wilks test for samples with up to 50 observations (Berman & Wang, 2012). A Kolmogorov-Smirnov test is a nonparametric test applied for making the comparison with a normal distribution (Green & Salkind, 2014). A significant test indicates that the distribution is meaningfully different from a normal distribution (Green & Salkind, 2014). A combined visual and statistical test is always used to determine normality of variables. A nonsignificant test ($p>.05$) tells me that the distribution of the sample is not significantly different from a normal distribution (Field, 2013).

I used the Kolmogorov-Smirnov test for normality (see Figure F1) and histograms (see Appendix E. The Kolmogorov-Smirnov statistic takes on a value of 0.44 for AFL. The p value is .001, $p < .001$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypothesis that the variable AFL is not normally distributed. For FUM, the Kolmogorov-Smirnov statistic takes on a value of 0.20. The p value is .001, $p < .001$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypothesis that the variable FUM is not normally distributed. For VOM, the Kolmogorov-Smirnov statistic takes on a value of 0.20. The p value is .001, $p < .001$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypothesis that the variable VOM is not normally distributed.

For temperature, the Kolmogorov-Smirnov statistic takes on a value of 0.10. The p value is .001, $p < .001$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypothesis that the variable temperature is not normally distributed. For precipitation, the Kolmogorov-Smirnov statistic takes on a value of 0.43. The p value is

.001, $p < .001$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypothesis that the variable precipitation is not normally distributed. For wind, the Kolmogorov-Smirnov statistic takes on a value of 0.08. The p value is .001, $p < .01$, which is less than 0.05. Therefore, there is significant evidence to reject the null hypotheses that the variable aflatoxin is not normally distributed.

Multicollinearity

To test for the assumption of no multicollinearity for linear regression, I examined tolerance and the variance inflation factor (VIF). The VIF indicates whether a predictor variable has a strong linear relationship with the other predictors. The tolerance statistic is reciprocal of the variance inflation factor (1/VIF). The assumption of no multicollinearity was met for the VIF.

First Hypothesis

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

$H_0 1$: There is no relationship between environmental factors and toxin level.

$H_a 1$: There is a relationship between environmental factors and toxin level.

For research question one, I conducted a Pearson correlation between all three environmental factors (temperature, precipitation, and wind) and all three toxins (AFL, FUM, and VOM). There was a significant negative relationship between FUM and maximum temperature, such that higher maximum temperatures predicted lower levels of FUM ($r = -.11$, $p < .01$). There was a marginal negative relationship between FUM and wind, such that higher levels of wind predicted lower levels of FUM ($r = -.07$, $p = .05$).

There was also a negative relationship between VOM and precipitation, such that more precipitation predicted lower levels of vomitoxin ($r = -.07$, $p < .05$). The results in Table 4 show that none of the other toxins were related to the environmental factors. As such, the null hypothesis is rejected; there is no significant relationship between environmental factors and toxin level.

Table 4

Pearson Correlation Analysis Results

Variable		AFL	FUM	VOM	Temp	Precip	Wind
AFL	Pearson Correlation	1	0.08	.[a]	0.02	0	0.06
	Sig		0.23	.	0.75	0.96	0.25
	N	437	228	1	423	408	426
FUM	Pearson Correlation	0.08	1	-0.54	$-.11^{**}$	0	-0.07
	Sig	0.23		0.34	0	0.96	0.05
	N	228	813	5	771	765	797
VOM	Pearson Correlation	.[a]	-0.54	1	0.01	$-.07^{*}$	-0.01
	Sig	.	0.34		0.76	0.04	0.7
	N	1	5	987	964	864	987
Temp	Pearson Correlation	0.02	$-.11^{**}$	0.01	1	0.03	$-.17^{**}$
	Sig	0.75	0	0.76		0.08	0
	N	423	771	964	4020	3741	4020
Precip	Pearson Correlation	0	0	$-.07^{*}$	0.03	1	$-.12^{**}$
	Sig	0.96	0.96	0.04	0.08		0
	N	408	765	864	3741	3831	3831
Wind	Pearson Correlation	0.06	-0.07	-0.01	$-.17^{**}$	$-.12^{**}$	1
	Sig	0.25	0.05	0.7	0	0	
	N	426	797	987	4020	3831	4155

Second Hypothesis

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

> H_02: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.
>
> H_A2: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

For research question two, I conducted a linear regression to predict AFL, FUM, and VOM levels from all three environmental factors (temperature, precipitation, and wind speed). For AFL, the results in Table 5 show that the overall model was not significant ($F(3, 402) = .60$, $p > .05$). The model accounted for less than 1% of the variance in AFL ($Adj.\ R^2 < .001$). There were no main effects of any of the three environmental factors. As such the null hypothesis is accepted; there is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

Table 5

Parameter Estimates from Linear Regression Predicting AFL from Environmental Factors

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	-4.88	8.16	-0.60	0.55		
Temp	0.12	0.09	1.31	0.19	0.96	1.05
Precip	-0.01	0.72	-0.01	0.99	1.00	1.00
Wind	0.19	0.33	0.57	0.57	0.96	1.04

For FUM level, I conducted a linear regression predicting from all three environmental factors (temperature, precipitation, and wind speed). The overall model was significant ($F(3, 740) = 4.57$, $p < .01$). The model accounted for 1% of the variance in FUM (*Adj.* $R^2 = .01$). There was a main effect of max temperature, such that a one unit increase in max temperature predicted a .04 decrease in FUM levels, while holding precipitation and wind speed constant ($B = -.04$, $SE = .01$, $t = -3.49$, $p = .001$). See Table 6.

Table 6

Parameter Estimates from Linear Regression Predicting FUM from Environmental Factors

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	6.44	0.92	7.02	0.000		
Temp	-0.04	0.01	-3.49	0.001	0.98	1.03
Precip	0.00	0.03	-0.15	0.88	0.96	1.05
Wind	-0.06	0.04	-1.67	0.10	0.95	1.06

To predict VOM level from all three environmental factors (temperature, precipitation, and wind speed). The overall model was not significant ($F(3, 847) = 1.37$, $p > .05$). The model accounted for less than 1% of the variance in VOM (*Adj.* $R^2 = .001$).

There was a marginally significant main effect of precipitation, such that a one unit increase in max temperature predicted a directional .08 decrease in VOM levels, while holding temperature and wind speed constant (*B* = -.08, *SE* = .04, *t* = -2.01, *p* = .05). See Table 7.

Table 7

Parameter Estimates from Linear Regression Predicting VOM from Environmental Factors

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	4.06	2.14	1.90	0.06		
Temp	0.00	0.02	0.05	0.96	0.83	1.20
Precip	-0.08	0.04	-2.01	0.05	0.98	1.02
Wind	-0.01	0.04	-0.21	0.83	0.83	1.21

Third Hypothesis

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

$H_0 3$: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.

$H_A 3$: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

For research question three, I performed a linear regression predicting AFL, FUM, and VOM levels from all three environmental factors (temperature, precipitation, and wind speed) and their interaction terms. For AFL, the overall model was not significant ($F(6, 399) = .51$, $p > .05$). The model accounted for less than 1% of the variance in AFL (*Adj.* $R^2 < .001$). There were no main effects or interactions of any of the three environmental factors (see Table 8). As such, the null hypothesis is accepted.

Table 8

Parameter Estimates from Linear Regression Predicting AFL from Environmental Factors and Interactions

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	8.15	23.12	0.35	0.73		
Temp	-0.05	0.31	-0.15	0.88	0.09	11.58
Precip	15.99	26.19	0.61	0.54	0.00	1330.21
Wind	-1.36	2.34	-0.58	0.56	0.02	52.01
Temp*Precip	-0.28	0.32	-0.86	0.39	0.00	1077.15
Wind*Precip	0.41	1.08	0.38	0.71	0.00	234.02
Temp*Wind	0.02	0.03	0.65	0.52	0.02	53.59

For FUM level, I conducted a linear regression from all three environmental factors (temperature, precipitation, and wind speed) and their interactions. The overall model was significant (*F*(6, 737) = 2.43, *p* < .05). The model accounted for 1% of the variance in FUM (*Adj.* R^2 = .01). There was a main effect of max temperature, such that a one unit increase in max temperature predicted a .04 decrease in FUM levels, while holding precipitation and wind speed constant (*B* = -.04, *SE* = .01, *t* = -3.49, *p* = .001). See Table 9.

Table 9

Parameter Estimates from Linear Regression Predicting FUM from Environmental Factors and Interactions

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	4.40	2.51	1.75	0.08		
Temp	-0.01	0.03	-0.31	0.76	0.10	9.80
Precip	0.27	0.75	0.36	0.72	0.00	898.13
Wind	0.14	0.24	0.59	0.56	0.02	43.18
Temp*Precip	0.00	0.01	-0.36	0.72	0.00	724.54
Wind*Precip	-0.01	0.02	-0.37	0.71	0.06	17.58
Temp*Wind	0.00	0.00	-0.86	0.39	0.02	46.70

I conducted a linear regression predicting VOM level from all three environmental factors (temperature, precipitation, and wind speed) and their interactions. The overall model was not significant (*F*(6, 844) = 2.17, $p < .05$). The model accounted for 1% of the variance in VOM (*Adj.* $R^2 = .01$). There was a significant main effect of wind, such that a one unit increase in wind predicted a 1.81 increase in VOM levels, while holding temperature and wind speed constant (*B* = 1.81, *SE* = .63, *t* = 2.89, $p < .01$). See Table 10.

Table 10

Parameter Estimates from Linear Regression Predicting VOM from Environmental Factors and Interactions

	Unstandardized B	Std. Error	t	p	Tolerance	VIF
Constant	4.40	2.51	1.75	0.08		
Temp	-0.01	0.03	-0.31	0.76	0.10	9.80
Precip	0.27	0.75	0.36	0.72	0.00	898.13
Wind	0.14	0.24	0.59	0.56	0.02	43.18
Temp*Precip	0.00	0.01	-0.36	0.72	0.00	724.54
Wind*Precip	-0.01	0.02	-0.37	0.71	0.06	17.58
Temp*Wind	0.00	0.00	-0.86	0.39	0.02	46.70

There was also an interaction between temperature and wind (*B* = -.02, *SE* = .01, *t* = 2.92, $p < .01$). For that one standard deviation above average on temperature, there was a significant effect of wind, such that a one increase in wind predicted a significant decrease in VOM levels by .25 (*B* = -.26, SE = .09, *p* = .01). See Figure G1). For that one standard deviation below average on temperature, there was a significant effect of wind, such that a one increase in wind predicted a significant increase in VOM levels by .24 (*B* = .24, SE = .10, $p < .05$). For that one standard deviation with an average level of temperature, there was no effect of wind on VOM levels (*B* = -.01, SE = .04, $p > .05$).

Summary

I tested the hypotheses using Pearson correlation and linear regression. The independent variables (IVs) were (temperature, precipitation, and wind speed) and dependent variable (DV) was the toxin level of (AFL, FUM and VOM). All variables showed some evidence of not being normally distributed with the Kolmogorov-Smirnov test. For the assumption of no multicollinearity, I examined the tolerance and the VIF for linear regression. All tolerance scores were above 0.1, and all VIF scores were below 10. Therefore, there was no multicollinearity between the variables in the linear regression results for collinearity diagnostics for tolerance. The assumption was met for VIF for linear regression.

For the first hypothesis, I conducted a Pearson correlation between all three environmental factors (temperature, precipitation, wind) and all three toxins (AFL, FUM, and VOM) that showed a marginal negative relationship between FUM and wind, such that higher levels of wind predicted lower levels of FUM. There was also a negative relationship between VOM and precipitation, such that more precipitation predicted lower levels of VOM. For the second hypothesis, I conducted a linear regression to predict AFL level from all three environmental factors (temperature, precipitation, and wind speed). None of the other toxins were related to environmental factors. For the third hypothesis, I conducted a linear regression predicting AFL, FUM, and VOM levels from all three environmental factors (temperature, precipitation, and wind speed) and their interaction terms. For AFL, the overall model was not significant ($F(6, 399) = .51$, $p > .05$). The model accounted for less than 1% of the variance in AFL ($Adj.\ R^2 < .001$).

There were no main effects or interactions of any of the three environmental factors. In Chapter 5, I will discuss the interpretation of the findings, limitations of the study, recommendations for future research, and implications for positive social change.

Chapter 5: Discussions, Conclusions, and Recommendations

Introduction

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed, and precipitation) in managing mycotoxins in Illinois between 2013 and 2018 for regulatory oversight of the USDA. I posed three research questions for this dissertation:

RQ1: Is there a relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level?

$H_0$1: There is no relationship between environmental factors and toxin level.

H_a1: There is a relationship between environmental factors and toxin level.

RQ2: Is there a relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors?

$H_0$2: There is no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

H_a2: There is a relationship between at least one of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

RQ3: Do the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors?

$H_0$3: There is no moderating effect of environmental factors on the relationship between environmental factors and compliance.

H_a3: There is a moderating effect of at least one environmental factor on the relationship between another environmental factor and compliance.

For this study, I used secondary sampling data to answer the research questions. The Illinois Department of Agriculture and the NOAA collected the data between 2013 and 2018. The data were comprised of wheat and corn sampling data and environmental conditions that included wind, temperature, and precipitation. I conducted linear regressions and Pearson correlation in my analyses of the statistical relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level (AFL, FUM, and VOM).

Interpretations of the Findings

RQ1

I designed this research question to investigate the relationship between environmental factors (temperature, precipitation, and wind speed) and toxin level. I conducted a Pearson correlation between all three environmental factors (temperature, precipitation, and wind) and all three toxins (AFL, FUM, and VOM). There was a significant negative relationship between FUM and maximum temperature, such that higher maximum temperatures predicted lower levels of FUM ($r = -.11$, $p < .01$). There was a marginal negative relationship between FUM and wind, such that higher levels of wind predicted lower levels of FUM ($r = -.07$, $p = .05$). There was also a negative relationship between VOM and precipitation, such that more precipitation predicted lower levels of VOM ($r = -.07$, $p < .05$). The results showed that none of the toxins were related to any of the other environmental factors. As such, the interpretation of the findings revealed there was a marginal negative significant relationship between environmental factors and toxin level.

RQ2

I designed this research question to investigate the relationship between each of the three environmental factors (temperature, precipitation, and wind speed) and toxin level (AFL, FUM, and VOM) while controlling for the effects of each of the other environmental factors. I conducted a linear regression to predict AFL level from all three environmental factors (temperature, precipitation, and wind speed). None of the other toxins were related to environmental factors. I conducted a linear regression to predict AFL, FUM, and VOM levels from all three environmental factors (temperature, precipitation, and wind speed). For AFL, the overall model was not significant $F(3, 402) = .60$, $p > .05$). The model accounted for less than 1% of the variance in AFL ($Adj.\ R^2 < .001$). There were no main effects of any of the three environmental factors. As such, the interpretation of the findings showed there was no relationship between any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level while controlling for the effects of each of the other environmental factors.

RQ3

I designed this research question to investigate if the effects of environmental factors (temperature, precipitation, and wind speed) on compliance depend on the effects of the other environmental factors. I used a linear regression to predict AFL, FUM, and

VOM levels from all three environmental factors (temperature, precipitation, and wind speed) and their interaction terms. For AFL, the overall model was not significant ($F(6, 399) = .51$, $p > .05$). The model accounted for less than 1% of the variance in AFL (*Adj.* $R^2 < .001$). There were no main effects or interactions of any of the three environmental factors.

Limitations of the Study

There were many limitations of this study. The lack of sufficient mycotoxin data in the United States were not available or accessible to make comparisons. The use of secondary data has limitations and only the variables in the data were used in the analysis. While there was a large sample size on toxin levels, the dependent variable (DV) and environmental conditions, the independent variables (IV's) temperature, precipitation, and wind speed, to make assumptions, the data was limited to the secondary sampling data collected from the Illinois Department of Agriculture and NOAA. The methodology used correlation which did not necessarily established a causal relationship among the variables used in this study but were used to make inferences and generalizations.

Illinois is one of the only states that produces mycotoxin survey data on grain crops every year (Mitchell et al., 2017). Currently there is a lack of publicly available state by state data (Mitchell et al., 2017). Also, another limitation to the study, was the use of secondary mycotoxin data which may lack reliability and accuracy. The data were collected by the Illinois Department of Agriculture and the NOAA for the state of Illinois and not me. Toxin levels may vary and may not adequately describe the relationship, or lack thereof, with the independent variables. The data was limited to 2013 to 2018 and did not contain any information on the *Produce Safety Rule*, which focuses on growing, harvesting, packing, and holding of fresh fruits and vegetables. The *Produce Safety Rule* became effective in January 2016 (Adalja & Lichtenberg, 2018).

Recommendations for Future Research

There are several recommendations that can be made for future research based on the limitations of this study. Mycotoxins produced by fungi can affect food and agricultural crops, which can cause economic burdens for farmers. There was limited research on the effects of environmental factors, such as temperature, precipitation, and wind speed, and the *Produce Safety Rule*. Mitchell et al. (2017) estimated that aflatoxin contamination could cause losses to the corn industry ranging from 52.1 million dollars to 1.68 billion dollars in the United States annually, taking into consideration losses caused by mycotoxins that are above the FDA recommended action levels and challenges of climatic change.

To date there is limited public data on mycotoxins in the United States. There is limited public information on mycotoxins and the *Produce Safety Rule*. In addition to the state of Illinois, other states could develop similar database or a national database on mycotoxins and make it accessible to the public. While there is a national survey on fruits and vegetables, there is none on grain crops and the *Produce Safety Rule* could be expanded to grain crops. I would also recommend a national strategy for food safety management and make public awareness and information on mycotoxins.

Social Change Implications

I designed this study to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed and precipitation) and toxin level (AFL, FUM, and VOM) in managing mycotoxins in Illinois between 2013 and 2018. The significance of the study was to look at the policy implication of the *Produce Safety Rule* for food safety. Food safety regulations are always changing for policymakers, food industry and consumers. This study contributes to the public awareness on mycotoxins and the implications for public health and policy making. The study contributes to positive social change that may bolster food safety regulations on mycotoxins and therefore, protecting public health.

Conclusion

The purpose of this quantitative study was to investigate which factors could put farmers' ability to remain in compliance with the *Produce Safety Rule* at risk of environmental conditions (temperature, wind speed and precipitation) in managing mycotoxins in Illinois between 2013 and 2018. I posed three research questions to explore this topic. I collected secondary sampling data from the Illinois Department of Agriculture and NOAA. Linear regressions and Pearson correlations were used to analyze the statistical relationship between IV's (temperature, precipitation, and wind speed) and the DV toxin level (AFL, FUM, and VOM). The results of the findings showed there were no main effects of any of the three environmental factors (temperature, precipitation, and wind speed) and toxin level. The results also show there was a marginal negative significant relationship between environmental factors and toxin level.

The results were not consistent with the findings in the literature. The findings in the literature indicate that an action level of mycotoxin that is above the FDA regulations is problematic to public health. The transaction cost economics theory was used. Food safety management is a regulating environment that needs various actors at the food chain.

References

Abebe, G., Chalak, A., & Abiad, M. (2017). The effect of governance mechanisms on food safety in the supply chain: Evidence from the Lebanese dairy sector. *Journal of the Science of Food and Agriculture, 97*(9), 2908-2918. doi:10.1002/jsfa.8128

Abrunhosa, L., Moraless, H., Soares, C., Calado, T., Vila-Chã, A. S., Pereira, M., & Venâncio, A. (2016). A review of mycotoxins in food and feed products in Portugal and estimation of probable daily intakes. *Critical Reviews in Food Science and Nutrition*, *56*(2), 249-65. doi:10.1080/10408398.2012.720619

Adalja, A., & Lichtenberg, E. (2018). Produce growers' cost of complying with the food safety modernization act. *Food Policy*, *74*, 23-38. doi:10.1016/j.foodpol.2017.10.005

Adetuniji, M. C., Atanda, O. O., Ezekiel, C. N., Dipeolu, A. O., Uzochukwu, S. V. A., Oyedepo, J., & Chilaka, C. A. (2014). Distribution of mycotoxins and risk assessment of maize consumers in five agro-ecological zones Nigeria. *European Food Research and Technology*, *239*(2), 287-296. doi.org/10.1007/s00217-014-2221-0

Adeyeye, S. A. O., & Yildiz, F. (Eds.) (2016). Fungal mycotoxins in foods: A review. *Cogent Food and Agriculture*, *2*(1). doi:10.1080/23311932.2016.1213127

Adinolfi, F., Di Pasquale, J., & Capitanio, F. (2016). Economic issues on food safety. *Italian Journal of Food Safety*, *5*(1), 5580. doi:10.4081/ijfs.2016.5580

Afsah-Hejri, L., Jinap, S., Hajeb, P., Radu, S., & Shakibazadeh, S. (2013). A review on mycotoxins in food and feed: Malaysia case study. *Comprehensive Reviews in Food Science and Food Safety*, *12*(6), 629-651. doi:10.1111/1541-4337.12029

Agyei-Baffour, P., Sekyere, K. B., & Addy, E. A. (2013). Policy on hazard analysis and critical control point (HACCP) and adherence to food preparation guidelines: a cross sectional survey of stakeholders in food service in Kumasi, Ghana. *BMC research notes*, *6*, 442. https://doi.org/10.1186/1756-0500-6-442

Agyekum, M., & Jolly, C. M. (2017). Peanut trade and aflatoxin standards in Europe: Economic effects on trading countries. *Journal of Policy Modeling*, *39*(1),114-128. doi.org/10.1016/j.jpolmod.2016.08.004

Aiko, V., & Mehta, A. (2015). Occurrence, detection and detoxification of mycotoxins. *Journal of Biosciences*, *40*(5), 943-954. https://www.ncbi.nlm.nih.gov/pubmed/26648039

Alberts, J. F., Lilly, M., Rheeder, J. P., Burger, H. M., Shephard, G. S., & Gelderblom, W. C. A. (2017). Technological and community-based methods to reduce mycotoxin exposure. *73*, 101-109. doi.org/10.1016/j.foodcont.2016.05.029

Aldars-García, L., Ramos, A. J., Sanchis, V., & Marín, S. (2016). Modeling postharvest mycotoxins in foods: Recent research. *Current Opinion in Food Science*, *11*, 46-50. https://doi.org/10.1016/j.cofs.2016.09.005

Alim, M., Iqbal, S. Z., Mehmood, Z., Asi, M. R., Zikar, H., Chanda, H., & Malik, N. (2018). Survey of mycotoxins in retail market cereals, derived products and evaluation of their dietary intake. *Food Control*, *84*, 471-477. doi.org/10.1016/j.foodcont.2017.08.034

Alimi, B., & Workneh, T. (2016). Consumer awareness and willingness to pay for safety of street foods in developing countries: A review. *International Journal of Consumer Studies, 40*(2), 242-248. doi:10.1111/ijcs.12248

Almond, P., & Esbester, M. (2018). Regulatory inspection and the changing legitimacy of health and safety. *Regulation & Governance*, *12*(1), 46-63. doi:10.1111/rego.12155

Alshannaq, A., & Yu, J.-H. (2017). Occurrence, toxicity, and analysis of major mycotoxins in food. *International Journal of Environmental Research and Public Health*, *14*(6), 632. doi.org/10.3390/ijerph14060632

American Public Health Association (APHA). (2016). *What is public health?* https://www.apha.org/membership/network-and-collaborate/what-is-public-health

Anelich, L. & Motarjemi, Y. (Eds.). (2016). Foodborne diseases: Prevalence of foodborne diseases in Africa. *Encyclopedia of Food Safety*, *1*, 262-275. doi.org/10.1016/B978-0-12-378612-8.00072-X

Antonissen G, Martel A, Pasmans F, Ducatelle R, Verbrugghe E, Vandenbroucke V, Li S, Haesebrouck F, Van Immerseel F, Croubels S (2014). The impact of Fusarium mycotoxins on human and animal host susceptibility to infectious diseases. *Toxins*, *6*(2), 430-52. doi: 10.3390/toxins6020430

Anukul, N., Vangnai, K., & Mahakarnchanakul, W. (2013). Significance of regulation limits in mycotoxin contamination in Asia and risk management programs at the national level. *Journal of Food and Drug Analysis*, *21*(3), 227-241. doi.org/0.1016/j.jfda.2013.07.009

Assunção, R., Vasco, E., Nunes, B., Loureiro, S., Martins, C., & Alvito, P. (2015). Single-compound and cumulative risk assessment of mycotoxins present in breakfast cereals consumed by children from Lisbon region, Portugal. *Food and Chemical Toxicology, 86*, 274–281. doi:10.1016/j.fct.2015.10.017

Australian Institute of Food Safety. (2016). *What is food safety?* https://www.foodsafety.com.au/resources/articles/what-is-food-safety

Baker, R. C., Ford, R. M., Helander, M. E., Marecki, J., Natarajan, R., & Ray, B. (2014). Framework for managing mycotoxin risks in the food industry. *Journal of Food Protection*, *77*(12), 2181-2188. https://search.proquest.com/docview/1627751779?accountid=14696

Bavorová, M., Hirschauer, N., & Martino, G. (2014). Food safety and network governance structure of the agri-food system. *European Journal of Law and Economics*, *37*(1), 1-11. doi:10.1007/s10657-013-9430-z

Berman, E. M., & Wang, X. (2012). *Essential statistics for public managers and policy analysts.* (3rd ed.). Sage

Bezerra da Rocha, M. E., da Chagas Oliveira Freire, F., Maia, F. E. F., Guedes, M. I. F., & Davide Rondina, D. (2014). Mycotoxins and their effects on human and animal health. *Food Control*, *36*(1), 159-165. doi.org/10.1016/j.foodcont.2013.08.021

Boutrif, E. (2014). Institutions involved in food safety: Food and agriculture organization of the United Nations. In E. Boutrif & Y. Motarjemi (Eds.), *Encyclopedia of food safety* (Vol. 4, pp. 354-358). doi.org/10.1016/B978-0-12-378612-8.00007-X

Bowman, S., Unwin, N., Critchley, J., Capewell, S., Husseini, A., Maziak, W., & Ahmad, B. (2012). Use of evidence to support healthy public policy: A policy effectiveness-feasibility loop. *World Health Organization Bulletin of the World Health Organization*, *90*(11), 847-53. https://search.proquest.com/docview/1243040448?accountid=14696

Bryden, W. L. & Nriagu, J.O. (Eds.). (2011). Mycotoxins: Natural food chain contaminants and human health. *Encyclopedia of Environmental Health*, 898-905. doi.org/10.1016/B978-0-444-52272-6.00701-7

Bureau, J.-C., & Swinnen, J. (2018). EU policies and global food security, *Global Food Security*, *16*, 106-115. doi.org/10.1016/j.gfs.2017.12.001

Canadian Food Inspection Agency (n.d.). Food safety action plan report 2013-2014 targeted surveys-chemistry. Aflatoxins in corn products, nuts and nut butters, dried fruits, cocoa powder, breads, breakfast and infant cereals and spice powders.

Capriotti, A. L, Caruso, G., Cavallere, C., Foglia, P., Samperi, R., & Lagana, A. (2012). Multiclass mycotoxin analysis in food, environmental and biological matrices with chromatography/mass spectrometry. *Mass Spectrometry Reviews*, *31*(4), 466-503. doi:10.1002/mas.20351

Carneiro, P., & Kaneene, J. B. (2017). Food inspection services: A comparison of programs in the US and Brazil. *Food Control*, *80*, 314-318. doi:10.1016/j.foodcont.2017.05.017

Cendoya, E., Chiotta, M. L., Zachetti, V., Chulze, S. N., & Ramirez, M. L. (2018). Fumonisins and fumonisin-producing fusarium occurrence in wheat and wheat by products: A review. *Journal of Cereal Science*, *80*, 158-166. doi.org/10.1016/j.jcs.2018.02.010

Centers for Disease Control and Prevention. (n.d.). *Lesson 1 understanding the epidemiological triangle through infectious disease working the epidemiological triangle.* https://www.cdc.gov/bam/teachers/documents/epi_1_triangle.pdf

Centers for Disease Control and Prevention (2001). Outbreaks of gastrointestinal illness of unknown etiology associated with eating burritos -- United States, October 1997-October 1998. March 19, 1999 *MMWR Weekly 48*(10): 210-213. https://www.cdc.gov/mmwr/preview/mmwrhtml/00056731.htm

Centers for Disease Control and Prevention. (2012). *Principles of epidemiology in public health practices, third edition an introduction to applied epidemiology and biostatistics: Lesson 1: Introduction to epidemiology*. https://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson1/section8.html

Centers for Disease Control and Prevention. (2015). *Fungal diseases*. https://www.cdc.gov/fungal/

Centers for Disease Control and Prevention. (2017a). *Foodborne diseases centers for outbreak response enhancement.* https://www.cdc.gov/foodcore/

Center for Disease Control and Prevention. (2017b). *Foodborne illness and germs*. https://www.cdc.gov/foodsafety/foodborne-germs.html

Center for Food Safety. (2018). *Consumer zone: Food contaminants.* https://www.cfs.gov.hk/english/consumer_zone/foodsafety_contaminants.html

Cerón-Bustamante, M., Ward T. J., Kelly, A., Vaughan, M. M., McCormick, S. P., Cowger, C., Leyva-Mir, S. G., Villaseñor-Mir, H. E., Ayala-Escobar, V., & Nava-Díaz, C. (2018). Regional differences in the composition of Fusarium Head Blight pathogens and mycotoxins associated with wheat in Mexico. *International Journal of Food Microbiology*, *273*, 11-19. doi.org/10.1016/j.ijfoodmicro.2018.03.003

Cheli, F., Campagnoli, A., & Dell’Orto, V. (2013). Fungal populations and mycotoxins in silages: From occurrence to analysis. *Animal Feed Science and Technology*, *183,* 1-16. doi:10.1016/j.anifeedsci.2013.01.013

Cheli, F., Pinotti, L., Rossi, L. & Dell'Orto, V. (2013). Effect of milling procedures on mycotoxin distribution in wheat fractions: A review. *Food Science and Technology*, *54*(2), 307-314. doi.org/10.1016/j.lwt.2013.05.040

Cheli, F., Battaglia, D., Gallo, R., & Dell'Orto, V. (2014). EU legislation on cereal safety: An update with a focus on mycotoxins. *Food Control*, *37*, 315-325. doi.org/10.1016/j.foodcont.2013.09.059

Cherkani-Hassani, A., Mojemmi, B., & Mouane, N. (2016). Occurrence and levels of mycotoxins and their metabolites in human breast milk associated to dietary habits and other factors: A systematic literature review, 1984–2015. *Trends in Food Science & Technology, 50*, 56-69. doi.org/10.1016/j.tifs.2016.01.024

Clarke, R., Connolly, L., Frizzell, C., & Elliott, C. (2015). Challenging conventional risk assessment with respect to human exposure to multiple food contaminants in food: A case study using maize. *Toxicology Letters*, *238*(1), 54-64. doi.org/10.1016/j.toxlet.2015.07.006

Cook, M., & Barry, P. (2004). Organizational economics in the food, agribusiness, and agricultural sectors. *American Journal of Agricultural Economics, 86*(3), 740–743. doi.org/10.1111/j.0002-9092.2004.00617.x

Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods Approaches* (Laureate Education, Inc., custom ed.). Thousand Oaks, CA: Sage Publications.

Da Luz, S. R., Pazdiora, P. C, Dallagnol, L. J., Dors, G. C., & Chaves, F. C. (2017). Mycotoxin and fungicide residues in wheat grains from fungicide-treated plants measured by a validated LC-MS method**.** *Food Chemistry*, *220*, 510-516.

Debanne, S., & Rowland, D. (2002). Logistic regression. *Gastrointestinal Endoscopy, 55*(1), 142-143.

Degraeve, S., Madege, R. R., Audenaert, K., Kamala, A., Ortiz, J., Kimanya, M., Tiisekwa, B., De Meulenaer, B., & Haesaert, G. (2016). Impact of local pre-harvest management practices in maize on the occurrence of fusarium species and associated mycotoxins in two agro-ecosystems in Tanzania. *Food Control*, *59,* 225-233. doi:10.1016/j.foodcont.2015.05.028

Demaegdt, H., Daminet, B., Evrard, A., Scippo, M. L., Muller, M., Pussemier, L., & Vandermeiren, K. (2016). Endocrine activity of mycotoxins and mycotoxin mixtures. *Food and Chemical Toxicology: An International Journal Published for the British Industrial Biological Research Association*, *96*, 107-116. doi:10.1016/j.fct.2016.07.033

De Saeger, S., Audenaert, K., & Croubels, S. (2016). Report from the 5th international symposium on mycotoxins and toxigenic moulds: Challenges and perspectives (MYTOX) held in Ghent, Belgium, May 2016. *Toxins*, *8*(5), 146. doi:10.3390/toxins8050146

Díez, J. G., Moura, D., Nascimento, M. M., & Saraiva, C. (2017). Web information for food operators: Is it enough to comply with the food safety and public health policy? *Public Health*, *149*, 39-44. doi.org/10.1016/j.puhe.2017.04.008

Djekic, I, Kuzmanovic, J., Andelkovic, A., Saracevic, M., Stojanovic, M. M. & Tomosevic, I. (2016). Relationships among hygiene indicators in take-away foodservice establishments and the impact of climatic conditions. *Journal of Applied Microbiology*, *121*(3), 863-872. doi.org/10.1111/jam.13211

Dunn, S. (2011). The modern food industry and public health: A Galbraithian perspective. *Journal of Post Keynesian Economics*, *33*(3), 491-516.

Escrivá, L., Font, G., & Manyes, L. (2015). In vivo toxicity studies of fusarium mycotoxins in the last decade: A review. *Food and Chemical Toxicology*, *78*, 185-206. doi:10.1016/j.fct.2015.02.005

Ezekiel, C. N., Sulyok, M., Somorin, Y., Odutayo, F. I., Nwabekee, S. U., Balogun, A. T., & Krska, R. (2016). Mould and mycotoxin exposure assessment of melon and bush mango seeds, two common soup thickeners consumed in Nigeria. *International Journal of Food Microbiology*, *237*, 83–91

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, *39*, 175-191.

Ferre, F. S. (2016). Worldwide occurrence of mycotoxins in rice. *Food Control*, *62*, 291-298. doi.org/10.1016/j.foodcont.2015.10.051

Fietz, A., Bavorová, M., Grüner, S., & Hirschauer, N. (2018). Compliance with food safety laws in Germany: Food businesses in Berlin. *Law & Policy*, *40*(3), 267-285. doi:10.1111/lapo.12105

Food and Agriculture Organization of the United Nations (2018). *Food security statistics.* http://www.fao.org/economic/ess/ess-fs/en/

Food and Drug Administration. (2017a). *CFR- Code of federal regulations Title 21.* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Food and Drug Administration. (2017b). *HACCP principles & application guidelines*. https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#defs

Food and Drug Administration. (2018a). *Code of federal regulations -Title 21 Food and drugs.*https://www.fda.gov/medicaldevices/deviceregulationandguidance/databass /ucm135680.htm

Food and Drug Administration (2018b). *FDA Food Safety Modernization Act (FSMA)*. https://www.fda.gov/food/guidanceregulation/fsma/default.htm

Food and Drug Administration. (2018c). *Hazard analysis critical control point (HACCP)*. https://www.fda.gov/food/guidanceregulation/haccp/default.htm

Food and Drug Administration (2018d). *The food defect action levels: Levels of natural or unavoidable defects in foods that present no health hazards for humans*. https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm056174.htm

Food and Drug Administration. (2018e). *What the produce safety rule means for consumers.* https://www.fda.gov/food/food-safety-modernization-act-fsma/what-produce-safety-rule-means-consumers

Frankfort-Nachmias, C., Nachmias, D., & DeWard, J. (2015). *Research methods in the social sciences* (8th ed.). Worth Publishers

Freire, L., & Sant'Ana, A. S. (2017). Modified mycotoxins: An updated review on their formation, detection, occurrence, and toxic effects. *Food and Chemical Toxicology*, *111*, 189-205. doi.org/10.1016/j.fct.2017.11.021

Garcia, D., Ramos, A. J., Sanchis, V., & Marín. S. (2009). Predicting mycotoxins in foods: A review. *Food Microbiology*, *26*(8), 757-769. doi.org/10.1016/j.fm.2009.05.014

García-Cela, E., Ramos, A. J., Sanchis, V., & Marín, S. (2012). Emerging risk management metrics in food safety: FSO, PO. How do they apply to the mycotoxin hazard? *Food Control*, *25*(2), 797-808. doi.org/10.1016/j.foodcont.2011.12.009

General Accounting Office. (2017). Food safety: National strategy is needed to address fragmentation in federal oversight. https://www.gao.gov/assets/gao-17-74.pdf

Government of the District of Columbia Department of Health. (2016). DC health people 2020 framework. https://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/FINAL%20DC%20HP2020%20Framework%20Report%205-23-16.pdf

Granados-Chinchilla, F., Molina, A., Chavarría, G., Alfaro-Cascante, M., Bogantes-Ledezma, D., & Murillo-Williams, A. (2017). Aflatoxins occurrence through the food chain in Costa Rica: Applying the one health approach to mycotoxin surveillance. *Food Control*, *82*, 217-226. doi.org/10.1016/j.foodcont.2017.06.023

Green, S. B., & Salkind, N. J. (2014). *Using SPSS for Windows and Macintosh: Analyzing and understanding data* (7th ed.). Pearson.

Gregori, R., Meriggi, P., Pietri, A. Formenti, S., Gianni Baccarini, G., & Battilani, P. (2013). Dynamics of fungi and related mycotoxins during cereal storage in silo bags. *Food Control*, *30*(1), 280-287. doi.org/10.1016/j.foodcont.2012.06.033

Gulis, G., & Fujino, Y. (2015). Epidemiology, population health, and health impact assessment. *Journal of Epidemiology*, *25*(3), 179–180. doi:10.2188/jea.JE20140212

Handford, C., Elliott, C., & Campbell, K. (2015). A review of the global pesticide legislation and the scale of challenge in reaching the global harmonization of food safety standards. *Integrated Environmental Assessment and Management*, *11*(4), 525-536. doi:10.1002/ieam.1635

Hurlbert, M., & Gupta, J. (2016). Adaptive governance, uncertainty, and risk: Policy framing and responses to climate change, drought, and flood. *Risk Analysis*, *36*(2), 339-356. doi:10.1111/risa.12510

Hussain. M. A. (2016). Food contamination: Major challenges of the future. *Foods (Basel, Switzerland)*, *5*(2), 21. doi:10.3390/foods5020021

Iqbal, S. Z., Rabbani, T., Asi, M. R., & Jinap, S. (2014). Assessment of aflatoxins, ochratoxin A and zearalenone in breakfast cereals. *Food Chemistry*, 157, 257-262.

James, A., & Zikankuba, V. L. (2018). Mycotoxins contamination in maize alarms food safety in Sub-Sahara Africa. *Food Control*, *90*, 372-381. doi.org/10.1016/j.foodcont.2018.03.018

Kansas Department of Agriculture. (2016). *Wheat industry.* http://agriculture.ks.gov/docs/default-source/ag-growth-summit/january-2018-documents/wheat-sector.pdf

Karjalainen, T., Hoeveler, A., & Draghia-Akli, R. (2017). European Union research in support of environment and health: Building scientific evidence base for policy. *Environment International*, *103*, 51-60. doi.org/10.1016/j.envint.2017.03.014

Keener L, Nicholson-Keener S.M., Koutchma T. (2013). Harmonization of legislation and regulations to achieve food safety: US and Canada perspective. Journal of Science Food and Agriculture, *94*(10),1947-53. doi: 10.1002/jsfa.6295

Khalid, S. M. N. (2016). Food safety and quality management regulatory systems in Afghanistan: Policy gaps, governance and barriers to success, *Food Control*, *68*, 192-199. https://doi.org/10.1016/j.foodcont.2016.03.022

Kimanya, M. E. (2015). The health impacts of mycotoxins in the Eastern Africa region. *Current Opinion in Food Science, 6*, 7-11. doi.org/10.1016/j.cofs.2015.11.005

King, T., Cole, M., Farber, J. M., Eisenbrand, G., Zabaras, D., Fox, E. M., & Hill, J. P. (2017). Food safety for food security: Relationship between global megatrends and developments in food safety. *Trends in Food Science & Technology*, *68,* 160-175. doi.org/10.1016/j.tifs.2017.08.014

Kirezieva, K., Jacxsens, L., Uyttendaele, M., Van Boekel, M. A. J. S, & Luning, P. A. (2013). Assessment of food safety management systems in the global fresh produce chain. *Food Research International*, *52*(1), 230-242. doi.org/10.1016/j.foodres.2013.03.023

Klingelhöfer, D., Zhu, Y., Braun, M., Bendels, M. H. K., Brüggmann, D., & Groneberg, D. A. (2018). Aflatoxin – Publication analysis of a global health threat. *Food Control*, *89*, 280-290. doi.org/10.1016/j.foodcont.2018.02.017

Kosicki, R., Błajet-Kosicka, A., Grajewski, J., & Twarużek, M. (2016). Multiannual mycotoxin survey in feed materials and feeding stuffs. *Animal Feed Science and Technology*, *215*, 165-180. doi 10.1016/j.anifeedsci.2016.03.012

Koutsoumanis, K. P., & Aspridou, Z. (2016). Moving towards a risk-based food safety management. *Current Opinion in Food Science*, *12*, 36-41. doi.org/10.1016/j.cofs.2016.06.008

Kovalsky, P., Kos, G., Nährer, K., Schwab, C., Jenkins, T., Schatzmayr, G., Sulyok, M., & Krska, R. (2016). Co-Occurrence of regulated, masked and emerging mycotoxins and secondary metabolites in finished feed and maize: An extensive survey. *Toxins*, *8*, 363. https://doi.org/10.3390/toxins8120363

Kumar, V., Basu, M. S., & Rajendran, T. P. (2008). Mycotoxin research and mycoflora in some commercially important agricultural commodities. *Crop Protection*, *27*(6), 891-905. doi.org/10.1016/j.cropro.2007.12.011

Kuruc, J., Hegstad, J., Lee, H. J., Simons, K., Ryu, D., & Wolf-Hall, C. (2015). Infestation and quantification of ochratoxigenic fungi in barley and wheat naturally contaminated with ochratoxin A. *Journal of Food Protection*, *78*(7), 1350-1356. https://search.proquest.com/docview/1694512178?accountid=14696

Kussaga, J., Jacxsens, L., Tiisekwa, B., & Luning, P. (2014). Food safety management systems performance in African food processing companies: A review of deficiencies and possible improvement strategies. *Journal of the Science of Food and Agriculture*, *94*(11), 2154-2169. doi:10.1002/jsfa.6575

Lahouar, A., Marín, S., Crespo-Sempere, A., Saïd, S., & Sanchis, V. (2017). Influence of temperature, water activity and incubation time on fungal growth and production of ochratoxin A and zearalenone by toxigenic *aspergillus tubingensis* and *fusarium incarnatum* isolates in sorghum seeds. *International Journal of Food Microbiology*, *242*, 53-60. doi.org/10.1016/j.ijfoodmicro.2016.11.015

Lake, R. J., Stein, C. E., Havelaar, A. H., & Motarjemi, Y. (Eds.). (2017). Risk analysis: estimating the burden of foodborne disease. *Encyclopedia of Food Safety*, *1*, 73-79. doi.org/10.1016/B978-0-12-378612-8.00032-9

Lamuka, P. (2014). Public health measures: Challenges of developing countries in management of food safety. *Reference Module in Food Science, from Encyclopedia of Food Safety*, *4*, 20-26. Academic Press.

Lee, H. J., & Ryu, D. (2015). Advances in mycotoxin research: Public health perspectives. *Journal of Food Science*, *80*, 12. doi: 10.1111/1750-3841.13156

Li, R., Wang, X., Zhou, T., Yang, D., Wang, Q., & Zhou, Y. (2014). Occurrence of four mycotoxins in cereal and oil products in Yangtze delta region of China and their food safety risks. *Food Control*, *35*(1), 117-122. doi.org/10.1016/j.foodcont.2013.06.042

Liu, Y., Lu, Y., Wang, L., Chang, F., & Yang, L., (2016). Occurrence of deoxynivalenol in wheat, Hebei Province, China. *Food Chemistry*, *197*, 1271-1274.

Luo, Y., Liu, X., & Li, J. (2018). Updating techniques on controlling mycotoxins - A review. *Food Control*, *89*, 123-132. doi.org/10.1016/j.foodcont.2018.01.016

Makofske, M. (2019). Inspection regimes and regulatory compliance: How important is the element of surprise? *Economics Letters, 177,* 30-34. doi:10.1016/j.econlet.2019.01.001

Manning, L., & Soon, J. (2016). Food safety, food fraud, and food defense: A fast evolving literature. *Journal of Food Science*, *81*(4), 834. doi:10.1111/1750-3841.13256

Marín, S., Ramos, A. J., Cano-Sancho, G., & Sanchis, V. (2013). Mycotoxins: Occurrence, toxicology, and exposure assessment. *Food and Chemical Toxicology*, *60*, 218-237. doi.org/10.1016/j.fct.2013.07.047

Marroquín-Cardona, A. G., Johnson, N. M., Phillips, T. D., & Hayes. A. W. (2014). Mycotoxins in a changing global environment – A review. *Food and Chemical Toxicology*, *69,* 220-230. doi.org/10.1016/j.fct.2014.04.025

Martinović, T., Andjelković, U., Gajdošik, M. Š., Rešetar, D., & Josić, D. (2016). Foodborne pathogens and their toxins. *Journal of Proteomics, 147,* 226-235. doi:10.1016/j.jprot.2016.04.029

McCormick, S. P., Stanley, A. M., Stover, N. A., & Alexander, N. J. (2011). Trichothecenes: From simple to complex mycotoxins. *Toxins*, *3*(7), 802-814. doi.org/10.3390/toxins3070802

McDavid, J.C., Huse, I., & Hawthorn, L.R.L. (2013). *Program evaluation and performance measurement. An introduction to practice.* (2nd ed). Sage.

McHugh, M. L. (2013). The chi-square test of independence. *Biochem Med (Zagreb).* *23*(2), 143–149. doi:10.11613/BM.2013.018

Medina, A., Akbar, A., Baazeem, A., Rodriguez, A., & Naresh Magan (2017). Climate change, food security and mycotoxins: Do we know enough? *Fungal Biology Reviews*, *31*(3), 143-154. doi.org/10.1016/j.fbr.2017.04.002

Milicevic, D., Nesic, K., & Jaksic, S. (2015). Mycotoxin contamination of the food supply chain - Implications for one health programme. *Procedia Food Science*, *5*, 187-190. doi.org/10.1016/j.profoo.2015.09.053

Miller, P., Marshall, J., French, N., & Jewell, C. (2017). SourceR: Classification and source attribution of infectious agents among heterogeneous populations. *PLoS Computational Biology*, *13,* (5). doi.org/10.1371/journal.pcbi.1005564

Mitchell, N. J., Bowers, E., Hurburgh, C., & Wu, F. (2016). Potential economic losses to the US corn industry from aflatoxin contamination. *Food Additives and Contaminants. Part A, Chemistry, Analysis, Control, Exposure and Risk Assessment*, *33*(3), 540-50. doi: 10.1080/19440049.2016.1138545

Mitchell, N. J., Chen, C., Palumbo, J. D., Bianchini, A., Cappozzo, J., Stratton, J., Ryu, D., & Wu, F. (2017). A risk assessment of dietary ochratoxin A in the United States. *Food and Chemical Toxicology*, *100*, 265-273. doi:10.1016/j.fct.2016.12.037

Moretti, A., Pascale, M., & Logrieco, A. F. (2019). Mycotoxin risks under a climate change scenario in Europe. *Trends in Food Science & Technology*, *84*, 38-40. doi.org/10.1016/j.tifs.2018.03.008

Motarjemi, Y. (Ed.) (2014). Public Health Measures: Modern Approach to Food Safety Management: An overview. *In Encyclopedia of Food Safety*, *4*, 1-12.doi.org/10.1016/B978-0-12-378612-8.00309-7

Moy, G. G., Todd, E. C. D. & Motarjemi, Y. (Eds.) (2014). Foodborne diseases: Overview of chemical, physical, and other significant hazards. *In Encyclopedia of Food Safety*, *1*, 243-252. doi.org/10.1016/B978-0-12-378612-8.00418-2

Muri, S. D., van der Voet, H., Boon, P. E., van Klaveren, J. D., & Brüschweiler, B. J. (2009). Comparison of human health risks resulting from exposure to fungicides and mycotoxins via food. *Food and Chemical Toxicology*, *47*(12), 2963-2974. doi.org/10.1016/j.fct.2009.03.035

Mwalwayo, D. S., & Thole, B. (2016). Prevalence of aflatoxin and fumonisins (B_1 + B_2) in maize consumed in rural Malawi. *Toxicology Reports*, *3*, 173–179. doi.org/10.1016/j.toxrep.2016.01.010

National Environmental Health Association (2018). Professional food manager (6th ed.). Author.

National Research Council (US) Committee on the Review of Food and Drug Administration's Role in Ensuring Safe Food. Wallace, R.B. & Oria, M. (Eds). Enhancing Food Safety: The Role of the Food and Drug Administration. National Academies Press (US); 2010. 2, The Food Safety System: Context and Current Status. Available from:https://www.ncbi.nlm.nih.gov/books/NBK220410/

Neme, K., & Mohammed, A. (2017). Mycotoxin occurrence in grains and the role of postharvest management as a mitigation strategies: A review. *Food Control*, *78*, 412-425. doi.org/10.1016/j.foodcont.2017.03.012

Nevalainen, A., Täubel, M., & Hyvärinen, A. (2015). Indoor fungi: Companions and contaminants. *Indoor Air*, *25*(2), 125-156. doi:10.1111/ina.12182

Nguyen, K. T. N., & Ryu, D. (2014). Concentration of ochratoxin A in breakfast cereals and snacks consumed in the United States. *Food Control*, *40*, 140-144. doi.org/10.1016/j.foodcont.2013.11.041

Nick, T., & Campbell, K. (2007). Logistic regression. *Methods in Molecular Biology (Clifton, N.J.)*, *404*, 273-301. doi:10.1007/978-1-59745-530-5_14

Nielsen, L. K., Cook, D. J., Edwards, S. G., & Ray, R. V. (2014). The prevalence and impact of Fusarium head blight pathogens and mycotoxins on malting barley quality in UK. *International Journal of Food Microbiology*, *179*, 38-49. doi.org/10.1016/j.ijfoodmicro.2014.03.023

Nychas, G. J. E., Panagou, E. Z., & Mohareb, F. (2016). Novel approaches for food safety management and communication. *Current Opinion in Food Science*, *12*, 13-20. doi.org/10.1016/j.cofs.2016.06.005

Odeyemi, O. A. (2016). Public health implications of microbial food safety and foodborne diseases in developing countries. *Food and Nutrition Research*, *60*, 29819. doi:10.3402/fnr.v60.29819

Ogunade, I. M., Martinez-Tuppia, C., Queiroz, O. C. M., Jiang, Y., Drouin, P., Wu, F., Vyas, D., & Adesogan, A. T. (2018). Silage review: Mycotoxins in silage: Occurrence, effects, prevention, and mitigation. *Journal of Dairy Science*, *101*(5). 4034-4059. doi.org/10.3168/jds.2017-13788

Omotayo, O. P., Omotayo, A. O., Mwanza M, & Babalola O.O. (2019). Prevalence of mycotoxins and their consequences on human health. *Toxicol Res*, *35*(1), 1-7. doi: 10.5487/TR.2019.35.1.001

Oskarsson. A. (2012). Environmental contaminants and food safety. *Acta Veterinaria Scandinavica*, *54*(1), S5. doi:10.1186/1751-0147-54-S1-S5

O'Sullivan, E., Rassel, G. R., & Berner, M. (2008). *Research methods for public administrators* (5th ed.). Pearson Longman.

Parker, J., DeNiro, J., Ivey, M., & Doohan, D. (2016). Are small and medium scale produce farms inherent food safety risks? *Journal of Rural Studies*, *44*, 250-260. doi:10.1016/j.jrurstud.2016.02.005

Patriarca, A., & Pinto, V. F. (2017). Prevalence of mycotoxins in foods and decontamination. *Current Opinion in Food Science*, *14,* 50-60. doi.org/10.1016/j.cofs.2017.01.011

Peng, W. X., Marchal, J. L. M., & van der Poel, A. F. B. (2018). Strategies to prevent and reduce mycotoxins for compound feed manufacturing. *Animal Feed Science and Technology*, *237*, 129-153. doi.org/10.1016/j.anifeedsci.2018.01.017

Pigott, D. M., Howes, R. E., Wiebe, A., Battle, K. E., Golding, N., Gething, P. W., & Hay, S. I. (2015). Prioritizing infectious disease mapping. *PLOS Neglected Tropical Diseases*, *9*, 6. doi.org/10.1371/journal.pntd.0003756

Pinotti, L., Ottoboni, M., Giromini, C., Dell'Orto, V., & Cheli, F. (2016). Mycotoxin contamination in the EU feed supply chain: A focus on cereal byproducts. *Toxins*, *8*(2), 45. doi:10.3390/toxins8020045

Pitt, J. I., Taniwaki, M. H., & Cole, M. B. (2013). Mycotoxin production in major crops as influenced by growing, harvesting, storage and processing, with emphasis on the achievement of food safety objectives. *Food Control*, *32*(1), 205-215.doi.org/10.1016/j.foodcont.2012.11.023

Raiola, A., Tenore, G., Manyes, L., Meca, G., & Ritieni, A. (2015). Risk analysis of main mycotoxins occurring in food for children: An overview. *Food and Chemical Toxicology*, *84*, 169-180. doi:10.1016/j.fct.2015.08.023

Rajkovic, A. (2014). Microbial toxins and low-level exposure of foodborne exposure. *Trends in Food Science and Technology*, *38*, 149-157.

Rehber, E. (2012). Food for thought: "Four ss with one f." *British Food Journal*, *114*(3), 353-371. doi.org/10.1108/00070701211213465

Remington, P. L., Brownson, R. C., & Wegner, M. V. (Eds.). (2016). *Chronic disease, epidemiology, prevention, and control* (4th ed.). APHA Press.

Ruyck, K. D., Boevre, M. D., Huybrechts, I., & Saeger, S. D. (2015). Dietary mycotoxins, co-exposure, and carcinogenesis in humans: Short review. *Mutation Research/Reviews in Mutation Research, 766*, 32-41 doi.org/10.1016/j.mrrev.2015.07.003

Saint Ville, A. S., Hickey, G. M., & Phillip, L. E. (2015). Addressing food and nutrition insecurity in the Caribbean through domestic smallholder farming system innovation. *Regional Environmental Change*, *15*(7), 1325-1339. doi.org/10.1007/s10113-015-0770-9

Sekyere, K., Addy, E., & Agyei-Baffour, P. (2013). Policy on hazard analysis and critical control point (HACCP) and adherence to food preparation guidelines: A cross sectional survey of stakeholders in food service in Kumasi, Ghana. *BMC Research Notes*, *6*(1), 1-12. doi:10.1186/1756-0500-6-442

Shafritz, J. M., Ott, J. S., & Jang, Y. S. (Eds.). (2016). *Classics of organization theory* (8th ed). Wadsworth Cengage Learning.

Shafritz, J. M., Russel, E. W., & Borick, C. P. (2011). *Introducing public administration* (7th ed.) Pearson Longman.

Sheikh-Ali, S. I., Ahmad, A., Mohd-Setapar, S. H., Zakaria, Z. A., Abdul-Talib, N., Khamis, A. K., & Hoque, E. (2014). The potential hazards of aspergillus sp in foods and feeds, and the role of biological treatment: A review. *The Journal of Microbiology*, *52*(10), 807-818. doi10.1007/s12275-014-4294-7

Smith, J., Lang, T., Vorley, B., & Barling, D. (2016). Addressing policy challenges for more sustainable local-global food chains: Policy frameworks and possible food "futures." *Sustainability*, *8*(4), 299. https://search.proquest.com/docview/1779945318?accountid=14696

Smith, P., & Gregory, P. J. (2013). Climate change and sustainable food production. *The Proceedings of the Nutrition Society*, *72*(1), 21-8 doi.org/10.1017/S0029665112002832

Snyder, F. (2015). No country is an island in regulating food safety: How the WTO monitors Chinese food safety laws through the Trade Policy Review Mechanism (TPRM). *Journal of Integrative Agriculture*, *14*(11), 2142-2156. doi.org/10.1016/S2095-3119(15)61111-X

Sobral, M. M. C., Faria, M. A., Cunha, S. C., & Ferreira, I. M. P. L.V. O. (2018). Toxicological interactions between mycotoxins from ubiquitous fungi: Impact on hepatic and intestinal human epithelial cells. *Chemosphere*, *202*, 538-548. doi.org/10.1016/j.chemosphere.2018.03.122

Stoelhorst, J. W., & Richerson, P. J. (2013). A naturalistic theory of economic organization. *Journal of Economic Behavior and Organization*, *90* (Suppl.), S45-S56. doi:10.1016/j.jebo.2012.12.012

Stoev, S. D. (2013). Food safety and increasing hazard of mycotoxin occurrence in foods and feeds. *Critical Reviews in Food Science and Nutrition*, *53*(9), 887-901. doi:10.1080/10408398.2011.571800

Stoev, S. D. (2015). Foodborne mycotoxicoses, risk assessment and underestimated hazard of masked mycotoxins and joint mycotoxin effects or interaction. *Environmental Toxicology and Pharmacology*, *39*(2), 794-809. doi.org/10.1016/j.etap.2015.01.022.

Sumner, T., Orton, R. J., Green, D. M., Kao, R. R., & Gubbins, S. (2017). Quantifying the roles of host movement and vector dispersal in the transmission of vector-borne diseases of livestock. *PLOS Computational Biology*, *13*(4). doi.org/10.1371/journal.pcbi.1005470

Thielecke, F., & Nugent, A. P. (2018). Contaminants in grain-A major risk for whole grain safety? *Nutrients*, *10*(9), 1213. doi:10.3390/nu10091213

Tibola, C. S., Fernandes, J. M. C., Guarienti, E. M., & Nicolau, M. (2015). Distribution of fusarium mycotoxins in wheat milling process. *Food Control*, *53*, 91-95. doi.org/10.1016/j.foodcont.2015.01.012

Trucksess, M. W., & Diaz-Amigo, C. (2013). Mycotoxins in foods. *Module in Earth Systems and Environmental Sciences, from Encyclopedia of Environmental Health*

Udomkun, P., Wiredu, A., Nagle, M., Bandyopadhyay, R., Müller, J., & Vanlauwe, B. (2017). Mycotoxins in Sub-Saharan Africa: Present situation, socio-economic impact, awareness, and outlook. *Food Control*, *72*, 110-122. doi:10.1016/j.foodcont.2016.07.039

Umesha, S., Manukumar, H., Chandrasekhar, B., Shivakumara, P., Shiva Kumar, J., Raghava, S., & Prakash, H. (2017). Aflatoxins and food pathogens: Impact of biologically active aflatoxins and their control strategies. *Journal of the Science of Food and Agriculture, 97*(6), 1698-1707. doi:10.1002/jsfa.8144

United States Department of Agriculture Agricultural Marketing Service. (n.d.). Federal Grain Inspection Service. https://www.ams.usda.gov/about-ams/programs-offices/federal-grain-inspection-service

United States Department of Agriculture. (2013). *Molds on food: Are they dangerous?* https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/molds-on-food-are-they-dangerous_/ct_index

United States Department of Agriculture. (2016). *Iowa 2015 corn for silage county estimates*.https://www.nass.usda.gov/Statistics_by_State/Iowa/Publications/Couny Estimates/2016/IA_CtyEst_CornSilage_14-15.pdf

United States Department of Agriculture. (2018). *Food defense and emergency response.* https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/molds-on-food-are-they-dangerous_/ct_index/!u

United States Department of Agriculture Food Safety and Inspection Service. (2018a). Our history. https://www.fsis.usda.gov/about-fsis/history

Unnevehr. L. (2015). Food safety in developing countries: Moving beyond exports. *Global Food Security*, *4*, 24-29. doi.org/10.1016/j.gfs.2014.12.001

VanWart, M. (2011). *Dynamics of leadership in public service*: *Theory and practice* (2nd ed). M.E. Sharpe, Inc.

Vejdovszky, K., Hahn, K., Braun, D., Warth, B., & Marko, D. (2017). Synergistic estrogenic effects of *fusarium* and *alternaria* mycotoxins in vitro. *Archives of Toxicology*, *91*(3), 1447-1460. doi:10.1007/s00204-016-1795-7

Von Braun, J. and Birner, R. (2017). Designing global governance for agricultural development and food and nutrition security. *Review of Development Economics*, *21*, 265-284. https://doi.org/10.1111/rode.12261

Wagacha, J. M., & Muthomi, J. W. (2008). Mycotoxin problem in Africa: Current status, implications to food safety and health and possible management strategies. *International Journal of Food Microbiology*, *124*(1), 1-12. doi.org/10.1016/j.ijfoodmicro.2008.01.008

Wallace, C. A. (2014a). Food safety assurance systems: Hazard analysis and critical control point system (HACCP): Principles and practice. *Module in Food Science, from Encyclopedia of Food Safety*, *4*, 226-239. doi:10.1016/B978-0-12-378612-8.00358-9

Wallace, C. A. (2014b). HACCP-based food safety management systems: great in theory but can we really make them work in practice? *Perspectives in Public Health*, *134*(4), 188–190. doi.org/10.1177/1757913914538735

Weiner, J. (2007). Measurement: Reliability and validity measures. John Hopkins Bloomberg School of Public Health. John Hopkins University. *ocw.jhsph.edu/.../hsre..*

Wever M, Wognum N, Trienekens J, & Omta O. (2010). Alignment between chain quality management and chain governance in EU pork supply chains: a Transaction-Cost-Economics perspective. *Meat Science*, *84*(2), 228-37. doi:10.1016/j.meatsci.2009.05.012

Wengle, S. (2016). When experimentalist governance meets science-based regulations; The case of food safety regulations. *Regulation & Governance*, *10*(3), 262-283. doi:10.1111/rego.12067

Williamson, O. (1981). The economics of organization: The transaction cost approach. *American Journal of Sociology*, *87*(3), 548-577. http://www.jstor.org/stable/2778934

Winter, G., & Pereg, L. (2019). A review on the relation between soil and mycotoxins: Effect of aflatoxin on field, food and finance. *European Journal of Soil Science, 70*(4), 882-897. doi:10.1111/ejss.12813

Womack, E., Brown, A., & Sparks, D. (2014). A recent review of non-biological remediation of aflatoxin-contaminated crops. *Journal of the Science of Food and Agriculture*, *94*(9), 1706-1714. doi:10.1002/jsfa.6520

World Health Organization. (2015a). Food safety: From farm to plate. *Eastern Mediterranean Health Journal*, *21*(4), 299-301. https://search.proquest.com/docview/1695268787?accountid=14696

World Health Organization: Alwan, A., & Elmi, M. (Eds.). (2015b). Food safety in the Eastern Mediterranean region: Time to act. *Eastern Mediterranean Health Journal*, *21*(3), 153-154. https://search.proquest.com/docview/1685695452?accountid=14696

World Health Organization. (2017). *Food safety*. http://www.who.int/en/news-room/fact-sheets/detail/food-safety

World Health Organization. (2018a). *Food safety*. http://www.who.int/news-room/fact-sheets/detail/food-safety

World Health Organization (2018b). *Mycotoxins*. http://www.who.int/news-room/fact-sheets/detail/mycotoxins

World Health Organization. (2018c). *Natural toxins in food*. http://www.who.int/news-room/fact-sheets/detail/natural-toxins-in-food

Wu, F., Groopman, J. D., & Pestka, J. J. (2014). Public health impacts of foodborne mycotoxins. *Annual Review of Food Science and Technology*, *5*, 351-72. doi:10.1146/annurev-food-030713-092431

Wu, F., & Guclu, H. (2012). Aflatoxin regulations in a network of global maize trade. *PLOS One*, *7*(9), e45151. doi:10.1371/journal.pone.0045151

Xu, W., Han, X., & Li, F. (2019). Co-occurrence of multi-mycotoxins in wheat grains harvested in Anhui province, China. *Food Control*, *96*, 180-185. doi.org/10.1016/j.foodcont.2018.09.006

Appendix A: Nomenclature

AFL	Aflatoxins
APHA	American Public Health Association
CDC	Center for Disease Control
CFR	Code of Federal Regulation
CODEX	Codex Alimentarius
DON	Deoxynivalenol
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FHB	Fusarium Head Blight
FUM	Fumonisins
FSIS	Food safety and Inspection Service
FSMA	Food Safety Modernization Act
FSMS	Food Safety Management Systems
FSO	Food Safety Objectives
GAP	Good Agricultural Practices
HACCP	Hazard Analysis Critical Control Point
IARC	International Agency for Research on Cancer
IFPRI	International Food Policy Research Institute

JECFA	Joint FAO/WHO Expert Committee on Food Additives
NEHA	National Environmental Association
NOAA	National Oceanic and Atmospheric Administration
OTA	Ochratoxins
PPB:	Parts per billion
PPM:	Parts per million
RASFF	Rapid Alert System Food and Feed
TLC	Total Liquid Content
TRC	Tricothecenes
USDA	United States Department of Agriculture
VOM	Vomitoxin
WFP	World Food Programme
WHO	World Health Organization
ZN	Zearalenone

Appendix B: Testing Assumption for Linear Regression

Figure B1

Scatterplot Relationship Between Maximum Temperature and AFL

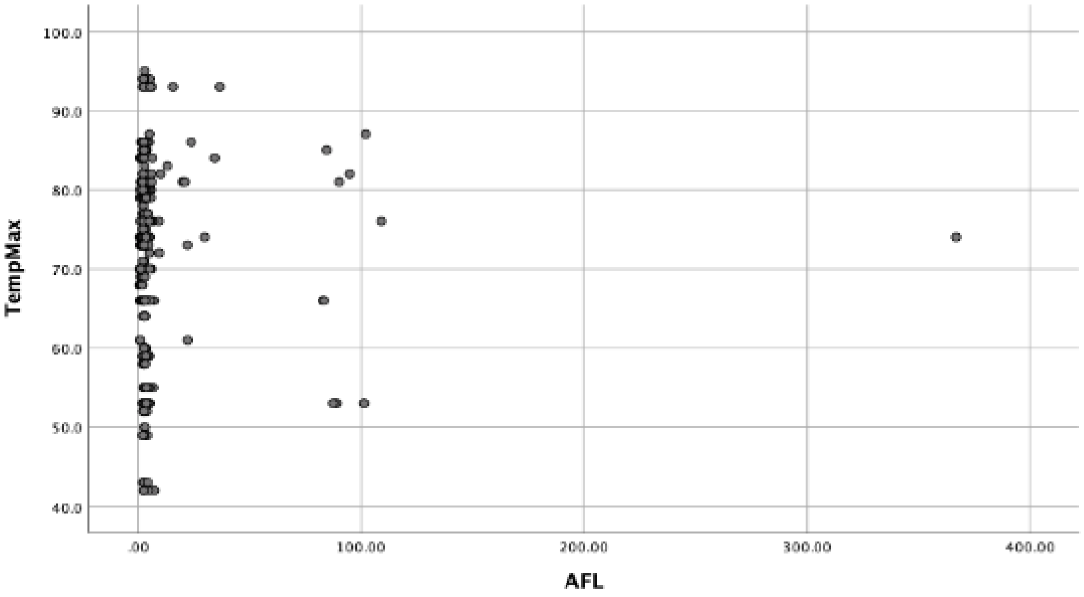


Figure B2

Scatterplot Relationship Between Total Liquid Content (TLC) and AFL

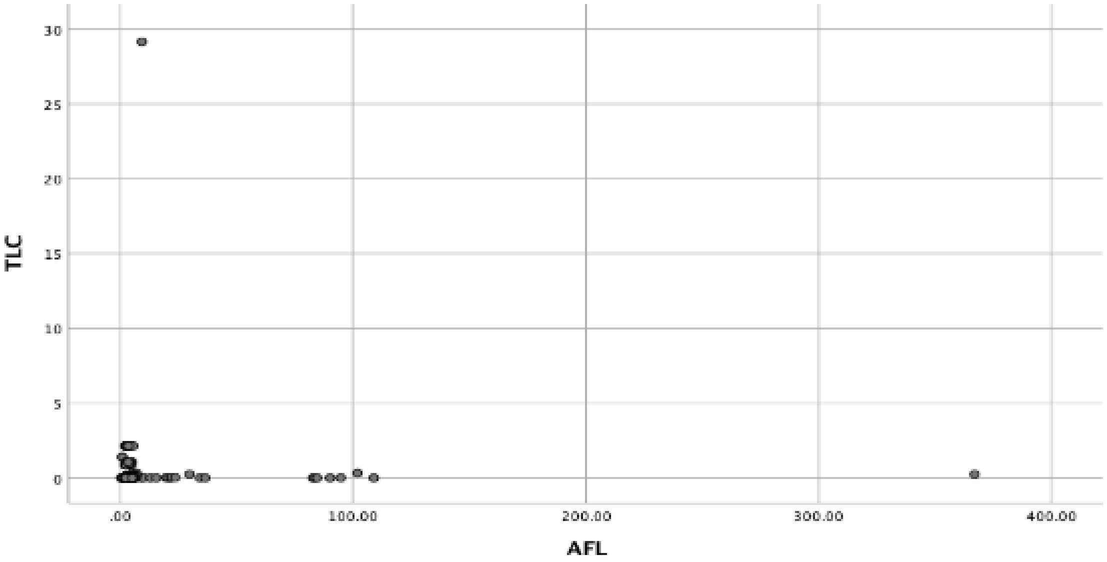
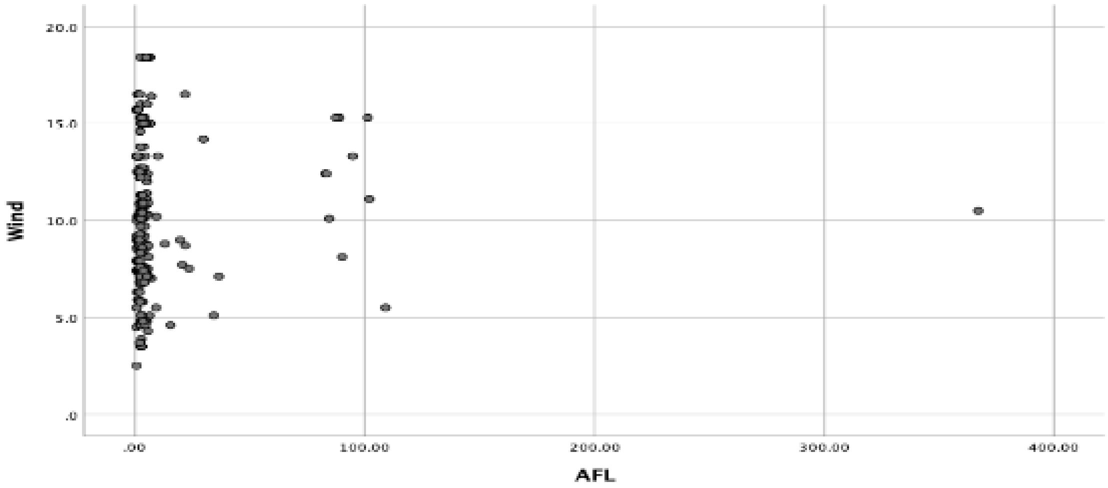


Figure B3

Scatterplot Relationship Between Wind and AFL



Appendix C: Testing Assumption for Linear Regression

Figure C1

Scatterplot Relationship Between Maximum Temperature and FUM

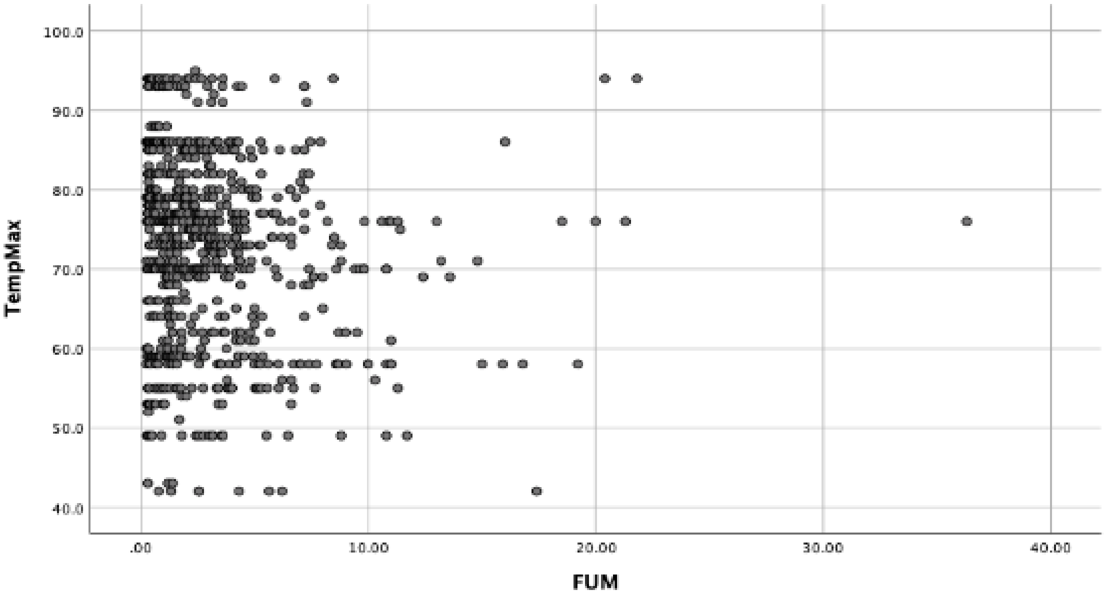


Figure C2

Scatterplot Relationship Between TLC and FUM

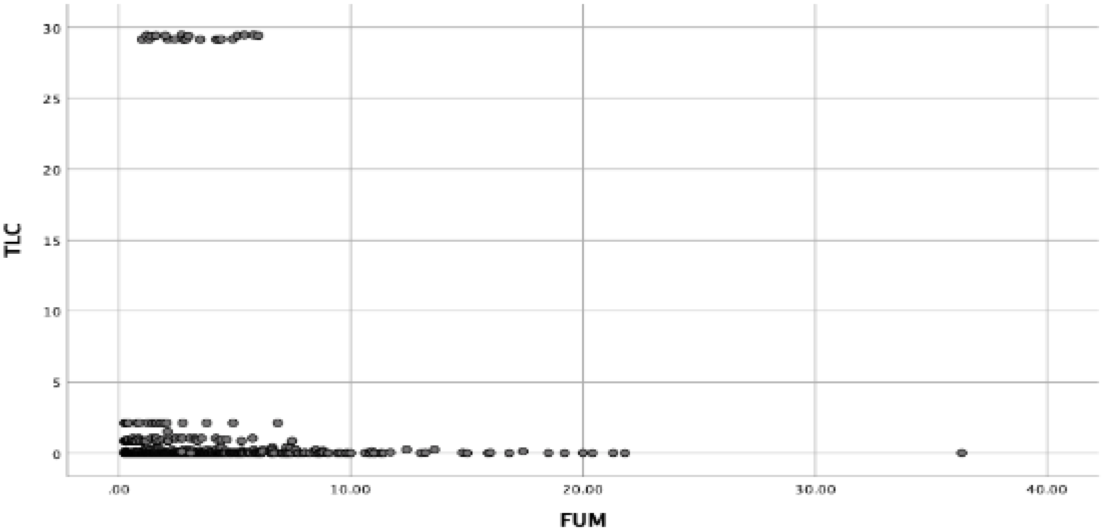
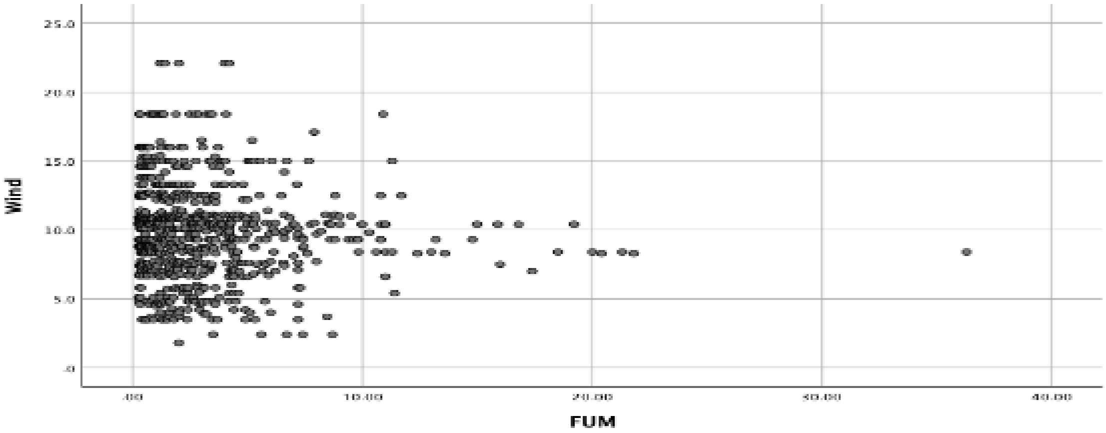


Figure C3

Scatterplot Relationship Between Wind and FUM



Appendix D: Testing Assumption for Linear Regression

Figure D1

Scatterplot Relationship Between Maximum Temperature and VOM

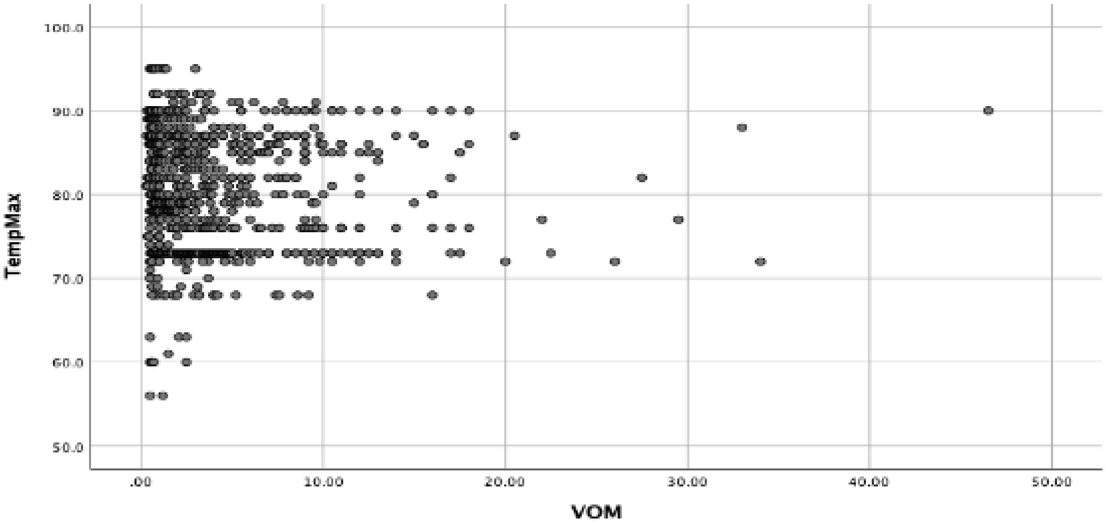


Figure D2

Scatterplot Relationship Between TLC and VOM

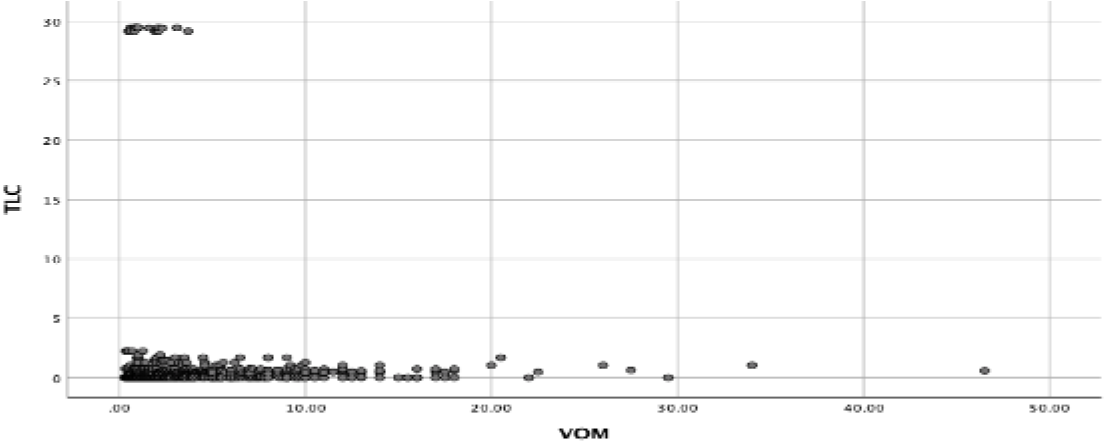
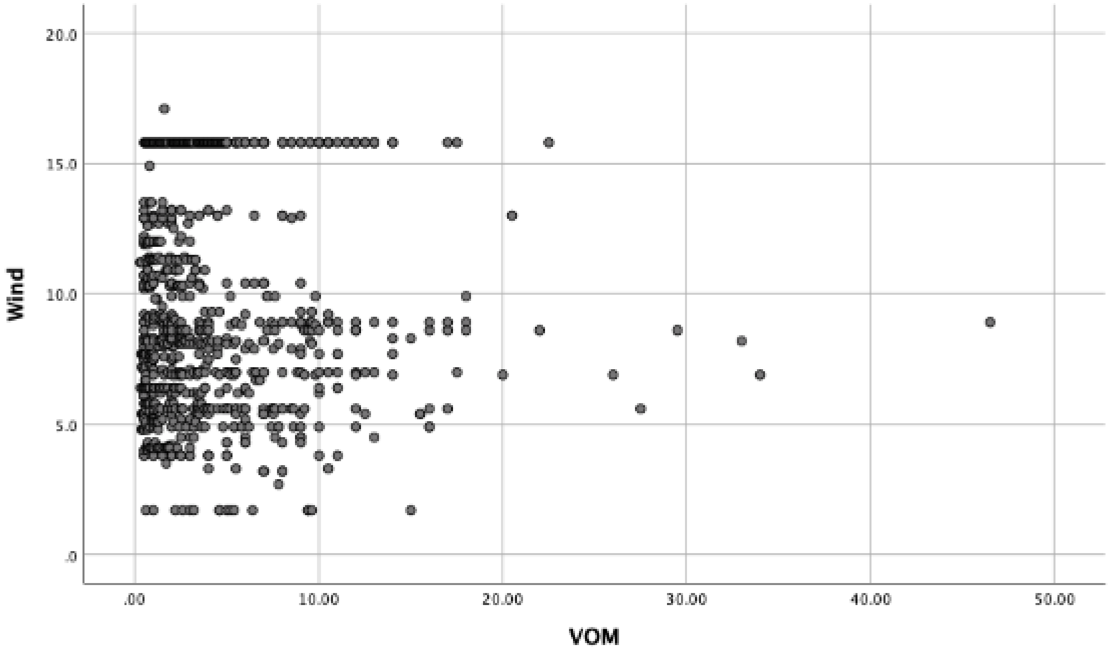


Figure D3

Scatterplot Relationship Between Wind and VOM



Appendix E: Testing Assumption for Linear Regression

Figure E1

Histogram Test for Normality Between Frequency and AFL

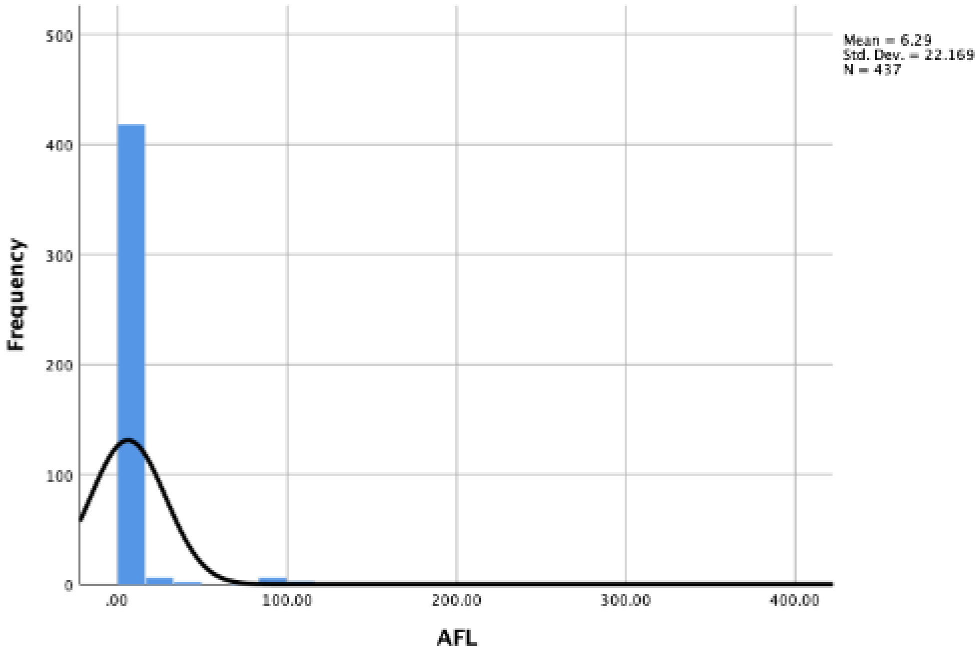


Figure E2

Histogram Test for Normality Between Frequency and FUM

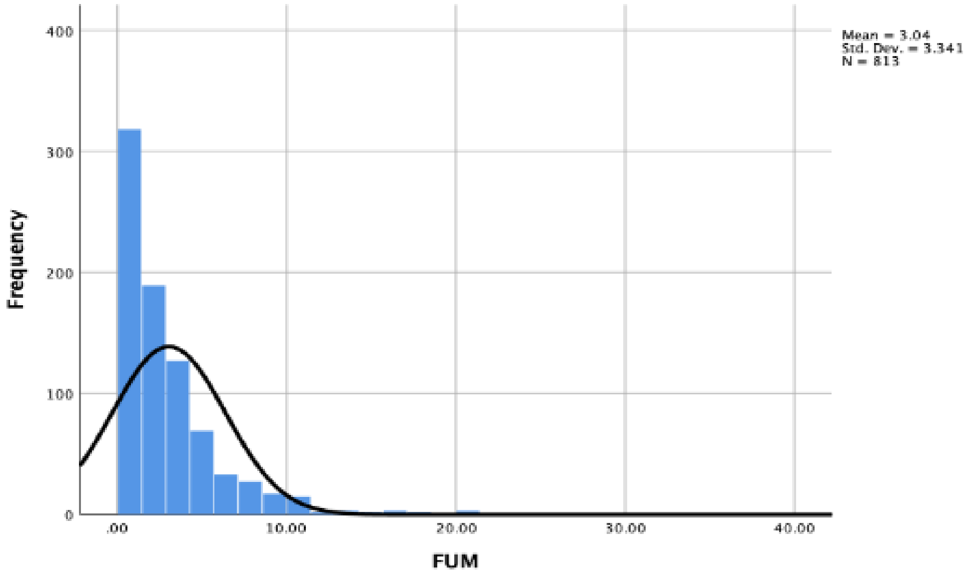


Figure E3

Histogram Test for Normality Between Frequency and VOM

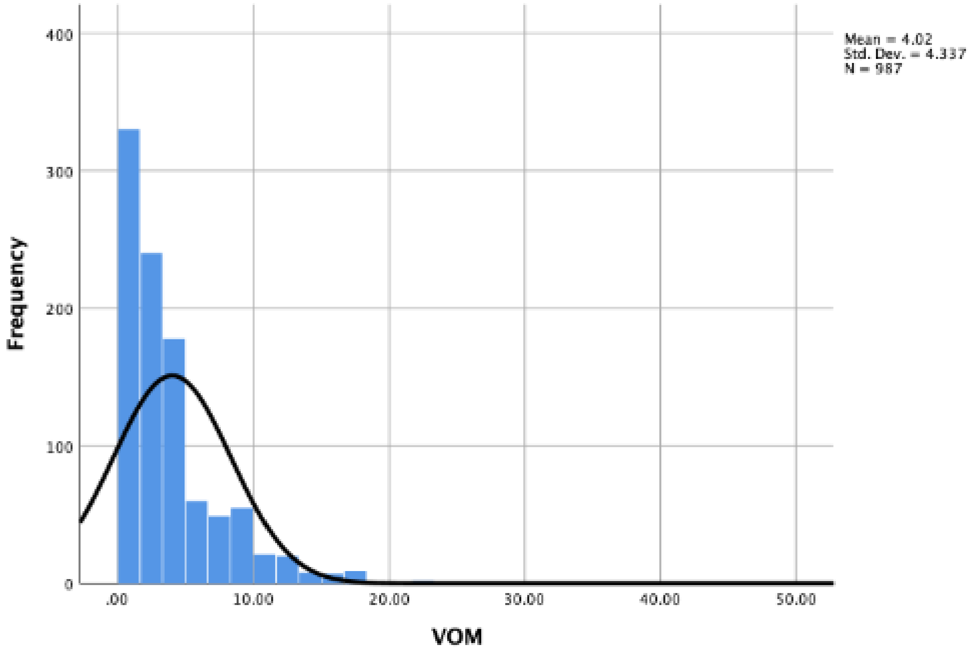


Figure E4

Histogram Test for Normality Between Frequency and Maximum Temperature

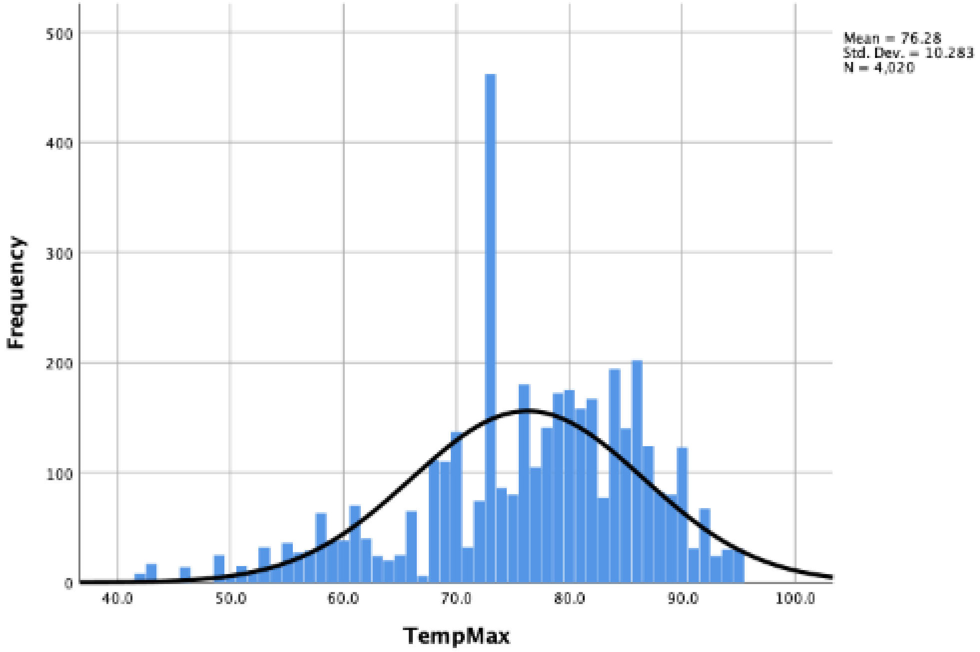


Figure E5

Histogram Test for Normality Between Frequency and TLC

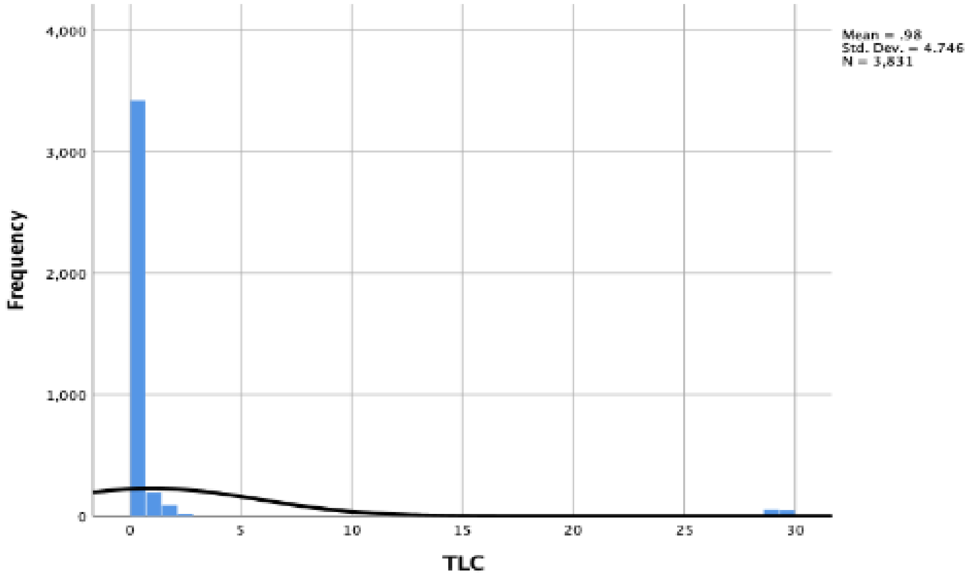
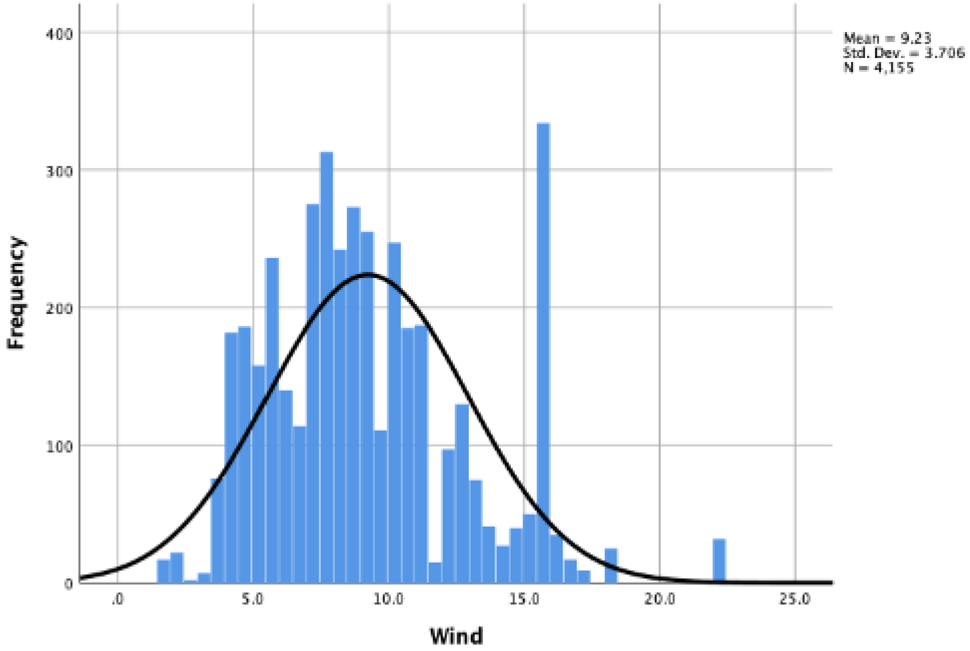


Figure E6

Histogram Test for Normality Between Frequency and Wind



Appendix F: Testing Normality Assumption for Linear Regression

Table F1

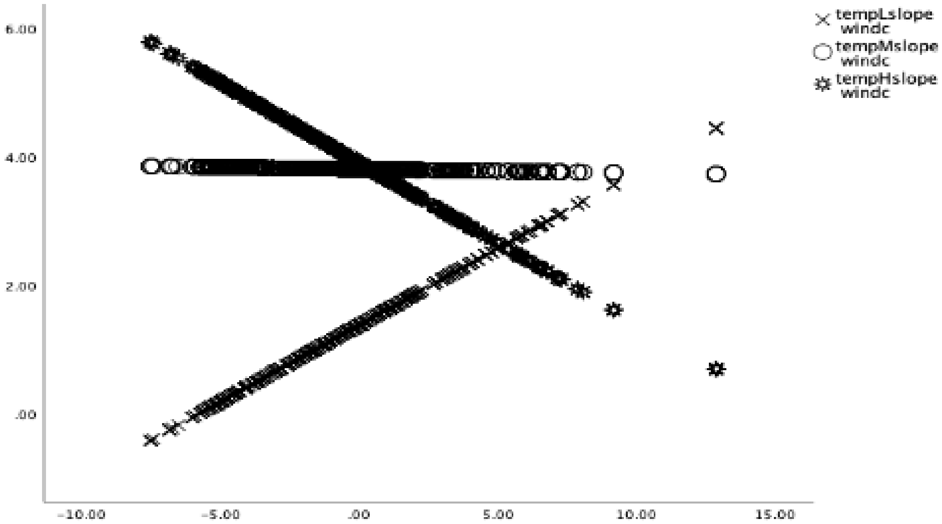
Kolmogorov-Smirnov Test Results

Variable	Kolmogorov-Smirnov	*p*-value
AFL	.44	<.001
FUM	.20	<.001
VOM	.20	<.001
Temp	.10	<.001
Precip	.43	<.001
Wind	.08	<.01

Appendix G: Effect of Wind by 1 Standard Deviation Above, Below, and Average Levels of Temperature on VOM Levels

Figure G1

Effect of Wind by 1 Standard Deviation Above, Below, and Average Levels of Temperature on VOM Levels



Appendix H: Major Mycotoxins US and EU Limits of Food and Animal Feed Levels

Table H1

Major mycotoxins US and EU limits of food and animal feed levels

Mycotoxin	**Fungal Species**	**Food Commodity**	**US FDA (µg/kg)**	**EU (EC 2006) (µg/kg)**
Aflatoxins B1, B2, G1, G2	*Aspergillus flavus* *Aspergillus parasiticus*	Maize, wheat, rice, peanut, sorghum, pistachio, almond, ground nuts, tree nuts, figs, cottonseed, spices	20 for total	2-12 for B1 4-15 for total
Aflatoxin M1	Metabolite of aflatoxin B1	Milk, milk products	0.5	0.05 in milk 0.025 in infant formulae and infant milk
Ochratoxin A	*Aspergillus ochraceus* *Penicillium verrucosum* *Aspergillus carbonarius*	Cereals, dried vine fruit, wine, grapes, coffee, cocoa, cheese	Not set	2-10
Fumonisins B1, B2, B3	*Fusarium verticillioides* *Fusarium proliferatum*	Maize, maize products, sorghum, asparagus	2000-4000	200-1000
Zearalenone	*Fusarium graminearum* *Fusarium culmorum*	Cereals, cereal products, maize, wheat, barley	Not set	20-100
Deoxynivalenol	*Fusarium graminearum* *Fusarium culmorum*	Cereals, cereal products	1000	200-50
Patulin	*Penicillium expansum*	Apples, apple juice and concentrate	50	10-50

Source: Environmental Research and Public research (Alshannaq & Yu, 2017)