A Systems Approach to Food Accident Analysis

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Dedication

This thesis is dedicated to those who have lost their lives to food borne illness and to the thousands of dedicated food industry professionals who work hard every day to prevent these illnesses. Hopefully this thesis will show the way to better outcomes for all.

Acknowledgements

Returning to MIT after 31 years has been a challenge and without the loving support of my wife, Lynn, I would have never made it through the program. To my fantastic sons, who thought school would "kick my butt", they were right. But through their support and interest, here I am still standing. And to my parents, thanks for putting me through MIT the first time!

Without the open-mindedness of Prof. Nancy Leveson, I would not have returned to MIT to work on the important topic of food safety. I thank her for welcoming me into her research group and providing me with the opportunity to make a contribution to the world of safety.

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To all who think you are too old for any challenge, I can say you are wrong. Life long learning is the key to a happy and healthy life. You are never too old for more learning!

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Abstract

Food borne illnesses lead to 3000 deaths per year in the United States. Some industries, such as aviation, have made great strides increasing safety through careful accident analysis leading to changes in industry practices. In the food industry, the current methods of accident analysis are grounded in regulations developed when the food industry was far simpler than today. The food industry has become more complex with international supply chains and a consumer desire for fresher food. This thesis demonstrates that application of a system theoretic accident analysis method, CAST, results in more learning than the current method of accident analysis. This increased learning will lead to improved safety performance in the food production system

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Chapter 1: The Case for Improved Food Accident Analysis

1.1 The Problem

The food supply in the United States is one of the safest in the world. However, each year the US Center for Disease Control (Scallan, Hoekstra et al. 2011) (CDC) estimates that 47.8 million food borne illnesses occur, resulting in more than 127,389 hospitalizations and 3037 deaths. The deaths, health care costs, loss of confidence in the food supply, and the loss of productivity make reduction of food-borne illnesses through improved food safety a major societal need. The Pew Foundation (Scharff 2010)estimates annual financial losses are estimated to be $152B.

On a global basis, the problem is even larger because of (or due to) the less developed state of food safety systems in the developing world. The global incidence of food borne disease is difficult to estimate, but the World Health Organization reported (WHO 2007) that in 2005 alone 1.8 million people died from diarrheal diseases. A great proportion of these cases can be attributed to contamination of food and drinking water. Additionally, diarrhea is a major cause of malnutrition in infants and young children.

My hypothesis is that that food borne illness can be reduced by changing the method of accident analysis from the current approach to a system theoretic method. The systems approach to food accident analysis will result in more information than the current approach. This change will increase learning by the food production system and hence reduce accidents. Increased learning has reduced accidents in other industries, such as aviation. The purpose of this thesis is to investigate system-based accident analysis methods to determine if they can improve learning over currently used methods.

The food production system is a complex, socio-technical system essential to maintaining and advancing the world's standards of living. While the roots are ancient, the food production system is a critical infrastructure for today's global population and the system is now undergoing unprecedented change. Consumers worldwide are seeking healthy, fresh food regardless of the growing season. These changes to the food system are leading to global supply of foodstuffs that transcend national boundaries. In addition, millions of people are moving from subsistence to middle class lifestyles, upgrading their diets to include animal protein.

These changes are restructuring the food production system. Current approaches to logistics, agronomy, and safety are based on assumptions that are no longer true. Tauxe, et al (Tauxe, Doyle et al. 2010) report on a number of changes taking place in the world food production system that are changing the way food issues should be addressed. For example, methods that kept food safe in the past need re-evaluation as food supplies are shipped globally. This thesis will examine a system theoretic approach to food safety that is in tune with today's complex and global food production system.

1.2 What is the Mechanism Behind Food Borne Illnesses?

Food borne illness are caused by the ingestion of four types of hazards[1]:

1. **Microorganisms in food: (a)** bacteria such **as** Salmonella, E Coli, Listeria or campylobacter, C. Botulinim or (b) viruses such as the norovirus.
2. **Mycotoxins** such as ergot, vomitoxin and aflatoxin
3. **Contaminants** such as Pesticides and Herbicides
4. **Economic Adulteration** such as recent incidents in China as reported in the New York Times (LaFraniere 2011).

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[1] I am not considering allergens or food intolerances, toxins formed during processing, the chronic safety of food additives or the effect of food on obesity in this thesis.

These threats to safety have been with humans since we began to time-shift food supplies through various preservation mechanisms. The current approach to food safety emerged out of a long history of attempts to control incidences of food contamination. The earliest food safety laws are biblical as we see in development of Jewish food practices. The technology of food preservation is even older, stemming from drying of grain in Assyria. Smoking, salting, drying, curing, fermenting, etc., were all technologies developed to prevent food from spoiling during storage. These methods prevented microbial and fungal spoilage of food by either reducing water activity (the availability of water for microbial growth) or creating a hostile environment for pathogens.

As the basics of food preservation reduced substantially the incidence of spoilage, other safety issues came to the fore. For instance, adulteration of foods, exemplified by watering down wine, were known in the Old Testament:

> Thy silver is become dross, thy wine mixed with water [Isaiah 1:22, King James Bible]

Adulteration for economic gain takes two main forms, replacing expensive ingredients with cheaper ingredients or masking the deterioration of food. Adulteration affects the consumer in two ways, reduction of quality and reduction of safety. As societies developed, governments played an increasingly larger role in developing regulations to control the adulteration of food supplies.

1.3 Creating a Food Safety Control System

Food Safety can be thought of as a control problem. Food borne illnesses are the result of ineffective control of processes, such as sanitation procedures or regulations, that have been designed to prevent food safety incidents.

Complex systems, like the food production system, can be broken down into hierarchical structures. System control theory was developed to understand how complex systems are controlled. According to system theory, the top level of the system enforces control on the one below through a feedback control loop. The second level in turn controls the level below it. This control enforcement cascades down through the system levels until it reaches the bottom level. The resulting structure is called the hierarchical control structure. The control objective is to enforce the system goals and constraints.

A Safety Control Structure is a hierarchical control structure that enforces the safety constraints in a complex system. In food systems, the control structure is built of a number of regulations, processes, and technologies. Understanding how this control structure works is central to finding ways of improving control of food borne illness. The current US food safety control structure has developed in an ad hoc manner over the last 150 years. A brief review of how the US food safety control system developed follows.

Initial control of adulteration was through caveat emptor. Consumers purchasing food, using their senses and their knowledge of context, had to be on guard against adulteration. Their control on the situation was not to not buy and to let their neighbors know of their concerns. As the food production system shifted to support urban living, the development of food supply chains created the need for new types controls.

For example, milk in the UK in the 1800's was routinely adulterated by skimming cream and adding water. Adulteration was so prevalent that some consumers insisted that the cow be milked right at their kitchen door to ensure that the milk was pure. Of course, this was not a scalable method and eventually, after much public haranguing, local government stepped in to set up a second method of control, laws and regulations. These laws and regulations were the first step in creating a food safety control structure.

The first food laws regulated weights and measures. As chemistry developed, new methods of chemical analysis were employed to monitor food adulteration. These chemical analyses created a new method of control, sampling of products in the market and laboratory analysis. As new methods of analysis were developed to detect adulteration, new adulterations techniques were deployed. A race between adulterators and regulators continues to this day.

In the US, food controls were initially scattered and conducted at the state and local level. Food controls were focused on retail purchasing and testing of the product. The sensors used for all of these analyses were the eyes and nose of the inspector combined with rudimentary analytic methods such as hygrometers, microscopic visual analysis, and balances. True advances required understanding of the science behind food spoilage.

1.4 The Development of Food Safety Science

The scientific breakthroughs in understanding the mechanisms behind food spoilage started with the experiments of Nicolas Appert in 1812. He developed a method of food storage based on packaging food into sealed glass bottles, which were subsequently heated to create a sterile food. Pasteur, in 1862, discovered that microorganisms were responsible for food spoilage and resulting illness. His discovery led to food safety technology that was based on a scientific footing.

1.5 Controlling Food Safety Through Regulation

In parallel with scientific development, laws regarding food safety, particularly in meat, began to emerge in the middle of the 19th Century. The earliest US meat inspection laws were put into force in the 1850's. In the late 1880's to early 1900's, countries in Europe began developing food safety systems for meat. This development of European food standards put US meat exports to Europe under pressure. The meat industry in the US fought these regulations until 1906. In that year, the larger meat producers realized that bad practices by smaller producers were ruining consumer confidence in US meat. Consequently, the larger companies dropped their opposition to Federal regulation and the Federal Meat Inspection Act (FMIA) of 1906 was quickly passed. This law created a national control structure that is the foundation of US food safety controls today.

The FMIA was focused on economic adulteration more than the safety of food. The Pure Food and Drug Act, passed at the same time, was also concerned with adulteration. Both acts installed controls through inspection of foods. The FMIA also established sanitary requirements for meat processing facilities. Later legislation in 1938 and 1958 reinforced the model of federal and state regulation of food quality, ingredients, and safety. The recently passed Food Safety Modernization Act continues to refine the current system by giving the FDA authority to initiate recalls and hire more inspectors. This model of "inspecting in quality" lasts to this day.

Under the 1938 US Food, Drug, and Cosmetic Act, regulations established "good manufacturing processes" (GMPs) (Sec. 402. [21 USC §342] 1938) to describe principles that must be observed during manufacture of food and drugs. Briefly, these principles preclude sale of food that:

> "has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

These principles form the foundation of the regulatory inspection scheme now in place in the US. These principles are grounded in a linear chain of events model, providing barriers to entry by harmful substances and pathogens. If the chain is broken, then the accident is prevented.

GMPs are designed to provide control of the manufacturing environment. In 1961, a new chapter in food safety opened. NASA contracted with the Pillsbury Company to develop a system to ensure foods produced for astronaut consumption in space would not result in astronaut illness. Pillsbury developed the Hazard Analysis/Critical Control Point (HACCP) methodology to deal with the problem of ensuring safe food during space flight. HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards. The FDA (FDA 2011) describes how the HACCP methodology is to be applied. HACCP was introduced into the food industry in 1971. It is in wide, but not universal, use today. The FDA and USDA require HACCP for a few food segments such as seafood and unpasteurized juices, but its use in the rest of the industry is voluntary. HACCP is hazard analysis and control model akin to HAZOP, a method developed by the chemical process industry . For a further description of HAZOP, see the summary at Wikipedia (Wikipedia 2011) .

1.6 An Alternative Systems-Based Approach to Controlling Food Safety

The current approach to food accident analysis is a combination of epidemiology to identify illnesses and track them to their origin and a regulatory standards approach. I call this the epi-regulatory approach to food accident investigation.

STAMP (System Theoretic Accident Modeling Processes)(Leveson 2004) (Leveson 2011) was developed to understand accident causation in complex systems, such as the food production system. Its origins are in software and aerospace safety; STAMP has been applied to pharmaceuticals (Couturier 2010) and water safety (Leveson, Daouk et al. 2003). Rather than focusing on identification and control of failures, STAMP treats safety as an emergent property of the system. Therefore, the management of safety is handled as a control problem of the system rather than a series of events or failures to be managed.

CAST (Causal Analysis using STAMP) is an accident analysis method based on the STAMP model. It is described in detail by Leveson (Leveson 2011) in a forthcoming publication. CAST uses system theoretic methods to analyze accidents and determine how and why they occurred by analyzing the control structure of the accident system. The CAST analysis begins with developing the control structure of the system and analyzes how the control structure enforces the safety constraints of the system. STAMP and CAST are explained in depth in Chapters 3 and 5 in this thesis.

My hypothesis is that the system approach embodied in STAMP, and its subsidiary accident analysis model CAST, will yield more learning than the current approaches to analyze food accidents. CAST will provide more comprehensive insights into food system accident causation that the traditional ad hoc epi-regulatory approach used today. I will explore this hypothesis by analyzing a case study with both approaches. The case study chosen for analysis is the 2008 Peanut Corporation of America Salmonella Incident. By analyzing the case using both the CAST and current approach, I will demonstrate which method yields the most knowledge and is most appropriate for the complex food production system. The method yielding the most knowledge will therefore offer the best opportunity to improve the safety of the food production system.

1.7 Summary

I will demonstrate my hypothesis by answering this research question:

> **To what extent does CAST generate more information about food accidents than the current epi-regulatory approach?**

Chapter 2 Comparing Methods of Accident Analysis: A Literature Review

Four literature domains need to be reviewed to understand previous work that relates to the research question underlying my hypothesis.

2.1 Linear Approaches to Accident Analysis

Accident analysis methods are always grounded in an accident causation model. The first accident model to be thoroughly documented is the chain-of-events model, first codified as the Domino Model by Herbert Heinrich in 1931 (Heinrich 1931). The Domino Model treats accidents as a linear series of events that result in an accident. The investigation is the reverse of the accident; trace the accident backwards and you will find the cause of the accident. Accident prevention is then a function of breaking the chain of events.

This model of accidents is alive today and has explanatory power for simple electro-mechanical systems. Initially, the method did not include any managerial or social causes. But social factors were later added to the model, as described by Leveson (Leveson 1995). This linear approach to accident modeling can be seen in the FDA's approach to inspection of facilities and finding violations of standards that then are declared the "cause" of accidents.

2.2 STAMP: A Systems Approach to Accident Causation

As systems became more complex through size, extensive connectivity or computer automation the simple models of the 1930s were no longer adequate to understand complex systems accidents.

In particular, the simple models were not capable of dealing with component interaction accidents. These interaction accidents are the result, not of component failure, but of complex interaction between components. New and different models grounded in system theory were needed to understand and eventually prevent accidents in complex systems.

Leveson, responding to the need to understand if software is “safe”, described (Leveson 1995) the beginnings of a system theoretic approach to safety. The essence of the approach is to treat safety as an emergent property of the system, rather than a by-product of component reliability. The emergent property is the result of a constraints imposed by the higher levels in the system hierarchy on the lower levels. Successful imposition of these constraints from one level to the next throughout the system results in the emergence of a safe state. The collective imposition of these constraints forms the hierarchical safety control structure of the system.

This system theoretic approach was dubbed STAMP (System Theoretic Accident Models and Processes) by Leveson (Leveson, Daouk et al. 2003). STAMP has been developed further with applications to aerospace, air traffic control, missile defense, pharmaceutical and water systems. A description of the possibilities of STAMP for food safety were described by Leveson and Couturier (Couturier and Leveson 2009).

Two methods, CAST and STPA, have been developed (Leveson 2011) based on the STAMP accident causation model to analyze accidents and to identify hazards during the system design process. CAST, for Causal Analysis using STAMP, analyzes data collected during an accident investigation through the lens of the hierarchical control system. CAST is a retrospective method that asks how and why an accident occurred. CAST is the method this thesis will use to compare to the current methods of food safety accident investigation.

STPA, System Theoretic Process Analysis, is a prospective method used to indentify hazards during the system design process. STPA has been used on a number of systems, such as air traffic control, and has been shown to identify more hazards than traditional hazard analysis techniques such as fault tree analysis. While STPA is not a focus of this thesis, it is clearly an area for further investigation in the study of food safety system design.

2.3 Methods of Evaluating Accident Analysis Techniques

Benner (Benner 1985) conducted the first comprehensive evaluation of accident investigation models on behalf of OSHA. Benner examined a broad range of accident models and investigation methods. He developed a set of 15 criteria and evaluated each method based on these criteria.

Benner's criteria were designed to rank methods used by the US Federal Government in an attempt to improve OSHA's accident investigation model. . Benner's analysis took place in 1985 before the development of system theoretic approaches, so of course these were not included in his analysis. Benner's criteria are not appropriate to use directly in this thesis, as the criteria were developed for occupational safety. A simplified approach inspired by Benner will be used in Chapter 6 to compare CAST to current accident investigation approaches.

2.4 Food Accident Investigation and Analysis Methods

Methods of investigation for food and water accidents have their historical roots in epidemiology. The first famous epidemiological investigation(Snow 1855) was by John Snow, who investigated a cholera outbreak in London in 1854. His groundbreaking investigation determined the source of cholera was a public water pump in Broad Street, London. His investigation established the fundamental tools of epidemiology still in use today and his paper, On the Mode of Communication of Cholera, was the first published epidemiological investigation.

As food borne illness is caused by a pathogen just as cholera is, epidemiological investigations naturally became the foundation of food accident investigations. The germ theory of food spoilage, established in 1862 by Pasteur, lent mechanistic understanding to epidemiological investigation. Food accident investigation and analysis methods were established in the US in parallel with the development of food laws. The Bureau of Chemistry in the USDA was the leader in developing chemical and physical analytical tools to investigate food safety accidents.

As legislation and consequent regulations developed over the first half of the 20th century, food safety investigational methods developed to mirror food regulatory models. The accident investigation model evolved into a combination of epidemiology, regulatory standards inspection, and an ad hoc involvement of media, law firms, and Congressional investigations. The current "official" approach is grounded in a combination of an epidemiological model and a regulatory standards model, the epi-regulatory approach.

The World Health Organization (WHO 2008) has published Guidelines for Food Borne Illness Outbreak Detection and Control that is a thorough summary of the current approach best practice approach to food accident investigation. The epidemiological portion of the method is well documented and constantly evaluated by the CDC. The regulatory standard approach is not as well documented nor is it evaluated on any public basis.

In addition to the structured investigations conducted by the CDC and the FDA, there are three groups that contribute to the public knowledge of food outbreaks on an ad hoc basis.

The first of these groups is the media. Ten Eyck (Ten Eyck 2000) has examined the role of print media in covering food outbreaks. He found that food outbreak coverage is, in his construct, marginal. By this he means that the issue is only covered when there is an outbreak; there is no ongoing consistent coverage of food-borne illness. This approach fits the model of ad hoc contribution to the public record. Ten Eyck also researched how food safety issues are framed in the media and how control is established between reporters and sources. The pressure from the public will then affect the evolution of food safety regulations. According to members of the food safety media (Moss 2011), public pressure on regulators to improve food safety is episodic. Therefore regulatory enforcement is expected to oscillate, responding to the crisis of the day.

The second of these groups are law firms that specialize in food safety litigation. According to members of the food safety plaintiffs bar (Marler 2011) ,the role of the civil court system in food accident investigation is uncovering additional information that may not have been revealed during the official investigation. I have found no literature examining the role of law firms in food safety investigations.

The final ad hoc area is congressional investigation. Under the chairmanship of ex-congressman Bart Stupak, the Oversight Committee of the House Energy and Commerce Committee conducted 13 hearings on food safety during Stupak's chairmanship. The proceedings from the PCA hearings (US Congress2009) revealed evidence of PCA shipping product that had tested positive for salmonella. Again I found no literature on the role of congressional investigations on food safety. According to Congressman Stupak (Stupak 2011), the chairman of the over sight committee decides whether to investigate a food illness outbreak, again making this path of investigation ad hoc.

I found no literature that specifically evaluates food accident investigation and analysis methods or determines if they are appropriate for the class of accidents that occurs in the food production system. This thesis will contribute to the literature in the field of food safety by performing a comparison of the current method of food accident investigation and a system theoretic approach to investigation. The comparison of the techniques will result in a recommendation regarding changing the current system of food safety accident analysis.

Chapter 3: Current US Food Production: Safety Systems Analysis

Before analyzing accident investigation methods, we must conduct a system analysis of the safety controls of the food production system. From that we can derive the safety requirements and constraints of the food production system. To do that we must start with the overall goal of the system based on stakeholder needs.

3.1 Food Production System: Stakeholder Analysis

The primary stakeholders of the food production are consumers as their needs drive the entire production system. The needs of the other stakeholders must also be factored into the constraints on the system.

Table 3-1 Food Production System Stakeholder Needs

Stakeholder		Needs
Consumer	Consumer of finished product	• Safe foods that are free from hazards • Affordability • Accessibility • Nutrition
Supply Chain	Retailer/Distributor/Restaurant	• Customers for products
	Food Manufacturers	• Raw materials free from hazards • Customers for products
	Suppliers	• Customers for ingredients
	Food Industry Workforce	• Employment
	Farmers	• Markets for crops
	Investors	• Return on capital invested
Governmental Authorities	Regulatory	• Enforcement of regulations
	Legislatures	• Satisfied Constituents
	Courts	• Justice
	Insurance Companies	• Low claims

	Academia	- Research Funding
	Plaintiff's Bar	- Clients

According to the USDA (USDA 2008) interpretation of these stakeholder needs, the USDA states the goal of the US food production system is:

> To ensure a safe, affordable, nutritious, and accessible food supply

To assess the food safety controls in the production system, we must understand what the hazards in the system are. Hazards are not inherent in the growing of food. Hazards are introduced by contamination during growth, harvest, processing and storage of the food.

3.2 Accident Definition

The next step in the safety systems analysis is to define an accident. In food safety, an accident is an illness or injury resulting from ingestion of one of the hazards listed above. Depending on the individual eating the food, ingesting the hazard may or may not result in illness or injury. For instance, microbiological hazards are more likely to cause illness in the elderly, very young, pregnant women, or those with suppressed immune systems. According to the US Center for Disease Control (CDC 2011), individuals outside of this group are less likely to have serious illness caused by microbiological agents. Some hazards, such as mycotoxins, do not have an immediate effect on health. It is well known that Aflatoxin ingestion, a toxin excreted by Aspergillus mold on peanuts, can result in liver cancer after prolonged exposure. For instance, see the Cornell (Cornell 2011) mycotoxin safety web site. For the sake of this analysis, we will be studying hazards that cause immediate illnesses (on the order of a few weeks).

3.3 Food Production System: Safety Constraints

Based on stakeholder needs, the subsequent system requirements, and the system hazards, the safety constraints on the food production system are as follows. Any system control design must control these hazards within regulatory limits.

Table 3-2 Food Production System Safety Constraints

Hazard	Safety Constraint
Pathogenic Bacteria	No pathogenic bacteria in food at point of consumption
Metal or other foreign object	No metal or other foreign objects > 1 mm in size
Toxins	Aflatoxin < 20 ppb(FDA 2000)

The system safety constraints will be used in the CAST method to analyze the safety control structure of the food production system.

Chapter 4: Current Methods of Food System Accident Investigation and Analysis

In the current US system, the investigation of a food accident is focused on finding the source of the accident and preventing a broader outbreak. The aim of the investigation is to stop losses from the accident, with a secondary emphasis on preventing future accidents. In contrast, in “instantaneous” accidents, such as plane crashes, the losses are immediate and cannot be stopped. “Instantaneous” accident investigations are focused on how the accident happened, with the aim of preventing future accidents and assigning liability for losses. This table depicts how accidents can be categorized by the parameters of temporal impact and investigational aim:

Table 4-1 Accident Investigation Aim vs Accident Temporal Impact

		Temporal Impact	
		Instant	Rolling
Investigational Aim	Stop Current Accident		Food
	Stop Future Accident	Aviation Transport Fire	Radiological

Table 4-1 Segmenting accidents by temporal impact and investigational aim

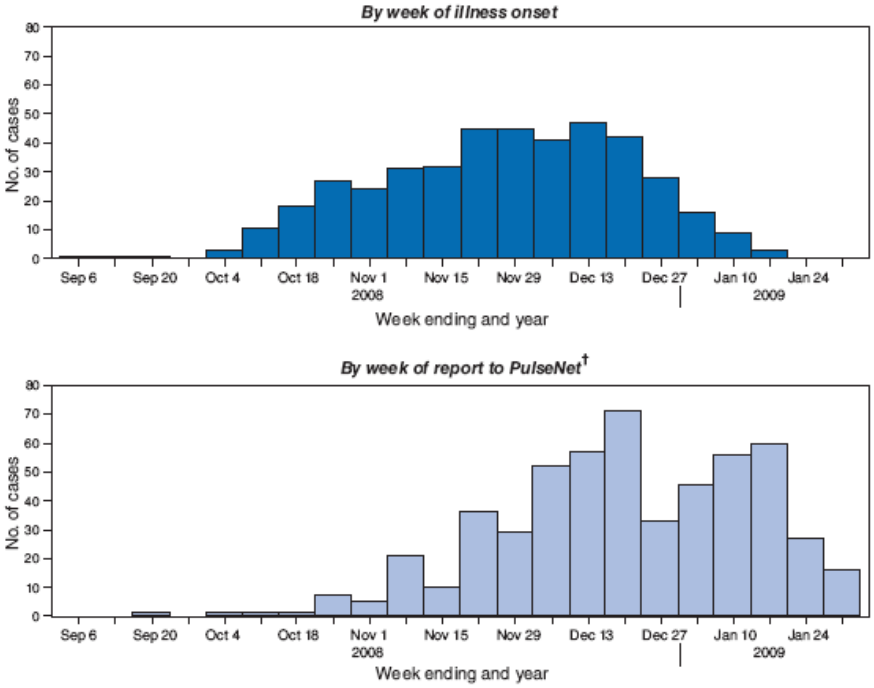
Food accidents are “rolling” accidents, in that losses develop over weeks and months. A food production system accident is not immediately apparent. The accident begins as gastrointestinal upsets whose cause could be many sources. Historically, food accidents came from a point source, such as a church dinner. These accidents were limited in scope as the point source could only affect people on a local scale. These local scale accidents were investigated and resolved by the local board of health. Usually, these accidents were caused by improper food handling practices that revealed no new information that needed to be shared. The current methods of investigation and analysis were developed for just such scale of incidents.

As the food supply grew to be national and international in scope, large-scale food illness outbreaks have become the focus for investigations. These changes in system scale, both geographically and temporally, result in the emergence of a new type of accident. These accidents are much more complex to investigate, as the outbreak is spread geographically and temporally.

4.1 Temporal Aspects of Food System Accidents

Food accidents evolve over weeks or months as contaminated food moves from the site of contamination through production and distribution to consumption. The distribution of foods from production to consumption can take anywhere from a day (in the case of baked goods or ready to eat meals) to many months. Food borne illnesses can take 1 to 3 days to manifest in consumers and can last from 4 to 7 days. Then there is a delay in reporting the illnesses through the public health reporting system. The result of these sequences of delays is a distribution of illness over time can be seen in this data published by the CDC (CDC 2009):

FIGURE 2. Number of laboratory-confirmed cases (N = 529)* of *Salmonella* Typhimurium infection with the outbreak strain associated with peanut butter and peanut butter–containing products — United States, 2008–2009



* Cases reported as of January 28, 2009. Cases beginning in the most recent 3 weeks might not yet be reported.

† The national molecular subtyping network for foodborne disease surveillance.

Fig 4-1 PCA accident illness reporting timelines

The investigation phase also requires time. In Figure 4-1 above, based on the Peanut Corporation of America (PCA) case, the CDC began an investigation on Nov 10, 2008 and identified the source of the outbreak on Jan 9, 2009. Recalls were initiated at that point and PCA stopped operations and liquid and filed for bankruptcy on Feb 15, 2009. The elapsed time from first case reported to shut down of PCA was 159 days. The length of time from first outbreak to resolution and the lack of an accident "scene" make food accident investigations different from other domain accident investigations and analysis methods.

4.2 Geographic Scale of Food System Accidents

As the food system supply chain has become national and international, the scale of food system accidents has grown. What used to be a local issue, has now grown in scale to be international. For instance, this CDC chart (CDC 2009) displays the geographic spread of the PCA outbreak:

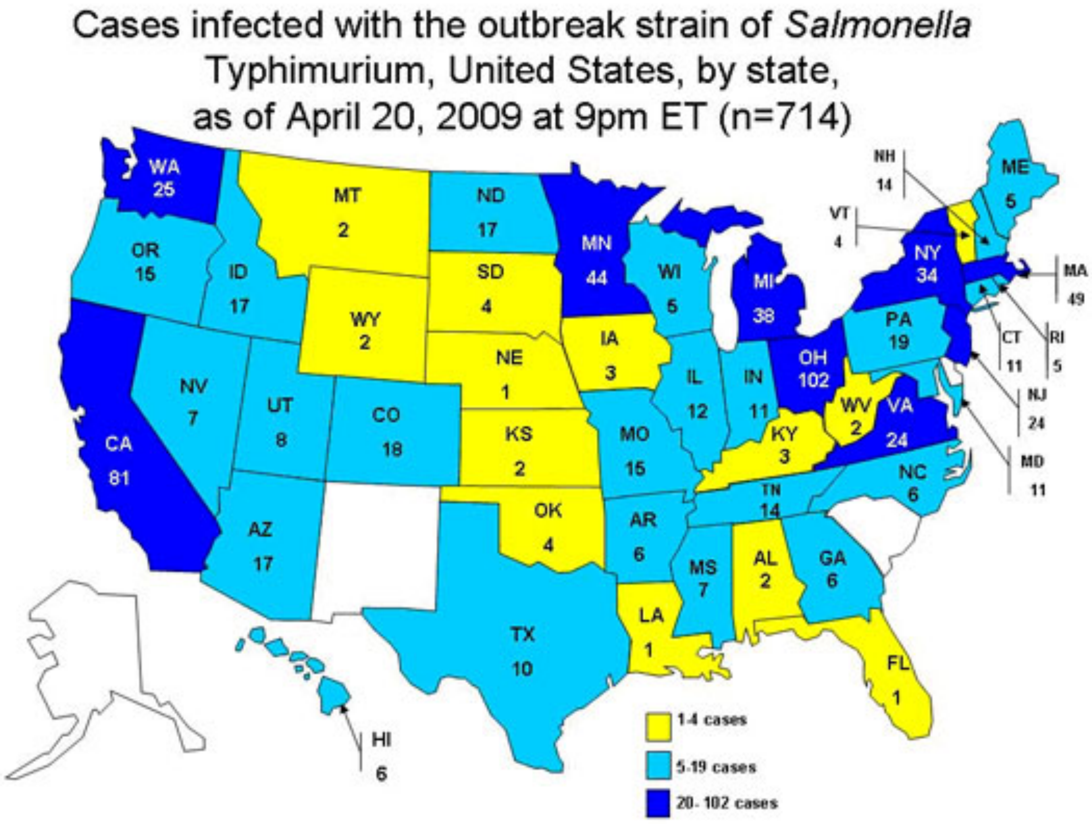


Fig 4-2 PCA Accident Geographic Spread

The outbreak resulted in illnesses in 47 states across the United States. This means that the investigation needs to be national in scope in both surveillance and investigations.

4.3 The Supply Chain Dimension

As the national food supply chain has become interconnected, a single outbreak can affect a large number of firms and products. PCA's position as a supplier of peanut paste to many other food manufacturers means the scope of the resulting recall was the largest in US history to date with over 1300 firms impacted. This means that the

FDA needed to communicate the recall of over 1300 hundred products, adding a burden to the investigation.

4.4 Current Accident Investigation Methods

Unlike an aviation or transportation accident, there is no agency responsible for developing and disseminating a full understanding of a food production system accident. The responsible regulatory agency is charged with managing the outbreak, finding the source of the pathogen causing the outbreak, and shutting that source down. If necessary, the regulatory agencies can ask departments of justice at the state or federal level to press criminal charges. Criminal charges are rare; the vast majority of judicial involvement is through the civil courts.

Neither the CDC, the FDA, nor the USDA have responsibility to prepare a comprehensive accident investigation. Accident lessons can eventually published by the FDA and the USDA through guidance documents. For the most part, the public record is a combination of CDC outbreak reports, FDA observation documents, newspaper reports, and documents uncovered in discovery in support of civil suits. No agency is charged with developing a complete accident report. Therefore the learning by others is limited to those who make the effort to assemble data and draw their own conclusions.

Even if there were a central "lessons learned" agency, the data collected about the accident is limited to the scope of the epi-regulatory model and the nature of epidemiological investigations. Epidemiological investigations are focused on detecting and determining the source of outbreaks. Regulatory investigations are focused on the "process" of manufacture, with no inclusion of system levels above the production facility. This is the scope of epi-regulatory approach and therefore it is not surprising that investigations remain inside the manufacturing system boundary. No socio-technical factors are included as the foundation of the method rests in a traditional chain-of-events model.

4.5 Case Study Using Current Methods: the Peanut Corp of America Incident

To illustrate how the current system investigates a food accident, I have chosen to use the Peanut Corporation of America accident from 2008-2009 as a case study.

In the fall and winter of 2008 and 2009, a *Salmonella Typhimurium* outbreak led to 741 illnesses and was linked to 9 deaths. The outbreak was traced to peanut products processed through the Peanut Corporation of America plants in Blakely GA and Plainview TX.

4.5.1 Peanut Corporation of America History

Peanut Corporation of America was incorporated in Feb 2001 with Board members Stewart Parnell, David Royster Sr, and David Royster Jr. The Parnell family had been involved in the peanut industry since the 1960s. PCA Purchased the Blakely GA facility in Feb 2001, which was operated previously as Casey's Peanuts.

PCA purchased another facility in Gorman Texas, which was then moved to an ex-Jimmy Dean Sausage plant in Plainview TX. PCA also purchased a facility in Suffolk, Virginia.

PCA's business model was to be a low cost provider. One buyer in particular had issues with PCA's business methods and refused to buy from them. Nestle had audited PCA twice in the early 2000's and declined to do business with them. (Nestle audit, 2002) PCA's Operational history prior to the incident contains a number of FDA warning letters. They also had a number of civil suits regarding aflatoxin in peanuts. Stewart Parnell served on the USDA's Peanut Quality Advisory Board.

4.5.2 The Accident Investigation

The first illnesses presented in early September 2008 and were diagnosed as Salmonellosis. Salmonella infections have these symptoms according to the CDC (CDC 2010):

> Most persons infected with *Salmonella* develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection. The illness usually lasts 4 to 7 days, and most persons recover without treatment. However, in some persons, the diarrhea may be so severe that the patient needs to be hospitalized. In these patients, the *Salmonella* infection may spread from the intestines to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness.
>
> Many different kinds of illnesses can cause diarrhea, fever, or abdominal cramps. Determining that *Salmonella* is the cause of the illness depends on laboratory tests that identify *Salmonella* in the stool of an infected person. Once *Salmonella* has been identified, further testing can determine its specific type.

The results of stool tests on infected consumers were forwarded to state health departments. The resulting cultures are "DNA fingerprinted" by state health labs through the use of PFGE.[2] The PFGE profiles are uploaded into a CDC database, PulseNet. This national surveillance database is managed by the CDC (CDC 2011). This database is monitored for outbreak clusters by epidemiologists at the CDC. When the levels of reported food borne illnesses exceeds a baseline value, the CDC begins monitoring the data more closely. When a cluster of cases with the same "DNA fingerprints" is detected by the CDC, an epidemiological investigation is initiated. The CDC epidemiologists detected the cluster of cases with identical PFGE "fingerprints" on Nov 10, 2008. This began the investigation phase.

Upon detection of the outbreak, the Minnesota Department of Public Health began investigation of cases of salmonellosis in nursing homes in western Minnesota on Dec 29, 2008. Through food intake surveys, the MDPH determined that the only food consumed in all cases was peanut butter. The MDPH, through analysis of invoices, traced the peanut butter to a distributor in North Dakota and then to the PCA plant in Blakely GA. On January 9, 2009, the MDPH confirmed presence of S. Typhirium in an open can of King Nut Peanut Butter, which was produced by PCA.

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[2] Pulsed-Field Gel Electrophoresis

At this point, the owner of PCA, Stewart Parnell, issued an email to his workforce stating that the contamination of the King Nut peanut butter must have been after the can was opened. He stated that the facility had “never had a salmonella” problem; this was untrue as Salmonella had been detected in PCA products as far back as 2006.

The Connecticut Department of Public Health removed all doubt as to the source of Salmonella when they detected the outbreak strain in an unopened can of King Nut peanut butter.

Upon detection of Salmonella in the King Nut Peanut Butter by the MDPH, the FDA Office of Regulatory Affairs immediately traveled to the PCA Blakely Ga facility on Jan 9, 2009. The inspection team observed a number of violations of Federal GMPs. These violations created conditions under which Salmonella could have contaminated peanuts. After receiving access to PCA business records through use of the BioTerrorism Act, the FDA found email evidence of shipping product after a negative salmonella response on a retest after receiving positive salmonella results. As salmonella is an adulterant, this violated Federal Law. Based on these observations, PCA voluntarily recalled products produced in the facility from the start of 2009.

The plant was shut down. Inspection of a second plant in Plainview TX found similar conditions and all product ever produced at that plant was recalled and the plant shut down. On Feb 15, 2009, PCA declared bankruptcy and ceased operations. All civil suits were settled in 2010 for a reputed $12MM. Criminal charges have not been brought, but are still under consideration by the Federal Department of Justice.

4.5.3 Detailed Analysis of PCA Accident Timeline

Table 4-3 PCA Accident Timeline

Date	• Event
2006	• Salmonella detected in chopped peanuts • JLA investigated • No conclusions as to source

	- Salmonella confirmed - Possibly Linked to lot of Organic Chinese Peanuts - Corrective actions not documented
June 2007	- Chopped peanuts with positive Salmonella, retested and released upon negative result - Salmonella continued to be detected, but released on subsequent negative retest
Sep 6 2008	- First illness recorded due to Salmonella Typhimurium
Sep 26 2008	- 2008 Peanut paste tested positive for Salmonella Typhimurium . Product released after negative retests
Nov 10, 2008	- CDC PulseNet identifies the first multistate cluster of Salmonella Typhimurium infections, with 13 cases reported in 12 states. CDC begins monitoring for additional reports of cases with the same DNA fingerprint.
Dec 28, 2008	- The Minnesota Department of Health learns of clusters of cases associated with different institutionalized settings (e.g., nursing homes, group homes), and begins assessment of foods that all the institutions may have received
January 9, 2009	- The Minnesota Department of Health reports Salmonella from an opened container of one brand of institutional peanut butter (Brand A). The Food and Drug Administration (FDA) begins investigation of the Peanut Corporation of America facility in Blakely, Georgia, where that brand of peanut butter was produced.
Jan 9, 2009	- An F.D.A. inspection team that visited the plant on Jan. 9 discovered that on 12 occasions in 2007 and 2008 tests conducted by the company found salmonella contamination in its products but that it shipped the contaminated products to customers after a retest found no contamination and did nothing to clean the plant
January 10, 2009	- Brand A issues a recall of its peanut butter.
Jan. 13th, 2009	- Peanut Corporation of America issued a recall for products it had made over the past six months
January 14, 2009	- Company Y announces a hold on its two major brands (Brands B and C) of peanut butter crackers
January 15, 2009	- The CDC Director activates the CDC Emergency Operations Center (EOC) in support of the outbreak response effort
January 16, 2009	- The Connecticut Department of Health identifies the

	outbreak strain in an unopened container of Brand A peanut butter. Peanut Corporation of America announces a recall of its peanut butter and peanut paste. Company Y announces a recall of its B and C brands of peanut butter crackers
January 17, 2009	• CDC and FDA issue a public health advisory regarding peanut butter and peanut butter--containing products.
January 18, 2009	• The Public Health Agency of Canada reports Salmonella Typhimurium in intact packages of Brand B peanut butter crackers.
January 19, 2009	• The results of the second case control study indicate association with consumption of peanut butter crackers and peanut butter eaten outside the home.
January 29, 2009	• The North Carolina Department of Health and Human Services confirms that Salmonella Typhimurium has been isolated from a tanker truck at a cracker processing facility in North Carolina. CDC publishes an early-release electronic MMWR article summarizing the outbreak investigation to date
Feb 2, 2009	• CDC PulseNet confirms that the Salmonella Typhimurium from a tanker truck in North Carolina is a match to the outbreak strain.
February 5, 2009	• Colorado identifies a fifth case possibly associated with a fifth location of Chain D who reports consumption of Chain D in-store ground peanut butter from Peanut Corporation of America roasted peanuts. The original source of the peanuts is under investigation by FDA. This investigation ultimately leads to implication of Plainview, Texas plant.
Feb 12, 2009	• Recall initiated by Peanut Corporation of America
Feb 15, 2009	• Peanut Corporation of America files for bankruptcy
March 17, 2009	• Heightened outbreak response ends. Close monitoring of newly uploaded cases continues.

4.5.4 Investigational Conclusions

The CDC's investigation is guided by epidemiological principles. The results and conclusions produced by the epidemiological phase of the accident investigation are:

1. The outbreak strain is *Salmonella Typhirium*
2. The control cases demonstrated that the likely vehicle for the Salmonella was peanut butter and peanut butter containing products
3. The outbreak was traced to peanut butter produced by PCA in Blakely GA

These are a complete set of outcomes for an epidemiological investigation. The role of the epi phase of a food safety accident investigation is to detect the outbreak and trace the outbreak to its source. Why the accident happened is beyond the scope of the epidemiological phase of the investigation.

Once the source of the outbreak is determined, then the regulatory phase of the investigation begins. In the PCA case, the FDA was the lead agency for this phase of the investigation. The conclusions of the regulatory standard phase are:

1. PCA was in violation of numerous GMPs at both facilities.
2. Recent 3rd party audits had not detected these GMP violations
3. PCA has knowingly shipped product adulterated with Salmonella
4. The FDA referred the case to the US DOJ for criminal investigation of Steward Parnell. As of the date of this thesis, no criminal proceedings have been initiated.

The ad hoc phase of the investigation resulted in new perspectives and information about the social dimensions of the accident:

1. Newspaper accounts clearly point the finger of blame at Stewart Parnell as the key malefactor. Anecdotes published by the press were from a variety of sources who either worked at or bought from PCA. The newspaper accounts added social dimensions to the case that are absent in the "official" investigations
2. The civil suits against PCA were settled by PCA's insurance company for a reputed $12 MM. As a result, no discovery took place that could reveal more information about the case.

3. The House Energy and Commerce Oversight and Investigation Committee held two hearings on the PCA incident in April and May in 2009. Both key actors from PCA took the 5th amendment avoiding testifying about what happened at PCA. However, PCA emails released by the committee, demonstrate PCA had released suspect product for sale and was clearly concerned about the financial ramifications of scrapping product.

Chapter 5: CAST analysis of the PCA Accident

As in chapter 4, the Peanut Corporation of America salmonella incident from 2008 will be used as a case study to examine how CAST is applied to food systems and to provide a basis of comparison to the epi-regulatory approach to accident analysis.

A system approach to accident investigation takes a fundamentally different approach than the epi-regulatory approach. The epi-regulatory approach is a chain of events method. The accident is treated as the consequence of a chain of events, from initiation to the accident. Therefore the investigation is a reverse of the chain of events. The investigators work backward from the accident until the source or cause of the accident is found. As demonstrated by Leveson and others (Leveson 2004) this method has served well for simple accidents, but is not adequate in more complex system accidents.

Central to the CAST method is the hierarchical control structure of the system. System theory states that a complex system can be decomposed into a set of levels or hierarchies. According to system theory, a complex system is controlled through the imposition of constraints from a higher level to a lower level. These imposition of these constraints creates a control structure that is responsible for the emergent behavior of the entire system. Checkland (Checkland 1981) fully describes this concept called system hierarchical control. Safety is an emergent property of complex systems and is best understood in terms of the control structure and safety constraints the hierarchy imposes the lower levels in the system.

Based on this concept of system hierarchical control, CAST examines the control structure to determine which controls were ineffective in enforcing the system safety constraints. Then the control loops are analyzed to determine why ineffective control actions were taken.

5.1 CAST Analysis

The first step in a CAST analysis is to determine the safety control structure used to enforce the system safety constraints. For example, as developed in Chapter 3, the food system safety constraints are as follows:

Table 5-1 Food Production System Safety Constraints

Safety Constraints	
SC1	No pathogenic bacteria in food at point of consumption
SC2	No metal or other foreign objects > 1 mm in size
SC3	Aflatoxin level < 20 ppb

To explain the hierarchical control concept, consider a simplified control system for a generic food production process. Figure 4-A sketches out a multi-level hierarchical control structure.

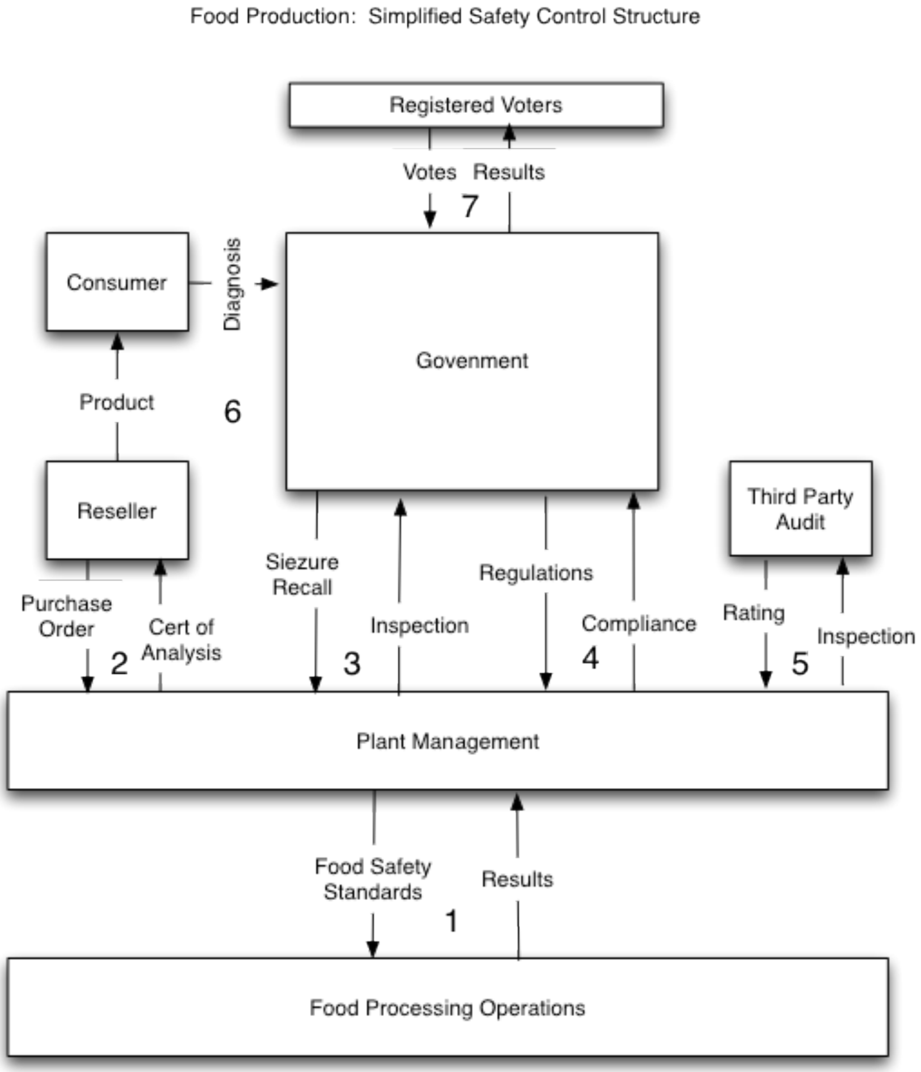

Figure 5-1 Generic Food Production simplified control structure

The topmost control (Loop 7) is the election, by registered voters, of legislators and executives to manage, among many other things, the food safety regulatory environment. The next control loop (Loop 4) is the legislatures and executive branches of the appropriate government who establish and enforce food safety laws and regulations to control food establishment management. These laws and regulations establish standards for business management to follow. Management (Loop 1) then exerts control on the process by converting regulations into standards that the operations must meet. Loop 1 operates at least daily and enforces the safety constraints at the process level. This loop is designed to prevent the entrance of pathogens into the food or control them if they are present in the food during processing. Loop 1 is based on both GMPs and HACCP.

Several other control loops enforce safety constraints, either through inspection (Loop 3) or by actual performance of manufactured products in the market place (Loop 6). Loop 6 is only activated when an outbreak occurs. Steady state regulatory enforcement of safety responsibilities are carried out through Loop 4

The safety constraints on plant management are enforced by three major control loops. The first and most frequently operated is the customer feedback loop (Loop 2). If the product does not meet the customer requirements for safety, the food is rejected and the customer will not re-order. If enough customers are lost, the supplying firm will cease to operate. This is a reactive loop and somewhat slow, but it is powerful as it shuts down the production of food that does not meet the safety constraints of the customer.

The second loop is the regulatory inspection loop (Loop 4). This is operated rather infrequently relative to the operational throughput time, on the order of once a year or less. While slow and reactive, the regulators have it in their power to seize product and suspend licenses resulting in closure of the enterprise. With the passage of the FSMA, the FDA now has the authority to recall products without the cooperation of the companies involved.

The last loop is the third party audit loop (Loop 5); an independent non-governmental inspection of the facility. This can be paid for by the supplier or the customer and is usually conducted on an annual basis. This loop helps a well-intended supplier obtain an outside perspective on the effectiveness of their own controls. For a mal-intentioned supplier, this loop can be gamed by cleaning the facility before inspection, resulting in a positive inspection and high rating.

The next step in the CAST method is to analyze each loop to understand how the loop enforces the system safety constraints. Each loop is broken down into its constituent elements to understand if the loop failed to enforce safety constraints.

The elements of a control loop are shown here in Fig 4-B:

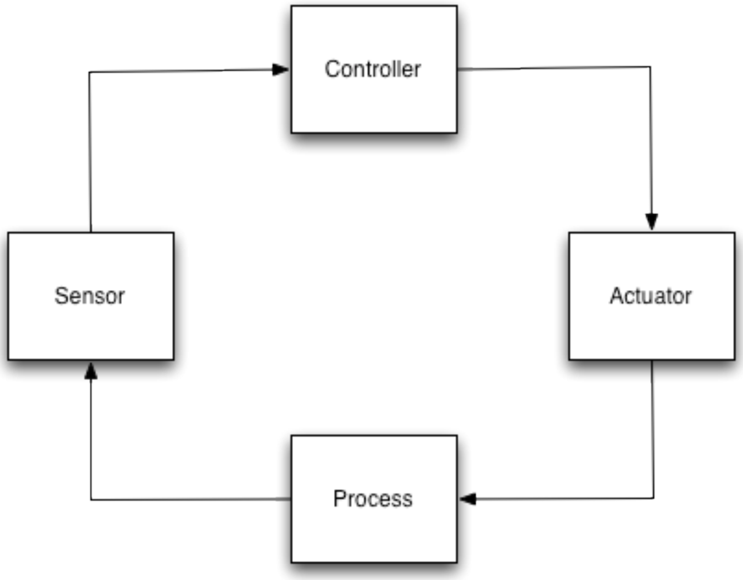

Fig 5-2 Control loop constituents

The controller takes in a signal from the sensor, processes that signal using a control algorithm and process model, and sends a signal to an actuator. The actuator in turn acts on the process being controlled to change the process in some way to maintain a set point. The sensor then measures the output of the process and sends a signal to the controller and the loop begins again.

The control loop has four elements, the controller, the sensor, the actuator and the process under control. Each of the elements can contribute to ineffective enforcement of safety constraints. The CAST analysis examines these elements and asks the following questions:

1. Safety Responsibilities – What specific safety responsibilities does this control loop undertake?
2. Inadequate control actions – What inadequate control actions are attributable to this loop? Where the control actions incorrect, missing, too early or too late?
3. Context in which decisions made - What pressures from the environment were on the control loop? In what context were control decisions taken in?

4. Mental model flaws - What mental model flaws were in the controller? What were the gaps between the controller's understanding of the process and the actual process?

For example, how would loop 1 be analyzed in a generic food safety accident? In this case, the controller is plant management, the actuator is the safety standards dictated by management, the process is the food manufacturing operation, and the sensor is data regarding food safety compliance from operations.

1. Safety requirements and constraints: Loop 1 enforces safety constraints 1 and 2, no pathogens or foreign objects in the food. It does this by establishing food safety standards for operations, ie testing frequency for pathogens in product.
2. Inadequate control actions: The controller is examined to ensure that food safety standards were complete, correct and communicated in a timely fashion.
3. Context - Were decisions taken under financial pressure, was the environment around the facility conducive to pathogenic contamination?
4. Process and Mental Models – The controller's mental or process models do not match the actual process

5.2 CAST Case Study: the PCA Accident

For the PCA accident, the safety constraint under consideration is no pathogenic bacteria in food at the point of consumption. The control structure around PCA clearly failed to enforce this safety constraint as thousands of consumers ate product containing a pathogen.

5.2.1 A Detailed Safety Control Structure for the PCA Case

To understand how the control structure failed to enforce the system safety constraint, we must construct a safety control structure around the system. The boundary I have chosen is the process from nut receipt to consumption by consumers. The hierarchy extends from the peanut butter process up through the federal government.

The safety control structure in Fig 5-3 was constructed based on the PCA case information made available by the CDC, the FDA, the House Energy and Commerce Oversight Committee, various newspaper reports, industry associations, and my personal knowledge of the peanut industry. The CAST analysis found 19 control loops that impact the enforcement of the system safety constraint. Each of these 19 loops will be examined to find where and how the system safety constraint failed to be enforced.

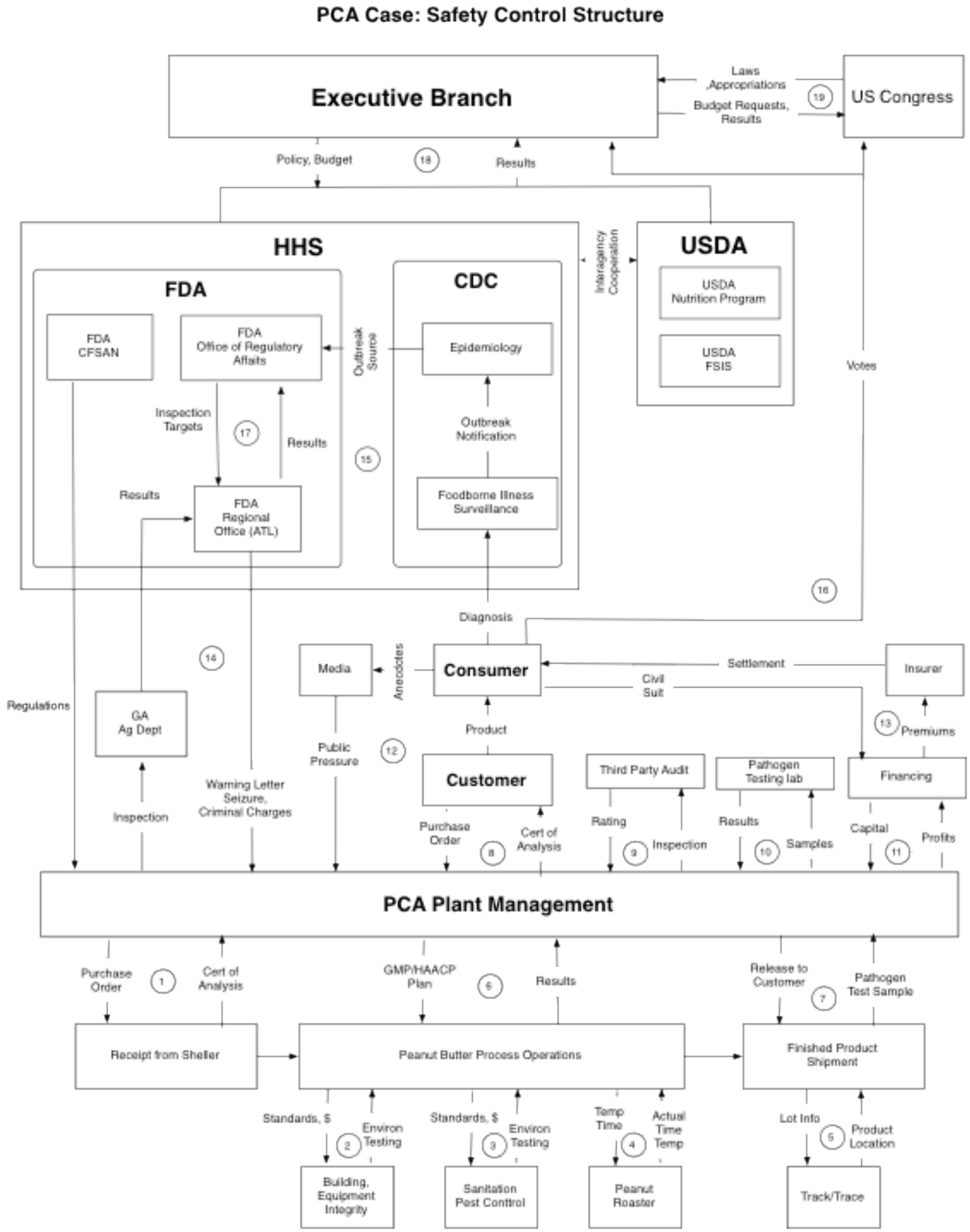

Fig 5-3 Safety Control System for the PCA Case

5.2.2 Safety Strategy - Peanut Butter Production Control System Control Flaws

Once the control structure is understood, the next step in CAST is to examine each loops in these four areas:

1. Safety Requirement and Constraints
2. Inadequate control actions
3. Context in which decisions made
4. Mental model flaws

The following table summarizes the control loops and their components.

Table 5-2 PCA Case Control Loops and Loop Constituents

Loop	Actors	Controller	Actuator	Sensor	Process
1	Parnell, Blanched Peanut Supplier	Parnell	Purchase Order	Cert of Analysis	Receipt from Sheller
2	Lightsley, PCA Maint	Lightsley	Standards, Budget	Environmental Testing	Building and Equipment Integrity
3	Lightsley, PCA Pest Control and Sanitation	Lightsley	Standards, Budget	Environmental Testing	Building and Equipment Sanitation and Pest Control
4	Lightsley, Process Operators	Lightsley	Roaster Operating Conditions	Peanut Dwell Time and roaster temperature	Peanut Roaster
5	Warehouse Personnel, Shippers	Warehouse Personnel	Lot information	Product Location	Track and Trace
6	Parnell, Lightsley	Parnell	GMP/HACCP Plan	Compliance to plan	Process Operations
7	Parnell, Warehouse Personnel	Parnell	Release product for shipment	Pathogen test	Shipment to customers
8	Parnell, Customer	Parnell	Cert of Analysis	Purchase order	Order receipt from customer
9	Parnell, AIB	AIB	Rating from AIB	AIB inspection	Third Party Audit
10	Parnell, Pathogen Testing Lab	Pathogen Testing Lab	Results of lab tests	Lab tests of finished product	Finish Product Testing
11	Parnell, Financiers	Financiers	Capital	Profits	Business Operations
12	Media, Consumers, PCA	Media	Public pressure	Consumer Stories	Business Operations
13	Insurers, Consumers, Courts, Financiers	Insurers	Settlements	Consumer claims or suits	Financing
14	FDA, Ga Dept of Ag, PCA	FDA ORA Regional Office	Warning letters	Inspections	Business Operations
15	CDC, FDA, Consumer, Customer, PCA	FDA ORA Regional Office	Inspection, Seizure, Criminal Charges	Inspections, Product Pathogen Testing, Consumer Stool Testing	Business Operations
16	Voters, Congress, President,	Consumers who are registered voters	Votes	Services, Performance	Congress, Executive Branch
17	FDA ORA, FDA regional office	FDA ORA	Inspection Targets	Results of inspection	FDA Regional Office
18	HHS, USDA, President	President	Policy, Budget	Results	HHS, USDA
19	Congress, Executive Branch	Congress	Laws, Appropriations	Budget Requests, Oversight Hearings	Executive Branch

Table 5-3 analyzes each control loop based on the four factors described above:

Table 5-3 PCA Control Structure Loop Analysis

Loop	Safety Resposibilities	Inadequate control action	Context in which decisions made	Process or Mental model flaws
1	Ensure no contaminated peanuts enter plant	No inbound pathogen tests conducted		No need to inspect inbound peanuts
2	Ensure building and equipment are maintained to prevent egress or growth of pathogens	Building had openings that allowed pests and rainwater to enter	No plant manager on site from April to Sep	?
3	Maintain adequate sanitation and pest control to prevent pathogens from entering the production environment	Pest control did not function, equipment not properly sanitized	No plant manager on site from April to Sep	?
4	Maintain proper dwell time and temperature in peanut roaster to kill pathogens	No records kept to determine if time and temp relationship were maintained	Roaster never proven to be "kill step"	Roaster was a "kill step" that would eliminate pathogens
5	Maintain records to determine which raw materials were used in what batch of finished product. Maintain record of destination of finished products.	None detected		
6	Food safety plan details critical control points necessary to prevent entry or kill pathogens in product	Food safety plan was not followed	Plan created for the sake of auditors and	Food safety plan needed to meet audit requirements but not used consistently in operations
7	No product is shipped to customers that contains pathogens	Product shipped that tested positive with a negative retest	Financial pressure Action had been taken before without negative consequences	OK to ship product on negative retest
8	No product is shipped to customers that contains pathogens	Certificate of analysis did not reflect positive salmonella test	Financial pressure Action had been taken before without negative consequences	OK to ship product on negative retest Cannot afford to scrap product when contamination is in question
9	Third party audit ensures that the facility meets GMP and HACCP requirements	Audits gave PCA a superior rating when facility was in violation of GMPs	Auditor wants to maintain inspection contract with PCA	Audits are for learning,not certification
10	Test finished product for pathogens and report to plant management for proper disposition	None		
11	Provide money to maintain plant in proper operating condition	Not clear whether maintenance funds were readily available	Wanted appropriate return on capital	Profits come before food safety
12	Create pressure on PCA to resolve food safety issue	None	Well publicized event	
13	Insurer makes sure that facility is taking action to minimize potential for liability claims	Insurer did not inspect facility	Food safety liability probably not part of industry standards	PCA was appropriately managing food safety risks
14	Inspection of the facility to ensure it is meeting regulatory requirements	State inspections did not identify issues found by FDA in Jan 2009	Georgia Dept of Ag conducting inspection under contract from FDA	
15	Detect and respond to outbreaks of food borne illness, determine source of illness and eliminate that source	None, illness detected and epidemiological investigation pinpointed PCA as source and PCA product was recalled and plant shut down	Nationwide outbreak affecting over 1300 products, largest food recall to date in the US	AAR conducted by CDC to determine flaws in CDC handling of this investigation
16	Registered voters elect representatives and executives who protect their safety	None	Food safety is not high on list of voter concerns	Voters do not regularly connect their votes to food safety effectiveness
17	FDA HQ assigns regional FDA office to investigate outbreak detected by CDC	None		
18	Executive branch directs policy and adequate funding to FDA to manage food safety responsibilities	Insufficient funds allocated to FDA food safety activities (?)	Cost pressures on overall US budget and the increasing importance of drug regulation at FDA	FDA is doing a good enough job with resources at hand
19	Congress passes laws and budgets that allow the executive branch to effectively manage food safety	Insufficient funds allocated to FDA food safety activities (?)	Cost pressures on overall US budget and the increasing importance of drug regulation at FDA	FDA is doing a good enough job with resources at hand

Loops 7 and 9 are of particular interest. Loop 7 safety responsibility was to ensure product was not shipped containing pathogens. Loop 7 was ineffective as the outbreak strain was found in unopened cans of peanut butter produced in the Blakely PCA facility. Loop 9 is of interest as the plant received a “Superior” rating from an audit by the American Institute of Baking (AIB) on March 27, 2008. NSF Cook & Thurber conducted a two-day audit at PCA’s Blakely, Ga., facility; audit receives a score of 91 of 100, or Exceeds Expectation/Excellent on April 29 and 20, 2008. In June 2008, Georgia Department of Agriculture conducts contract inspection at the Blakely facility for the FDA; a summary of the Georgia report (AIB 2009) notes that “[a]ll objectionable conditions were corrected during the inspection. The inadequate enforcement of food safety responsibilities by these two loops warrant further discussion.

5.2.3 Loop 9: Third Party Audit

Third Party Audits (TPA) are inspections and audits by an entity independent from the buyer or seller. The Third Party Auditors are brought into a system to provide an independent assessment of the food safety practices of a supplier. These TPAs can be an independent company or a governmental body. In the PCA case, the American Institute of Baking (AIB) acted as an independent TPA, hired and paid for by PCA. AIB audit results were used to assure Kellogg Company that PCA was a safe supplier to purchase from. The reasons to use a TPA are as follows:

1. Expertise
2. Independence
3. Credibility

There is an inherent conflict of interest in the TPA role when they are hired by either seller or buyer. If the buyer hires, then the TPA has incentive to be hard on the supplier. If the supplier hires, the TPA has incentive to go easy on the supplier as they wish to be invited back to conduct further audits.

5.2.4 TPA Control Hierarchy

Assessing the TPA loop (Loop 9), we see the following structure:

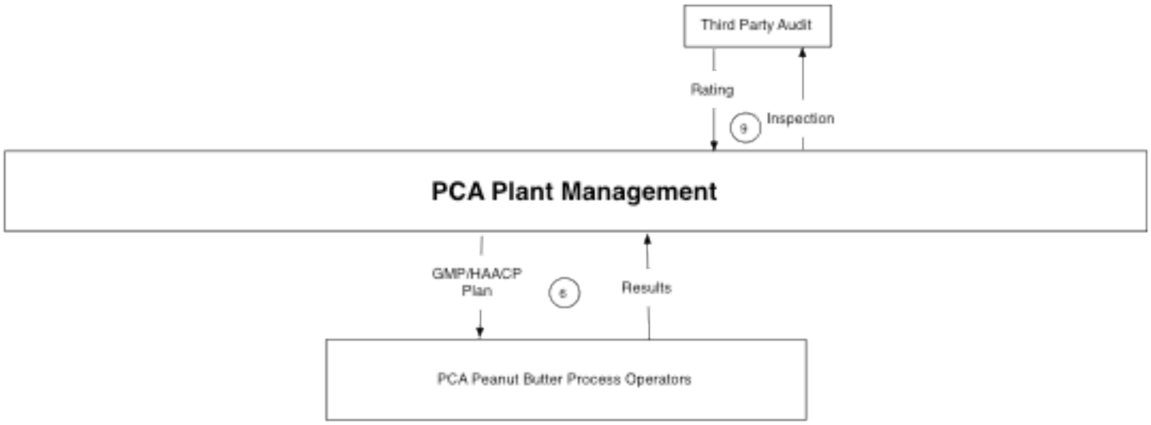

Fig 5-4 Third Party Audit Control Loop

The specific elements of the TPA control loop are shown in this table:

Table 5-4 Specific elements of the Third Party Audit Control Loop

Sensor	Signal to Controller	Controller		Signal to Actuator	Actuator
		Algorithm	Process Model		
Inspector	Inspection of facility and review of documentation	Comparison of results to pre-determined standards	Pre-determined standards	Rating and report on findings	Sponsor of TPA Audit

The control loop can provide inadequate control of safety requirements as shown here:

1. The sensor can fail through lack of knowledge of the production system, unconscious bias in reviewing facilities, simple oversight, or fraud.
2. The signal to the controller can be an incomplete or unclear report.

3. The process model can be flawed as the standards in the model can be wrong or outdated.
4. The algorithm comparing the signal to the standards can be incorrect or produce a flawed answer.
5. The signal to the actuator can be altered through “editing” by the controller due to bias or a conflict of interest with the sponsor of the audit.
6. The actuator, the sponsor of the audit, can ignore the audit findings and not act on issues revealed in the audit.

Bias can occur at a subtle level in this loop. For instance, Bazerman et al (Bazerman, Loewenstein et al. 2002) show that accounting audits exhibit bias towards the company paying for the audit, even if the auditor is made aware of the potential for bias.

The key advantage of the TPA is presumed independence. While certainly more independent than a self-audit, there are risks that a TPA paid for by the auditee will have inherent bias.

This bias has been observed in the financial industry and can be mitigated by these methods:

1. TPA is credentialed by an accreditation body. This also can be gamed, but it reduces the likelihood of TPA bias.
2. TPA is on a fixed contract and cannot be rehired at the end of the contract. This eliminates the need to bias the audit to keep the business.
3. The audit could be paid for by an independent funding source, perhaps through industry wide fees

5.2.5 TPA and the PCA Case

In the PCA case, both the independence and the expertise of the American Institute of Baking (AIB) were questioned by the media (Moss 2009; Sun 2010). AIB inspected the facility the summer before the detection of the salmonella. The AIB inspector gave the facility a score of 910, which resulted in a “Superior” rating. This rating was feedback to the owners that they were doing things “right”. AIB claims that the resignation and absence of the PCA plant manager led to deterioration of the facility between the time of inspection and the salmonella incident. This is possible, as PCA employees were quoted saying that the facility was cleaned extensively before announced inspections. I could not find any literature describing the rate of facility deterioration from a safe to unsafe state to validate AIB’s claim.

5.2.6 The Role of TPAs in the Overall Control System

Third Party Audits are part of a system of controls of food safety. They are not guarantees; they are audits at a point in time. The industry may have assumed this was a “certification” rather than a snap shot. TPAs cannot stand alone from other control loops in the production system.

5.3 Loop 7: Causes of Inadequate Control Actions

The CAST analysis of the PCA accident identified inadequate control actions in Loop 7, the release of products to customers by Parnell. The inadequate control action was the order to release finished product in spite of a positive Salmonella test. In Loop 7, Stewart Parnell, the owner, is the controller. The sensor is the pathogen testing lab and the actuator are Parnell’s employees. What was the cause of this inadequate control action? This chart (Leveson 2011) diagrams the ways an inadequate control action can arise:

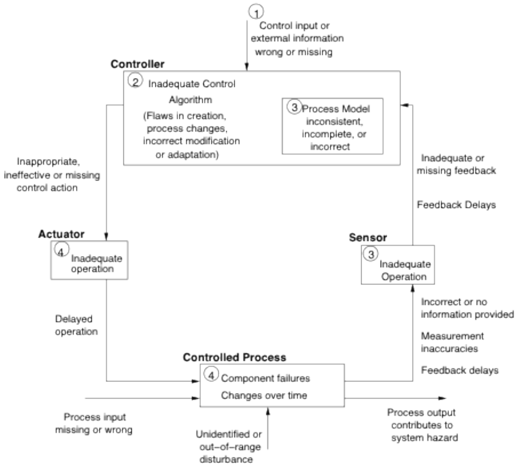

Fig 5-5 Reasons for Inadequate Control Actions

In the PCA case, the controller sent the incorrect control action to the actuator (ship the product even though there is a salmonella positive test). Based on Fig 5-5, there are three reasons the incorrect signal could be sent to the actuator:

1. The incoming signal from the sensor (in this case the pathogen testing lab) to the controller (Stewart Parnell) is incorrect because of sensor failure or communication failure. In the PCA case, the owner received the correct signal from the pathogen testing lab. As Salmonella testing has a low rate of false positives, it is very unlikely that the positive Salmonella test results were wrong.
2. Control input or external information was missing. There is no evidence that external forces caused the incorrect control action to be sent.
3. The controller (Stewart Parnell) had process model flaws and/or flaws in his control algorithms.
    a. Parnell's process model of peanut butter manufacturing could have been flawed. This is unlikely as Parnell was an industry veteran with extensive industry knowledge. For instance, Parnell was appointed to the USDA Peanut Quality Board on the basis of his industry knowledge.
    b. Stewart Parnell's control algorithm (i.e. his decision rules) led to decisions that are inconsistent with industry norms and practices. His algorithm could have been incorrect because of:
        i. Misplaced priorities, for instance placing costs higher than safety. This is likely as the email correspondence from the owner to his plant manager shows overriding concern about the financial effects of a positive Salmonella in finished product
        ii. Parnell's algorithm was influenced by lags in feedback. For instance, the time lag between decision and consequence maybe so long, that Parnell did not connect decisions he made to the eventual results of that decision. This is possible if his

previous releases of product with Salmonella had no negative consequences

5.3.1 Loop 7 Inadequate control action cause

Based on the above analysis of Loop 7, Parnell's flawed control algorithm was likely the cause of the inadequate control action. This conclusion is consistent with the facts of the case:

1. When faced with positive salmonella results, Parnell ordered retests on the product. When these came back negative, product was released for shipment. The algorithm of the owner was "negative retest, ok to release", the industry norm is "positive result, destroy product"(Diebel 2009; Worsley 2011)
2. When faced with recall and seizure of product, Parnell requested the FDA allow processing of peanuts on plant floor to create cash for operations. Parnell's decision rule was "OK to process peanuts in a compromised plant". The correct decision was " no conversion until plants are cleaned up".

What can we surmise from these actions about the decision making process of Parnell?

1. We can infer that Parnell's decision making was influenced by the "getting away with it", meaning that his decisions created no negative consequences, so he learned that his decisions were "correct".
2. We can also infer that his decision making was strongly influenced by his firm's financial situation. His company's strategy was low cost and his decisions were taken to support that strategy.
3. External affirmations that he was "doing things right" may have emerged from the AIB and others audits of his facility. For instance, see these comments from a televsion interview (WSLS 2009) of Stewart Parnell's sister, Beth Falwell:

a. “Private companies they [PCA] do business with send their own inspectors to the plant to check things out. Companies like Kellogg's would not have done business with PCA, if they found poor conditions.”

5.4 Summary

In summary, the CAST method reveals a deep and nuanced view of the PCA accident. The traditional method focuses on the source of the contamination and the elimination of the source. CAST considers the entire socio-technical system during the investigation, working to determine how the accident happened and what control loops failed to enforce their safety responsibilities.

Loops 7 and 9 were ineffective in enforcing safety responsibilities. Loops 1-3,6,8,11,13,14, 18 and 19 were shown to contribute to the accident. The remaining loops fulfilled their responsibilities. The overall control structure was not robust as ineffectiveness in Loops 7 and 9 resulted in the system not to enforcing the overarching safety constraint, no pathogens in product at point of consumption. This inadequate control action allowed the system to move to an unsafe state and sicken thousands.

Chapter 6 - Comparison of the Two Methods of Food Accident Analysis

The purpose of a food accident analysis is to generate information that can be used to stop a current outbreak and to prevent future outbreaks. Therefore, better methods of accident analysis will generate broader and deeper information than less effective analysis methods. To compare CAST with the current method, we need to compare the depth and breadth of information generated by the two methods.

We can do this comparison at two levels. The first is to compare the methods generally. The second is to see what information CAST and the epi-regulatory method generate for the specific case of the PCA accident.

Factors that must be considered in a systems based assessment of accident analyses are as follows:

1. Safety is an emergent property of the system, therefore a complete accident analysis method should consider the boundaries and levels of system hierarchy and how these interact to create emergent safety behavior.
2. Both technical and social issues must be considered as system safety emerges from both the technical and social domain
3. The complexity of the system (ie non-linear behavior, effect of feedback, connectivity of system components) strongly effects the type of analyses used to analyze accidents.

6.1 High Level Comparison of CAST and Epi-Regulatory Methods

To compare CAST and the epi-regulatory methods at the general level, we will compare the system boundaries the two methods consider, how each method treats the social and technical aspects of the food production system, and how the accident analysis method deals with system complexity.

The current epi-regulatory method system boundary is the production facility and the downstream distribution processes. The CAST analysis uses a broader system boundary, which includes the consumer, food company management, legislatures, and regulators. This greater scope of analysis will yield more information from CAST than the current approach.

The food production system is a complex system, comprised of both technical and social components. As shown by WHO guidelines (WHO 2008), the technical aspects of food safety, such as proper processing and holding temperatures, are fully considered in the current method of accident analysis. Behavior of employees, managers, and consumers impact food safety as evidenced by the considerable amount of effort put into training to prevent food safety outbreaks. For instance, the National Restaurant Association (NRA) (NRA 2011) has developed ServSafe training to certify food handlers in proper food safety procedures. An analysis method that includes both social and technical factors will generate more information regarding accident prevention.

CAST, as a system theoretic method, includes both social and technical aspects of the food system. The epi-regulatory method considers technical factors only as shown in Chapter 4 of this thesis. In a complex system like food production, CAST will generate more information than the current method due to the inclusion of social factors. CAST and the current system should deliver equivalent information on the technical factors of a food production accident.

At the general level, CAST will generate more information about a food system accident than will the current epi-regulatory approach. The greater information from CAST arises from a broader system boundary and the inclusion of social factors in the accident analysis.

A final comparison at the general level is the accident model that the two analysis methods are built on. CAST is built on a well- established system theoretic foundation. This theoretic foundation has been found useful to understand complex systems in a range of domains. The epi-regulatory system was originally based on a simple, linear accident model. This aspect of the model evolved into GMPs. The addition of HACCP added the notion of control to the accident model, but this is still based on a linear model of the food production system. Therefore, CAST is more suitable for complex food system accidents. The current method is suitable for simpler, linear accidents.

Therefore, at the general level, CAST will generate more information about complex food system accidents than the current epi-regulatory approach.

6.2 PCA Case Comparison of CAST and Epi-Regulatory Methods

To see if this holds up for a specific case, we will compare the results of the CAST analysis of the PCA accident with the results of the epi-regulatory analysis.

One way to compare CAST vs the current methods is to count the number of control loops contained within the system boundary. In the PCA case, CAST includes all 19 identified loops in the control structure, the current method considers only 8. This broader scope of CAST generates more information which, when fed back into the system, should result in greater learning and hence less losses. Table 6-1 shows the analysis of the loops included in each method:

Table 6-1 Control Loop Comparison: CAST vs Epi-Regulatory Method

Loop	CAST	Epi-Regulatory
1	X	X
2	X	X
3	X	X
4	X	X
5	X	X
6	X	X
7	X	X
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	X

15	X	
16	X	
17	X	
18	X	
19	X	

How do the conclusions of the epi-regulatory method analysis and CAST analysis compare? The results of the epi-regulatory analysis of the PCA accident are summarized in Chapter 4. As discussed above in this chapter, all the conclusions of the epi-regualtory method are technical in nature. The results of the CAST analysis of the PCA accident were summarized in Chapter 5. Rather than a list of "findings", the CAST method summarizes the inadequate control actions that were taken across the system. These inadequate control actions do not affix blame, but uncover where the system control structure did not enforce the safety constraints of the system.

By comparing the conclusions of the two accident investigation methods in Chapters 4 and 5, it is clear that the details of the CAST analysis are broader than the conclusions of the epi-regulatory method. The CAST results include social factors, such as financial pressure on ownership (Loop 7) and the potential for bias in third party audits (loop 9). Importantly, the CAST analysis shows which loops had effective control actions. This knowledge helps to focus improvement activities on the right areas of the system.

6.3 Summary of Comparison of CAST and Epi-Regulatory Methods

CAST generates more information about the complete system than the epi-regulatory method. It also demonstrates specifically where improvements are needed. The epi-regulatory analysis determines what failed, the CAST analysis determines how and why the control system did not enforce safety constraints. The information that CAST generates paints a more complete picture of the accident causation and points the way to a comprehensive improvement plan.

CAST is by design blame free, constructed to learn the why as well as the what of the accident, and is consistent with other system methods to improve system safety.

The Epi-regulatory method has evolved from a time when assessing blame was the major objective of accident investigations. There is also no consistent method to feedback the findings of the investigations back into food safety improvements.

The general and specific accident analysis method evaluation both lead to the same conclusion: **A systems based approach, such as CAST, is more appropriate for food system accident analysis. More information is uncovered and the analysis is more suited to a food production system accident.**

Chapter 7 Conclusions

Based on the case study and analysis in the preceding chapter, CAST is a better tool than the current epi-regulatory system in finding inadequacies in the food production safety control system. The current food accident analysis system should be augmented with CAST to identify and control more extensive system hazards. In particular CAST uncovered control inadequacies in the following areas:

1. Management actions under financial pressure
2. Process models of food plant ownership
3. Third Party Audit effectiveness
4. Rate of regulatory inspection relative to “drift” in the food production environment
5. The control of food safety constraints by customers

These findings suggests these changes to the Food Safety Control System

1. Reduce production pressure
2. Create independent third party auditors that are accredited by an independent body
3. Create feedback loop from labs and auditors to CDC
    a. Radically reduces time lag in resolving contamination
    b. Does not use consumers as part of control system
4. Surprise random inspections
    a. Reduces ability to game the inspection by cleaning intensely before inspection
5. Customers should return to conducting their own audits of suppliers to enforce their safety constraints.

This analysis focused on the effectiveness of CAST and the epi-regulatory, future research should examine the efficiency of the methods. The cost of doing a CAST analysis versus the epi-regulatory approach will need to be understood if CAST is to be adopted by the food industry.

While this thesis focuses on accident analysis, it is fair to conclude that system theoretic hazard analysis techniques like STPA would result in the identification of more and different sets of risks than today's methods.

References

AIB (2009). "Chronology of Events Related to Peanut Products Recall Involving PCA." Retrieve 4/15/2011 from https://www.aibonline.org/press/AIBStatement04022009/Chronology.html.

Bazerman, M. H., G. Loewenstein, et al. (2002). "Why good accountants do bad audits." Harvard Business Review **80**(11): 96-103.

Benner, L. (1985). "Rating accident models and investigation methodologies* 1." Journal of safety research **16**(3): 105-126.

CDC (2009, Feb 6, 2009). "Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter--Containing Products --- United States, 2008--2009." MMWR. Retrieved 3/15/2011.

CDC (2010). "What is Salmonellosis?". from http://www.cdc.gov/salmonella/general/index.html Retrieved 3/15/2011.

CDC (2011). "Foodborne Infections: General Information." from http://www.cdc.gov/nczved/divisions/dfbmd/diseases/foodborne_infections/#precautions. Retrieved 3/15/2011

CDC (2011). "Steps in a Foodborne Outbreak Investigation." from http://www.cdc.gov/outbreaknet/images/investigations/outbreak_process_900px.jpg. Retrieved 3/15/2011

CDC (2011). "What is PulseNet?". from http://www.cdc.gov/pulsenet/whatis.htm. Retrieved 3/15/2011

Checkland, P. (1981). "Systems thinking, systems practice." NY,NY, John Wiley

Cornell (2011). "Aflatoxins: Occurence and Health Risk." from http://www.ansci.cornell.edu/plants/toxicagents/aflatoxin/aflatoxin.html. Retrieved 3/15/2011

Couturier, M. and N. Leveson (2009). "Re-engineering the United States food safety system." Food Protection Trends **29**(9): 571-576.

Couturier, M. M. J. (2010). A case study of Vioxx using STAMP. Technology and Policy Program Masters Thesis. Cambridge MA, MIT.

Diebel, R. (2009). PCA Investigation. House Oversight and Investigation Committee. Hearing Date: Feb 11, 2009

FDA (2000). "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed." from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm#afla.Retrieved Feb 11, 2011

FDA (2011). "Hazard Analysis and Critical Control Point Principles and Application Guidelines."Retrieved: May 15, 2011 from http://www.fda.gov/food/foodsafety/HazardAnalysisCriticalControlPointsHACCP/ucm114868.htm

Heinrich, H. W. (1931). Industrial accident prevention; a scientific approach. New York, London,, McGraw-Hill book company, inc.

LaFraniere, S. (2011). In China, Fear of Fake Eggs and 'Recycled' Buns. New York Times. May 7,2011.

Leveson, N. (1995). SafeWare : system safety and computers. Reading, Mass., Addison-Wesley.

Leveson, N. (2001). Evaluating Accident Models using Recent Aerospace Accidents, NASA IV&V Report. June 28,2001

Leveson, N. (2004). "A new accident model for engineering safer systems." Safety Science **42**(4): 237-270.

Leveson, N. (2011). Engineering a Safer World. Cambridge MA, MIT Press.

Leveson, N., M. Daouk, et al. (2003). Applying STAMP in accident analysis NASA CONFERENCE PUBLICATION 2003, ISSU 212642, pages 177-198

Marler, W. (2011). Personal Communication

Moss, M. (2009). Food Problems Elude Private Inspectors. New York Times Mar 5, 2009.

Moss, M. (2011). Personal Communication

NRA (2011). "ServSafe® Food Handler Program." Retrieved May 24, 2011, from http://www.servsafe.com/Starters/index.aspx.

PCA Hearing. House Energy and Commerce Oversight Sub Committee. (2009) Hearing Date: Feb 11, 2009 .

Scallan, E., R. M. Hoekstra, et al. (2011). "Foodborne illness acquired in the United States--major pathogens." Emerging infectious diseases **17**(1): 7-15.

Scharff, R. L. (2010). "Health-Related Costs From Foodborne Illness in the United States." Produce Safety Project at Georgetown University.

(Sec. 402. [21 USC §342] Adulterated Food (1938)

Snow, J. (1855). On the mode of communication of cholera, John Churchill.

Stupak, B. (2011). Personal Communication.

Sun, L. (2010). Conflicts of interest mar food producers' independent inspections. Washington Post.10/22/2010

Tauxe, R., M. Doyle, et al. (2010). "Evolving public health approaches to the global challenge of foodborne infections." International Journal of Food Microbiology **139**: S16-S28.

Ten Eyck, T. A. (2000). "The marginalization of food safety issues: An interpretative approach to mass media coverage." Journal of Applied Communications **84**(2): 2000-2029.

USDA (2008). "2008 Performance and Accountabilty Report." from http://www.ocfo.usda.gov/usdarpt/par2008/usdarpt.htm. Retrieved April 24, 2011

USDA (2010). "Peanut Standards Board." from http://www.ams.usda.gov/AMSv1.0/PeanutStandardsBoard. Retrieved April 24, 2011

WHO (2007). "Food Safety and Foodborne Illness." Retrieved May 3, 2011, 2011, from http://www.who.int/mediacentre/factsheets/fs237/en/.

WHO (2008). "Foodborne disease outbreaks : guidelines for investigation and control." from http://whqlibdoc.who.int/publications/2008/9789241547222_eng.pdf Retrieved May 3, 2011.

Wikipedia (2011). "Hazard and operability study." Retrieved May 13, 2011, from http://en.wikipedia.org/wiki/Hazard_and_operability_study.

Worsley, J. (2011) Personal Communication.

WSLS (2009). Daughter of Peanut Corp. founder speaks about salmonella case. Retrieved on May 3, 2011 from http://www2.wsls.com/news/2009/jan/30/wsls_exclusive_daughter_of_peanut_corporation_of_a-ar-385685/#comments

(2009). PCA Hearing. House Energy and Commerce Oversight Sub Committee.

AIB (2009). "Chronology of Events Related to Peanut Products Recall Involving PCA." from https://www.aibonline.org/press/AIBStatement04022009/Chronology.html.

Bazerman, M. H., G. Loewenstein, et al. (2002). "Why good accountants do bad audits." Harvard Business Review **80**(11): 96-103.

CDC (2009, Feb 6, 2009). "Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter--Containing Products --- United States, 2008--2009." MMWR. Retrieved April 25, 2011.

CDC (2010). "What is Salmonellosis?". from http://www.cdc.gov/salmonella/general/index.html.

CDC (2011). "Foodborne Infections: General Information." from http://www.cdc.gov/nczved/divisions/dfbmd/diseases/foodborne_infections/#precautions.

CDC (2011). "What is PulseNet?". from http://www.cdc.gov/pulsenet/whatis.htm.

Checkland, P. (1981). Systems thinking, systems practice.

Cornell (2011). "Aflatoxins: Occurence and Health Risk." from http://www.ansci.cornell.edu/plants/toxicagents/aflatoxin/aflatoxin.html.

Couturier, M. and N. Leveson (2009). "Re-engineering the United States food safety system." Food Protection Trends **29**(9): 571-576.

Couturier, M. M. J. (2010). A case study of Vioxx using STAMP. ESD. Cambridge MA, MIT.

Diebel, R. (2009). PCA Investigation. House Oversight and Investigation Committee.

FDA (2000). "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed." from http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm#afla.

FDA (2011). "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

Heinrich, H. W. (1931). Industrial accident prevention; a scientific approach. New York, London,, McGraw-Hill book company, inc.

LaFraniere, S. (2011). In China, Fear of Fake Eggs and ‘Recycled’ Buns. New York Times.

Leveson, N. (1995). SafeWare : system safety and computers. Reading, Mass., Addison-Wesley.

Leveson, N. (2004). "A new accident model for engineering safer systems." Safety Science **42**(4): 237-270.

Leveson, N. (2011). Engineering a Safer World. Cambridge MA, MIT Press.

Leveson, N., M. Daouk, et al. (2003). Applying STAMP in accident analysis, Citeseer.

Marler, W. (2011). Personal Communication. J. Helferich.

Moss, M. (2009). Food Problems Elude Private Inspectors. New York Times.

NRA (2011). "ServSafe® Food Handler Program." Retrieved May 24, 2011, from http://www.servsafe.com/Starters/index.aspx.

Scallan, E., R. M. Hoekstra, et al. (2011). "Foodborne illness acquired in the United States--major pathogens." Emerging infectious diseases **17**(1): 7-15.

Scharff, R. L. (2010). "Health-Related Costs From Foodborne Illness in the United States." Produce Safety Project at Georgetown University.

Snow, J. (1855). On the mode of communication of cholera. London, John Churchill.

Stupak, B. (2011). Personal Communication with John Helferich.

Sun, L. (2010). Conflicts of interest mar food producers' independent inspections. Washington Post.

Tauxe, R., M. Doyle, et al. (2010). "Evolving public health approaches to the global challenge of foodborne infections." International Journal of Food Microbiology **139**: S16-S28.

Ten Eyck, T. A. (2000). "The marginalization of food safety issues: An interpretative approach to mass media coverage." Journal of Applied Communications **84**(2): 2000-2029.

USDA (2008). "2008 Performance and Accountabilty Report." from http://www.ocfo.usda.gov/usdarpt/par2008/usdarpt.htm.

WHO (2007). "Food Safety and Foodborne Illness." Retrieved May 3, 2011, 2011, from http://www.who.int/mediacentre/factsheets/fs237/en/.

WHO (2008). "Foodborne disease outbreaks : guidelines for investigation and control." from http://whqlibdoc.who.int/publications/2008/9789241547222_eng.pdf.

Wikipedia (2011). "Hazard and operability study." Retrieved May 13, 2011, from http://en.wikipedia.org/wiki/Hazard_and_operability_study.

Worsley, J. (2011). Discussion of PCA incident.

WSLS (2009). Daughter of Peanut Corp. founder speaks about salmonella case.