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Outbreak: a case study analysis

By

Holly Elizabeth Mace

A thesis submitted to the graduate faculty
in partial fulfillment of the requirements for the degree of

Master of Public Administration

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Iowa State University
Ames, Iowa
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Chapter 1. Introduction

Food safety is not a typical topic of conversation for people around the world; in fact, it rarely enters our conversation until there is reason to question the foods that we are consuming. With the exception of specific foodborne illnesses or contamination issues, the concept of food safety is an afterthought for most people. We trust that restaurants have our best interest in mind and that our food is prepared in an untainted environment. Most of us who cook at home understand that proper preparation is necessary to prevent illness, and when we go to the grocery store we rarely question the produce, meat and other items that we purchase. Thankfully, we live in a nation where the majority of the food is safe to consume without question or thought.

In Congress the topic of food safety has been debated for years. Following September 11, 2001 the safety of the infrastructure of the agriculture and food industry in the United States became a topic of highest importance due to fear of an intentional contamination of the food supply. In the months following 9/11, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, to help protect the food supply from an intentional act of terrorism. Food safety and food defense seemed to become synonymous, yet they are two very different things that impact each and every individual in the United States and millions more abroad. Food safety specifically deals with the protection of the food supply from unintentional contamination, while food defense addresses the need to protect the infrastructure and food supply from intentional acts of terror. Since the passing of the Public Health
Security and Bioterrorism Preparedness Response Act studies have addressed the possible weaknesses of the food safety or defense system as a threat to national security, nearly all address the complexity of the food safety system in the United States but few propose solutions for the current situation.

The food safety system as it is currently executed involves dozens of agencies at the federal, state and international level. Dozens of federal agencies are part of the food safety system with state agencies administering their own regulations within the state and in many cases operating as federal proxy (Brown, 2000). Imported foods are subject to inspections at U.S. borders while the plant or place of origin is subject to inspection by either U.S. officials or through collaboration with the exporting nation (Pathway to Global Product Safety and Quality, 2011). The discourse surrounding food safety nearly always focuses on the complex system of regulations and the fact that many of the laws have not been updated since their inception. Since the creation of the various regulatory bodies that govern food systems, a plethora of laws and mandates have been added to the major bills that regulate our food. These bills and mandates add to the complexity of the regulations and add to the inefficiencies of the system. In 2007, Senator Dick Durbin (D-IL) introduced the Safe Food Act which would have established a Food Safety Administration, streamlining the inspection and regulatory agencies into one new agency; however, the bill died on the floor (Durbin, 2007). A version of the bill was introduced again, but with major revisions including the elimination of the proposed Food Safety Administration. In 2011, the Food Safety Modernization Act (FSMA) was signed into law by President Obama. This is being called the biggest overhaul to food safety
regulations since the 1938 Food, Drug and Cosmetic Act (Layton, 2009). The goal of FSMA is to transition the FDA from reactive policy to proactive regulations. One of the criticisms of FSMA is that it specifically addresses issues within the FDA and does not close the gap between collaborating agencies. Protection of the food supply involves multiple agencies and governments and the cooperation between stakeholders is necessary.
Chapter 2. Literature

Safe food practices have increased over the past two decades while media coverage of foodborne illnesses have also increased (Crutchfield, 2000; Fein, 2011). Current food safety literature varies from the scientific community, to government committees and consumer advocacy groups to economics and political science. Most of the government reports address the specific agencies and their responsibilities. Nearly all of the reports and literature address, even briefly, the complexity of the system. Studies conducted by the Government Accountability Office address the complexity of the United States’ food safety regulatory system and have published several reports about the inefficiencies and overlap in the food safety system (United States Government Accountability Office, 2005). The Congressional Research Service has published a primer for members of Congress on how the system works, what agencies are involved in the system and what agency has what responsibility. Several government and independent studies address the complex nature of the food regulatory system as a potential weakness. Many of these studies focus on the complexity as a potential for terrorist activity, while others address inefficient use of government spending. While nearly all admit that the system is complex, few discuss how those complexities have resulted in some of the most devastating foodborne illnesses in the United States. Without stating that the system is to blame for some of the outbreaks some studies have used other nations as examples of a simplified food safety system (United States Government Accountability Office, 2008). Interagency collaboration and cooperation is essential to many government departments and agencies. Dorothy Daley states that the majority of
agencies collaborate with personnel from other agencies at least a few times a year and in some cases several time a year (Daley, 2009). When agencies fail to collaborate the result is often times public and devastating (9/11 Commission Report: Final Report of the National Commission on Terrorist Attacks upon the United States, 2004; Hansen, 2009; Schreck, 2009).

Collaboration between food safety agencies and levels of government is essential to ensure the safety of food production. In the case of foodborne illnesses, the coordinated effort to trace the outbreak involves cross-level cooperation between local, state and federal agencies and private industries (Service, 2008; Sobel, 2002). The collaborative efforts between the agencies, governments and private industries allow millions of Americans to be protected from adulterated foods. When this system fails it can have wide-spread and damaging results to the individuals, the image of the agencies and the businesses or manufacturer involved in the illness. The agencies primarily involved in the U.S. food safety system acknowledge the fact that collaboration and cooperation is necessary and vital to its mission (Taylor, 2009). As the food safety system is modernized the issue of interagency collaboration continues to be discussed but not as the source of the government’s failure to prevent tainted food from reaching the food supply.
Chapter 3. Research Question, Theory, Methods and Case Selection

The World Health Organization estimates that 2.2 million people globally die annually from foodborne illnesses ("Food Safety," 2012). In the United States it is estimated that approximately 3,000 people die each year from foodborne pathogens ("Estimates of Foodborne Illness in the United States," 2011). Foodborne illnesses cannot be completely prevented as food safety involves everyone from the producer to the chef. When outbreaks occur in the United States, multiple agencies respond to investigate the outbreak to discover the source, prevent additional cases and in some way find the “culprit” to blame. Recent cases have focused on government oversight and regulations as the “culprit” this leads to my central research question:

*Did deficient regulations or policies fail to prevent tainted foods from entering the food supply?*

My theory is that it was a combination of factors that failed to prevent foodborne illnesses. While policies and regulations are in place, if they are not executed, the government is depending upon the manufacturer to self-regulate. The governing agencies were established due to industries that failed to self-regulate.

**Methods**

This thesis is a qualitative assessment through case study comparison and analysis. It is an exploration into how the food safety regulatory system developed and protects the food supply in the United States and if those systems fail. Using a lease similar case design I will select two cases of failed protection of the food supply to
examine if it was the regulations that failed or if other factors failed to prevent the outbreak from happening (George, 2005; Seawright, 2008). Using a consistent structure to compare two cases evidence showing what caused the product to be sold will be extracted. This evidence will then be compared against the new regulations of FSMA to assess if FSMA is enough to combat future outbreaks. Government reports, congressional testimony and other sources will be evaluated to conclude the reasons behind the failure to stop the outbreak from happening.

**Case Selection**

To select case studies for this thesis an in-depth look at recent animal disease outbreaks and foodborne illnesses had to be completed. Since 2006, the CDC has reported 55 foodborne illnesses that can be considered for evaluation. It is necessary to use foods or products that are regulated by the FDA as FSMA directly impacts the FDA. The next criterion that needed to be met was outbreaks that are removed enough to have had a thorough investigation completed to discover the exact cause for the outbreak. This requirement eliminated outbreaks from 2012 and 2011. In the list of outbreaks provided by the CDC the most recent are:

2010

- Alfalfa Sprouts *Salmonella* I 4,[5],12:i:
  - Affected 140 individuals in 26 states
- Shell Eggs *Salmonella* Enteriditis
  - Affected 1,939 people in at least 11 states
- Cheese *Escherichia coli* O157:H7
  - Affected 38 people in 5 states
- Cheesy Chicken Rice Frozen Entrée *Salmonella* Chester
  - Affected 44 people in 18 states
- Frozen Mamey Fruit Pulp *Salmonella* Typhi (Typhoid Fever)
  - Affected 9 people in 2 states
- Restaurant Chain A - *Salmonella* Hartford and *Salmonella* Baildon
  - eliminated due to regulations by local health departments
- Frozen Rodents - *Salmonella* I 4,[5],12:i:
  - eliminated due to the fact that this is not a food for consumption
- Alfalfa Sprouts - *Salmonella* Newport
  - affected 44 people in 11 states
- Shredded Romaine Lettuce from a Single Processing Facility - *Escherichia coli* O145
  - affected 26 people in 5 states
- Red and Black Pepper/Italian-Style Meats - *Salmonella* Montevideo
  - affected 272 people in 44 states
- Water Frogs - *Salmonella* Typhimurium
  - eliminated due to the fact that this is not a food for consumption
- Beef from National Steak and Poultry - *Escherichia coli* O157:H7
  - eliminated due to USDA regulations

2009
- Beef from Fairbank Farms - *Escherichia coli* O157:H7
  - eliminated due to USDA regulations
- Beef from JBS Swift Beef Company - *Escherichia coli* O157:H7
  - eliminated due to USDA regulations
- Prepackaged Cookie Dough - *Escherichia coli* O157:H7
  - affected 72 people in 30 states
- Alfalfa Sprouts - *Salmonella* Saintpaul
  - affected 235 people in 14 states
- Peanut Butter - *Salmonella* Typhimurium
  - affected 714 people in 46 states
- Pistachios - *Salmonella* (multiple types)
  - eliminated due to the fact that the outbreak is not well documented due to multiple forms of *Salmonella*.

All beef products can be eliminated immediately from potential case studies due to USDA regulations. Restaurants are inspected by state health departments and therefore do not meet the criterion. The selection of cases is based upon several factors including the number of reported, the number of states that were affected and the type of vector or carrier of the illness. By selecting a minimum of 200 people and 10 states affected, four outbreaks remain to be evaluated. The 2009 cases that remain are the *Salmonella Typhimurium* in peanut butter and *Salmonella* St. Paul in alfalfa sprouts. The 2010 cases
that remain are *Salmonella* Enteriditis in shell eggs and *Salmonella* Montevideo in black/red peppers in Italian sausage. Selecting the two cases with most number of individuals affected, I am left with outbreaks involving peanut butter and shell eggs.
Chapter 4. Overview of Regulatory Bodies

Background

The growth of the food industry caused food safety to become a concern for producers and consumers alike but this has not always been the case. As the population of the United States continued to expand and grow the need for a variety of foods also grew. As trends in dietary habits changed in America, manufacturers have attempted to give the consumer what they desire. A transition from an agricultural and rural society to an urban society has changed the way that food is produced in the United States.

Prior to the refrigerated railcar, live animals were shipped to the East from the stockyards in the Midwest. According to Connor and Schiek, the advent of mechanically refrigerated railway cars caused the Midwestern beef industry grew even faster (1997). The publication of The Jungle caused the government to scrutinize the meat packing industry and lead to an investigation and ultimately to new regulations for the meat industry. Drs. Senauer, Asp and Kinsey from the University of Minnesota state “few, if any, foods that we ate in 1909 have disappeared from our diets, but they appear in different forms—more processed, more packaged, more labeled, more convenient and sometimes, more mysterious” (1991).

During and following World War II food manufacturing and marketing continued to evolve and change. Women entered the workforce and convenience became central to the eating process. The processed food industry continues to flourish today. As the food industry expanded the need for regulations also grew. During the early to mid-19th
century the need for regulatory government bodies was not seen as necessary as the majority of people were raising their own food. A 2002 report by Brian Halweil estimates that food in the United State typically travels up to 2500 kilometers from production to plate (Halweil, 2002).

A move from subsistence farming to conglomerate food has made for a different way of eating and preparing our meals. This move is not necessarily bad, but it does create a new level of production that must be regulated and policed to ensure safe foods. As fewer and fewer of us know where our food comes from we depend on regulations and inspectors to ensure that our food is safe to consume. Food safety involves every person from the producers to the consumer. With continued vigilance, the expectation of everyone, from producer to consumer, will be a decrease in cases and recalls.

**Overview of Food Safety Policy and Regulatory Bodies**

To grasp the complex nature of our food safety agencies an overview and history of the agencies and laws must be provided. The Government Accountability Office (GAO) has identified as many as 15 federal agencies collectively administering at least 30 laws related to food safety. The Food and Drug Administration (FDA), which is part of the U.S Department of Health and Human Services (HHS), and the Food Safety and Inspection Service (FSIS), which is part of the United States Department of Agriculture (USDA), together comprise the majority of both the total funding and the total staffing of the government’s food regulatory system. (Johnson, 2012)
In addition to the government agencies, there are thousands of private companies that are also stakeholders in food safety and millions of consumers who advocate, even if it is unintentionally, for safe food.

Currently the Food and Drug Administration has the responsibility of maintaining the safety of nearly 80% of the food produced and imported in the United States while the U.S. Department of Agriculture monitors approximately 20% of the nation’s food supply. These are the two biggest stakeholders in food safety regulation; however, the Environmental Protection Agency (EPA), the Center for Disease Control (CDC), the U.S. Department of State and the U.S. Department of Commerce all have their role in food safety. In addition to these agencies or departments, individual states have government units that either enforce federal regulations or in most cases govern in-state food sales. Additionally, many universities and private labs are contracted for work. An explanation of how all of the agencies work together to protect the food supply and consumers is vital to understanding how complex the system is.

1. **U.S. Department of Agriculture (USDA)**

   The oldest agency that has a role in food safety is the USDA, founded in 1862 as part of the Agriculture Act by Abraham Lincoln, originally was designed to stimulate food production due to the growing population of the United States. The food safety division of the USDA began as the Division of Chemistry, the predecessor to the Food and Drug Administration. As the population moved westward and with the development of the refrigerated railroad car, the growth of international trade and an increase in animal production, new policing was needed. In 1884 the Bureau of Animal Industry (BAI) was
created by President Arthur. This industry was designed to help regulate animal health and prevent animal diseases from entering the food supply. As part of the USDA this industry was the predecessor of the Food Safety Inspection Service.

Today the USDA is comprised of 17 departments, six that play a vital role in food safety including, Food Safety Inspection Service (FSIS), the Animal and Plant Health Inspection Service (APHIS), the Agricultural Research Service (ARS), the Agricultural Marketing Service (AMS), the Agricultural Economic Service (ERS) and the Grain Inspection, Packers and Stockyard Administration (GIPSA). Figure 1 shows an overview of the USDA. The USDA does have an undersecretary of food safety that oversees the Food Safety and Inspection Services department of the agency; however, this department regulates approximately 20% of the nation’s food supply.
Figure 1: USDA Overview
A. Food Safety Inspection Service (FSIS)

The FSIS is the department within the USDA that has the most responsibility for protecting the food supply by executing the inspections of meat, poultry and processed egg products to ensure they are safe (USDA, 2012). Figure 2 shows the complexity of this department alone.
B. **Animal and Plant Health Inspection Service (APHIS)**

The role of APHIS in food safety is to help protect plant and animal health through inspection of plants and animals entering the United States. Just as zoonotic disease can devastate livestock in the United States, agricultural pests can devastate crops, leading to a decline in the health of the animal (USDA, 2009).

C. **Agricultural Research Service (ARS)**

The ARS provides research services to the American people and uses science to help solve problems in food safety, both animal and crop (USDA).

D. **Agricultural Marketing Service (AMS)**

The AMS provides the marketing side of the USDA and is responsible for establishing the quality grade standards for cotton, dairy, fresh fruits, livestock, nuts and specialty crops, poultry and eggs, processed fruits and vegetables, and tobacco (USDA).

E. **Economic Research Service (ERS)**

The ERS serves as a projector of the economic risks of foodborne illnesses. In the event of an outbreak they also monitor consumer response to the outbreak (USDA).
F. Grain Inspection, Packers and Stockyards Administration (GIPSA)

The GIPSA facilitates “the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products, and promote fair and competitive trading practices for the overall benefit of consumers and American agriculture” (USDA).

The remaining departments of the USDA all have a vested interest in the health of both the food and health of the nation, but they do not play a direct role in food safety. The USDA, while monitoring only 20% of the food supply, has the largest budget for food safety at over $1 billion in FY 2011 with their total budget being an estimated $146 billion (USDA, 2011).

2. The Food and Drug Administration (FDA)

Originally part of the USDA, the Division of Chemistry was designed to monitor drugs and the chief chemist, Harvey Wiley dedicated his career to developing standards for food processing and informing the public on adulterated foods. The Division of Chemistry became the Bureau of Chemistry in 1901 and was the predecessor to the current FDA. In 1927 the BoC was reorganized into the Food, Drug and Insecticide Administration. In 1931 the Insecticide was dropped from the name and the FDA was established. It was not until 1940 that the FDA was moved from the USDA to become at division in the Federal Security Agency (FSA) which eventually became the Department of Health, Education and Welfare, now the Department of Health and Human Services (HHS) (USDA, 2012); The organization of the HHS is shown in figure (HHS, 2007).
The organization of the FDA is shown in the figure 4 (FDA, 2012)
Figure 4: FDA Overview
Housed within the FDA is the Office of Foods. This office is divided into two main offices; the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition. Together these offices work together to ensure the safety of nearly 80% of the U.S. food supply and veterinary vaccines, pet food and many of other animal related products.

A. **Center for Food Safety and Applied Nutrition (CFSAN)**

CFSAN regulates over $417 billion in domestic food each year, as well as the approximately 150,000 registered food processing facilities (FDA, 2012). The CFSAP is responsible for everything from food additives to consumer education. When considering the responsibility of the CFSAP and the FDA the approximately $3.2 billion budget in FY 2010, with an estimated $1 billion dedicated for food safety, seems miniscule. With the passage of the Food Safety Modernization Act (FSMA) in 2010, the FY 2011 budget increased to $40 billion with an increase of $326.3 million for food safety.

B. **Center for Veterinary Medicine (CVM)**

The CVM impacts food safety by regulating animal vaccines or medication that is added to animal feed. In addition to this responsibility, the CVM helps protect all domesticated animals by regulating pet food and animal feed (FDA, 2012)

3. **Center for Disease Control and Prevention (CDC)**

The CDC is responsible for tracking foodborne illnesses and investigating outbreaks. The Foodborne Disease Active Surveillance Network or FoodNet was established in 1995 as a collaborative program between state health departments, the
CDC, the USDA-FSIS and the FDA. Working together FoodNet assesses the impact of foodborne illnesses on the American people and the potential cost of foodborne illnesses.

4. **Environmental Protection Agency (EPA)**

The EPA is tasked with regulating the amount of residues from chemicals found in or on treated crops and animals. Additionally the EPA works to set limits and regulations for water and air quality. All of these tasks combined with the nature of commercial farming and the potential of run-off into the water supply makes the role of the EPA vital to the health of Americans and the safety of the food supply in the United States.

5. **U.S. Department of State**

Due to globalization or the prevalence of free trade, we live in a world that is more connected than at any time in history. Food Safety in the United States is necessary to encourage international trade. While the economic health of the United States does not completely rely upon the food or agriculture industry the recent recession in the United States proves how necessary agriculture is to the economy.

U.S. agricultural exports generated employment, income, and purchasing power in both the farm and nonfarm sectors. ERS estimates that each dollar of agricultural exports stimulated another $1.34 billion in business activity in 2010. The $115.8 billion of agricultural exports in 2010 produced an additional $154.9 billion in economic activity for a total economic output of $270.7 billion. Every $1 billion of U.S. agricultural exports in 2010 required 7,800 American jobs throughout the economy. Calendar year 2010 agricultural exports required 907,000 full-time civilian jobs, which included 609,000 jobs in the nonfarm sector. The agricultural export surplus helped to offset some of the nonagricultural trade deficit (USDA, 2012).
The U.S. Department of State is directly involved in protecting the U.S. food supply through diplomatic relationships with various trade partners. By promoting trade and global health the U.S. Department of State plays an important role in both food safety and food defense.

6. **The Department of Commerce**

The National Oceanic and Atmospheric Administration’s (NOAA) National Marine Fisheries Service (NMFS) is part of the Department of Commerce and is responsible for the management of living marine resources within the United States Exclusive Economic Zone or waters up to 200 miles from U.S. coasts. The NMFS has a role in food safety by providing a fee-based inspection service to ensure that government standards for seafood are met (NOAA).

In addition to the number of federal agencies that are involved in food safety, individual states have Departments of Agriculture that work to ensure a healthy and safe food supply within the state. Many cooperative agreements are utilized between agencies to provide services in the event of an animal disease or foodborne illness outbreak (FDA, 2004). Many universities are working alongside the USDA and the FDA to provide assistance and research on various projects (USDA, 2012).

**Policies**

When the USDA was founded its purpose was not to govern or protect the food supply, yet just a few years from its inception, the purpose had changed. The first major policy that began the regulation of the U.S. food supply was the 1884 creation of the
Bureau of Animal Industry. It was not until the publication of The Jungle in 1906 that the food industry was put on display for the world. Incidentally, that same year two bills were signed into law to regulate the food system; (a) the 1906 Federal Meat Inspection Act and (b) the Pure Food and Drug Act, also known as the Wiley Act was enacted. The former gave the USDA the authority to inspect and regulate the slaughter of meat. The Pure Food and Drug Act gave authority to inspect meat products and regulate the manufacturing, sale and transportation of medication (Ayers, 1907).

The Food, Drug and Cosmetic Act which, signed into law in 1938 by Franklin D. Roosevelt; at the time was the biggest step forward for food safety; the act gave authority to the U.S. government to establish food standards, regulate poisons in food production and control over drug manufacturers and cosmetic devices (Hickman, 2003).

The 1906 Federal Meat Inspection Act (FMIA) gave authority to inspect meat to the USDA; similarly the 1957 Poultry Product Inspection Act (PPIA) authorized the USDA to inspect poultry. The 1970 Egg Product Inspection Act is perhaps one of the more confusing acts of Congress related to food safety. This act authorized the USDA to inspect egg-breaking plants in which eggs are being processed, grade shell eggs, while the FDA controls eggs that are for human consumption (Title 21 Chapter 15 C.F.R. § 1033, 2007).

Following World War II and the increased use of processed foods, the independent companies began to focus on food safety and many of them began implementing their own measure to protect, not only the health of consumers and company reputations. In the 1970s the FDA contacted the Pillsbury Company to request
that they provide training of their own safety measures; what would become known as the Hazard Analysis and Critical Control Points (HAACP) System thus was first developed by a private company but since has been adopted by governments and companies worldwide (Dr. Sperber, 2009) (Hazard Analysis Critical Control Point System, 2007). In the United States HACCP is primarily used in regulating juice and seafood under the FDA. Today HAACP are applied to many other food processes including dairy and retail food services (Hazard Analysis and Critical Control Points, 2011).

July 2009 saw additional changes to shell egg regulations. Due to the number of *Salmonella Enteriditis* (SE) outbreaks, the FDA proposed changes to the transportation and storage of shell eggs. The rule, originally proposed in 2004 and finally accepted in 2009, affected any producer with more than 3,000 laying hens or layers. The rule requires farms to have written and implemented SE prevention plans, biosecurity procedures in place to attempt to limit the number of potential diseases, that shell egg producers be registered with the FDA, that shell eggs be stored and transported in refrigerated trucks and it require producers to conduct egg testing when a hen or the environment tests positive for SE (Title 21 Chapter 16 C.F.R. § 118, 2009)

Enacted in 2010, the Food Safety Modernization Act (FSMA) was considered the biggest overhaul to food safety since the Food, Drug and Cosmetic Act of 1938. Chapter 6 will analyze FSMA and its impact on the food supply in the United States.
Summary

Given the overview of the various agencies and departments without even mentioning the private companies, it is easy to see why food safety has become such a web of confusion. With so much overlapping authority, or in some cases the inability to act due to policy constraints, the food system is placed in a maze of policies, regulations and budget constraints. Consumers are often at the mercy of the producers and inspectors to ensure safety of their food. Chapter 5 will provide two case studies that demonstrate what happens if consumers fall victim to the holes in the regulations and how the policies that were meant to protect the food system failed.
Chapter 5: Case Studies

Case Study 1: *Salmonella* Enteriditis (SE)

*Introduction*

Eggs have become so integral to the American diet that the American Egg Industry estimates that the average American consumed 247.7 shell eggs in 2011 (Egg Industry Fact Sheet, 2012). Eggs are a staple at Sunday brunches and are served on nearly every restaurant’s menu, yet eggs can be one of the most dangerous items to eat, if they are not prepared properly. While many of us may remember as a kid ordering “dippy” or “sunny-side up” eggs, under-cooked eggs pose a risk to our health. Thousands, if not millions, have eaten eggs that are not fully cooked and have walked away to tell the tale of the deliciousness, so does this mean that only some eggs carry the risk of making us ill? According to the FDA, unless an egg is treated through pasteurization to destroy *Salmonella*, every egg poses a threat to our health; therefore a warning label, see example below, must be on every carton of un-pasteurized eggs (FDA, 2012).

*Safe Handling Instructions*

To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly. Eggs that have been treated to destroy *Salmonella* — by in-shell pasteurization, for example — are not required to carry safe handling instructions.

So what happened in 2010 that caused nearly 2,000 people in nearly a dozen states to become ill? By evaluating government documents, congressional testimony and other secondary sources, I will attempt to answer this question.
Background

Beginning in April of 2010, individuals began reporting illness and public health officials were alerted to a potential outbreak of SE. Epidemiological investigations identified 29 restaurants or clusters in which more than 1 person had become ill. A traceback investigation traced the tainted eggs to Wright County Egg of Galt, Iowa.

Wright County Egg issued a voluntary recall of eggs on August 13, 2010

August 13, 2010 - The following statement was released by officials of Wright County Egg regarding the US Food and Drug Administration’s (FDA) on-farm records review and egg testing for Salmonella.

Wright County Egg of Galt, Iowa is voluntarily recalling specific Julian dates of shell eggs produced by their farms because they have the potential to be contaminated with Salmonella. Salmonella is an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with Salmonella often experience fever, diarrhea, nausea, vomiting and abdominal pain. In rare circumstances, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections, endocarditis or arthritis (FDA, 2010)

Five days later the recall was expanded to include additional states that may have been supplied tainted eggs. Two days later Hillandale Farms of Iowa issued a voluntary recall of shell eggs. When the story broke that there was as outbreak of SE, the media began reporting about the number of cases and illnesses attached to the suspected outbreak and questioning how this could have happened. Congress began to question and called the owner of Wright County Egg, Austin “Jack” DeCoster, and the CEO of Hillandale Farms, Orland Bethel, to testify about the conditions of their farms. During the congressional hearing, Bethel pled the fifth and questions were answered by the farm
representative Duane Mangskau. Austin “Jack” DeCoster and his son Peter answered questions regarding the outbreak. DeCoster stated

As FDA was beginning their review of our records and inspecting our farms, we undertook our own food safety investigation. Our farm voluntarily secured more extensive testing and review procedures of our own. We conducted 894 environmental tests, using both an accredited private lab and the testing lab at Iowa State University. We pulled 70,200 eggs for samples, representing each farm, and sent those for testing at an accredited private laboratory. When the results of those tests became available, they were immediately provided to FDA. These tests confirmed that Wright County Egg was producing eggs contaminated with SE (DeCoster, 2010).

During the investigation, Hillandale Farms and Wright County Farms were not allowed to continue production until all the reported violations were rectified.

In the time since the initial outbreak there has been discussion about how this outbreak was able to happen. According to Dr. Darrell Trampel, a leading poultry specialist at Iowa State University, SE is not and has not been a reportable disease according to the Iowa Department of Agriculture (Trampel, 2012). Perhaps the most troubling issue with the SE outbreak is the fact that according to testimony, Wright County Farms was aware of positive Salmonella tests prior to the first reported illness (Foley, 2012).

Inspections

Following the outbreak and the testimony of the owners and CEO, the policies that govern egg safety were called into question. As mentioned previously, egg safety regulations changed in July 2010 and the outbreak in discussion began in April of 2010, but would those regulations prevented this outbreak from happening? The farms in question have upwards of 500,000 birds on each site. The Wright County Farms had an
estimated 1 million hens and would have been subjected to inspections under the new regulations. The question remains, which agency was responsible for inspections prior to July 2010? The answer is not as simple as “the FDA” or “the USDA.” According to a report by the Office of Inspector General of the Department of Health and Human Services about the FDA Inspections of Domestic Food Facilities, over 50% of facilities had gone more than years. Additionally, the report found that when inspectors had cited facilities for violations, i.e. official action was indicated (OAI) many had received previous violations and were cited often again the following year (Levinson, 2010).

The regulation of egg production sites is split between the FDA and the USDA. If there is a breaking plant on site, the USDA inspector visits daily to ensure the safety of egg products. The shell egg is graded by the USDA but under the jurisdiction of the FDA. The facility is under the jurisdiction of both agencies. Certain things on the farms are to be inspected by the USDA, while any danger to the actual egg falls under the jurisdiction of the FDA.

The farms in Iowa were subject to the FDA inspectors; however, the only inspection form found for Wright County Farms is from the state of Iowa Department of Inspections and Appeals which performed a 15 minute routine inspection on April 15, 2010, during which the inspector marked every category as Not Observed and made special note of the fact that a full-time USDA inspector was on-site. The so-called inspector actually was an egg grader and was not allowed in the actual henhouse for biosecurity reasons and had made several official observations about the conditions of the farm (Strickler and Rand, 2010) (Strickler, 2010). That the two agencies responsible for the safety of eggs did not communicate is not explicitly detailed by the agencies
themselves, yet the fact that one agency, responsible for certain aspects of the facility observed issues and the other agency, responsible for other aspects of the health of the egg did not cooperate to inspect the facility and shut down other aspects of it, implies a break down in cooperation and communication between the two agencies.

Consequences

Following the investigation of the outbreak, Wright County Egg was issued a warning letter by the FDA stating that “failure to take prompt corrective action may result in regulatory action being initiated by the Food and Drug Administration without further notice” (FDA, 2010).

Since 2010, several lawsuits have been filed against Wright County Egg for damages associated with the illness. Currently there have been no criminal charges associated with the SE outbreak. The policies that were in place during the outbreak were unable to prevent the outbreak from occurring, even though Wright County Egg had been fined by the Iowa Department of Natural Resources for several years and in 2009 had been penalized, yet this was not enough to draw the attention of the FDA inspectors.

Case Study 2: Salmonella Typhimurium

Introduction

For many of us that grew up as picky eaters, peanut butter was a staple in our diets. According to a survey done by the J.M. Smucker Company in 2002, the average American will eat 1,500 peanut butter and jelly sandwiches before finishing high school
(PB&J is A-OK, 2002). In 2009, a massive peanut butter recall struck fear in the hearts of parents and people everywhere as peanut butter snacks were pulled from the shelves and linked to Salmonella Typhimurium. Unlike the shell egg recall, the peanut butter recall affected both humans and pets. While jar peanut butter sold in stores was not affected in this recall, peanut butter snacks, like the cheddar peanut butter crackers and peanut butter-flavored crackers were affected. Adding to the danger of this recall is the fact that the company supplied peanut butter to schools around the nation. President Obama weighed in on the issue stating “that’s what Sasha eats for lunch…probably three times a week. I don’t want to have to worry about whether she’s going to get sick as a consequence of eating her lunch” (Obama, 2009). In the same interview he called for a complete review of the FDA’s functions regarding food safety.

The peanut butter product recall revealed just how complex the food processing system in the United States had become. The traceback linked the tainted peanut butter products to the Peanut Corporation of America (PCA) in Blakely, Georgia. Due to the number of companies and products involved in this recall it has been called one of the largest in U.S. history (FDA, 2009).

**Background**

PCA manufactured approximately 2.5% of peanut products in the United States until their closing in February 2009 (Chapman, 2009). The peanut butter that PCA manufactured was not for direct sale to the public, but was sold to institutions such as schools, nursing homes and hospitals. The peanut butter paste that was manufactured was
used in cookies, crackers, candies and many other items that were sold by several different companies.

Beginning in November 2008 the Center for Disease Control and Prevention’s PulseNet noted small numbers of *Salmonella* Typhimurium cases in several states. The number of cases began to increase throughout November and into December causing the CDC with the cooperation of local and state health officials to begin an assessment of the cases. One of the complications surrounding *Salmonella* is the varieties of strains. Once a case is suspected the timeline for identification and then reporting to the appropriate authorities can take anywhere from one to three weeks, see figure 5 (CDC, 2010).

Figure 5: *Salmonella* timeline
This fact led to a delay in the recall from PCA. The first of the recalls was issued on January 10, 2009. This initial recall included all peanut butter and peanut butter paste sold under the King Nut and Pride labels. The recall expanded on January 16th to include all peanut butter and peanut butter paste products manufactured at PCA in the Blakely, Georgia, plant since July 2008. The recall grew even larger ten days later when all peanut products produced in the Georgia plant since January 2007 were added to the recall list. The recall included products sold under the Keebler, Kellogg, Jenny Craig and Austin brands. By late 2009 nearly 4,000 products had been added to the recall list published by the FDA including everything from crackers to dog treats. The recall was complicated when in February 2009 PCA filed for Chapter 7 bankruptcy protection. Although the company had ceased operations, consumers were left with unanswered questions and the government was left to answer the questions of how this could have happened.

Investigation

In the midst of the recalls the government began its investigation of PCA in Georgia and its two affiliate plants in Texas and Virginia. The investigation showed massive gaps in the regulatory oversight of the plants, including the Texas plant operating without a license or never having had an inspection completed by the state. The federal code of regulations in 2008 states:

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:
(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests (21 C.F.R § 110.20, 2008)

When the investigation began at the Georgia plant, the Georgia Department of Agriculture (GDA) found the plant to be in violation of the federal regulations, even though it had had GDA/FDA inspections in 2007 and 2008. The 2007 inspection report stated

Current inspection on 8-23-2007 notes firm operates as a manufacturer of peanut butter and roasted nut products. The Firm was producing peanut butter during the inspection. Official identification and inspection findings discussed with Danny Kilgore Plant Manager. Objectionable findings: Product containers (30lbs buckets) were stored uncovered in the storage area. (corrected on site) Damaged lid on rework tank in the butter room surface was not smooth and difficult to clean. Tote (no wheels) on bulk butter fill line had damaged wall rough surface not easily cleanable. The findings of the inspection were discussed with the Plant Manager Danny Kilgore and QA Jeff McFay. Mr. Kilgore stated a new top for the rework tank would be fabricated by 8-29-2007. Mr. Kilgore also stated the tote on the bulk line would be repaired by 8-29-2007. Susan Alexander GDA. Sanitarian was also present during the inspection. No FDA samples were collected. Mgr. Firm is registered with FDA Bioterrorism. The inspection was conducted by Chad Beard, GDA Agriculture Sanitarian (FDA, 2007).

Due to the findings at the plant a subsequent inspection was completed in 2008 by the FDA. This inspection again failed to take samples, but once again found issues with the plant:

Current inspection on June 10, 2008 notes firm operates as a manufacturer of roasted peanuts and peanut butter. Official identification and inspection findings discussed with Raymond Kimbrel, Plant Manager. Objectionable findings: Steel
wool pad in butter room used for cleaning not approved due to possible contamination, scraper used to work final bulk tank improperly stored above reject tank also no cleaning and sanitizing schedule for scraper, and dust build up on fan in butter fill area. All objectionable conditions were corrected during the inspection. FDA requested an evaluation of the firms metal detection procedures due to rejected product being held at the firm due to complaint of metal fragments in granule size roasted peanuts. The normal process the roasted nuts would pass under several magnets then packaged and run through a metal detector as the final process. The firm’s procedure seems adequate for regular runs of product however the product in question was not checked for metal because of the metal/foil bags used in the original shipment that was rejected. The firm wishes to rework the rejected product by running it through the butter line which has a metal detector (Model) at the end of the process. The firm could not produce the manual for the detector so no determination could be made about the capabilities and effectiveness of the detector. No FDA samples were collected. Firm was processing peanut butter during today’s inspection Firm was registered with FDA Bioterrorism. Firm was given information during today’s inspection regarding the FDA Food Defense and Terrorism initiative ALERT. The inspection was conducted by Chad Beard, GDA Agriculture Sanitarian (FDA, 2008).

These inspections were conducted during a time in which the plant was producing tainted products, and had samples been taken the number of cases could have been lessened if not eliminated entirely. As with the Salmonella Enteriditis outbreak, it was uncovered that the plant operators were aware that the product had tested positive for Salmonella through private lab results (FDA, 2007).

In both the Texas and the Georgia plants the FDA relied upon state agencies to inspect food manufactures under signed cooperative agreements ("2008-2009 Contract Audits," 2011).

Consequences

Due to the outright neglect of the company, nine people lost their lives and more than 700 people were sickened. In the investigation conducted by the FDA and the U.S. Congress following the outbreak, it was determined that though unintentional, the
company was responsible for the distribution of tainted product. The U.S. House of Representatives Subcommittee on Oversight and Investigations commenced an investigation of the outbreak. The investigation found a total systemic breakdown between the agencies involved in the inspection process. This investigation led to a complete investigation of the FDA and its role in food safety.

PCA no longer operates as it closed in the midst of the outbreak. Since the outbreak the Federal Bureau of Investigation (FBI) launched a criminal investigation against the president and CEO, Stewart Parnell. Criminal charges in food safety cases have proved to be difficult and complicated under the Food, Drug and Cosmetic Act of 1938. Most of the violations are considered civil and only if proven to be repeated or intentional (Flynn, 2012). Many of the lawsuits are waiting to be heard, the case of the Texas plant of PCA had had a very different outcome.

The Plainview, Texas, PCA plant was subject to a complete recall of all products by the Texas Department of State Health Services. In the subsequent investigation by the state, gross negligence of the building and equipment was cited as one of the many causes of the presence of *Salmonella*. The investigation failed to produce a license for operation and documented the failure to be inspected by either the state or the FDA. The state of Texas issued a fine of $14.6 million against PCA, one of the highest ever issued by the state (Flynn, 2010).

**Summary**

The two previous case studies have attempted to show how the FDA and its complicated policies have left massive gaps in the regulatory system. While the
regulations are in place to help avoid foodborne illnesses, the lack of fulfillment of these regulations, for certain caused the massive *Salmonella* Typhimurium outbreak. The lack of inspections of the egg producing plants in Iowa may have led to the outbreak of *Salmonella* Enteriditis, although conclusive evidence is not possible to gain due to the nature of the outbreaks.

The next chapter gives an overview of the new Food Safety Modernization Act and how regulations for inspections must change to prevent future outbreaks.
Chapter 6. Food Safety Modernization Act of 2010 (FSMA)

Public Law 111-353 or FSMA has been called the greatest change to food safety since 1938, but what does it change and how will it protect the food supply?

One of the biggest changes to food safety is the frequency of inspection of facilities based upon risk. High risk is determined using the FDA’s decision tree found below (FDA, 2012)
Under FSMA, high risk facilities must be inspected within 5 year of FSMA’s implementation and every 3 years after that. An additional provision in the law requires that all manufacturing plants keep records, and have those records available for inspection for 2 years. One of the biggest changes to the law is the mandatory recall
authority of the FDA; prior to FSMA, the FDA could only request companies issue a recall of suspected products. FSMA requires that manufacturers register with the FDA and gives the FDA the authority to suspend registration if reasonable probability of causing serious adverse health consequences or death to humans or animals is uncovered (Title 1 Section 102, 2010). Under, FSMA the Secretary of Homeland Security in coordination with the Secretary of Health and Human Services and the Secretary of Agriculture the council’s responsibilities include

(1) facilitating partnerships between public and private entities to help coordinate and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each council relating to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of–

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food (Title 1 Section 106, 2010)

While this section of FSMA is designed to address issues of food defense against foreign biological or agro-terrorist attacks, cooperation is vital to the safety of the entire food supply. Perhaps the changes that will prevent the greatest number of outbreaks are provided in Section 422 of FSMA. This section requires laboratories to conduct testing to be accredited and to provide the results to the FDA. (Act Title II Section 202, 2010) This
provision alone had the potential to prevent the two cases discussed in the previous chapter.
Chapter 7: Conclusion

Findings

After reviewing FSMA, I can say that it is possible to prevent foodborne illnesses similar to the ones discussed in Chapter 2 under the new regulations. While the inspection regulations in place during 2007, 2008 and 2009 did not prevent the tainted items from being sold, the provision requiring accredited laboratories to report to the FDA rather than to the company would have prevented the tainted peanut butter and eggs from entering the food supply. While the entire law is designed to transition the regulations from reactive to proactive, without the money to execute the new regulations the law will not prevent any new outbreaks. Arguments prior to the adoption of FSMA focused on overlap among agencies and making more efficient use government spending and that streamlining the system would help prevent outbreaks more effectively than simply passing overhauling legislation. The 2002 Bioterrorism Act allows the FDA to contract USDA inspectors to help facilitate their own inspections. In over a thousand facilities both the FDA and the USDA have jurisdiction over certain products and which creates a confusing situation for manufacturers. Under the Bioterrorism Act cooperation between agencies focuses on food defense and not necessarily on food safety. To utilize the national budget to its fullest without interagency overlap, a broader study of the system that includes all aspects of food safety should be conducted.
Discussion

The original food safety law that was introduced before the House proposed a Food Safety Administration similar to that of many other developed nations. Many nations belonging to the European Union have transitioned to a unified administration that oversees food safety including imports and domestic foods. The United States has a farm-to-table program to promote food safety but within that program the number of agencies, departments and companies that have their hand in the pot all add to the confusion of the regulatory process. During the 2009 peanut product recall, this issue became evident as over a thousand companies had to issue recalls because of the tainted product (Weise, 2009).

The way food is processed is not the issue here, how the regulatory system inspects and oversees the processing is at issue. Confusion regarding which agency inspects what and what the inspection entails is partially to blame for the two outbreaks discussed. FSMA is a move forward to protect the food supply, but the issue of overlap was not addressed besides encouraging cooperation between agencies. A 2010 study conducted by the Institute of Medicine and the National Research Council found that “for more than a decade, various organizations, consumer groups, and individuals have recommended organizational changes in the U.S. food safety system, with the goal of increasing its efficiency and enhancing the public health” (National Academy of Sciences, 2010). One of the shortfalls of FSMA is to unify all food safety responsibilities that are shared by the USDA and FDA. FSMA provides a step forward for clarification on several areas, yet fails to rectify the overlap of agencies.
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Appendix: Images