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WHO'S ON FIRST: UNRAVELING THE COMPLEXITY OF THE UNITED STATES' FOOD AND AGRICULTURAL REGULATORY SYSTEM IN THE REALM OF HOMELAND SECURITY

by

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December 2009

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The food and agricultural sector received the designation of critical infrastructure important to national security after the events of September 11, 2001. With an increase of foodborne illnesses at the national level since the new designation, there has been increased concern about the current regulatory approach to the sector, in the paradigm of homeland defense and security. A continuing reliance on a complex web of regulatory oversight from multiple agencies from both unintentional and intentional contamination of the food supply sets the premise for the overarching research question and argument for the thesis. Is it time to restructure the food safety regulatory system into a single agency to provide a smarter focus to a globally expanding and vulnerable sector? The thesis uses secondary qualitative analysis of data as a method to explore existing information and patterns to answer the research question and support of the argument that a single agency is a smarter approach. A conceptual framework is provided of what a new agency will look like based on existing information and realistic concepts garnered from the research. The thesis produces a more efficient and effective focus and balance on the protection of this vital sector to national security while maintaining vigilance to the traditional focus on day-to-day food safety.

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ABSTRACT

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LIST OF ACRONYMS AND ABBREVIATIONS

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
AQI	Agricultural Quarantine Inspection
ARS	Agricultural Research Service
BAC	Bureau of Chemistry
BAI	Bureau of Animal Industry
BCR	Biological, Chemical and Radiological
BSE	Bovine Spongiform Encephalopathy
CAMRA	Center for Advancing Microbial Risk Assessment
CBP	United States Customs and Border Protection
CBRN	Chemical, Biological, Radioactive, and Nuclear
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
CFSAN	Center for Food Safety and Applied Nutrition
CIKR	Critical Infrastructure and Key Resources
CIP	Critical Infrastructure Protection
CNS	Center for Non-Proliferation Studies
CRS	Congressional Research Service
CSPI	Center for Science in the Public Interest
CSREES	Cooperative State Research, Education, and Extension Service
CVM	Center for Veterinary Medicine, FDA
DHHS	Department of Health and Human Services (HHS)
DHS	Department of Homeland Security
DNI	Director of National Intelligence
DOC	Department of Commerce
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
ERRC	Eliminate-Reduce-Raise-Create
ERS	Economic Research Service
EU	European Union
FAO	Food and Agricultural Organization
FAV	Food, Agriculture, and Veterinary Defense
FAZD	National Center for Foreign Animal and Zoonotic Disease Defense
FDA	Food and Drug Administration
FMCPFA	Federal Ministry of Consumer Protection, Food, and Agriculture
FSA	Food Standards Agency
FSIS	Food Safety Inspection Service

GAO	General Accounting Office
GIPSA	Grain Inspection, Packers and Stockyards Administration
HEW	Department of Health, Education and Welfare
HSPD	Homeland Security Presidential Directive
IHB	Office of International Affairs (International Health and Biodefense)
IOM/NRC	Institute of Medicine/National Research Council
NASS	National Agricultural Statistics Service
NCFPD	National Center for Food Protection and Defense
NCTR	National Center for Toxicological Research
NIH	National Institutes of Health
NIPP	National Infrastructure Protection Plan
NIST	National Institute of Standards and Technology
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
OCI	Office of Criminal Investigation, FDA
ODNI	Office of the Director of National Intelligence
OES	Bureau of Oceans, Environment and Science
OHA	Office of Health Affairs at the Department of Homeland Security
ORA	Office of Regulatory Affairs, FDA
PDD	Presidential Decision Directive
PHF	Potentially Hazardous Foods
SSP	Sector-Specific Plan, in NIPP
USDA	U.S. Department of Agriculture
WHO	World Health Organization
WMD	Weapons of Mass Destruction

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I. INTRODUCTION

A. PROBLEM STATEMENT

Since the events of September 11, 2001, stakeholders of the critical infrastructure sectors have tried to identify infrastructure vulnerabilities. The food and agricultural sector is no exception to this evaluation. While stakeholders and researchers recognize the importance of the food/agricultural industry as a critical infrastructure, few studies have addressed how to protect the infrastructure from intentional attacks. Since September 11 and the Bush administration's declaration of a "War on Terror," there has been scant research on the intelligence and information needs for the agricultural/food infrastructure. With many incidents of food-related illnesses in recent years and current recognition that the food and agriculture infrastructure is critical to national security, there has been much discussion about the need to explore changes in the U.S. food and agriculture regulatory system.

Many are concerned that the system, as now framed, is inefficient and not well prepared to handle the challenges of potential intentional contamination of the nation's food supply. Discussions often focus on the complexity of the regulatory structure and questions about its inability to handle and control the number of unintentional contamination problems adequately that have occurred in recent years. The U.S. regulatory structure, with its many agencies and departments and their respective responsibilities in protection of the food infrastructure, was created around the turn of the 20^{th} century. Over the years, an accumulation of legislation has added to the inefficiency of the regulatory system. Refocus on protecting our nation's critical infrastructures from terrorism has led to a debate about whether it is time to revisit the food and agricultural regulatory structure and change the way we approach food safety and now food defense.

B. RESEARCH QUESTIONS

How can the U.S. food safety/defense systems be improved to meet the challenges of protecting the food/agricultural sector from both unintentional and intentional food-related illnesses in an ever-expanding global food supply? Does the present system need to be restructured? If yes, how do we design a system to support the concept of a single food safety/defense agency in the United States?

Ancillary to the initial research questions is whether the leadership of the United States and of the food safety regulatory system will meet the challenge to explore innovative concepts related to a new food regulatory structure. Any solution that answers these questions would require an innovative and practical structure designed to bring about consolidation of smart practices, best knowledge in food safety, and a more effective management of resources and budget.

C. THE LITERATURE

1. Initial Findings

Most of the documents available in the literature are government and think tank reports that address the critical importance of the food/agriculture sector. Most of these documents are from the Government Accounting Office (GAO), the Congressional Research Service (CRS), RAND Corporation, the Institute of Medicine, National Research Council (IOM/NRC), the Center for Science in the Public Interest (CSPI), and the Heritage Foundation. It is interesting that these documents often offer similar views, recommendations, and information about the food/agricultural sector and the U.S. food safety regulatory structure (Center for Infectious Disease Research and Policy, 2008). Numerous documents, both recent and dated, include information about the food/agricultural sector, the food safety regulatory system, and an abundance of suggestions for change.

Before September 11, 2001, there remained little published about the vulnerability of the infrastructure to terrorism and the national security issue implications of an attack on the food and agriculture sector. One pre-9/11 research report from the RAND

Corporation did address the vulnerability of the infrastructure and attempted to focus concern that the sector could be targeted by terrorists with the goals of economic destabilization, political gain, and fear (Chalk, 2001). After September 11, 2001, reports on issues about the criticality of the food infrastructure, enhanced food safety efforts (food security and food defense), and their significance to homeland security issues began to appear with more frequency. It was not until the National Strategy for Homeland Security in 2002 (Revision in October 2007) and the January 31, 2004 release of Homeland Security Presidential Directive 9 that the highest levels of government in the United States finally started to focus on the importance of the food/agricultural infrastructure to the nation's sustainability and the criticality of the infrastructure. However, even the release of the 2002 strategy did not present an immediate direction about preparation of the sector to prevent attacks or for information sharing between the regulatory and private sector communities to protect it from intentional attacks (White House, 2002).

As mentioned, food and agriculture has not always been recognized as a critical infrastructure vulnerable to terrorist attacks. For example, terrorism analyst Peter Chalk wrote that the infrastructure was not listed as critical in the Clinton administration's *Presidential Decision Directive 63*, one of the first directives to identify the nation's critical infrastructures, being complete left out (Chalk, 2004). Peter Chalk wrote in the same 2004-RAND report:

> Agriculture and food production and supply, however, are industries that have received comparatively little attention in the general field of counterterrorism and homeland security. In terms of accurate threat assessments and consequence management procedures, the agricultural sector is somewhat of a latecomer to the growing emphasis on critical infrastructure protection (CIP) in the United States. (Chalk, 2004)

Homeland Security Presidential Directive 9: Defense of U.S. Agriculture and Food (HSPD-9) discussed the food infrastructure as a critical infrastructure that, while not completely overlooked, has been often neglected in discussions of homeland security

(White House, 2004). HSPD-9 brought to the forefront the need for development of intelligence and analysis capabilities to include collection and analysis of threat, delivery, and methods information directed to the food and agriculture sector.

In the 17 months of research completed for this thesis, members of the media, consumer groups, industry Web sites and associated documents have also called for a new food safety regulatory course. The primary call has been for improvements in how the United States regulates the food/agricultural infrastructure. Concern for the safety and now defense of the infrastructure has grown because of incidents of biological contamination in processed and raw foods and agricultural products, from both the domestic and foreign food supply chains. These same organizations and groups have linked these foodborne illness outbreaks to inadequacies in the network of regulatory agencies that are responsible for the infrastructure's protection (Marler Clark, *Food Poison Journal*, 2008). The increases in illnesses that have occurred from ingestion of these food products by humans and pets have begun to heighten concerns about how we protect our food supply.

Some members of Congress have attempted a legislative dialogue and called for changes to the U.S. food safety regulatory structure. While perhaps a coincidence since September 11, foodborne illness outbreaks associated with products such as spinach, lettuce, tomatoes, jalapeno peppers and peanut butter, imported seafood and pet food from China have brought attention to global security and protection of the food supply from terrorists beyond our borders (Fischetti, 2007). If terrorism is linked to biological and chemical incidents, the consequences to the U.S. population, the food industry, and our national economy could be devastating. The cost of the Salmonella Saintpaul-related illness associated with tomatoes and jalapeno peppers to the industry in August 2008 was estimated between $130 million to $150 million, with 1,442 people ill, 286 hospitalized, and two deaths as a result (Hsu, 2008). Information and reports like the above demonstrate why the nation's food infrastructure may need more than traditional food safety programs.

The same private think tanks such as RAND and government agency reporting services, such as GAO and CRS, have also recommended a move away from the structure of multiple agencies and departments now responsible for the safety of different components in the nation's food supply. Additional reports call for a new direction and need for protection of the agricultural/food infrastructure against terrorists.

Evidence showing the intentions of international terrorists to target agriculture and food was found in Afghanistan in Operation Anaconda in 2002 (Williams, 2005). Documents found showed the expressed desire of Al Qaeda to contaminate food, agricultural and water supplies. These documents also present confirmation of terrorist intentions to use the infrastructure for terror. The documents prove the need to suggest to U.S. leaders that a re-evaluation of our strategies in allocation of resources and best practices in food safety that also include a viable intelligence component being added to any regulatory structure.

2. Conclusion

The literature reveals that while the importance of the food infrastructure has been gradually moving forward in respect to homeland security, there remain gaps in how the current agencies handle intelligence information on the sector and how it is distributed to those who need it most. The literature does include formal science-based information about the nature of biological, chemical, and radiological threats and contaminants and the consequences of not protecting the food supply. Information is plentiful about pathogens and their interactions with food. What is missing, however, is information about food safety for homeland security purposes.

The industry, while supportive of the concept of food defense generated after September 11, may have difficulty embracing a separation between food safety and food defense especially with multiple agencies. Industry stakeholders may believe that without information suggesting an increased level of intentional threat that current safety precautions are sufficient to protect the food products that they produce. Facilities that are inspected by more than one federal or state regulatory agency may have one agency suggest or regulate by statute one direction on food defense, as they do on food safety of

specific commodities, while the other agency, per their statute, goes in another direction.[1] Many documents explain how the food safety regulatory system works. Some authors say that the system and processes do not need change, while others suggest enhancements to the system by tweaking budgets, adding laws and statutes, or wholesale changes through creation of a new regulatory structure. Some authors discuss whether anything the government does will be sufficient to protect consumers, create transparency, or be too restrictive to the industry being regulated both foreign and domestic.

However, how do we get to a collective agreement on the move toward a modernized food protection regulatory system in the United States? In addition, why would we want to move in this direction if given the chance?

D. ARGUMENT

Establishment of a single food safety oversight agency could help close one of many important gaps. Such an agency can establish a single portal for a smarter and more efficient and focused use of resources for food safety/defense. A focused and combined regulatory approach to food safety/defense efforts can be established for the sector. This approach would establish a more focused mechanism for research of food and agricultural pathogens, including emerging pathogens. Better education at all levels of the farm-to-table continuum on food safety/defense involving all stakeholders, combined with the fusion of intelligence information pertinent to the food and agricultural sector, would also provide a clearer perspective of existing and emergent problems and provide a path to strengthen outcome solutions. Additionally, it is important to explore a workable solution or policy for information sharing between the regulatory system, DHS, the intelligence community, and ultimately, the state and local regulatory systems to analyze probabilities of attack and prevent terrorist threats against the sector. The importance of

[1] My experience as a state regulatory, as we moved toward an educational campaign to let retail food service establishment operators know about the concept of food defense, helps to strengthen this statement. When the federal system started discussion of the need to secure and defend the food and agricultural infrastructure, the primary federal food regulatory authorities went from food security to food defense terminology before settling and agreeing to use the term food defense.

all of these will require a new direction. Exploration of this new direction is the basis for establishing a different concept, which will be discussed in this thesis of an administrative agency dedicated to singular oversight of food safety/defense.

Can something be done to bring all of the resources available among the various agencies together within the confines of current statutes and laws that govern the various food safety agencies? There is plenty of discussion occurring with the current rash of food-related illness outbreaks. The illnesses associated with the outbreaks have focused for the moment, lawmakers' attention on examination of the problem, and whether it is self-healing under the present system, or whether the system requires fundamental change. There is a great deal of blame and frustration among stakeholders on how agencies can do better, which agency is in charge of safeguarding what component of the food and agriculture sector, and how agencies can share what information and when. The arguments for solutions and the questions and answers continue, often repeating the same ones continually. What can be done, and who can best filter out a workable solution from the myriad of questions and answers being discussed for so long? It all begins with the first question.

1. The Food and Agriculture Regulatory System—Who's on First?

The U.S. food safety system is set up from the top down, federal to state to local. These agencies are comprised of primary federal agencies such as the FDA, USDA, and EPA, and for surveillance of diseases associated with food and water, the CDC. At the state level, state and local agencies (depending on the state) regulate the safety of the food and water supply, investigation and surveillance of food-related disease outbreaks, and respond in their respective jurisdictions. Regulatory agencies at all levels (federal, state, and local) of the food/agricultural sector rely on the cooperation and knowledge of the food industry, research, and academic components in the food supply chain. Unintentional foodborne illnesses in the food infrastructure and supply chain have led to confusion as to who is protecting what, how the regulatory system is set up, who is in charge of what, and why there is such difficulty in finding the sources of foodborne illnesses when they occur. It leads some to imagine a scenario of "Who's on first? What's

on second? And I don't know is on third" (Abbott & Costello, 1939). The complex nature of product regulation, foodborne illness investigations, and tracing back to the source of contamination leads to frustration among consumers and the media as to why distinct illness outbreaks are not contained and the source of the contamination determined and eliminated more quickly. On the question of possible intentional contamination of food, it is difficult to gain adequate buy-in from industry about the potential threat of terrorist activities against the food supply without credible intelligence to motivate the industry to spend additional money to protect against a terrorist threat. It has been difficult enough to prevent unintentional contamination.

2. From "I Don't Know"—To Better Understanding

This thesis will examine whether there is a need for strategic policy recommendations that can provide guidance for structural improvement of the U.S. food safety regulatory system. We will explore concepts that could break down barriers between the parties that can obstruct effective protection of the food supply. This thesis is not intended to diminish the hard work that agencies and departments are presently putting forth in their current roles as protectors of the nation's food supply. With 28 years of experience in the food regulation industry at the state level, I recognize that current laws or statutes require agencies at all levels to perform their duties as well as they can with the resources they have, based on legal requirements.

This thesis will present the argument that the structure can be combined into one central federal governmental agency to produce a more effective agency and better regulatory oversight and collaboration among federal, state, and local agencies. A single food safety agency can also build a stronger foundation for better consistency of message and use of resources to educate and train stakeholders in how we protect and defense the food supply.

E. SIGNIFICANCE OF RESEARCH

1. Future Research Efforts

This thesis will provide an additional literature resource that can be used to investigate future questions. Additional research performed after this thesis is needed to examine whether terrorist threats from international sources to the food/agricultural sector are significant. Intelligence information on intentional contamination is needed to explore whether significant gaps exist because of a lack of expert knowledge about sector-specific threats. What policies and strategies are absent? What improvements are needed for preparation against threats, with the ultimate goal of protection of the food and agricultural sector from intentional threats? It is hoped that this thesis will open up a future research dialogue and provide guidance to future policy and strategy for protection of the food and agricultural sector.

2. The Immediate Consumer

Immediate consumers are defined as all stakeholders interested in continual improvements in food safety/defense within the food and agricultural infrastructure. The list of immediate consumers includes federal, state, and local food safety/defense regulatory agency leaders and personnel responsible for overall food safety, and the Department of Homeland Security, which is tasked with homeland security and food defense coordination in the event of an intentional attack on the infrastructure. In any system, all are responsible for implementation of strategy and policy for protection of the food and agriculture sectors.

Equally important stakeholders include the industry, academic research institutions, law enforcement at all levels (for intentional threats), consumer groups that focus on food safety, and ultimately, the U.S. consumers who keep all of the nation's infrastructures running. This research will give these consumers a better understanding of threats and their important roles and responsibilities in the protection of the nation's food

supply. Consumers have an equally important role in the protection of the food supply and protection from food-related illnesses. This is the importance of education and transparency in food safety and protection.

3. Homeland Security Practitioners and Leaders Nationally

The significance of the research from this thesis to homeland security practitioners and leaders will be the impetus it places on the decision and policymakers to become better strategic planners, informed about the criticality of the food/agriculture sector and to understand what modifications to existing food protection regulatory structures are warranted. With better *understanding* of the nature of the threat, probing into the myriad of choices based on intellectual awareness and insightful information, these decision-makers should be able to achieve realistic goals and a manageable structure for the food and agricultural regulatory and industry sector in the homeland security environment. A positive movement forward and collective change to the food safety/defense structure in the United States will be beneficial to all.

F. METHODOLOGY

1. The Problem

The issue surrounding change to the current regulatory structure is a sensitive topic. With over 100 years in development of the current regulatory food safety structure, discussions of change to that system are not always well received. When choosing a method of research for the primary research questions, problem statement, and argument posed in the thesis, the original intent was to conduct interviews with subject matter experts with a vested interest in the food safety and food defense paradigm. The difficulty in a method of analysis based on interviews to a research question related to change to the food safety regulatory structure was the reluctance by some government officials within regulatory structures to discuss questions about change and this method proved futile. Other stakeholders within the food and agricultural industry, while willing to discuss the

issue were not certain that the discourse through interview was appropriate from their position, without discretionary anonymity. While anonymity was affirmed, there was still reluctance to participate.

2. Method Used and Why

With the above in mind, it was important to choose a method that would allow for an objective and balanced approach to the research questions, while maintaining the rigor required of research. While there are several alternative methods of research available beyond interviews, the method chosen was secondary qualitative analysis. The majority of information and literature surrounding food safety and now food defense issues and associated regulatory issues are rooted in government research, private think tanks, and consumer advocacy group reports. The use of secondary qualitative analysis is appropriate in several ways as a research method.

Secondary analysis of qualitative data allows for the utilization of existing data or research on the issue of change to the way the United States protects the food supply. Secondary analysis of qualitative data from research reports and literature allows a similar analysis and evaluation of the data linked to the research question as that of interviews and similar research methods, but is not limited to a question set that may require additional interviews. Government, private think tank, and consumer group research and reports also allow a look across a wide spectrum of the stakeholder community. The method allows the author the opportunity to research objectively the questions posed without influence of opinion as a regulatory stakeholder himself.

Secondary qualitative analysis also allows the use of other methods incorporated into the overarching approach of the method, such as the use of comparative qualitative data. Through this approach, the research can include an exploration of the current regulatory structure and history, threats and gaps in the infrastructure, and comparative review of changes already made by other developed countries and changes proposed by others to the current regulatory system that an interview method alone could not do. The

secondary analysis is used to reveal the primary overarching sentiment, through secondary research data towards the research question, whether there is a consensus on the importance of the issue of food safety/defense regulatory reform.

3. How the Data will be Used

The secondary qualitative analysis will examine the literature for patterns of direction on the issue of growing concerns about food safety from both unintentional and intentional threats. The research method chosen will further explore comparative examples of similar concerns and the processes of success and failure from actions of concept change. These changes came out of crisis and the desire for a more efficient, effective, and transparent system. By using secondary qualitative analysis of existing information on the thesis topic, it is possible to examine what other countries have done to improve their overall food safety structures. Continuing on, the secondary qualitative analysis will be used to draw information from the emerging proposals for changes in the current food regulatory system, which range from statutory change to proposals for a new regulatory system in the United States currently being considered.

4. End Product

As a product of the thesis research, I will propose a conceptual model generated from the best practices taken from the information researched and my own twenty-nine and a half years of experience as a subject matter expert in food safety and defense. The author's experience also includes interactions with the federal and state regulatory community, the food and agricultural industry, academic researchers, and citizen groups involved in the food and agricultural sector.

All of the information synthesized creates a conceptual design structure and description of a future food and agricultural regulatory oversight agency. The conceptual configuration will present a visual and written blueprint for a single food protection regulatory system that can stimulate discussion on this important issue. This may add to the clarity of the primary research question. The recommendations and conclusion will also clarify the position taken away from the thesis as to the importance of change in the

food safety and defense regulatory system. For interested researchers who read this thesis in the future, the recommended concept framework could lead to a strategy and policy recommendation for implementing a new agency.

G. CHAPTER HIGHLIGHTS

- Chapter II provides an overview of the U.S. food safety regulatory structure. It introduces the reader to assumptions made by critics who consider it a fragmented system through a glimpse of some of the many components of each food regulatory agency.
- Chapter III explores the challenges and gaps in the food and agricultural regulatory structure.
- Chapter IV looks into threats to the food/agricultural infrastructure and discusses the importance of the infrastructure.
- Chapter V includes a comparison of changes made to the regulatory systems of three developed countries. These changes consolidated the food/agricultural regulatory structures in each of these countries to a single (smaller) and modernized regulatory footprint.
- Chapter VI examines proposals by others to improve our regulatory structure. With the onslaught of food-related illness outbreaks and the possibilities of the food infrastructure being used for terrorist gains, the reader will receive some insights about the crisis in the infrastructure.
- Chapter VII includes a discussion of a conceptual framework or model of change, borrowing from the best proposals for change and from changes already made in the countries reviewed.
- Chapter VIII is intended to stimulate ideas among those interested in food safety/defense. The conceptual model should give decision-makers in the U.S., the food and agricultural industry, academic communities interested in food safety research, consumer advocacy groups, and consumers themselves the insight to collaborate and to create a paradigm shift towards a safer food supply for the United States.

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II. BACKGROUND—THE PRESENT REGULATORY SYSTEM

> The history of government regulation of food safety is one of government watchdogs chasing the horse after it's out of the barn.
>
> David A. Kessler, M.D. (FDA Commissioner 1990–1997)

A. COMPLEXITY OF THE CURRENT FOOD SAFETY REGULATORY SYSTEM IN THE UNITED STATES: AN OVERVIEW

To illustrate the extensive growth of the regulatory structure overseeing the food and agricultural sector, a brief history of food safety regulation and an understanding of the make-up of each agency (department) are essential. While the U.S. Department of Agriculture (USDA) and the Food and Drug administration (FDA) under the Department of Health and Human Services (DHHS) are the primary federal agencies responsible for primary protection of the nation's food supply, many other stakeholders are involved. Oversight of food safety in the nation at the federal level has blossomed since the creation of the USDA in 1862 and the foundational statues for the current regulatory in 1906. The food safety regulatory structure in 2008 involves at least 15 agencies or departments, of which five are at the executive branch level, four with cabinet status, and one independent agency (Robinson, 2005).

The cabinet level agencies include the USDA, DHHS, Department of Commerce, and the Department of Homeland Security. The Department of State is also recognized as having a stake in food security from a global perspective. The State Department is considered a fifth executive branch with an ancillary role and responsibility included in the food and agricultural regulatory structure. In addition, the Environmental Protection Agency is an independent agency involved in food and agricultural safety.

When asked to prepare a report on the food safety regulatory system in 2004, Lawrence Dyckman, then Director of Natural Resources and Environment with the General Accounting Office (GAO), described in testimony before the U.S. Congress what was seen as a complex federal food protection regulatory system. He testified that the present federal regulatory system for agricultural and food safety had appeared gradually over many years in response to public health concerns and economic emergencies. The

years of response to food and agricultural concerns led to the alignment of food safety regulatory organizational structures into a cumbersome system of agencies and internal departments (Dyckman, 2004).

Dyckman believes that the responsibilities split between USDA and FDA hinders effective congressional oversight and leads to public confusion. “For example, congressional oversight committees and GAO must review and analyze multiple agencies' programs, policies, and budgets, in order to address questions of overall food safety oversight, rather than focus on food safety inspection programs under one agency's jurisdiction,” Dyckman said (*Food and Drink Weekly*, 2004).

A historical timeline of food safety regulation in the nation and a brief description of each agency involved, gives a better picture of the complexity of the system.

B. HISTORY OF REGULATORY GROWTH

When the U.S. population began moving from rural to urban settings and into the industrial age, there was growing demand for food products. The first true federal agency responsible for food safety was the Department of Agriculture, which was established by legislation signed by President Abraham Lincoln in 1862. The first U.S. Department of Agriculture did not have executive branch or cabinet status. The initial purpose of the USDA was to stimulate food production by providing seed for food crop production and to provide farmers with information about fair trade (U.S. Department of Agriculture, 2006). In addition, during Lincoln’s administration and within the USDA, the Bureau of Chemistry (BAC) was established. The BAC was the forerunner of the present-day Food and Drug Administration (FDA). With the expansion of the United States toward the west following the Civil War, the development of the refrigerated railway car, the growth of the livestock industry, international trade, and the meat packing industry, USDA’s role was extended to include responsibility for efforts to prevent diseased animals from entering the food supply. In 1884, President Chester Arthur signed the Bureau of Animal Industry Act, which created USDA’s Bureau of Animal Industry (BAI). This was the first predecessor of USDA’s Food Safety Inspection Service (FSIS) and it marked the beginning of regulatory growth.

1. Major Changes Ahead (U.S. Department of Agriculture, 2007)

In 1905, Upton Sinclair's book, *The Jungle* (1905), exposed unsanitary conditions in the Chicago meat packing industry. Public outrage about unsanitary conditions prompted President Theodore Roosevelt to establish a commission to investigate the allegations. The commission confirmed Sinclair's allegations. In 1906, President Roosevelt signed two new acts into law. These acts were the Meat Inspection Act and the Food and Drug Act. The Meat Inspection Act was assigned to USDA's Bureau of Animal Industry (the Bureau later became the Food Safety Inspection Service) to oversee meat inspections. In addition, the Food and Drug Act was assigned to USDA's Bureau of Chemistry (later to become the Food and Drug Administration) to oversee the misbranding and adulteration of food, drink, and drug products (U.S. Food and Drug Administration, 2005).

Fast forward to 1927, and we see the Bureau of Chemistry changing its name to the Food, Drug and Insecticide Administration, and then, in 1931, changing to the Food and Drug Administration. In 1940, the now Food and Drug Administration was moved out of the USDA into a new agency, the Federal Security Agency, which in 1953 became the Department of Health, Education, and Welfare—the predecessor to the Department of Health and Human Services (DHHS) that we have today.

After World War II, with the advent of refrigerated trucks and the federal interstate highway system, food processing and meat packing plants began moving to rural locations. Modernization and new technologies led to increased production and the food processing industry began to flourish. To keep up with the changes, President Eisenhower again reorganized the USDA. The 1953 USDA internal transformation was to move the Bureau of Animal Industry and the Bureau of Dairy Industry into a research type service, the Agricultural Research Service (ARS). In 1957, the poultry industry expanded, and another statute was signed into law, the Poultry Products Inspection Act. These types of reorganization continued through the next few decades. During these decades, the Animal and Plant Health Inspection Service (APHIS) within USDA was created to administer all regulatory functions of the ARS in the 1970s. In addition, the

Food Safety and Inspection Service (FSIS) started its modern day transformation during the 1970s and early 1980s to develop into the agency it is today (U.S. Department of Agriculture, 2007).

The two original statutes created in 1906 to address food and agriculture safety—the Meat Inspection Act and the Food and Drug Act—have undergone several transformations. As changes are made to statutes, so is the process of continual modification in how we regulate food and agriculture. The other agencies with food safety responsibilities followed a similar path as their statutory authorities were moved from one agency to another over the years. All food and agricultural responsibilities for the different agencies had some original connection to the USDA.

Administration, strategy, and policy changes over time have built a food safety regulatory system much larger than the single agency structure formed in 1862. The size and complexity of the shift to multiple agencies have morphed through years of food safety crisis, statutes, and reorganizations under several presidential administrations.

C. THE CURRENT REGULATORY STRUCTURE

Responsibility for the safety and defense of the U.S. food supply is distributed among multiple agencies that collectively administer more than 30 laws (Shames, 2007). These agencies include the USDA with eight departments; the DHHS with three internal departments (FDA, CDC, NIH); the EPA and the DOC with one department each; the DHS with three internal offices; and the Department of State. Each regulatory entity and their component departments or offices are briefly described below.

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

The present composition within the USDA in relation to food safety includes eight departments. The USDA is responsible for overseeing the safety of 20 percent of the nation's food supply, both domestic and foreign (Food Safety Central, 2007). Following is a list of the individual USDA departments and their responsibilities.

a. Food Safety Inspection Service (FSIS)

FSIS is the USDA's public health agency responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg product is safe and wholesome. This includes processed meat products. Figure 1 shows the size of the organizational structure within FSIS alone.

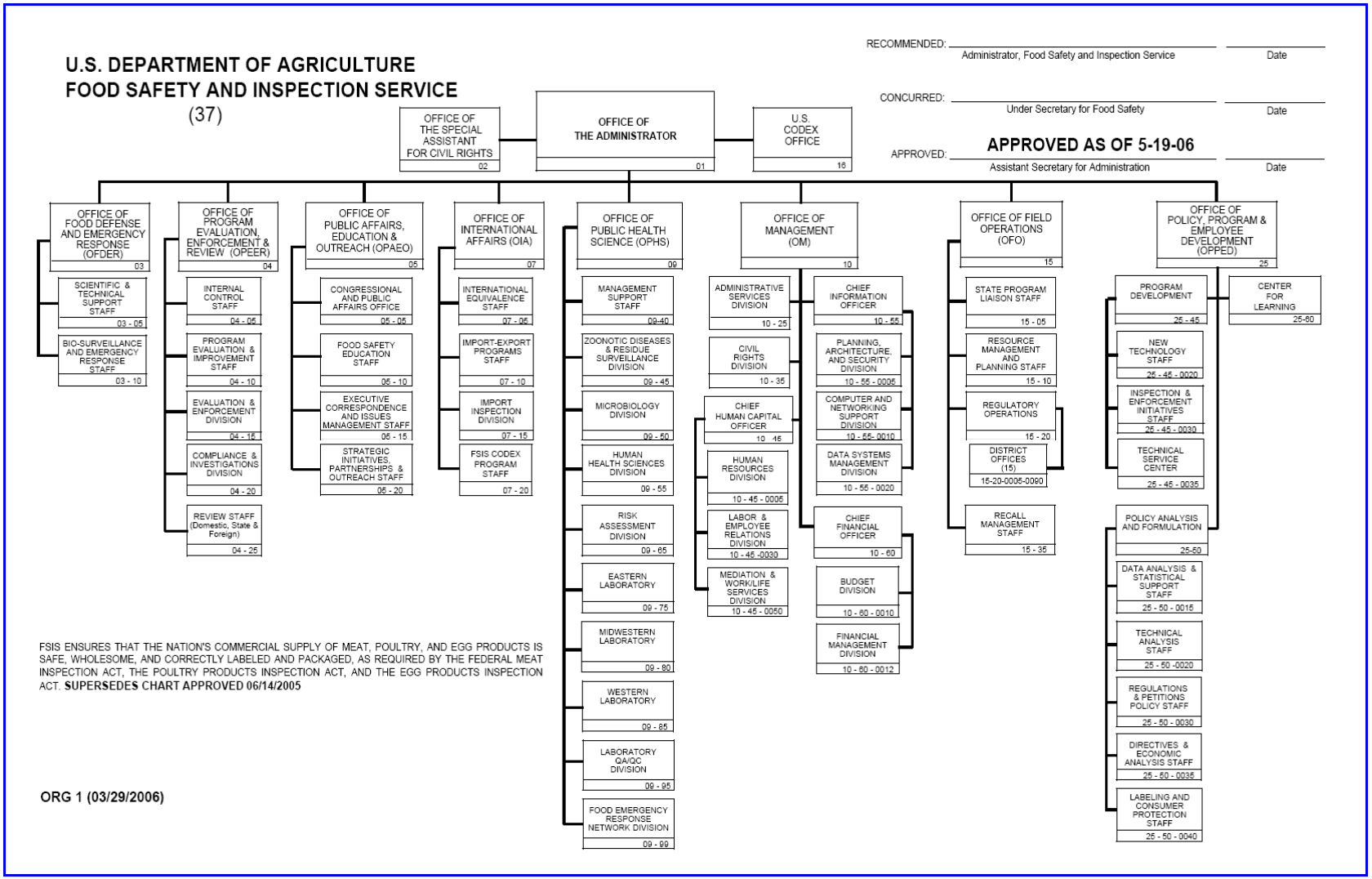

Figure 1. USDA—FSIS Organizational Chart (From: USDA, 2008, www.fsis.usda.gov/OM/orgcharts/fsis.pdf)

b. Animal and Plant Inspection Service (APHIS)

APHIS provides leadership to ensure protection of the health and value of U.S. agricultural resources. APHIS also indirectly protects the nation's food supply through programs to protect plant and animal resources from domestic and foreign pests and diseases, such as brucellosis and bovine spongiform encephalopathy ("mad cow" disease).

c. Agricultural Research Service (ARS)

ARS performs food safety research in support of FSIS's inspection program.

d. Agricultural Marketing Service (AMS)

AMS establishes quality and condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products.

e. Economic Research Service (ERS)

ERS provides analysis of economic issues affecting the safety of the U.S. food supply.

f. Grain Inspection, Packers and Stockyards Administration (GIPSA)

GIPSA establishes quality standards, inspection procedures, and marketing of grain and other related products.

g. National Agricultural Statistics Service (NASS)

NASS provides statistical data, including agricultural chemical usage data, related to the safety of the food supply.

h. Cooperative State Research, Education, and Extension Service (CSREES)

CSREES supports food safety research, education, and extension programs in the land-grant university system and other partner organizations.

The USDA is by far the largest of the U.S. agencies responsible for food safety at the federal level with the largest budget. The FY 2009 budget request for USDA and all of its programs is $95 billion. The budget outlay for FSIS alone for food safety will be around $1.1 billion. The food and agricultural defense initiative budget for USDA will be $277 million for FY 2009 (U.S. Department of Agriculture, 2008). The USDA inspects 20 percent of the nation's food supply, but has 80 percent of the food safety and food defense budget (Shames, 2007).

2. Department of Health and Human Services (DHHS)

Three primary agencies within DHHS have roles in food safety—the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), and the National Institutes of Health (NIH). Following is a list of the individual DHHS agencies that have food safety responsibilities.

a. Food and Drug Administration (FDA)

The Food and Drug Administration is (along with USDA) one of the primary agencies responsible for the safety of the nation's food supply. The FDA's programs are responsible for protecting 80 percent of the U.S. food supply; even though it's staff and budget are much smaller than the USDA (Robinson, 2005). The roles of the various components within FDA for federal food safety oversight are broken down further as follows.

(1) Center for Food Safety and Applied Nutrition (CFSAN)

- CFSAN is responsible for all domestic and imported food products except for meat, poultry, and processed egg products
- CFSAN is also responsible for the food defense efforts for FDA in conjunction with the Office of Regulatory Affairs (ORA) and the Office of Criminal Investigation (OCI) in FDA

- CFSAN operates an oversight compliance program for fishery products. This program is listed later as in conjunction with a seafood program established in the Department of Commerce

Figure 2 shows the organizational structure of CFSAN and the various programs within the center related to food safety/defense.

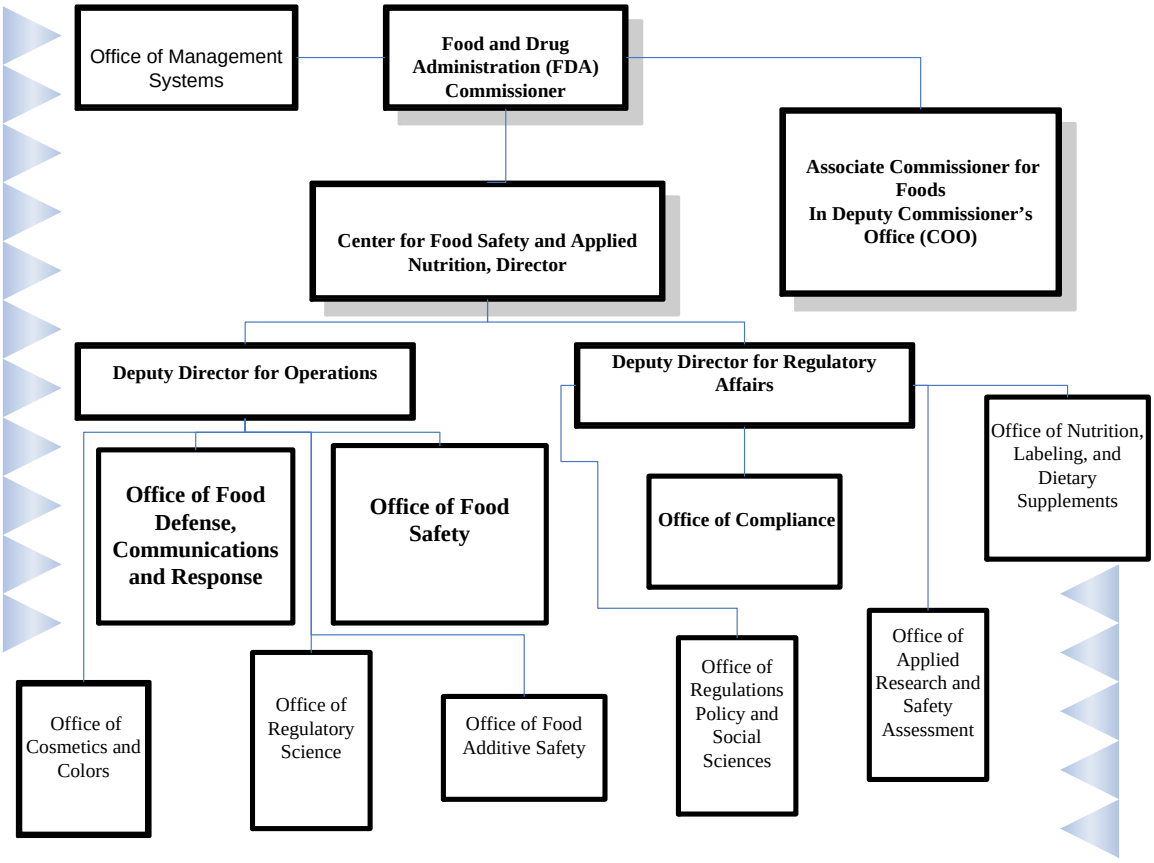

Figure 2. Center for Food Safety and Applied Nutrition (From: FDA/CFSAN, 2008, http://www.fda.gov/oc/orgcharts/CFSANOMS.pdf)

(2) The Center for Veterinary Medicine (CVM). The CVM is responsible for assuring that animal drugs and medicated feeds are safe and effective and that food from animals is safe to eat.

Also important to the FDA food safety mission are the Office of Regulatory Affairs (ORA) and the National Center for Toxicological Research (NCTR). Within FDA, ORA is the lead office for all field activities of the Food and Drug

Administration (FDA, ORA, 2008). ORA is also the conduit for state and federal relations in protection of the nation's food supply. The NCTR's mission is to conduct peer-reviewed scientific research and provide expert technical advice and training that enable FDA to make sound science-based regulatory decisions and improve the health of the American people (U.S. Food and Drug Administration, NCTR, 2008).

b. Centers for Disease Control and Prevention (CDC)

Among CDC's responsibilities are the tasks it performs in foodborne related illnesses. The CDC works with federal (FDA, FSIS, NMFS), state, and local food safety programs to monitor, identify, and investigate foodborne disease problems to determine contributing factors. CDC also works with FDA, FSIS, NMFS, state and local public health departments, universities, and industry to develop control methods for a food-related illness, and then evaluate the effectiveness of the control methods. In 1995, CDC launched "FoodNet," a collaborative project with the FDA and USDA to improve data collection on foodborne illness outbreaks. FoodNet uses active surveillance of clinical microbiology laboratories to obtain a more accurate account of positive test results for foodborne illness. Along with surveys to analyze ongoing practices, FoodNet uses population surveys to identify unreported illness, and research studies to obtain new and more precise information about which food items or other exposures may cause diseases (Congressional Research Reports for the People, 2008). FoodNet data allows CDC to obtain a clearer picture of the incidence and causes of foodborne illness to establish baseline data, against which to measure the success of changes in food safety programs. The Public Health Service Act provides legislative authority for CDC's food safety activities. CDC's responsibility for disease surveillance makes the center a major stakeholder in food safety/defense issues (U.S. Centers for Disease Control, 2008).

CDC's Food Safety Budget for FY 2009 (identified under "All Other Food Safety") is $22,415,000 to support collaborative surveillance systems. The CDC works with state and local partners, as well as USDA and FDA, conducts laboratory and epidemiologic research, and responds to foodborne disease outbreaks (Centers for Disease Control, Office of Budget, 2008).

The CDC's responsibility in food safety is one of the components of the current system that has shown a need for consistent collaboration. The support that CDC programs provide to FDA, USDA, and EPA is a good example of what is possible, especially if the efforts were integrated into a single collective food safety agency.

c. National Institutes of Health (NIH)

The National Institutes of Health is composed of 27 institutes and centers. Several NIH institutes provide research and information on food safety diseases and organisms responsible for foodborne illness as part of their mission (National Institute of Health, 2008a). During analysis of NIH functions, it was observed that in 1998, NIH's National Library of Medicine, in concert with USDA's National Agricultural Library and the Library of Congress, developed a joint policy on human nutrition. This was seen as a positive move to resolve information collection issues related to separate agencies involved in related study. The joint policy was an attempt to collect, retain and preserve all significant information on human nutrition and food that had been collected by the separate parent agencies. However, some aspects of the subject areas are collected and treated differently at each organization, depending on its particular mission and the needs of its users. This again shows that separate agencies have competing concerns (National Institutes of Health, 2008b).

While all of the organizations described under the DHHS umbrella are involved in food safety, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) has the greatest budget for the task, however smaller than USDA's FSIS. The total FDA budget for protecting America's food supply for FY 2009, which amounts to 80 percent of America's food supply, will be $661.844 million (U.S. Food and Drug Administration, 2008). The FDA budget for food safety is less than half the budget of USDA, even though FDA carries the bulk of the food safety responsibilities. The budget examples provide a glimpse of the convoluted system that has evolved through years of reorganization and separation of the food safety agencies and their responsibilities.

3. Department of Homeland Security (DHS)

a. History and Relevance to Food Safety and Food Defense

The Department of Homeland Security (DHS) began its role in food defense and food security as part of the department's reorganization in 2007. Within the DHS structure, the Office of Health Affairs has a mission to protect the health and security of U.S. citizens by collaborating and coordinating with other DHS components,[2] federal partners, state partners and the private sector (McGinn, 2007).

Within the DHS, additional areas in the organizational structure have some related roles in food protection. It may appear that DHS has a complex structure in its food safety role similar to that of the food safety regulatory structure. However, there is a unique difference. The food programs at DHS are under one command structure, namely the Secretary of DHS, and its primary mission in food and agriculture is tied to coordination of food defense and homeland security. The DHS's goals are to enhance the capabilities of the regulatory structure in coordinating food defense from intentional and natural disasters. The agency works closely with agencies that perform the nation's food safety regulatory functions. There are at least four programs at DHS with direct ties to food and agriculture (U.S. Department of Homeland Security, 2008). The following areas have ties to the food infrastructure from a homeland security perspective.

b. The National Protection and Programs Directorate and Its Program Areas

- Office of Infrastructure Protection, under which the National Infrastructure Protection Plan falls

c. The Directorate for Science and Technology and its Program Areas—Homeland Security Centers of Excellence

- National Center for Food Protection and Defense (NCFPD)

[2] The National Protection and Programs Directorate and, the Directorate of Science and Technology, and the United States Customs and Border Patrol to name three.

- National Center for Foreign Animal and Zoonotic Disease Defense (FAZD)
- Center for Advancing Microbial Risk Assessment (CAMRA)

d. The Office of Health Affairs and its Program Areas—The Office of Weapons of Mass Destruction and BioDefense

- Food, Agriculture, and Veterinary (FAV) Defense

e. United States Customs and Border Protection (CBP)

- Assistance with Import and Export Control of Foods at the border to the United States

In 2003, the Agricultural Quarantine Inspection (AQI) program (once under the USDA's Plant Protection and Quarantine program) was transferred to CBP as part of their border protection duties under DHS. There was a transfer of 2,700 employees along with the program at the time.

4. Food Defense Emphasis

The main task of the various offices at DHS with food and agricultural functions are to assist federal and state food regulatory agencies to prevent, respond, and recover from natural disasters, disease outbreaks of national consequence, and agroterrorism affecting the nation's food supply, crops, and livestock (McGinn, 2007). For purposes of food defense and safety, in this section, we will focus on the Office of Food, Agriculture, and Veterinary Defense and its ties to the food safety regulatory community.

a. Office of Food, Agriculture, and Veterinary Defense

Within OHA, the Office of Food, Agriculture and Veterinary Defense (FAV) was established to ensure that food and agriculture receive attention as critical infrastructures. The office was created to strengthen public confidence in food protection and align with regulatory agencies and other stakeholders in assessing vulnerabilities of food/agricultural from a homeland security perspective. Since regulatory responsibilities are spread among many agencies, the supposition was that from a national security

position, the FAV office would create a bridge between all agencies for food defense. The goal is that FAV will foster effectiveness across programs within DHS regarding food and agricultural and veterinary defense and between the federal food protection programs (McGinn, 2007).

The Department of Homeland Security (DHS) was established to coordinate efforts to maintain an increased level of security among domestic agencies. One of its primary tasks is to leverage resources within federal, state, and local governments and to coordinate multiple agencies and programs into a single integrated agency. With the current make-up of the U.S. food safety regulatory system, it would appear that food defense efforts to interact and coordinate with multiple agencies in the defense of the food supply would be a greater challenge than if DHS had the opportunity to deal with a single food safety agency structure.

5. Department of Commerce (DOC)—Relevance to Food Safety

a. National Marine Fisheries Service (NMFS)

The NMFS operates under the National Oceanic and Atmospheric Administration (NOAA). Although the FDA is the primary agency responsible for ensuring the safety, wholesomeness, and proper labeling of domestic and imported seafood products, NMFS conducts, on a fee-for-service basis, a voluntary seafood inspection and grading program that focuses on marketing and quality attributes of U.S. fish and shellfish. The NMFS provides fisheries inspection services to assure the safety of commercial fisheries products. The primary legislative authority for NMFS's inspection program is the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.). As of 2008, NMFS has approximately 160 seafood safety and quality inspectors, and inspection services are funded by user fees (Becker & Porter, 2008).

b. National Institute of Standards and Technology (NIST)

NIST works with other federal agencies such as the FDA and the USDA to regulate standards, weights, and measures for food products. Research at NIST includes standards and measurement issues related to nutrients in food products, as well as contaminants and adulterants in food products.

The responsibilities of the Department of Commerce in protecting a portion of the nation's food supply add yet another layer to the food safety regulatory system. The roles of both NMFS and NIST in their regulatory and research functions also cross paths with other agencies with primary food protection roles, such as FDA and USDA. The mixed roles of food safety among agencies such as NMFS and FDA can lead to confusion when standards differ or when interagency agreements for sharing information are not met.

6. Environmental Protection Agency (EPA)

a. History and Relevance to Food Safety

The EPA was created in 1970 as an independent agency to protect the environment. The question at first was whether to place control of environmental issues under an existing government agency. At first, President Nixon was reluctant to create the EPA as an independent agency. The final decision was based on two arguments. The first argument was that the primary mission of an existing department, if given control of all environmental issues, would bias any decisions it made on a government-wide basis with reference to the environment. The second argument was that questions could be raised about the objectivity of the same department for similar reasons as a standards-setting body for other agencies and departments (Lewis, 2007).

The EPA was woven together from components of various programs at other departments.

- From the Department of Health, Education and Welfare (HEW) (which is now DHHS) components given up were:
    - National Air Pollution Control Administration

- Bureaus of Water Hygiene and Solid Waste Management
- Bureau of Radiological Health

- From the Food and Drug Administration at HEW
  - Control over tolerance levels for pesticides
- From the Department of the Interior
  - Functions of the Federal Water Quality Administration and
  - Portions of its pesticide research responsibilities
- From the Department of Agriculture
  - Gained functions respecting pesticide registration
- From the Atomic Energy Commission and the Federal Radiation Council
  - Gained responsibility for radiation criteria and standards.

7. EPA Programs Involved in Food and Agriculture

The Office of Pesticide Programs of the EPA is responsible for setting *tolerances*, that is, the limits of the amount of residues from chemicals that can safely be found in or on food and for promoting safer methods of pest management. The Office of Water sets standards for water, including drinking water, water used in food and agricultural applications, and standards on wastewater treatment and release back into the environment. Overall, the statutory responsibility for EPA is designed to ensure that chemicals used on food crops do not endanger public health and to protect water resources from contamination.

The EPA is another administration that evolved from the collective combination of several agency components to construct a more efficient governmental body. The only discrepancy from a food safety perspective is the role that the EPA serves to oversee pesticide and other chemical tolerances in agriculture, food, and water. There is a specific discrepancy in the overlapping jurisdictional area between three agencies regarding pesticides and chemical tolerances. While the EPA is the primary agency, its efforts are duplicated by the FDA and the USDA, making for inefficient use of resources. The inefficiency is not the fault of the agencies themselves, but of the way, these agencies are structured.

8. Department of State

a. Food Safety and Food Defense Relevance

The globalization of the food supply and our country's growing reliance on foreign food products and free trade involves the interaction of both developed and non-developed countries (U.S. Department of State, 2008a). The Department of State is well suited for the task of involvement in world food security, safety, and defense issues that can affect directly and indirectly the U.S. food supply from an international perspective. The State Department has an auxiliary but important role in food safety and defense through its international diplomacy mission. Within the organizational structure of the Under Secretary for Democracy and Global Affairs, the Bureau of Oceans, Environment and Science (OES), and the Office of International Affairs (International Health and Biodefense, (IHB)), the Department of State plays an important role in protecting U.S. health security and global economic growth through promotion of global health. Following is a brief description of some of the U.S. Department of State office functions related to food safety under the Office of International Health Affairs (U.S. Department of State, 2008b).

b. Surveillance

The IHB works with countries and their public health systems to strengthen national and international disease surveillance and response systems.

c. Bioterrorism, Biodefense, and Health Security

The IHB works with countries to control and understand the threats associated with the spread of biological agents and other infectious-disease-causing agents that could quickly spread across borders. One vector that could be used to spread biological agents is the food supply. There have been presentations about food defense by Marc L. Ostfield, senior advisor for Bioterrorism, Biodefense, and Health Security on "the importance of diplomacy, international cooperation and collaboration to protect the food supply from international contamination" (Ostfield, 2007). Ostfield is particularly

interested in defense of the food supply from a bioterrorism perspective and the implications of an attack on the global food supply (Marc L. Ostfield, personal communication, 2008).

In an era of intense globalization of the food supply when there is the possibility of contamination of food by terrorists, international cooperation through diplomacy is essential. The Department of State is well suited for this diplomacy. With international trade and the movement of food commodities globally, the State Department plays an outlying but important role in food safety/defense, disease, and bioterrorism issues. Also, with a plethora of international food producers and processors supplying the needs of consumers, the State Department constantly interacts with the U.S. food regulatory community and industry.

9. Other Barriers to Comprehensible Food Safety/Defense Harmonization

a. Involvement of Multiple Congressional Committees

Several Congressional committees are responsible for considerations of food safety/defense legislation, statutes, and issues. Both chambers have several committees through which deliberation of food and agricultural legislation may take place. Some of the committees involved with food safety are as follows.

In the Senate, food safety issues are considered by the following committees.

- Agriculture, Nutrition, and Forestry
- Homeland Security and Governmental Affairs
- Health, Education, Labor, and Pensions

In the House, food safety actions fall under the influence of the following committee.

- Agriculture
- Energy and Commerce

- Oversight and Government Reform
- Science

There are also several agriculture subcommittees in both the House and Senate. Add to this mix the appropriation committees that serve congressional functions on oversight and funding roles on how the major agencies carry out food safety policies (Becker & Porter, 2008).

With so many committees influencing legislation, it is difficult to envision a collaborative movement toward a consolidated regulatory system.

b. Statutes and Agreements Governing Food Safety and Defense

At least 30 laws or statutes govern food safety oversight among U.S. food regulatory agencies. In addition, more than 71 interagency agreements govern the combined food safety oversight responsibilities (Robinson, 2005).

Federal officials argue that by working cooperatively and through formal understandings among the agencies, federal agencies now, for the most part, avoid duplicating efforts. However, the overlapping agreements are complicated and not always followed because of conflicting oversight and unproductive coordination between the agencies (Shames, 2008). The federal system is further complemented by the 50 states and the U.S. territories, all of which have their own regulations and agencies for regulating and inspecting the safety and quality of food products.

c. State and Local Agencies

State-level agencies are the backbone of the country's food protection efforts that monitor and inspect food commodities at the intrastate wholesale and retail level. State and local agencies regulate the safety of the food, agriculture, and water supply; investigate and monitor food-related disease outbreaks and the response from their respective jurisdictions. In almost every instance, these food protection regulatory systems mimic their counterparts at the federal level. Oversight of regulations of any sector in the food supply chain also relies on whether the food industry component

participates in interstate or intrastate commerce or sells wholesale or retail. Thus, even at the state and local level, the statutory structure governing food safety yields a regulatory system that makes jurisdiction over food dependent on the type of food, the way the food is processed, or the type of adulterants found in a particular food. This additional regulatory layer duplicates the federal system and further dilutes the efficiency of food safety/defense oversight.

d. Industry and Academia

The importance of both the food industry's and academic research institutions cannot be understated. The insights that these entities provide in analyzing foodborne pathogens have provided valuable information for the safe handling of food products to feed people all over the world. However, many of these organizations must also deal with the multiple layers of regulatory agencies, especially as new statutes are implemented or specific research is ordered.

Additionally, there is sometimes competition among these organizations for federal research money when illness events occur or emerging pathogens are discovered. Since 9/11, there has even been an increase in research for food defense purposes, not only from a biological and chemical contamination perspective, but also from a technological and physical protection angle. This has led to more federal dollars being spent and provided through grants and research funding, not only from a single regulatory agency to these research entities, but from several. This adds confusion to what research is being duplicated and how the information resulting from the research is shared.

D. CONCLUSION

One could argue that divided or not, the separations of responsibilities among the federal food safety regulating agencies keeps a focus on specific items in the food supply chain, yielding a keener awareness and protection of the food supply. However, in recent years, incidents of food-related illnesses and food commodity contamination have brought the validity of this argument into question. The primary food safety programs in

the United States were created and formed out of the Department of Agriculture more than 100 years ago.[3] Years of differing statutes, obligations, and responsibility shifts have led to the regulatory framework of food and agricultural safety programs that we see today. Distribution of food safety regulatory responsibilities for specific commodities based on years of differing, but similar, legal statutes are what the current regulatory structure is built on.

Paths often cross among regulatory agencies with food safety responsibilities, and duplication of efforts is common. Historically, this duplication has not necessarily been counter-productive to food safety, and sometimes lent an extra level of protection. A science-based approach has always been used to identify biological and chemical contaminates that relate to food safety and/or response models have been applied accordingly (Haines, 2004, Chapter 3, pp. 81–83). The system components in federal food and agricultural regulatory agency mission statements have always mentioned a focus on preventive methods to keep contaminants from entering the food supply. The introduction of contaminants into the food supply has generally been seen as accidental.

Critics charge that duplications of effort waste taxpayers' money and result in a fragmented system that prevents effective focus of resources on areas where the risks of contamination are greatest. The complexity of the regulatory system can have a dramatic affect on the protection of the food infrastructure. In general, there has been limited collaboration or passing of the problem and investigation to another agency at a different stage in the event if warranted.

Regulatory agencies at any level (federal, state, and local) of the food and agricultural sector continuum rely on the cooperation and knowledge of the food industry component in the food supply chain, as well as on academic and research institutions. It is difficult to administer food safety protection regulation without the efforts of the industry and without the science garnered from research about food-related pathogens and methods to reduce them. However, the large number of entities and statutes involved tends to complicate and further divide improvements in food protection.

[3] USDA's Food Safety and Inspection Service (FSIS) and the Food and Drug Administration's (FDA) that was once the Bureau of Chemistry within the USDA. FDA primary food inspection and regulatory department within the FDA is the Center for Food Safety and Applied Nutrition (CFSAN).

Thus, why are there so many regulatory agencies involved in food safety and protection? What are some of the challenges and gaps created by the regulatory structure? We will explore these questions in Chapter III.

III. CHALLENGES AND GAPS IN TODAY'S HOMELAND SECURITY ENVIRONMENT FOR THE U.S. FOOD AND AGRICULTURAL REGULATORY SYSTEM

A. INTRODUCTION

With an expanding global food market and the potential of intentional threats to the food supply, more focus has been placed on how we regulate agriculture and food in the United States. Questions of confidence in our system and its ability to protect the food supply have surfaced among consumer protection groups (DeWaal, 2007).

B. UNINTENDED GAPS AND CHALLENGES

The formation of several food and agricultural regulatory agencies over the years since creation of the U.S. Department of Agriculture in 1862, while intended to improve food and agricultural safety and security, has evolved into a system with unintended gaps. The large number of agencies that have been created to improve food protection may have inadvertently increased gaps about who covers what, and who will be in charge of what aspect of food protection, as new statutes are added. While regulatory agencies work to keep the nation's food supply safe, they cannot do it alone. All federal and state agencies have missions focused on protection of the food infrastructure. However, differing statutes, laws, and directives initiated in the 1800s form the foundation for the nation's food safety system and have kept these agencies on alternate paths in how they manage food protection (Center for Science in the Public Interest, 2005). The following categories are a glimpse into some of the challenges of the system.

1. Duplication of Food Safety/Defense/Security Roles

There are now 15 federal agencies that collectively, but separately, administer at least 30 different statutes on food safety (Shames, 2008). Over the years, we have seen an increased separation of food safety divided by commodity, food components, or ingredients, and crisis that has increased or changed statutes to define the food safety actions that are now necessary. There has been a history of response to crisis rather than

proactive preparation. While reactions to food safety crisis often have brought about new laws intended to avert new crisis, they also have caused a weakening of agency structures as resources are stretched. Some agencies cannot meet all of their statutory obligations (Shames, 2008). While different statutes and agencies are responsible for different commodities, the nature of food/agricultural products has led to a crossing of agency statutory assignments in the same facilities, creating duplication. Statutes written for the different food regulatory agencies sometimes prevent one agency from assisting another when each statue is taken to the letter of the law.

a. Food Product Safety Duplication

One example used often in the literature is the pizza plant scenario. In pizza production plants, there are at least two inspecting agency representatives, one from the USDA and one from the FDA. If the pizza is topped with more than 2 percent meat product, then the USDA inspects the product. If it is less than 2 percent meat product or a cheese-topped pizza, the FDA will inspect it. Figure 3 illustrates the number of agencies that represent the farm-to-retail path of a processed pizza product.

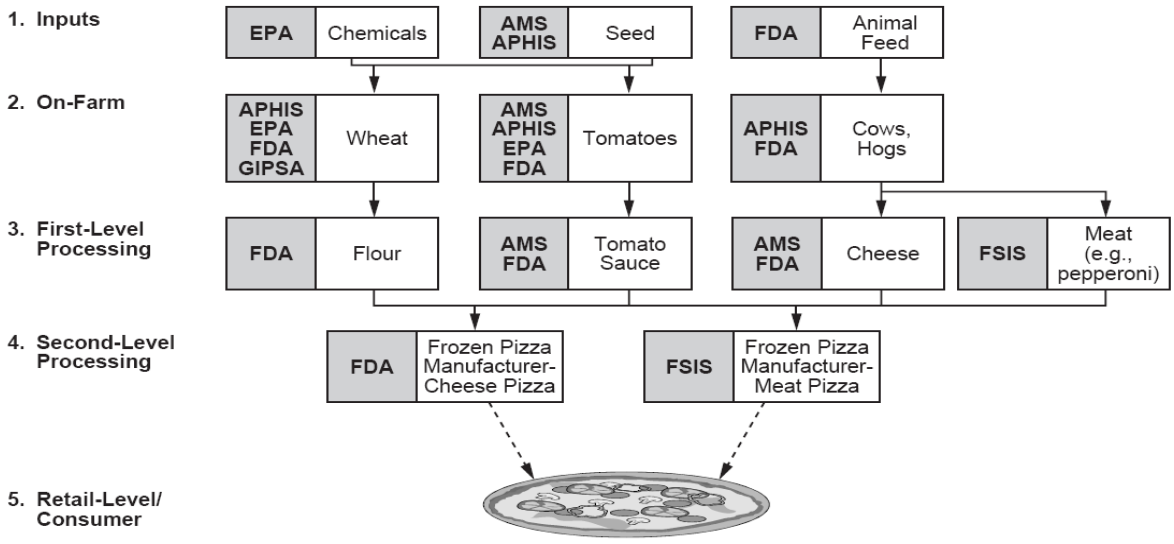

Figure 3. Federal Agency Responsibility for Pizza Production (From: Dyckman, 1999)

The same situation applies to open-face sandwiches with meat as opposed to closed-face sandwiches with meat. Open-face means the FDA inspects the product, and closed-face means the USDA inspects it. Figure 4 illustrates this example of multiple federal agency involvement and duplication of efforts in a processing plant. The inconsistencies attributed to statutory oversight gave rise to a GAO report that generated this excellent example of duplication of effort, but separation of responsibilities. Gaps can occur in the inspection process when it is assumed that one agency and not the other handle specific processes. In both examples, funding and statute differences cause discrepancies in inspection frequencies. USDA has a mandatory charge to be in the production (processing) plant and to make daily inspections. FDA does not have a mandatory charge for inspection and because of a lack of funding and staff, it may be in a plant only once every two to five years. With differing statutes, however, one agency cannot cross lines to assist the other with inspection of products under their charge. An example of where this leads in economic terms is the current crisis in the automotive industry, where the union can dictate who can work on what part of an automobile assembly line or component product. In critical economic times, when food safety regulatory agencies are not able to inspect or regulate a product in the same facility, it leads to ineffective use of resources and weakening of the regulatory process.

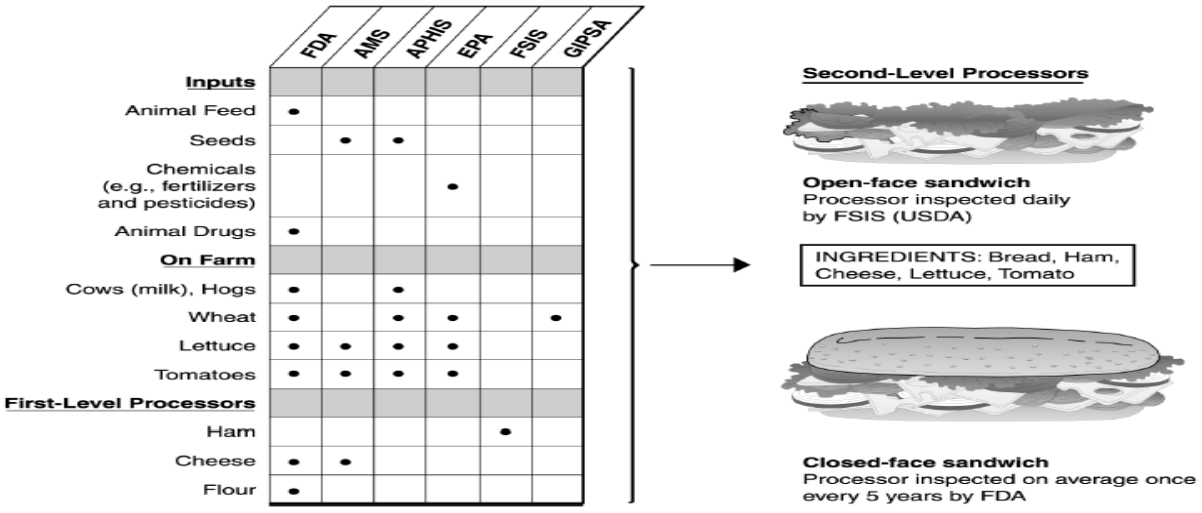

Figure 4. Federal Agency Duplication on Inspection of an Open- and Closed-Faced Sandwich Product (From: Robinson, 2001)

b. Food Defense Duplication

There is also duplication of offices within each agency. A search of the words "food defense" at each of the primary and ancillary agency Web sites that have food and agricultural responsibility turns up results showing that each agency has a food defense or security office (usda.gov, fda.gov, epa.gov, nmfs.noaa.gov). When we consider that each agency's office handles not only food safety, but also criminal investigations of intentional adulteration or abuse of food commodities, then the picture, metaphorically speaking, is larger than life. Within the text of new laws such as the Bioterrorism Act of 2002, the concept of collective actions of regulatory agencies to carry out the work of food safety/defense is presented (U.S. Food and Drug Administration, 2008a). As more responsibilities are added to the work of each agency, there is actually more separation of agencies by statutes and duplication of food defense activities. The new laws under which the agencies operate do not take into account the consistent problem of original statutes that still impede what agencies can or cannot do together. With globalization, complexity continues to grow.

2. Globalization—Challenges with Tracing Back

The potential for attacks using food products has now gone global. There are now more opportunities along the food supply chain for food products to be deliberately contaminated. An anomaly that may appear to be a contradiction to this increase is the increase in distribution from fewer food-processing venues. Modernization and free trade have led to consolidation of more and more food processing activities by fewer facilities. This means that a larger volume of food products could be contaminated at a single point and its distribution could have global implications.

Analysis, at first, might suggest that fewer processing facilities would improve our ability to prevent terrorist attacks on the food supply. However, the ability to trace back origins of product from different sources that funnel into processing and distribution facilities seems to be still missing. The recent tomato and jalapeño pepper-related Salmonella outbreak shows the problems associated with a non-uniform standard for trace-back of food commodities and the problems that can arise from commingling

commodities from different sources. The global demand for seasonal fresh fruit and vegetable products throughout the year is a factor here. A product deliberately contaminated in an approved foreign country that has mutual trade acceptance of food commodities with other countries can make its way around the world within 24 hours. Figure 5 shows the evolution of travel, which can apply fairly well to the actual growth of the global food supply chain, in terms of both access to food commodities in time and the growth of the population that demands on-time delivery of food products and non-seasonal choices of food products. The following statement describes the effect that globalization of food production has on food safety.

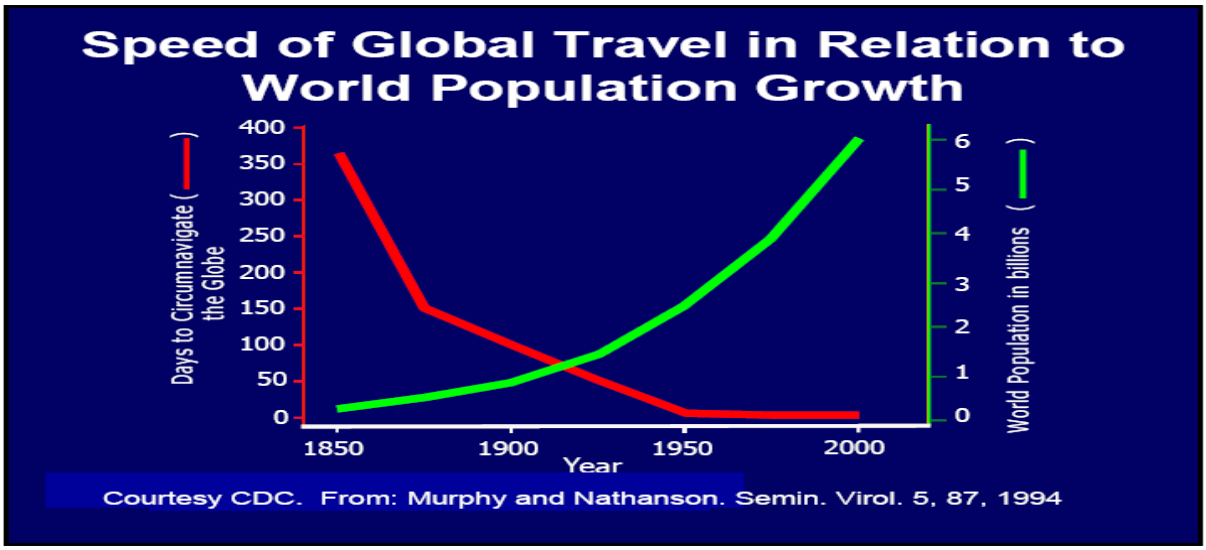

Figure 5. Speed of Global Travel in Relation to World Population Growth (From: Murphy and Nathanson, 1994)

> We eat out from the world's gardens, but not all are well-kept. Raspberries from Guatemala made thousands of Americans ill from a parasite called Cyclospora, which was in the water used to spray and irrigate the raspberries. Potential disease-carrying insects and contaminated foods, plants, and other products cross U.S. borders every day. Since the 1980s, food imports to the U.S. have doubled. Increases in food imports strain the nation's food safety system. While we rely on the FDA, USDA and other government agencies to protect our food supply, inspections have dropped to half of what they were five years ago. As the world's nations become more intertwined, interdependent and intensely competitive, will the rest

> of the world's standards become more like those of the U.S. or will the U.S., despite high standards, become more vulnerable to the rest of the world's microbes? (Health Media Lab, 2004)

3. Intelligence—Important to National Security of the Food and Agricultural Infrastructure

Intelligence efforts, along with science and education, are basic components of a successful food defense/food safety effort. In an interview with a high-ranking bioterrorism expert in the U.S. federal government, the issue of whether there was pertinent information on the intent of terrorists to use biological, chemical, or radiological agents against the food and agricultural infrastructure was discussed (Marc L. Ostfield, PhD, Senior Advisor, Department of State, personal communication, July 2008). Dr. Ostfield is very familiar with the destructive potential of biological agents as weapons of mass destruction. As part of a discussion of bioterrorism and the class agents identified by the Centers for Disease Control and Prevention, the topic of threat intelligence came up. There was an understanding during this discussion that classified information is not available for discussion unless it is first properly vetted and scrubbed for open source distribution on the issue of food and agricultural threats from terrorist organizations. Open source information in the form of evidence showing the intentions of international terrorists to target agriculture, food, and water is available. Documents were found in 2002 in caves during a military operation called Operation Anaconda (Williams, 2005). The evidence referred to the use of food, water, and other vectors to deliver biological agents targeting people, culture, and the economy. Dr. Ostfield agreed that the open source evidence identified by the author was probably “as good as it gets” when identifying the desire of terrorist organizations to use biological and chemical elements as a weapon of terror using food, agriculture and water as a vector. While direct evidence may be limited, the evidence discovered so far does show that there is a need to remain vigilant and proactive in the defense of the food infrastructure. Information about threats from intelligence gathering is equally important to the food sector. With regulatory separation among the various agencies, the potential for gaps in sharing of pertinent information on threats to the sector may be lost or at least delayed.

As with many infrastructures in the 21st century, the use of technology to run production processes is a mainstay. However, the use of technology, especially cyber-technology, to disrupt processes is an area of terrorism concern not often discussed as a threat; not only from known terrorist groups, but from rogue nation states that may seek to disrupt the U.S. economy. These groups may employ cyber-crime on the U.S. food industry to induce disfavor of a nation's or industry's commodity (J. Bumgarner, personal communication, July 2008). Computer systems used for automated food processing that control temperatures critical to keeping potentially hazardous foods out of the danger zone of bacterial growth[4] could be used to disrupt control of these functions.

For example, controls that indicate proper function of equipment can be disrupted to falsify temperature readings that are critical for safe food products. Laboratory test results of dairy products for antibiotics controlled by computers and computer programs can be disrupted to alter test results. Bumgarner explained that dairy milk laboratory test results could be altered to indicate a need to retest a product or to show that a product is contaminated, when in fact correct test results would show the product to be safe. Critical information sharing that indicates such cyber-activity is a challenge with the various agencies, even in the areas when duplication of service occurs (J. Bumgarner, personal communication, July 2008). Gaps are created in the area of intelligence and information sharing when each food regulatory agency follows a separate path based on statutes and differing philosophies for prevention and response.

4. Homeland Security Presidential Directives and National Security of the Food and Agricultural Infrastructure

The food sector and the importance of its protection as a critical infrastructure from a *national security* perspective have become more evident in recent years. Following September 11, 2001, at least five Homeland Security Presidential Directives (HSPD), have mentioned the food and agricultural infrastructure directly or indirectly. HSPD's 5, 7, 8, 9, and 10 all mention the food/agricultural infrastructure, with HSPD–9

[4] The danger zone of bacterial growth is defined in South Carolina as the temperatures between 130º F. and 45º F. Under ideal conditions of moisture, food source, and a time- temperature relationship microorganisms known to be food pathogens will grow exponentially in this "danger zone."

being very sector-specific to food and agriculture. By virtue of now being a recognized critical infrastructure, the food regulatory system agencies are directly involved in fulfilling their requirements to national security. Each of the five presidential directives follows a path that illustrates the gaps and challenges of agencies responsible for food safety and defense by adding layers of complexity (U.S. Department of Homeland Security, 2008).

a. HSPD-5: Management of Domestic Incidents

HSPD-5 enhances the ability of the United States to manage domestic incidents by establishing, a single comprehensive national incident management system.

b. HSPD-7: Critical Infrastructure Identification, Prioritization, and Protection

HSPD-7 establishes a national policy for federal departments and agencies to identify and prioritize critical infrastructure and key resources in the United States and to protect them from terrorist attacks.

c. HSPD-8: National Preparedness and Its National Planning Annex

HSPD-8 identifies steps for improved coordination in response to incidents. This directive describes how federal departments and agencies will prepare for such a response, including prevention activities during the early stages of a terrorism incident.

d. HSPD-9: Defense of U.S. Agriculture and Food

HSPD-9 establishes a national policy to defend the food/agriculture system against terrorist attacks, major disasters, and other emergencies.

e. HSPD-10: Biodefense for the 21st Century

HSPD-10 provides a comprehensive framework for our nation's biodefense.

A search on issues of food safety and defense related to national security at each agency Web site that has any connection to the food infrastructure showed the added layer of structure each agency has formalized since establishment of each directive. Spread across several agencies with similar missions, the duplication of efforts adds to a continued flow of complexity and widening of the gap in regulatory missions.

In today's world with a myriad of agencies that have responsibilities in the infrastructure, how do you communicate to the industry and the public the importance of food safety and food defense? Therein lays one of the problems involved in communicating the need for infrastructure protection when the regulatory system that is charged with protecting the infrastructure is spread among so many federal, state, and local agencies. For example, the National Infrastructure Protection Plan (NIPP) addresses and identifies 17 critical infrastructures in the United States (U.S. Department of Homeland Security, 2006). Within NIPP, sector-specific plans are identified. Further delineated are the critical infrastructure and key resources (CIKR) sectors and plans identifying sector-specific agencies (U.S. Department of Homeland Security, 2008). Both the USDA and the FDA are described as key agencies responsible for planning the defense and protection of the food/agricultural infrastructure.

The NIPP sector-specific plan (SSP) identifies the USDA and DHHS/FDA as the federal agencies responsible for the defense of the food/agricultural infrastructure and clearly shows the separation of the food safety regulatory system in the United States. The 2007 report cover of the food and agricultural SSP identifies the differences in one sentence. The cover title includes an asterisk (*) that refer to this footnote: "Contains both the U.S. Department of Agriculture and the U.S. Department of Health and Human Services/Food and Drug Administration portions of the plan" (U.S. Department of Homeland Security, 2007). The efforts for this one critical infrastructure's protection, while primarily shared between USDA and FDA, are also shared to even more specific component pieces of food commodities. To varying degrees of responsibility, other agencies, including the EPA, DOC, and now DHS, have roles in the oversight of food and agricultural products as shown in Chapter II.

5. Education

One of the best ways to prepare for and prevent problems is through education. Each federal agency has a responsibility to educate their regulatory partners at the state level, regulated stakeholders, and consumers on the issues of food safety and defense. One of the best ways to prevent foodborne illnesses is to increase awareness. However, on all levels, there have been reductions of expenditures and budgeting for education and training, not only for the industry and consumers, but also for the regulators themselves. With an increase in food production facilities from the farm to the retail level and limited growth in the number of inspectors, the effort devoted to education has been reduced.[5] With differing levels of funding, resources, and personnel, not all agencies can dedicate a significant amount of their budget to education and training, which in turn affects the food/agricultural sector. One missing link of knowledge about food safety can make the difference between an illness occurring or not. Also, when education is provided, there is sometimes a conflict about what each agency's statutes may require for any specific food protection procedure. For example, USDA may require raw poultry products to be cooked to an internal temperature of 170 degrees F., while FDA may require the same poultry product to be cooked to 165 degrees F. On cold holding of potentially hazardous foods (PHF), the federal agencies may say to "hold PHFs at 41 degrees F. or below," while some state agencies may require cold holding at 45 degrees F. or below.

A collective effort by regulatory agencies, the industry, and consumer groups to agree on food safety/defense educational awareness goals and definitions would help eliminate conflicting requirements.

6. Industry Buy-In

Like most other national infrastructures, the bulk of the food/agricultural infrastructure is privately owned. Any time a component of industry is required by statute

[5] This has been first-hand experience in my state. Our program has over the last few years, by choice of management, reduced the amount of education given to regulators, industry, and consumers. A process that is slowly being reversed, it remains without adequate funding. An increased ability to pursue proactively educational and training efforts, understanding of food safety and food defense for the public cannot be enhanced locally, regionally, or nationally without proactive planning and funding.

to comply with a requirement of a regulatory agency, from the industry's perspective, it costs time and money. Complying with regulations is a cost of doing business for the industry, and it is in the best interest of consumers, the industry, and the regulatory agencies. Regulation of the food infrastructure was born out of concern for the safety of consumers. Most people who work in the food industry understand this, knowing that the public expects safe, wholesome, unadulterated food. Industry components that do not follow safe food handling practices do not last long, especially since the media is sure to broadcast information about illnesses caused by lack of care. Industries need to buy-in to the concept of food defense and how that differs from food safety.

If an industry is regulated by several agencies, new requirements from the multiple agencies who are involved will only create confusion as to the differences between what they are already required to do. This also makes the job of the regulatory employees who perform inspections more difficult. Whatever the complexities, however, it all comes down to consumer protection and the vitality of the nation's food system. Consistency of regulatory messages, are important factors for consolidating an industry's buy-in to any new challenges or threats. Beyond industry buy-in, however, is the consistency that such a message will bring to the regulatory community as it addresses consumer concerns and confidence.

C. CONSUMER CONFIDENCE CHALLENGES—MULTIPLE EFFECTS

The CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. Known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths; while, unknown agents account for the remaining 62 million illnesses, 265,000 hospitalizations, and 3,200 deaths (Mead et al., 1999). These figures are for unintentional illnesses and does not account for the new concern of intentional contamination, yet no new estimates have been considered since the late 1990s. Also, although these estimates are for the United States alone, they are often quoted in World Health Organization (WHO) documents produced by its United Nations Food Safety Office when addressing world food safety issues. According to the WHO, foodborne

diseases affect up to approximately 30 percent of the population in industrialized countries each year. The international agency reports that an estimated 1.5 million people die annually from diarrheal diseases linked to contaminated food or water. Again, these numbers refer to unintentional contamination. A new category and focus in food protection has been added to the regulatory vocabulary to address the post 9/11 mentality and protection of the food supply from intentional contamination.

With globalization of the food supply, the possibilities of an intentional contamination of the world's food supply to cause fear and chaos and affect stability of economies of the world are increasingly plausible (Williams, 2005). The mad cow crisis that affected the United Kingdom and Germany could easily have been an intentional contamination. The crisis led to a distrust of the food safety regulatory systems in both countries and a fear of eating beef. However, even beyond the possibility of intentional contamination of beef in these European countries, an extended consequence of the fear factor about what one should or should not eat could cause an economical crisis. As stated in the *Psychology of Terrorism* (Bonger et al., 2007, p. 123), "the consequences of socially amplified fears are not simply psychological." The mad cow crisis cost the European Union $2.8 billion and more than 4 billion pounds in the United Kingdom (Powell, 2001). A deliberate attack on the food supply could have a similar economic impact in the United States where one in every eight people is employed in a food-related occupation (Bonger et al., 2007).

The psychological effects on consumer behavior because of fear and frustration over the possibility of a contaminated food product (loss of consumer confidence) would have a "ripple effect" on other aspects of the economy.

1. Terrorists and Terrorism—Added Psychological Issues

Some consumers are concerned that the recent food contaminations and food-related illnesses may have been deliberately caused. While no direct evidence supports this concern, this apprehension has a multiplier effect and influences attitudes on the premise that the food infrastructure makes a soft target for terrorist activity. While attacks on this infrastructure would not provide the "big bang" of some violent types of terrorist

attacks, food-illness outbreaks show the potential damage that such an attack could cause. Damage to the economy, fear among the public, and distrust in the government and potential destabilization of the U.S. government are the goals of some terrorists.

Recent outbreaks of foodborne illnesses show the difficulty that investigators face when tracing back to the source of the outbreak. The recent Salmonella Saintpaul outbreak first linked to tomatoes and then to jalapeño peppers, shows the potential of contamination of the food supply as a weapon of terror. The investigation to identify the source of the contamination was in full swing for more than three months, but investigators had no definitive answers as to where the source of the contamination was located. Eventually, there were questions about whether tomatoes were the actual vector for the Salmonella bacteria or whether the vector was jalapeño peppers in fresh salsa products. This shows how easily terrorists could contaminate food at several locations. The anxiety of not knowing whether your food will make you ill leads to distrust of the food industry and the government regulating food safety.

CDC reports that for every one person who is a stool-culture-positive victim of Salmonella in the United States there is a multiplier of 38.6 who are ill, who remain uncounted (Voetsch et al., 2004). The Salmonella Saintpaul outbreak had more than 1,000 confirmed cases. So, using this as an example, when we calculate with the CDC method the number of people who did not report illness for various reasons (fear of doctors, affordability, no medical insurance, etc.), we can estimate that another 38,000 people likely became ill from the same source but were undiagnosed and not counted.

2. Stress and Coping

The longer an investigation continues without identification of the source of the contamination or the foods involved, the more anxiety, fear, stress and distrust develops between the food grower, the food processor, the government, and the consumer—especially those who have become ill. It was difficult for those involved, both the ill and the several sectors affected by the outbreak, to cope with the size of the Salmonella outbreak. The frustration of not being able to identify the source of the outbreak leads to increased stress and an inability to alleviate the fears of consumers and others involved.

The difficulty of the process lies in the fact that in the tomato and Jalapeño pepper case(s), for example, the investigation went on for so long (more than three months) with no definitive results. Consumers surveyed by Deloitte LLC (2008) expressed distrust in the government and resentment of the food industry. The respondents also expressed stress and fear about the government and its inability to resolve this issue.

3. Consequences

The tomato-Jalapeño foodborne illness related outbreak ultimately involved more than 1,000 people with confirmed cases of Salmonellosis in 40 states and cost about $100 million. In addition, there were indications that the public was losing faith in the regulatory system (CBS Evening News, 2008).

Another case that demonstrates why food infrastructure vulnerabilities need to be reexamined is the case that involved South Korean demonstrations against imported beef from the United States. In this incident, it was believed that a “downer” cow suspected of having Mad Cow Disease might have made it through the slaughter process. The incident led to the recall and destruction of several thousand pounds of U.S. beef in 2003. In July 2008, more than five years after the recall, South Koreans demonstrated against the South Korean government’s trade agreement with the United States to begin importing beef again to South Korea. There is still fear after five years by many South Koreans that U.S. beef is contaminated, when in fact there is no evidence of contamination.

Two years after the spinach E. coli-related outbreak, many people are still apprehensive about eating spinach. Peter Pan peanut butter was contaminated during processing with Salmonella several years ago, and some people still will not eat peanut butter. Some people called health agencies two years after the event and asked whether they would get sick from eating a specific peanut butter. One caller was asked if she had eaten the peanut butter, what the lot number was of the peanut butter, what her symptoms were, and whether she had seen a physician to confirm any illness. The answer to all

these questions was “no.” The caller then explained that she had not even opened the jar of peanut butter. She was distressed because she thought that she would get ill from eating it, and was feeling ill from just the thought of it (firsthand account).[6]

4. The Media

The buildup of false information from the media, the government, and the industry can worsen even a small incident, causing panic, fear, and distrust in what is being done to eliminate the crisis. False, inaccurate, or withheld information, on any scale, whether national, state or local, can lead to roadblocks in the investigation and confusion among the public. While too much knowledge may sometimes have a boomerang affect and increase angst, information presented in a straightforward manner is critically important to lower anxiety among the public (Laliberte, 2008).

5. Conclusion and Best Practices

The national security implications of an attack on the food infrastructure could be devastating from both an economical and psychological standpoint.

What is needed is better risk communication to all parties involved in the investigation and the reporting of the investigation. Simple and straightforward principles in the practice of risk mitigation are important tools to identify the source of the illness and lessen the psychological effects of illness outbreaks. Accurate information builds trust and confidence. Communication and management of risks to those involved in an illness outbreak and those affected by the outbreak can be powerful tools in limiting or reducing negative reactions. It is important in risk communication and risk management to stay on top of the situation at hand. This gives some assurance that the information will be accurately relayed (Cross & Parker, 2004, p. 100).

If the public is aware of the consequences of contamination to the food infrastructure, they can better understanding how they can play a role in preventing, anticipating, reducing, and even eliminating potential terrorist threats by becoming a

[6] First hand account by the author during the recall of Peter Pan peanut butter.

better informed and vigilant population. By increasing awareness of the causes of foodborne illnesses, the steps being taken to prevent further illnesses, the management of fear may be enhanced, at least in understanding the threats to the food infrastructure. Risk communication and risk management are principles discussed but rarely implemented by regulatory agencies in times of crisis. Risk mitigation strategies are among the gaps and challenges faced by food and agricultural agencies. Shortfalls in risk communication and management strategies are products associated with the gaps and limited educational resources provided by regulatory agencies to their workforce. Most of these shortfalls in risk education, as this author sees it, are a by-product of a complex regulatory system that leaves some agencies under budgeted and incapable of providing the necessary skills needed to deal with the aforementioned challenges.

D. SUMMARY

The present system is highly complex and has shown inconsistency in how it has handles instances of unintentional contamination. The importance of the food and agricultural sector to national security cannot be overemphasized since the industry is critical for sustaining life. Changes in the regulatory system have often been discussed over the years for many reasons. Can we afford not to explore a more consolidated food safety regulatory system with the added concern of terrorism against the food supply?

This question warrants a look in Chapter IV at the importance of the food and agricultural infrastructure and the threats that challenge its security.

IV. FOOD AND AGRICULTURE IMPORTANCE AND THREATS TO THE INFRASTRUCTURE

> Osama bin Laden urged his followers to "hit hard the American economy at its heart and core." Nothing is more at the heart and core of our economy than our agriculture and food industry. It is a $1 trillion economic sector that creates one-sixth of our gross national product. (Senator Susan Collins, 2003, Quote to the Senate Governmental Affairs Committee)

A. INTRODUCTION

Psychological terror, destabilization, and devastation to governments and citizens are some of the primary goals of terrorist organizations. Terrorists, both domestic and foreign, lone wolf or group, have used many methods and devices to attain their goals. The food supply provides a vector that is vital to the economy and sustainability of a nation and a vast sector that can be easily attacked without major expense.

With the ease of acquiring biological and chemical agents, in particular, those zoonotic biological agents known to cause food-related illnesses, the food supply is a major infrastructure that requires constant and vigilant protection. At threat are the health of humans, animals, plants, water, and the economy of a nation. Plants and animals, like humans, are susceptible to disease or cellular destruction caused by microorganisms, chemical toxins, and even radiological materials. Terrorists who are intent on destruction to humans, plants, animals, and the economy, will eventually see, if they have not already, the food sector as the new front in asymmetrical warfare. The importance of international and domestic trade to our domestic economy is why the food sector makes for an almost perfect target for the use of biological and chemical contaminants or other means by those individuals or groups intent on attacking the United States.

B. FOOD AND AGRICULTURE—IMPORTANT TO A NATION'S SURVIVAL

The National Strategy for Homeland Security of 2002 and its revision in 2007 focused on identifying the nation's critical infrastructures. The food and agricultural

infrastructure were identified as critical infrastructure sectors (White House, 2002, Revision 2007). The basic importance of food to sustaining life gives the sector importance among the critical infrastructures. The interdependence of the food and agricultural sector to other infrastructures also has importance from an economical perspective. Depressed or destroyed food resources would impact many areas. Without nutrition from food, the workforce in other infrastructures could be disrupted, causing a cascading affect over time.

Figure 6 illustrates the overlap of the U.S. food infrastructure with other critical infrastructures. Ted Lewis (2003) illustrated this interaction in his Critical Infrastructure Protection Hierarchy diagram. The diagram, though showing a hierarchy, is not necessarily hierarchical in the truest sense (Lewis, 2003). However, it does show the dependency of each sector on the others. Every component shown has a link to the food sector. Critical damage to this key sector could trickle down to all other sectors and vice versa. While Lewis' illustration considers level 1 sectors as the primary sectors, which if destroyed or damaged could affect level 2 and level 3 sectors, food and agriculture are needed, along with water, for sustaining life.

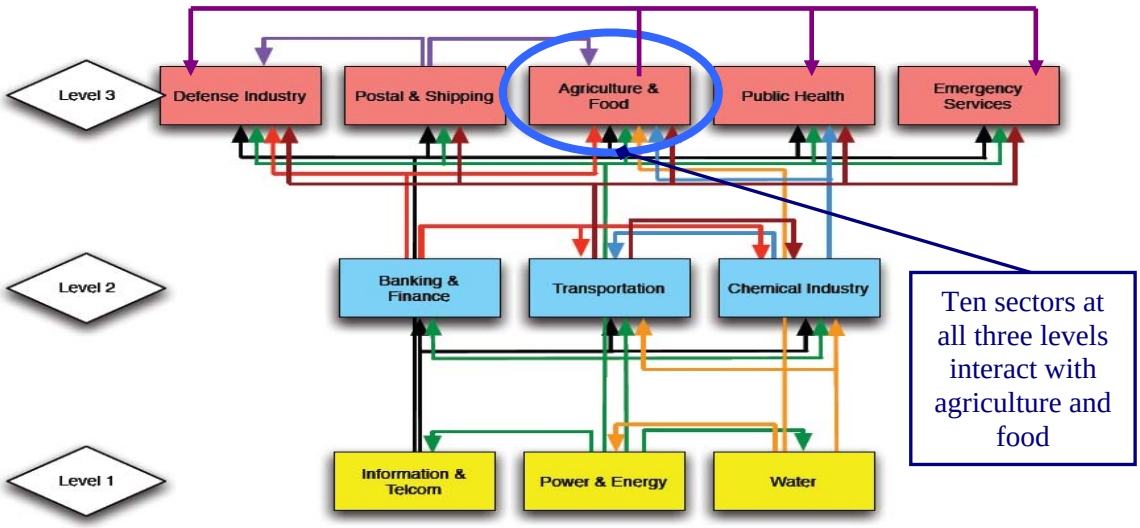

Figure 6. CIP Hierarchy (From: Lewis, 2003)

History shows that food and water have been used as tools to win wars and conflicts. By controlling these elements or destroying them, countries have prevented opposing forces from keeping their soldiers and citizens nourished. Their will to fight and their willingness to submit can be affected (Saltveit, 2008, American Historical Association, n.d.). A quote attributed to Napoleon Bonaparte on the importance of food in war was "An army marches on its stomach" (FamousQuotes.com, n.d.). Food is important to survival, and threats against the food supply lead to fear, panic, distrust, and destabilization of economies and eventually governmental control, as described in Chapter III. So what are some of the threats to food and agriculture?

C. THREATS TO THE FOOD AND AGRICULTURAL SUPPLY

The food supply in the United States appears so far not to have been exploited by terrorist groups. However, when food-related illnesses occur, it may be hard to distinguish an intentional attack from an unintentional attack. As with 9/11, no one would have expected airplanes to be used so effectively in way that caused so much destruction in lives and property and economic destabilization so quickly.

1. Terrorism Against the Food and Agricultural Sector

The global and domestic food commodity markets are so intertwined with the economies of other nations that the impact of terrorist attacks on them could be enormous. Acts of terrorism could be used to slow down the movement of food products that are perishable to the point of ruin. Terrorism against food products can be an effective tool affecting trade on both the international and the domestic front.

D. FOOD AND AGRICULTURE A SOFT TARGET: THE NEXT TERRORISM NEXUS?

Intentional contamination, destruction, or disruption in the food infrastructure is most likely to occur by insertion of biological, chemical, or radioactive materials into the food, agricultural, and water supply. The use of biological and chemical elements as weapons of terror and violence had been frequently mentioned before September 11, 2001 in research and writings. Stories of unconventional weapons related to food and

agricultural vectors range from studies of war in societies of the past to fictional literature, novels, and plays. Since September 11, documents about the vulnerability of the food/agriculture infrastructures have multiplied. A list of documents at the Center for Infectious Disease Research and Policy (2008) provide some selected reading showing research being done on food vulnerability. Three years after 9/11, Health and Human Services Secretary Tommy Thompson said he worries constantly about food poisoning.

> I, for the life of me, cannot understand why the terrorists have not, you know, attacked our food supply because it is so easy to do. … We are importing a lot of food from the Middle East, and it would be easy to tamper with that. (Branigin, Allen, & Mintz, 2004)

RAND Corporation analysts have testified before Congress about the impact of a major disaster of the food and agricultural sectors. Especially significant was an excerpt from testimony in 2001 by Peter Chalk:

> The impact of a major agricultural/food-related disaster in the U.S. would be enormous and could easily extend beyond the immediate agricultural community to affect other segments of society. It is possible to envision at least three major effects that might result—mass economic destabilization, loss of political support and confidence in government, and social instability. (Chalk, 2001)

Whether intentional or not, contamination or destruction of food and agricultural products anywhere along the food supply chain, have been considered potential target vectors for terrorists, domestic and foreign. “An enemy bent on victory at any cost could and will make the food supply of a populace a main target” (ShoahEducation.com, 2003). Biological, chemical, and radiological (BCR) elements represent a silent and invisible class of weapons that unless detected early, could be devastating in many ways. If used as a weapon, any BCR agent used by terrorists to cause fear, economic downturn, and instability of government, followed by a loss of trust by a government’s citizens, will have served the purpose of the terrorist mission.

1. Evidence from Afghanistan

Evidence from Afghanistan showed the direct link some terrorist organizations have in their intent to use food, agriculture, and water as vectors to deliver biological and

chemical weapons of destruction. Documents have been found showing a desire to damage agriculture, animal livestock, plant production, and water supplies (Williams, 2005). Figure 7 shows a diagram found in an Afghanistan cave during the war against Al Qaeda and the Taliban during Operation Anaconda in 2002.

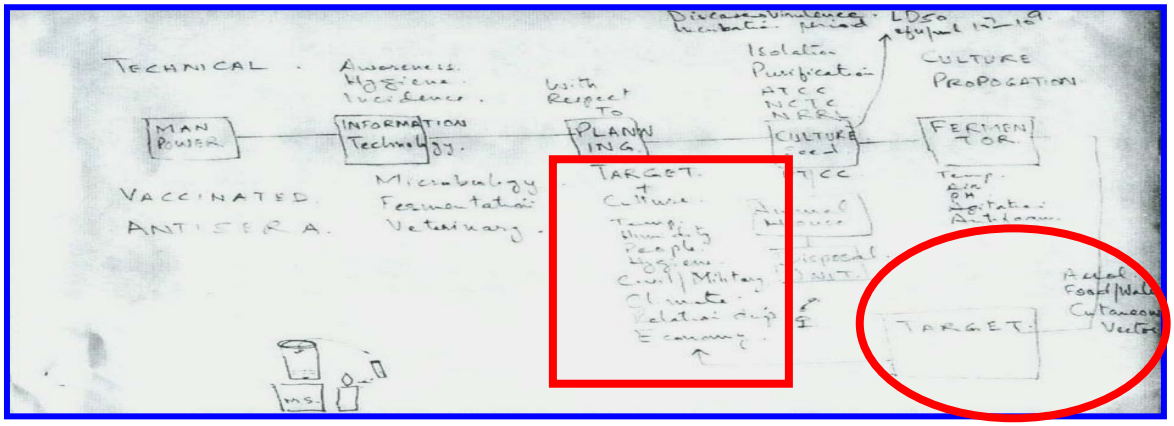

Figure 7. Documents Found in Afghanistan Caves during Operation Anaconda in 2002 (From: Williams, 2005).

The Great Depression and the Dust Bowl have given us historical evidence of a weakened economy disrupted by problems with the food infrastructure (Public Broadcasting Service, 2008). Awareness of the destructive powers of even small weapons of mass destruction in the form of microorganisms, toxins, and radioisotopes requires vigilance and knowledge of the agents themselves and an understanding of the possible vectors in the food infrastructure.

What form of agent should be our primary focus of preparation for an attack on the food and agricultural sector, biological, chemical, or radiological? All have the same potential and can be delivered in the same manner. Each one has its own unique signature and path to cause harm. Some may cause illnesses to appear slowly, while others may cause illnesses to occur rapidly. All, however, have the potential to cause fear, panic, and death and therefore should be treated as equals when it comes to protection of the food supply. Weapons of mass destruction do not have to be only in the form of big bang explosions. Sometimes big things come in the form of small packages, in this case biological, chemical, and radiological forms, unseen but deadly.

2. Biological, Chemical, and Radiological Materials as Weapons

"Biological weapons pose a far more serious long-term terrorist threat to the West than nuclear weapons, according to Washington's leading counter-terrorism expert" (Coughlin, 2006). This statement was from an article in the *Daily Telegraph* newspaper from an interview in January 2006 with Henry Crumpton, the head of the U.S. State Department's counter-terrorism program. While he led with the statement about biological weapons, Crumpton discussed the concept of weapons of mass destruction (WMD) including chemicals, radiological, and nuclear materials. Crumpton made an interesting statement in the interview that shows that the small size of these materials and the small size of terrorist cells themselves do not translate into an ineffective weapon.

> We are talking about micro targets such as al Qa'ida, which when combined with WMD, have a macro impact. I rate the probability of terror groups using WMD [to attack Western targets] as very high. It is simply a question of time. (Coughlin, 2006)

Food and agricultural products fit the profile of a perfect vector for these often invisible elements in the microbiological, chemical, and radionuclear world.[7]

Attacks have been documented showing the use of the food as a vector for delivery. One documented case was the contamination of restaurant salad bars in Dalles, Oregon, with Salmonella in 1984 to influence an election (Burton & Stewart, 2008).

> While there have been no documented terrorist attacks on U.S. agriculture, the number and variety of foodborne illnesses and crop and livestock diseases may make it hard to distinguish terrorist attacks from natural events. For instance, it took a year for U.S. officials to conclude that the Oregon attack was deliberate. (Council on Foreign Relations, 2006)

Mohtadi and Murshid (2006), in a white paper supported by a U.S. Department of Homeland Security grant, presented a chronology of global incidents from 1950 to 2005 in which attacks using biological, chemical, radioactive, and nuclear materials were

[7] Except for chemicals that may impart an odor, almost all microbes and radioactive materials present at a level that could cause harm when used, are not visible to the naked eye or noticeable by smell. In almost all cases, including toxins released by bacteria, detection is only possible by laboratory analysis and/or specialized equipment.

carried out. In their collation of information on incidents involving chemical, biological, radioactive, and nuclear (CBRN) materials from several terrorism and non-terrorism databases around the world, they created a dataset of their own showing the chronology of events. While the data represent a collection of intentional contamination events and attempts, they do not convey that the activities were perpetuated by known terrorist groups. Further analysis of their datasets brought up an interesting thought of how one would distinguish a terrorist act from a criminal act with the use of CBRN. This question is important when discussing the use of the food products as a vector of terrorism. The question would be whether the intentional contamination is an individual lone wolf incident, a group incident based on criminal activity alone, a hate crime, or for creating fear to cause ideological or political change. Either way, protection of the food supply and prevention of intentional and unintentional contamination are the ultimate goals. The collation of information by Mohtadi and Murshid helps establish a history of contamination with the intent to cause harm using food, agricultural, and water supply vectors.

Their eventual total number of events where CBRN-materials were used totaled 448 (Mohtadi & Murshid, 2006). One item that makes their dataset unique from the others used in their research is that it excludes CBRN-material data from hoaxes. This difference helps distinguish the factual nature of CBRN-material use from theoretical use. Analysis of the research done by Mohtadi and Murshid for the thesis showed 81 separate cases, both domestic and foreign, in which food, agriculture, or water were used as vectors to deliver biological, chemical, and radioactive materials to cause harm, death, or political statements. Additional research indicating use of biological and chemical agents used as weapons in the food and agriculture reinforce the concern for the sectors importance in national security. The James Martin Center for Non-Proliferation Studies in Monterey, California, lists a timeline of chemical and biological use events in food and agriculture from 1915 to 2006. They wrote, as a forward to the list:

> This list contains allegations and threats, along with confirmed incidents, of deliberate use of chemical or biological agents to contaminate the food supply at any point of the 'food continuum' from harvest or production to the consumer, with the intent to cause death, sickness, or economic damage. (James Martin Center for Non-Proliferation Studies, 2006)

The last incident in the CNS list was on October 15, 2003, when an unknown suspect left a vial of Ricin at a Greenville, SC, postal facility with threats to dump Ricin into national water supplies. The incident was close to home and involved the public health function of this thesis author's state public health agency.

a. Biological Agents—Microorganisms

The use of biological materials, poses a threat of great proportion. History has shown what microorganisms such as bacteria, viruses, fungal agents, and proteins[8] prevalent in nature are capable of great harm to humans, plants, and animals. If attacks from terrorist groups are meant to cause harm, fear, or devastation, biological agents provide a good strategy. Food and agriculture provide a vector appropriate for microorganisms because of the growth potential. Potentially hazardous foods such as meats and some fruits and vegetables provide an environment capable of supporting the growth of microorganisms. The CDC lists bioterrorism agents in three categories. The three categories are separated depending on how easily they can be spread and the severity of illness or death they cause. Category A agents are considered the highest risk, and Category C agents are considered emerging threats for disease (U.S. Centers for Disease Control and Prevention, 2007). The following are categories of bioterrorism agents as defined by the CDC.

(1) Category A (Anthrax, Botulism Toxin, Tulmarmia). These high priority agents include organisms or toxins that pose the highest risk to the public and national security because of the following.

[8] Proteins can be in the form of toxins such as the toxin produced by Clostridium botulinum. There are also the Prions (proteins) responsible for "Mad Cow Disease" and their human varients.

- They can be easily spread or transmitted from person to person
- They result in high death rates and have the potential for major public health impact
- They might cause public panic and social disruption
- They require special action for public health preparedness

(2) Category B (Brucellosis, Clostridium perfringens, Salmonella, E. coli O157:H7, Shigella, Ricin, Vibrio, Cyrptosporidium, Staphylococcal enterotoxin B)**.** These agents are the second highest priority because of the following.

- They are moderately easy to spread
- They result in moderate illness rates and low death rates
- They require specific enhancements of CDC's laboratory capacity and enhanced disease monitoring

(3) Category C (Nipah Virus and Hantavirus). These third highest priority agents include emerging pathogens that could be engineered for mass spread because of the following.

- They are easily available
- They are easily produced and spread
- They have potential for high morbidity and mortality rates and major health impact

According to CDC,

> a bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants. These agents are typically found in nature, but it is possible that they could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment. Biological agents can be spread through the air, through **water**, or in **food**. Terrorists may use biological agents because they can be extremely difficult to detect and do not cause illness for several hours to several days. (U.S. Centers for Disease Control and Prevention, 2007)

Biological agents can be covertly added to food or water, and except for some biological agents, they are relatively low risk for the handler.

b. Chemical Agents

Chemicals can be used for human and animal harm, to destroy crops, and contaminate soil used to grow grains, fruits, and vegetables.

An example of chemicals used to destroy plant life was Agent Orange, Agent White, and Agent Blue during the Vietnam Conflict to protect U. S. military from the enemy who used the surrounding foliage for cover (U.S. Department of Veterans Affairs, 2003). Our own country's use of these herbicides shows what could be done with chemicals to destroy agriculture and contaminate soil used in planting. If given the opportunity, terrorists could cause disruption in the growth of vegetables and fruits in specific areas. The Salinas Valley area of California, called the nation's salad bowl, is one area where an attack could be devastating. In recent years, links to biological contamination in spinach and lettuce crops from E. coli and Salmonella had an economic effect on the industry in the area where the crops were grown (Shinn, 2006). A chemical destruction or contamination would have a similar effect. One case that was in the international news was the suspected use of chemicals to influence an election, specifically the use of dioxin in the poisoning of Ukrainian presidential candidate Viktor Yushchenko in 2004 (Holley, 2007).

c. Radiological Agents

There have been a few cases of radiological agents used for intentional contamination of food. With access to radiological materials available from medical equipment and for medical treatment, the potential for use of these agents is highly possible. While some materials would be hard to handle since the perpetrators themselves would be at risk of contamination, radiological agents would be an effective choice of weapon because of two factors. First, the reality of any material of a radioactive nature found in the food, agricultural, and water supply would bring about fear that could result in anxiety if the source were not quickly identified. Second, the use of radioactive materials by terrorists using nuclear material could result in mass panic and a fear that government is not able to protect its citizens.

There has been one prominent recent case involving people from the former Soviet block of countries and the use of radioactive materials as a weapon in food and water. The case involved the radiological poisoning of former Russian spy Alexander Litvinenko with Polonium 210. An article in the *Washington Post* reported that John Henry, a toxicologist, was asked by Litvinenko's family to investigate the case. Henry, who examined Litvinenko before his death, said the type of polonium involved is "only found in government-controlled institutions." In an interview, Henry called Polonium 210 an "extraordinary poison" that is lethal in doses so small "you can lose it on the point of a pin" (Jordan & Finn, 2006). Radiological agents cannot be ruled out as weapon for use in food.

E. CONCLUSION AND SUMMARY

Biological agents that affect the health of humans, animals, and plants are readily available. As seen in recent stories in the media, biological contaminants have had an impact on regulatory agencies and they have struggled to handle the unintentional outbreaks of illnesses associated with these agents promptly. It has been difficult for the federal regulatory community to keep up with the pressure created by the rash of illness outbreaks associated with unintentional contamination of food and agricultural products. Imagine the potential problems that would appear if intentional contaminations were to occur by terrorists. Would the complex web of regulatory agencies be prepared to handle this added threat? Would a change in our regulatory structure help to shape smarter and better strategies for food safety and the defense of the food and agricultural infrastructure? To answer that question, in the next chapter, we will look at comparisons of what others have done to improve food safety and at the experience of countries with similar ideas of government and food protection.

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V. WHAT OTHERS ARE DOING—A COMPARISON

A. A COMPARATIVE STUDY OF THREE OTHER COUNTRIES

Before recommending policy changes for the regulatory authority of the United States food safety/defense system, it is reasonable to study similar democratic and developed countries with established food safety regulatory programs. The three countries chosen here for comparison are the United Kingdom, Germany, and Canada. The first two countries are part of the European Union and are committed to achieving compliance with food safety standards as developed by the European Union's (EU) European Food Safety Authority (EFSA) formed in 2002 (European Food Safety Authority, 2002). While the use of standards developed by the EFSA are not obligatory for any of the member states, the trade policies and food safety standards were developed by the participating states, and the general agreement has been that countries generally follow the standards in order to coalesce the free flow of trade between the member countries without added restrictions.[9]

The third country, Canada, is an established trading partner that follows similar guidelines to those set by the European Food Safety Authority. It is included since it is a major trading partner with countries in the European Union and with the United States. The close relationship Canada has with the United States, the similar historical timeline of development in both countries, and our shared border also factor into the comparison.

All three countries' governments have embraced a single (or smaller) food safety agency culture and streamlined their respective food safety responsibilities. These changes were based on events that led to a loss of public confidence in how some of these countries handled food safety incidents such as "Mad Cow" disease in the 1990s and 2000. Over time, the development of relationships in the European community of states, the need for smooth flow of trade and food products across the now open borders between all European Union countries, made the issue of streamlined food protection

[9] The European Union and its European Food Safety Authority have been important in pressing food safety changes throughout the European Continent.

more important. The events of 9/11 have elevated the need for more precise oversight of all critical infrastructures to include the food and agricultural infrastructure of all countries (Food Navigator, 2003).

While all three countries are democratic, the way their respective governments have handled the traditional responsibilities to food safety have varied.

B. EUROPEAN UNION COUNTRIES

1. The United Kingdom

The United Kingdom consolidated its food safety system after a loss of public confidence in food safety that largely resulted from the appearance of mishandling food safety responsibilities with the discovery of Bovine Spongiform Encephalopathy (BSE), better known as "Mad Cow Disease" in cattle. When the human form variant of BSE, Creutzfeldt-Jakob disease, caused 35 deaths in 1999, concern for food safety increased (U.S. General Accounting Office, 2005). It was widely believed by the public that a fragmented and decentralized food safety system allowed this outbreak to occur. Consumers believed that the Ministry of Agriculture, Fisheries, and Food, which had dual responsibilities to *promote* the agricultural and food industry and to *regulate* food safety, favored industry over consumers in making decisions. This perception by U.K. consumers prompted change in the food safety system. The pattern of improved consumer confidence and the reliability of the single food safety agency system to improved industry compliance are important elements to remember as the U.K. system is also compared to system changes in Germany and Canada. Legislation went into effect on April 3, 2000, that established an independent Food Standards Agency in the U.K. (Food Standards Agency, 2000).

Before reorganization of the U.K.'s food safety system in 2000, food safety responsibilities were divided among several central government departments, such as the Ministry of Agriculture, Fisheries, and Food and the Department of Health, as well as local authorities. The Meat Hygiene Service, a subunit of the Ministry of Agriculture, Fisheries, and Food was responsible for meat inspections, including enforcement of

hygiene in slaughterhouses. Other food inspections conducted by local authorities received no oversight from the central government. So in order to address public concerns, the Parliament passed the Food Standards Act of 1999 to establish the independent Food Standards Agency (FSA) as the country's leading food safety agency. The Meat Hygiene Service was moved out of the Ministry of Agriculture, Fisheries, and Food and placed within FSA as well (GAO, 2005). FSA was granted audit authority over local enforcement at this time (Food Standards Agency, 2008). This is an interesting comparison because it indicates that the local and regional elements will be checked for standardization to the country as a whole when before they had not. This is an important element of consistency in standards and transparency of efforts.

FSA is now responsible for scientific risk assessments, risk management, standard setting, education, and public outreach in the United Kingdom. The Meat Hygiene Service, now a component of FSA, is responsible for meat inspections. For other foods, FSA forms inspection policy and audits local inspection authorities. FSA has the power of an agency in a ministry, but is not part of a ministry, which gives it independence from other ministry influence thought to be political.

The agency however, has accountability to the Westminster Parliament and devolved administrations in Scotland, Wales, and Northern Ireland through Health Ministers. Also, an independent board consists of a Chairman, a Deputy Chair, and up to 12 other members appointed to act collectively in the public interest. The Board manages the FSA and determines food policy and holds discussions on policy issues in public meetings.

In general, the establishment of FSA improved the food safety system because the agency has made the system more transparent (U.S. General Accounting Office, 2005). FSA has increased public education about food safety. The most significant result of the consolidation was a shift from an industry focus to a consumer focus on food safety matters (U.S. General Accounting Office, 2005). The consolidation appears to have also increased accountability within the food safety system. A key element here, other than those already mentioned, is the increase in education to the public on food safety. A

consolidated approach allows for a more consistent educational message. Another key element is that consumers feel more confident that the government is there to protect their food supply and not the industry's profits (U.S. General Accounting Office, 2005).

2. Germany

Germany's creation of a new food safety regulatory system involved a three-pronged response for food safety improvement. The first was in response to public concerns about handling of finding BSE, or "Mad Cow Disease" in cattle in 2000, other food safety concerns, and a new commitment to improve compliance with new European Union (EU) food safety legislation.[10] In 2002, the German parliament approved creation of two new food safety agencies in response. Both new agencies are in the Federal Ministry of Consumer Protection, Food, and Agriculture (U.S. General Accounting Office, 2005).

Before consolidation, Germany's food safety system, responsibilities for research, risk assessment, and communication were shared by the Federal Ministry of Health and the Federal Ministry of Food, Agriculture and Forestry. Responsibility for implementation of federal legislation and oversight of inspections were shared by each of the 16 federal German states, and inspections were performed by municipalities and other local governments (U.S. General Accounting Office, 2005). This is important in comparison to the United States. When analyzing the former food safety system with the present system, and then comparing both to the U.S. system, the old system had a distinct resemblance to the United States. The former food safety system agencies had different regulations and responsibilities depending on the food commodity.

The new agencies under the auspices of FMCPFA are the Federal Office of Consumer Protection and Food Safety, a coordinating body responsible for leading food safety risk management (U.S. General Accounting Office, 2005). It serves as Germany's contact point with the European Commission, acting as a coordinator of audits of

[10] As previously stated this is non-binding or non-obligatory legislation, however trade from one member state to another can be streamlined through common acceptance of the legislation into a country's own food safety legislation.

compliance with EU food safety legislation and implementing in Germany, the European Rapid Alert System for consumer health protection and food safety.[11] In addition, this agency's responsibilities include coordinating food safety surveillance at the federal level and formulating general administrative rules to guide the implementation of national food safety laws by the German federal states. The federal states continue to be responsible for implementation of food safety legislation and oversight of food inspections performed by local governments. With one agency serving as the contact point for those departments under its umbrella, this provides for better information sharing both horizontally and vertically through one entity, not only within Germany, but also to its global and regional country trading partners. This helps provide a unified and consistent standard and method for internal and external communication.

The other new food safety agency is the Federal Institute for Risk Assessment, whose responsibilities include providing impartial scientific advice and support for the law-making activities and policies of the federal government in all fields concerning food safety and consumer health protection, except for animal diseases. This office performs risk assessments and communicates risk assessment results to the general public. According to officials, this agency was created to separate risk assessments from decision making.[12] The purpose of this separation was to increase public confidence in risk assessments by distancing these assessments from possible political interference. Negotiations between the federal government and the federal states concerning reform of food safety law were complicated, because some reforms that would give the federal government increased authority required constitutional changes. Once again, this change in Germany compares favorably to the same importance that the United Kingdom and Canada placed in separating risk assessment from risk management while under one oversight agency. This shows again the power of consolidation in the food safety/food security/food defense arena.

[11] Similar to the United States Health and Human Services CDC Health Alert Network.

[12] Similar to the Canadian risk assessment and separation of its food safety agency responsibilities. However they are linked.

The German food industry and consumer organization stakeholders have supported the consolidation. The German food industry, in general, supports the creation of the Federal Office of Consumer Protection and Food Safety because it has increased coordination of the federal states' food safety activities and has improved Germany's ability to *respond* to potential food safety crises, including improvement of Germany's ability to *prevent* potential food safety crises. In consideration of impending EU legislation, the food industry advocated increasing the authority of the Federal Office of Consumer Protection and Food Safety to coordinate the federal states' food safety activities, thus enabling increased harmonization of food safety standards and control procedures across states (U.S. General Accounting Office, 2005). The food industry also viewed the separation of risk assessment and risk management to giving the food safety system more credibility in the public and industry eyes. The consolidation seems to have made the food safety system more effective (U.S. General Accounting Office, 2005). Consumer representatives appear to see that the consolidation has increased German consumers' confidence, though they have less confidence than consumers do in other European countries. Consumer organizations favor giving the Federal Office of Consumer Protection and Food Safety increased authority (U.S. General Accounting Office, 2005). One key aspect of the Germany comparison was the concept that the system was more effective than the previous food safety system.

C. NORTH AMERICA

1. Canada

Canada originally had food safety tasks shared between three separate but viable agencies—the Agriculture and Agri-Food Canada, Health Canada, and Fisheries and Oceans Canada (U.S. General Accounting Office, 2005). Each of these agencies originally had its own food safety inspection system, food policy, and risk assessment responsibilities. With each entity having similar responsibilities, there was confusion about who was in charge of what. Industry had to respond to several different inspection compliance and enforcement requests. With multiple inspection types and compliance policies, it was difficult to remember who required what and how to correct the

compliance requirements adequately. There was no clarification of responsibilities and there was a perceived lack of confidence by consumers and the industry in the consistency of enforcement of the food safety laws.

When the Canadian Parliament approved the Canadian Food Inspection Agency (CFIA) Act in 1997, the country appeared to have a solution to improve consistency in food safety (U.S. General Accounting Office, 2005). Out of this Act, Canada created the Canadian Food Inspection Agency (Canadian Food Inspection Agency, 2007). What is interesting is how this affected food safety responsibilities and structure. All agricultural and food industry components of inspection were consolidated to remove the basis for the question of why there were multiple inspection agencies. The goal and reasoning for consolidation by Canadian lawmakers and policymakers was that by joining once separate entities, there would now be clarification of the responsibilities of each segment of the food chain. Additionally, there would be improved effectiveness and consistency in inspections and enforcement. Duplication of inspection and overlap of food regulatory activities would be reduced and efficiency improved. They hoped that consolidation would also reduce federal spending. It may be too early to say if this has been successful since there is little open source information on spending. In 2004, additional reform legislation was introduced that contained commodity-specific laws. The effect was a strengthening and added consistency on interpretation of requirements for eight different food commodities. It also was positive toward inspection and enforcement capabilities, allowing authorities to hold suspicious food products for testing and the time needed for return of results. Once confirmation is received that the food is safe to consume, it is then allowed to be released for sale or distribution. This authority is relevant and important to regulators and food safety, especially with imported food and cases where intentional contamination of food product may be an issue.

One other interesting event occurred with the change in the food safety laws. While the system is designed to work as a single agency, there are actually two entities that are interlinked—the Canadian Food Inspection Agency (CFIA) already mentioned and Health Canada. This is an important distinction when analyzing the food safety changes. The CFIA consolidated all of the inspection activities of the former agencies,

while Health Canada was given the responsibility of setting food safety standards, performing food safety research, and risk assessments (Health Canada, 2004). In essence, CFIA is responsible for risk management and Health Canada is responsible for risk assessments.

Thus, while there is separation of agencies between CFIA and Health Canada, they are linked by law and dependence on each other. Health Canada can concentrate on independent scientific research and analysis of food risk factors and set standards based on the scientific process. CFIA can focus on inspection and enforcement or risk management. The standards they enforce will be consistent across all food commodities. The fox will no longer also be guarding the hen house, so to speak. This change made for positive feedback from the food industry and the consuming public.

Changes have been positive for consumers and the industry. Food industry stakeholders were consistently supportive of Canada's consolidation. Among the consolidation, related benefits they cited were improved communication; better interaction with regulators through having a single contact for enforcement and compliance; clarification of responsibilities; and increased consistency in the enforcement of food safety laws (U.S. General Accounting Office, 2005). While expressing overall support for the consolidation, representatives of some food industry organizations cited a need for timely decision-making.

One negative comment about this new way of handling food safety issues from industry representatives was that on specific matters, industry may have to wait excessively long periods for issues of risk management to be resolved. CFIA had to wait for a food safety question on a standard to be answered by Health Canada. Added to that comment, the same industry representatives stated that Health Canada's setting standards should better reflect CIBA's ability to enforce the standard (U.S. General Accounting Office, 2005). This concern can be addressed as more time is allowed for the new system to work. However, from personal experience, the last issue is debatable, for even the smallest challenges to food safety laws may require legislative or regulatory changes that take time to process. The change to streamline and separate risk assessment from risk

management in this case study remains, for this analysis, a positive change. It is worth studying because of the influence that Canada's new system may have in an evaluation of the need for changes to the U.S. food safety system.

D. SUMMARY

By comparing the single food safety regulatory systems that have been created in the United Kingdom, Germany, and Canada, we have looked at examples of what can be done to streamline and improve the food safety system. These countries all had multiple agencies originally, similar to those in the United States. Germany has a system of government that closely resembles our own, with a national government structure and a state government structure. In particular, the new food safety structure created by Germany shows that a system of federal and state systems could be realigned to create a flow from a single regulatory system that can work with existing state structures. Once such a single food safety agency is created, regulations can be more consistent between federal and state food regulatory authorities. For the United Kingdom and Germany, in particular, who were members of the European Union (EU), creation of a single (or smaller) food safety agency and reporting bodies has been extremely beneficial to all countries in the EU. Benefits have included similar food safety strategies and policies, even with different governmental structures and overarching laws. Safety inspections and delivery of imported and exported food supplies between the countries is hastened because of agreements that each country follows in their respective food safety laws and food safety structures by using similar protocols. This has been influenced by laws established by the European Food Safety Authority (U.S. Government Accountability Office, 2008). With a distinct food safety agency structure and consistency of system governance, it eliminates the confusion about what other agencies are doing and what their roles are in their respective countries.

There will always be arguments among policy and decision-makers from the agencies representing the food safety regulatory system in the United States that the countries discussed are smaller and less complex than ours in the United States (U.S. General Accounting Office, 2005). Some may argue that the cost of restructuring would be a tremendous strain on the budget and staff. However, preliminary results show that

there have been cost benefits, especially with staff retirements and small organizational shifts as well as reduced needs for equipment and documents (regulations) (U.S. General Accounting Office, 2005).

These comparisons show that change is possible without major disruption. The concepts and definitions of food safety, food defense, and food security can benefit from a single entity where risk management and risk assessment systems can be integrated to create a streamlined approach to prevent foodborne illnesses. This concept also meets the global view of food safety/security and may lead to better coordination with the United States and its global food safety regulatory partners.

The comparative analysis highlights the fact that bold initiatives such as realignment and structural changes are possible in the food safety arena without total disruption of the government's ability to protect consumers and the industry. While continued study is needed as data are collected by the countries studied on the efficiency of the changes made to long-standing regulatory structures, the benefit of movement to a single (or smaller) footprint for governmental food safety oversight has increased consumer confidence in how the government handles food safety (U.S. Government Accountability Office, 2008). Also, while under a single entity there has been a separation of risk assessment from risk management, which has created a transparency that has benefited both industry and consumer and developed a new sense of confidence in the government's posture on protecting its citizens. The comparison countries show how strong leadership and the desire to protect its citizens influenced the call for the positive change made in each country and the EU as a whole. This shows a trend toward positive change in a global perspective (U.S. Government Accountability Office, 2008).

VI. PATHS TO CHANGE—WHAT OTHERS ARE PROPOSING

A. INTRODUCTION TO CHANGE—PATHS ALREADY FOLLOWED

There appears to be a persistent resistance to change. The idea of creating a single food safety agency to oversee protection and defense of the U.S. food and agricultural supply is perceived by some critics to have the potential to become a bureaucratic nightmare. Some agency leaders disagree with the idea that the system needs repair. In 2007, Dr. David Kessler, former FDA commissioner under presidents George H. W. Bush and Bill Clinton, told the House Oversight and Government Reform Committee, "Simply put, our food safety system in this country is broken. … The fact is that food safety has been a second-tier priority within the FDA." Dr. Andrew C. von Eschenbach, the current FDA commissioner, took issue with Kessler. "I disagree that the food safety system is broken," he told the panel, "we will never have a 100% fail-safe" system (Alonso-Zaldivar & Goldman, 2007)."

1. Two Paths of Change Already Followed

The creation of the U.S. Department of Homeland Security (DHS) under the secretary of Homeland Security shows that the process of creating a new agency at the executive branch level of the U.S. government can be achieved quickly (U.S. Department of Homeland Security, 2008). This example also shows the president's authority to create cabinet-level positions within the executive branch under Article II of the United States Constitution (U.S. Government Printing Office, 2007).

Additionally, if questions about transparency are raised, an alternative solution besides a cabinet-level position could be an independent agency. The process to create an independent agency at the executive level follows a similar path, and it would also be possible to establish such an agency quickly in this manner. In 1970, when there was concern for environmental and health issues for water and air, the Environmental Protection Agency was created as an independent body to help alleviate concerns of nontransparency under President Nixon's administration (Lewis, 2007).

Another seemingly impossible consolidation was creation of the Office of the Director of National Intelligence (ODNI). President George W. Bush signed four Executive Orders in August 2004, which strengthened and reformed the intelligence community to the extent that the President can without legislation. Shortly thereafter, both houses of Congress passed bills with major amendments to the National Security Act of 1947. Reconciliation of both bills led to the Intelligence Reform and Terrorism Prevention Act of 2004 signed into law by President Bush on December 17, 2004. After appointment and confirmation of the first DNI in February 2005 and swearing into office in April 2005, the ODNI opened for business on April 22 of the same year (Office of the Director of National Intelligence, 2008a).

The ODNI was established to create a vision of "a globally networked and integrated intelligence enterprise," with a mission to "create decision advantage" through a strategy of "integrating foreign, military, and domestic intelligence capabilities through policy, personnel, and technology actions to provide decision advantage to policymakers, warfighters, homeland security officials and law enforcement personnel," with Commitment, Courage, and Collaboration." (Office of the Director of National Intelligence, 2008) The office has oversight, from a homeland security perspective, of the combined collection of vital information from the intelligence community representative of 16 different intelligence organizations. The collaborative nature of the new agency, while on the surface seemingly difficult to accept in such a secretive society, now represents an example of what can be achieved and offers an example for beginning a process of reformation in the food and agricultural regulatory structure. These examples show what is possible in government restructuring. Let us start with three ideas of how these examples can lead us to creation of a food safety oversight agency, since that is the focus of this thesis.

2. Potential Paths for Change Described

Three possible paths could be followed in formation of an oversight agency.

Path one is the creation of an oversight agency that incorporates existing agencies or departments with similar functions along with various components of other agencies

that directly link to the primary mission of the new agency. Most of the original agencies would stay intact and carry out their primary missions, but could operate under the umbrella of the new oversight agency. Some agency components could be dissolved from their original agencies and would become a part of the oversight agencies command organization. The DHS and the EPA (with its original role of protector of air and water resources) are examples of this type of oversight agency.

Path two is the creation of an oversight authority with the responsibility of managing other agencies with similar tasks. All of the communities placed under this type of agency would remain separate in their day-to-day missions, but would be aligned on overarching issues through collaboration. In the business world, an example of this would be a parent company that owns several food companies. Each company might produce separate products and be governed from within by their own management structures. The parent company, however, would control the direction of the community as a whole. In the intelligence community, the Office of the Director of National Intelligence is an example of this type of oversight agency and is the equivalent of a parent company. It has a vested interest in the success of the companies (agencies or departments with intelligence functions, whole or partial) under its guidance.

Path three is the creation of an oversight agency, which, as in path one, takes over specific functions from existing agencies or departments that are related to the new agency's mission. Path three differs in how the new agency controls all authority. The components of the new agency would be melded into one. The new agency would control and guide a specific area of expertise, combining all toward a new mission dedicated to a particular function. Examples of this in industry are Daimler-Chrysler and U.S. Airways-American West Airlines. Their mergers created new automobile and airline companies, respectively, with similar missions. Both companies operate under the same rules. The purpose of the mergers in both cases was to consolidate into a more efficient company.

All three paths have the potential for success. The question is, however, which would be the right path to follow if a new food safety oversight agency were to become a reality? Our thesis analysis to this point has examined three areas.

In this chapter, we survey legislation being introduced in the United States, which indicates that changes in the food safety regulatory system, in whole or in part, is being considered. Several bills by the 110th Congress were proposed to enhance, improve, or change the U.S. food safety regulatory system. Consumer advocacy groups have also called for the food protection regulatory system to be restructured into a more streamlined system (Center for Science in the Public Interest, 2008).

One problem with the legislative proposals for the food safety regulatory system is the sheer volume of legislation proposals. The 110th Congress considered more than 2,000 pieces of legislation related to food. Keyword searches at the U.S. Library of Congress Web site (2008) and other Web sites using word combinations that include *food, agriculture, food safety, agricultural safety, food defense, agriculture defense, food security, agricultural security,* and *food and agricultural terrorism* revealed a plethora of legislative proposals and bills. Several bills related to food safety and defense were slanted toward protection of the food supply by creation of two of the three paths here described and were still in committee. The Durbin-Delauro Bill entitled the "Safe Food Act of 2007" [S. 654 IS and H.R. 1148 IH] would follow path three, while the Burr-Collins Senate Bill entitled "National Agriculture and Food Defense Act of 2007" would follow path two.

The conduit for legislation introduced into both bodies of Congress is long and tedious. This is one of the obstacles in creating a new oversight agency beyond the authority of the president without consensus (U.S. Library of Congress, 2003 Revised).

A proposed bill, of course, cannot become a law until it has been approved by both the Senate and the House. After a bill has passed both chambers, it must then be made identical by a conference committee (U.S. Library of Congress, 2003 Revised). The bill would then be sent to the President for signature, and if signed, it would then become law. The mechanism forward to implementation of the new law could be time consuming and laborious (U.S. Library of Congress, 2003 Revised).

Moving legislation out of committees is the first order of business. A search of bills considered by the 110th Congress and earlier sessions reveals that some of the food-

related legislation presently in committee had been proposed in earlier sessions of Congress and had the same problems. None of the proposals had yet made it to the floor of either the House or the Senate beyond the first and second readings that are needed to get them introduced into the process.

B. BILL PROPOSALS OF SIGNIFICANCE FOR CHANGE

Due to a wide range of food-related illness and food contamination issues that have been in the news over the past five years, the 110th Congress has stepped up a call for change and enhancement of the way the United States performs its regulatory function on food protection. The recent incidents of contaminated food products and foodborne illnesses have led to food protection concerns being a high agenda issue for some lawmakers in the 110th Congress (Congressional Research Service, 2007). The recent tomato and jalapeño pepper contamination and illness outbreak have increased the demands for change, not only from Congress, but also from consumers, consumer groups, and industry. Several members of Congress have introduced bills to alter the current U.S. food safety system and/or increase spending, which they assert is needed to protect consumers from unsafe food (Congressional Research Service, 2007). These issues have led to the large number of bills introduced in the 110th Congress.

While more than 2,000 pieces of legislation are related to food, food safety, and food defense there are some proposed bills that address similar concerns and ideas to the conceptual model that is proposed in this thesis and alternatives that do not address the model, including the following bills:

1. Enhancing the Current Regulatory System—No Widespread Change (Center for Science in the Public Interest, 2008)

Some bills under consideration that would enhance the current food safety system are in committee. These bills represent a sampling of the proposals being introduced to help alleviate the burden of tackling the rash of recent outbreaks associated with products at the federal inspection level. Some of the proposals serve to give the Food and Drug Administration (FDA) and its Center for Food Safety and Applied Nutrition more tools to engage in dealing with tracing the flow of domestic non-meat products in the farm to

processor and retail levels, both foreign and domestic. Some proposals would give FDA recall authority, the ability to require methods and mechanisms that the food industry will use, along with implementation plans for tracing back the origin of all food products. There is similar legislation being proposed for meat and poultry products to enhance the U.S. Department of Agriculture.

Some of these bills are listed below, and they convey the enormity of the task of trying to improve the already existing regulatory structure with its many departments and agencies. While the bills proposed are a positive step, they do not address how the changes will be funded. In brief, the complexity of the regulatory system feeds off the complexity of the legislation that tries to enhance the system.

- The Consumer Food Safety Act [H.R. 3624] (referred to the House Committee on Energy and Commerce)
- The Food and Drug Import Safety Act [H.R. 3610] (referred to the House Energy and Commerce Committee, Subcommittee on Health)
- The Imported Food Security Act [S. 1776] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry)
- The Human and Pet Food Safety Act [S. 1274 and H.R. 2108] (read twice and referred to the Committee on Health, Education, Labor, and Pensions; referred to the Subcommittee on Health)
- The Fresh Produce Safety Act [S. 2077 and H.R. 5620] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry; Referred to the Subcommittee on Horticulture and Organic Agriculture; has been through two House committees and three subcommittees)
- The Safer Meat, Poultry, and Food Act [H.R. 3484] (referred to the Subcommittee on Health; has been through two House committees and one subcommittee)
- The Trace Act [S. 1292 and H.R. 2997] (Read twice and referred to the Committee on Agriculture, Nutrition, and Forestry; referred to the Subcommittee on Health; has been through two committees and one subcommittee)
- The Meat and Poultry Products Traceability and Safety Act [S. 1292 and H.R. 3584] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry; referred to the Subcommittee on Health. (Has been through two Committees and one Subcommittee)
- The Assured Food Safety Act [H.R. 2997] (referred to the Subcommittee on Health)

- The Food and Product Responsibility Act [S. 2081 and H.R. 5069] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry. Referred to the Subcommittee on Specialty Crops, Rural Development, and Foreign Agriculture)
- The Food Import Safety Act [H.R. 3937] (referred to the Subcommittee on Health.)
- Keeping America's Food Safe Act of 2008 [H.R. 5827 IH] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry)
- Food Safety Modernization Act [S. 3385] (read twice and referred to the Committee on Health, Education, Labor, and Pensions)

a. Summary

The bills listed above are intended to enhance or change statutory regulation to existing federal food safety agencies. In essence, they do not change the status quo. Pending appropriations would need to go hand-in-hand with any of these proposals, and would keep the existing regulatory food and agricultural structure in place, if enacted. These bills could enhance programs, but would not answer the question of the need for a food safety oversight structure for the nation.

2. Changing the Current Regulatory System—Partial or Complete Change to the Structure

Congress is now considering two bills that change the current food safety system. One bill would enhance the new food defense mission by creating a link of administrators from the primary food, agriculture, and water regulatory agencies to the Department of Homeland Security (DHS) to monitor food defense issues related to intentional attacks on the food supply. This bill is closely aligned to Homeland Security Presidential Directive–8 and Homeland Security Presidential Directive–9.

The second bill calls for creation of a food safety administration. It would put the food and agricultural food safety functions that presently are under separate agencies, under one umbrella. The following is a brief summary of each bill.

a. Partial Change

The areas below that appear to be significant are highlighted in bold. When warranted, questions and comments are shown in parenthesis about who would develop the components or notes to give the reader a sense of possible problems.

The National Agriculture and Food Defense Act [S. 1804] (WashingtonWatch.com, 2008)[13] (read twice and referred to the Committee on Homeland Security and Governmental Affairs)

An overview of what the bill proposes to achieve in food defense is as follows.

The Secretary of Homeland Security (Secretary) shall **lead** federal, state, local, tribal, and private efforts to enhance the protection of critical U.S. infrastructure and key resources, including the agriculture and food system;

The Secretary of Agriculture shall **lead** federal efforts relating to agriculture, meat, poultry, and egg food products;

The Secretary of Health and Human Services (DHHS) shall **lead** federal efforts relating to other food products; and

The Administrator of the Environmental Protection Agency (EPA) shall **lead** federal efforts relating to drinking water and waste water.

Establishes in the Department of Homeland Security (DHS):

- A Chief Medical Officer who shall serve as **the Assistant Secretary for Health Affairs**
- The agriculture and food defense rotational expertise program.

[13] This bill was proposed in the 110th session of Congress. Sessions of Congress last two years, and at the end of each session all proposed bills and resolutions that have not passed are cleared from the books. The 110th Congress is about to end (2007–2008). Members often reintroduce bills that did not come up for debate under a new number in the next session. The 111th Congress begins in 2009 and the bill will most likely be reintroduced.

Establishes in the Department of Agriculture (USDA):

- The position of Under Secretary for Protection, Preparedness, and Response
- Directs the Secretary of HHS to coordinate the public health surveillance of zoonotic diseases (a CDC function under HHS)

b. Summary

The National Agriculture and Food Defense Act would, in summary, create a network with new and established administrators in DHS, USDA, HHS/FDA, and EPA (to a lesser degree) established to carry out functions under the direction of the Secretary of Homeland Security through the new Assistant Secretary for Health Affairs to do the following.

- **Prepare a combined national** agriculture and food defense **strategy** (Who are all the stakeholders that would be involved in combining the strategy in the venue of transparency? Will state and local regulatory agencies, consumer and industry groups be involved?)
- **Perform vulnerability** assessments of the agriculture and food system (Who would actually carry out; DHS or separate agencies, or a combined force to evaluate?)
- **Implement mitigation strategie**s to protect critical production and processing nodes from diseases, pests, and poisonous agents (Who actually would develop the strategies?)
- Ensure that **combined federal, state, and local capabilities are adequate** to respond to a terrorist attack, disease outbreak, or other disaster affecting the U.S. agriculture and food system (If not adequate, who would fund to make them adequate?)
- Assist the states with food and agriculture protection activities (Additional funding and resource issues)
- Establish the Food and Agriculture Government Coordinating Council (this is a good idea because it includes public and private interaction on food defense issues)

It further directs the Secretary of Agriculture to do the following.

- Develop a national veterinary stockpile
- Develop a national plant disease recovery system

- Establish a National Veterinary Stockpile Advisory Committee
- Carry out a program (Agricultural Biosecurity Corps) to develop veterinary leaders with epidemiological expertise to respond to animal agriculture threats
- Develop a national plant diagnostic network
- Develop a national food emergency response network (FDA has a system called FERN (Food Emergency Response Network) already in existence that could be enhanced. (**This is a good idea if the FERN is enhanced. This would prevent duplication of an already existing system)**
- Develop a national animal health laboratory network
- Identify an increased production capacity goal for the rendering industry to meet animal disposal needs following a catastrophic animal disease outbreak
- Conduct a study of irradiation technology use to enhance food defense capabilities

The Act also directs the administrator of EPA to provide assistance to state, local, and tribal governments in assessing, decontaminating, and recovering from an agriculture or food emergency. This is one of the few responsibilities mentioned for the EPA. The concern in context of the response to a food emergency is for ground water contamination problems from agricultural events requiring massive disposal efforts.

There are several key points of analysis from the bill. The first is the call for the secretaries of DHS, USDA, and HHS/FDA to submit an integrated food safety defense budget. How the existing budgets can be combined regarding what each separate federal agency brings to the table may be significant. The budget proposals may be different depending on the agencies' existing missions. There is a need for independent analysis of cost as a guide for discussions on a combined and integrated budget.

Second, the weight of the bill, while integrating food defense budgets, leans more toward the agricultural and food responsibilities existing within USDA. There is less lean toward the overall existing HHS/FDA food regulatory responsibility. The bill directs the secretary of HHS to coordinate the public health surveillance of zoonotic diseases. This surveillance function would fall under HHS's Centers for Disease Control and Prevention. This is a positive proposal, but leaves out any responsibility for the Food

and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), which is a major component of the nation's food regulatory system for federal inspection of all food items other than meat and poultry, which USDA inspects. This does not imply that FDA and its responsibility for food safety and food defense issues are left out of the bill's overarching message or plan, but it must be considered.

Overall, the bill is a positive effort to respond to the issues of agricultural and food defense issues and should be considered by Congress. It is a first step in the right direction in integrating the new food defense mission in protecting the food and agricultural infrastructure. While it does not address the overarching research questions of this thesis on the need for a single food safety oversight agency or administration, the proposed legislation does focus attention on the critical nature of the food and agricultural infrastructure and its protection. Integration of the three existing departments or administrations through the Department of Homeland Security for food defense does create a missing link that would be tied to law for collaboration on this important issue.

The track of this bill would keep the existing food, agricultural departments, and agencies intact, but it would create administrative positions at the secretary and administrator level at each agency. However, creation of direct links specific to the food defense missions of each department or agency at USDA and HHS/FDA merits expedited consideration by Congress.

c. Complete Change

As in the partial change section of the chapter, the areas in this section that appear to be significant are highlighted in bold. When warranted, questions and comments are underlined regarding who would develop the components or notes. This was done to give the reader a sense of possible problems.

The Safe Food Act [S. 654 IS and H.R. 1148 IH] (U.S. Library of Congress, 2008b)[14] (read twice and referred to the Committee on Agriculture, Nutrition, and Forestry) Referred to the Subcommittee on Health. (Has been through two House Committees and one Subcommittee)

The bill as proposed would move the nation toward a single oversight agency.

- Would establish a Food Safety Administration to administer and enforce food safety laws
- Develop new regulation to ensure security of the food supply
- Implement federal food safety inspection, enforcement, and research efforts in the name of public health
- Develop consistent and science-based standards for safe foods
- Prioritize resources at the federal level in both effort and deployment for the highest benefit of reducing foodborne illness

d. Summary

The Safe Food Act would create a new agency to provide oversight of all food safety functions by integrating previous food safety and defense functions from the USDA, HHS/FDA, EPA, DOC, and other ancillary federal food safety programs under the umbrella of one administration. Specifically, the bill would transfer to the new administration all functions of specified federal agencies that relate to the administration or enforcement of food safety laws. The legislation upon enactment would require the new administrator to do the following.

- **Administer a national food safety program** based on an a**nalysis of the hazards associated with different** food and the processing of different food. (<u>This approach can be and is important to consistency, transparency, and providing for a streamlined risk-based approach to food safety and defense. This approach would also be consistent with food protection based on scientific research and known evidence of food-related hazards</u>

[14] This bill was proposed in the 110th session of Congress. Sessions of Congress last two years, and at the end of each session all proposed bills and resolutions that have not passed are cleared from the books. The 110th Congress is about to end (2007–2008). Members often reintroduce bills that did not come up for debate under a new number in the next session. The 111th Congress begins in 2009 and the bill will most likely be reintroduced.

and to the administration of policy and regulation that provides the tools and consistency necessary for collective and collaborative food safety and defense)

- **Establish standards** for food processors and food establishments. (Important to standardizing risk assessment, risk management, and risk communication across all food commodities and levels of regulation, federal to state to local)
- **Establish** a **certification system** for **foreign governments or food establishments** seeking to **import** food to the United States. (Will help establish food safety standards, at least on process equal to or better than the U.S. regulation)
- **Establish requirements for tracing food and food producing animals from point of origin to retail sale.** (The ability to trace food back to its original starting point is critical to timely reduction of illness. If the source of the illness can be identified along its route in the supply chain, the spread of the potential illness can be reduced or even prevented. Random sampling of commodities listed below can also help track potential problems)
- **Maintain** an **active surveillance system** of food, food products, and epidemiological evidence. (Important to the identification of illnesses and tracking of the actual pathogens or chemicals responsible for an illness. Surveillance and epidemiological evidence are important to both preventing the spread of disease and identifying and stopping disease from spreading once it has started)
- **Establish a sampling system** to monitor contaminants in food
- Rank and analyze hazards in the food supply
- **Establish a national public education campaign on food safety. (**The importance of **education** cannot be overemphasized in the context of food safety and food defense. Continuous **education, training, and transparency** through these programs provide for the involvement of all stakeholders and relay the message that food safety and food defense is truly a farm-to-plate collaborative effort)
- **Conduct research** relating to food safety. (Science and technology of existing hazards and innovations to detect and prevent pathogens and chemicals before reaching the farms, processing plants, and consumers at the retail level are essential to a preventive program through preparation and response. This is “an ounce of prevention is worth a pound of cure” philosophy)

The Food Safety Act also sets forth provisions regarding prohibited acts, administrative detention, condemnation, temporary holds, recall, penalties for violations

of food safety laws, whistle-blower protection, and civil actions. These provisions will provide the authority that some of the existing food safety regulatory agencies do not currently have, specifically, enforcement and protection authority that is well defined.

The bill as written would set up a system based on hazards responsible for illnesses from different foods under one roof, standardize requirements for processors, and establish certification protocols for importers. The Safe Food Act would also establish a much needed protocol for tracking food products and maintain an active surveillance program on foods to keep sight of trends in food-related illnesses. Creation of food-sampling and ranking systems for food hazards would help create a knowledge base on agents that are responsible for foodborne illnesses and their potentials. Establishment of a national public education campaign on food safety and research on food products will be vital to the success of food protection.

If illness outbreaks occur on a national level, provisions regarding the prohibition of acts related to non-food safety compliance, added strength for administrative detention, condemnation, temporary holds, recall, penalties for violations of food safety laws, whistle-blower protection, and civil actions are all components of a food safety system that would have some teeth.

On the issue of reorganizing, streamlining, and modernizing the food and agricultural system, the legislation would have the same budgeting issues from a different perspective and an added dimension of organizational realignment, but once over the initial hurdles, could actually provide a more directed focus to the issues of enhanced food safety and the new culture of food defense.

The Safe Food Act calls for a complete revamping of the current food safety regulatory system. It provides the U.S. legislation already in Congress for consideration of a legislative proposal for a system that can be used to provide oversight of the entire food supply chain. The move toward a single oversight food safety system has been discussed since the 1960s, while in the same period, the food and agricultural

regulatory system has been expanding rapidly and moving away from the concept of a single oversight agency. The Safe Food Act has potential and is relevant to the conceptual model that will be introduced in the next chapter.

C. CONCLUSION

1. A Guiding "Act" for Change

A move toward a single food safety agency will need a beginning process to strengthen the idea. The Food Safety Authority Modernization Act, Senate Bill S. 2245, would be a positive place to start. The bill would provide an opportunity for all stakeholders in the current U.S. food safety system to come together and discuss modernization of the food regulatory system.

Food Safety Authority Modernization Act [S.2245.IS] (U.S. Library of Congress, Thomas Home, 2008a)[15] (read twice and referred to the Committee on Homeland Security and Governmental Affairs)

A synopsis of the proposed bill is below. The bill would begin an in-depth investigation to enable the nation to move positively toward a single oversight agency.

- Establish a Congressional Bipartisan Food Safety Commission to:
  - Review the U.S. food safety system and relevant statutes, studies, and reports;
  - Prepare a report that summarizes information about the current system, makes specified **recommendations** (including ways to **modernize** the system, **improve coordination** of food safety activities, emphasize preventive strategies, and **provide funding mechanisms to federal agencies to carry out food safety responsibilities)**; and
  - **Draft statutory language** that would **implement** the recommendations.

[15] This bill was proposed in the 110th session of Congress. Sessions of Congress last two years, and at the end of each session all proposed bills and resolutions that have not passed are cleared from the books. The 110th Congress is about to end (2007–2008). Members often reintroduce bills that did not come up for debate under a new number in the next session. The 111th Congress begins in 2009 and the bill will most likely be reintroduced.

- Additionally, the bill directs the Secretary of Agriculture and the Secretary of Health and Human Services to provide the Commission with specified funding and support services. It would also terminate budget authority to implement food and food safety provisions of the Poultry Products Inspection Act, the Federal Meat Inspection Act, the Egg Products Inspection Act, and Chapters I through IV of the Federal Food, Drug, and Cosmetic Act two years after its enactment. These last two items would depend on the findings and consolidation of a bill coming out from the Commission's recommendations and its enactment it the form of a legislative act.

Analysis shows the specific Food Safety Authority Modernization Act to be a process that may help to gain bipartisan support and stakeholder support for the proposed Safe Food Act. It would provide for a detailed forum to discuss and strengthen support for enhancement of food safety toward a modernized food safety structure and harmonize statutes (U.S. Library of Congress, 2008a). Any significant change to modernize the food safety regulatory structure will require the support of all stakeholders. At the top level, it will take the support and action of the legislative and executive branches of our government. Until there is consensus and the votes necessary for what most agree is the best practice to provide citizens with a collective system that covers requirements for protection of the food supply at all levels and under one agency, modernization of the regulatory system could stall.

VII. A REALISTIC CONCEPT—A CONSOLIDATED FOOD AND AGRICULTURAL SAFETY OVERSIGHT ADMINISTRATION

A. INTRODUCTION—CAN THE FOOD SAFETY REGULATORY SYSTEM BE CONSOLIDATED?

Any move toward consolidation of the food safety regulatory system will take strong leadership. Some resistance to change evolves from unease at the thought of removal from familiar turf and an atmosphere of lost control and comfort zone. Steven Kelman (2005), in his book, *Unleashing Change: A Study of Organizational Renewal in Government,* wrote, "Resistance to change originating in a worry that change will upset power relationships is an organizationally created example of how existing practice becomes embedded in something larger" (p. 25). A change in regulatory structure by government leadership may be perceived also as a lack of confidence and trust in the current system and leadership ideals and vision.

1. Consolidation Challenges Met

Canada, the United Kingdom, and Germany embraced the challenge to improve their food and agricultural safety systems through consolidation of the various agencies that had been protecting the food/agricultural supply. The United Kingdom and Germany embraced a single food safety regulatory system change based on a necessity to control disease events occurring in the food supply (food-use animals) and human and animal-related illnesses. Others based their regulatory system change on concerns about potential negative economic impacts borne out of trade restrictions placed on food products by other countries. In all three countries, there was concern that importing countries in the European Union (trading partners) would not allow the former's food and agricultural products to be exported into other countries, if the country did not consolidate their food safety regulatory program toward a shared vision of efficiency and proactive commonality in food protection regulatory structure.

These concerns were based on how the country was focusing their protection efforts on their nation's food supply chain outward toward the regional and global

community. In each of the three countries, the negative impact on their national economies from ignoring both concerns would be detrimental to the countries affected by trade restrictions. All three countries, however, were equally aware of one of the most important problems they faced—the concerns of their own citizens about the protection of the food/agricultural supply and the need for greater transparency and knowledge of what was actually being done.

There are more examples in the literature about democratic countries around the world creating a single or more focused food safety system.[16] All of these countries also made the commitment to follow a new direction and create a shift in culture or a "Blue Ocean Strategy" on how a single (more focused) food safety system should look, and then made it a reality. A *Blue Ocean Strategy,* as described by Kim and Mauborgne (2005) in their book of the same name, is a strategy when existing boundaries and limitations are transcended to create a new culture or the creation of innovative value to unlock new demand. With recent concerns over the increases in the number of food-related illnesses and contaminations in almost every food product category, shouldn't the United States embrace the same strategy change and the same positive outlook for improvement of the regulatory system? A serious deliberation of such a shift in regulatory structure, with a focused effort toward combined food safety and defense, is especially important if progressive food protection is to become a reality.

2. Changes Proposed

Chapter VI analysis shows the efforts of various individuals and groups through proposed legislation to meet the challenge and create some type of a new focused food safety regulatory system that moves away from the multiple system approach we have been using in the United States. Analysis showed that while good quality legislation is being considered, it has yet to make it out of the initial committees in which the legislation was placed for deliberation. The policy of a more focused and single (smaller) food safety regulatory agency is definitely one that needs to be considered as we face the possible challenges of the food/agriculture infrastructure being used for intentional

[16] For example, GAO-08-794 examined also New Zealand, Denmark, Ireland, and the Netherlands.

contamination by terrorist organizations. We should always remember the lessons of 9/11 and take nothing for granted. A more focused food safety regulatory system can meet that threat and create an infrastructure that is both resilient and defendable.

While specific food and agricultural legislative proposals, as addressed in Chapter VI, have the best chance for success, there appears to be a complex reluctance to move ahead with the legislation. Steven Kelman (2005) also wrote in his book, U*nleashing Change*, that "Behavior in government organizations is harder to change than in other organizations—and bureaucratic organization in government is particularly resistant to change" (p. 28). In essence, there is a delaying tactic by affected organizations and internal leaders within government organizations to slow down any change proposals and the process for change itself.

The above perspective can create a hope among those opposed to change in the current regulatory food safety system that congressional leaders, and advocates for food safety restructuring in the United States, will shift attention from the issue and amble on to something else and that "this too shall pass" (Kelman, 2005, p. 28). So far, the perspective appears to have followed these traits. Some believe that if they resist long enough, the idea for change will go away. The frequent occurrence of the same legislation described in the latter portion of Chapter VI for change in the structure of the food safety regulatory structure, having moved from the 109th to the 110th congressional legislative sessions without any action at all, is direct evidence of the "this too shall pass" mentality. The legislation will now have to be reintroduced into the upcoming 111th congressional session. What will it take to move toward a single food safety oversight administration in the United States? Will the current workable legislative proposals continue to stall in Congress and be ignored? Or, will additional legislation be proposed to further confuse the system and muddle any chance for appropriate improvement of the regulatory system? Where do we go from here?

3. The Move Forward to a New Concept

Others have proven that food regulatory systems can be consolidated to improve the process, and we have legislative proposals in the pipeline here in the United States to

move forward toward a similar system. While democratic government legislative processes will always be complex, the impetus needed for change may be as simple as a strategic concept blueprint of what a single food safety and defense regulatory oversight administration might resemble in structural appearance. This chapter will present a visualization of strategic concepts. The conceptual designs will be used to stimulate the thought process of how innovative value can be created to break the mold of inefficiency, and ineffective use of resources from multiple statutes, duplication of mission, and confusion of who is in charge of what food commodity. The strategy will also be a shift away from the old "*Red Ocean Strategy"* used by each entity that makes up the U.S. food safety regulatory system where they unwittingly vie against one another for the same resources in their roles as protectors of the food supply (Kim & Mauborgne, 2005).

The regulatory niches created by numerous statutes and rules that each of these agencies have operated under for over a century creates a protective culture against any change, whether positive or not, to rejuvenate and strengthen regulated food and agricultural safety (Kelman, 2005, p. 28). This chapter presents the author's strategic concept of what a new food safety/defense system framework could look like. It takes the road less traveled in its exploration of the innovative value of a consolidated regulatory system. It is an attempt to break the pattern of the separate, but similar organizations that exist today. The concepts presented in this chapter are also based on the author's confidence, from both research and experience, that a focused food safety and regulatory structure is the best way to meet the challenge of future food and agricultural threats and to optimize available resources effectively.

B. A CANVAS TO PORTRAY A STRATEGIC CHANGE

A portrait of change to a new system for food safety defense/security in the United States can begin with the creation of a strategy canvas, which visually compares the move from the current system to a new system. A strategy canvas is defined by W. Chan Kim and Renée Mauborgne (2005) as an analytic framework, both diagnostic and action oriented, to build and describe a visual blue ocean strategy for change (p. 25). Kim and Mauborgne explained that a strategy canvas has two purposes. First, it helps explain

the current system's place in the sector matrix, allowing us to understand competition factors and current investment strategies. Second, it can drive us to act on innovation that can rearrange our focus toward alternatives and away from competition, which creates a stand-still environment contradictory to growth and change.

1. The Elements of Change: The Eliminate-Reduce-Raise-Create Grid

Creation of a strategy canvas allows for observation of the big picture of what the current system is and what something new can offer. Kim and Mauborgne (2005) provided supplementary tools that are also supportive in creating the strategy canvas. One is called the Eliminate-Reduce-Raise-Create (ERRC) Grid. The use of an ERRC grid in analyzing the change to the food safety regulatory system from multiple agencies to a single food safety oversight administration concept allows a move forward, which is needed to scrutinize the current system and consider the following.

- What factors should be eliminated
- What factors would be reduced
- What issues would need to be raised
- What factors should be created to add value to a new food safety regulatory structure

Table 1 shows the results of my analysis of these factors of what are some of the value elements to be reconstructed in a move away from the current food and agricultural regulatory system.

Eliminate	Raise
•Multiple Food Safety Statutes with Competing Standards on Same Point Issues •Multiple Agency Oversight of Food Commodities (FDA, USDA, EPA, etc.) •Duplication of Inspections and Regulations for Similar Commodities •Competition for Resources •Illness Investigation and Surveillance Separation Based on Multiple Agency Oversight	•Consumer Confidence and Awareness of Food Safety and Defense Issues - through Transparency and Consistency of Message •Industry Responsibility and Buy-In of Food Safety and Defense Regulatory Message – Transparency and Consistency •Risk Assessment Focus •Risk Management Standards •Risk Communication and Educational Awareness
Reduce	**Create**
•Imbalanced Resource Allocation •Industry Confusion of Who Inspects What Commodity or Food Product •Consumer Apprehension, Fear, and Distrust of Government's Ability to Protect Food and Agricultural Supplies	•Single Food Safety Oversight Administration –Administrator Tier –Liaison Tier –Risk Awareness and Control Tier –Food Safety and Food Defense Program Implementation Tier –Education, Epidemiological, Intelligence, and Law Enforcement Tier –State, Local, and Industry Affairs Tier

Table 1. Food Safety System ERRC Grid (From: Kim & Mauborgne, 2005)

2. The Strategy Canvas for Value Movement to a New Food Safety Regulatory System

The strategy canvas for movement away from the current food safety regulatory system toward a streamlined single food safety agency is presented in Figure 8 using some of the factors observed in the ERRC grid. The objective of the strategy canvas is to provide a picture to analyze the value of movement away from the standard way of doing business. For the food safety regulatory reconstruction strategy proposed in this thesis, the canvas provides a visual representation of the value innovation that can come from consideration and exploration of a new streamlined system. It also shows a reconstructionist view of strategy. Built on the theory of internal development, Kim and Mauborgne explain this view as one which "proposes that such a change process of creation can occur in any organization at any time by the cognitive reconstruction of existing data and elements in a fundamentally new way" (Kim & Mauborgne, 2005, p. 210). What this implies in the movement toward a single food safety oversight system is that change can come without tremendous impact, and with a proper reallocation of existing knowledge and resources. The greatest challenge is to convince those affected by change in the current system of their value to the process and to develop their trust in the reorganization.

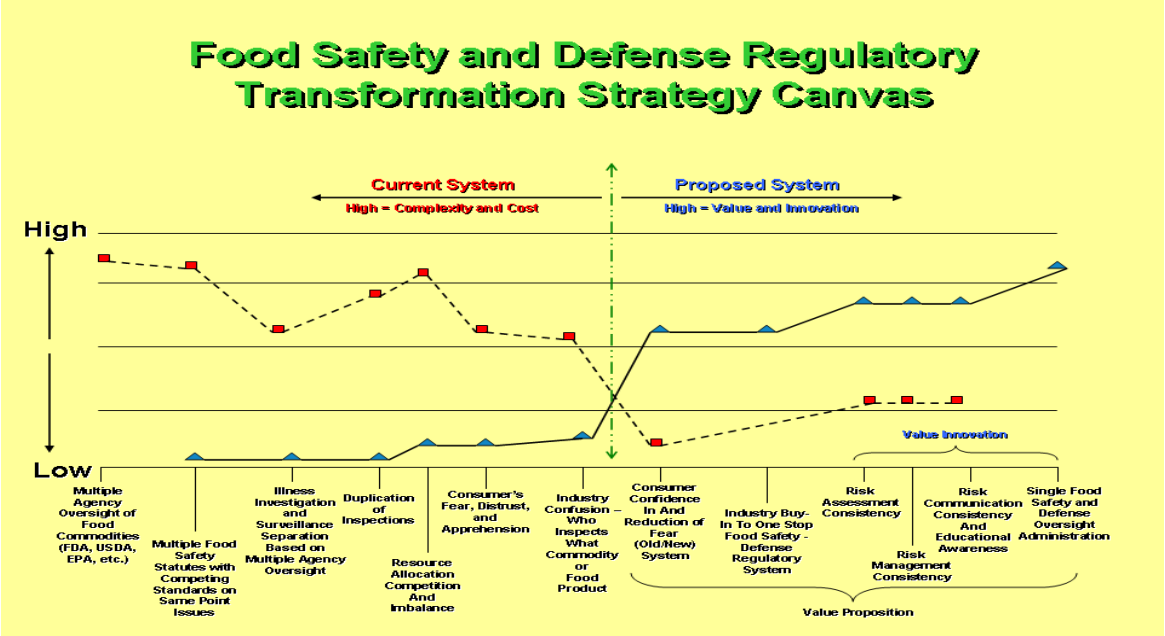

Figure 8. Food Safety and Defense Strategy Canvas (From: Kim & Mauborgne, 2005)

The strategy canvas presents a picture of how the current system and the proposed system differ. It also shows the value proposition that can be associated with the proposed new system through a collective food and agricultural food safety system. The new single oversight agency should increase consumer confidence, create an environment in which those in the food/agricultural industry know what is expected at any given time from a regulatory focus, and provide consistency in risk analysis across all spectrums of food protection, defense, and even global food security. The next step in the process is to provide a visual tour of how the author envisions a singularly focused food safety oversight agency and its strategic value.

C. FOOD AND AGRICULTURAL OVERSIGHT ADMINISTRATION

New legislation will be necessary for the reduction and elimination of current statutes on food safety to guide the new food safety oversight administration. The first task during the formation of the new oversight agency is the streamlining and reduction of statutes that duplicate and complicate the change to a single agency for food protection oversight. The enactment of new guiding statutes for the new singular regulatory oversight would require detailed analysis. The Food Safety Authority Modernization Act

(U.S. Library of Congress, Thomas Home, 2008a) is focused on accomplishment of such a task. If passed, the act would establish a mechanism to evaluate all of the ideas for change that have been discussed by government, private, and academic think tanks over the past several years and to analyze the 35 laws now in use and the legislative proposals introduced in the latest session of Congress.

The passage of the Food Safety Authority Modernization Act would be a valuable innovation to prepare the nation for guiding legislation on actual workable statute(s). A movement toward creation of new food safety statutes for the oversight agency and elimination of the current multiple statutes for the protection of food commodities would, in effect, set the path for concentrated focus on the singular concept change to food safety in the United States. Figure 9 provides a look at the authors' visual image of a proposed new food safety and defense oversight agency. The image is followed throughout the next section of this chapter with brief descriptions that provide a visual and written presentation tour of the structure of the new administration.

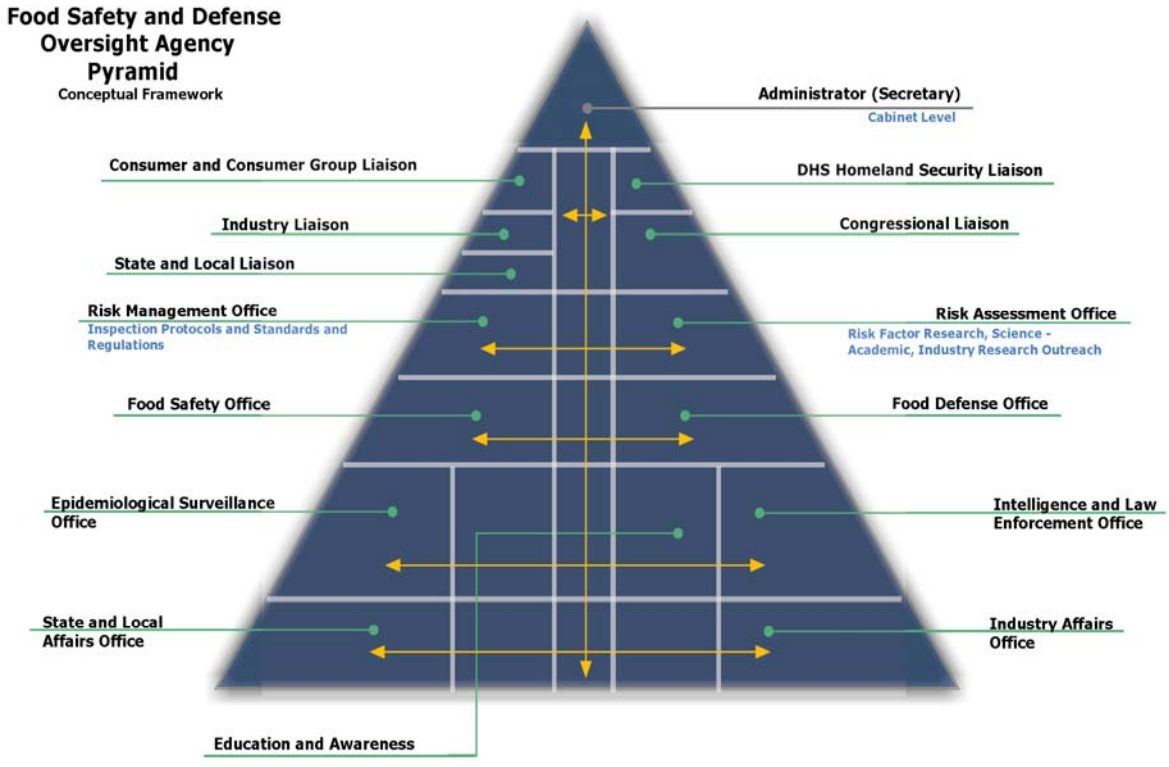

Figure 9. Food Safety Oversight Administration Pyramid

1. Organizational Structure

The pyramid structure used to convey the concept of the new food safety and defense oversight agency is meant to convey a visualization of a system built with foundational strength. The view is for a federal system that covers all aspects of food and agricultural safety without division among multiple agencies. The administration developed is one that will be transparent, where all stakeholders will see value and know that they will be a part of a focused system. There will be room for growth and improvement along the way, provided by an administration established from the ground up, where the voice and sounding of food safety for the first time in over a century will come from a focused entity. The structure as presented may appear to be general in nature, but it is provided to present my concept from an uncomplicated strategic view.

We will examine each tier of the new administration beginning at the top with the administrator (secretary). The concept is for the new food safety and defense oversight body to be located in the executive branch of government for the new system to be effective. The question whether the new body will be a cabinet level position or an independent agency, similar in example to the Environmental Protection Agency, is left for the leadership to wisely answer, but either way, hopefully, in the near future. The importance, however, is that the new oversight body has the support from both the executive and legislative branches of the United States, and by rule of law, the constitutional backing of the judicial branch. The formation of any new system will depend on a concerted effort by all parties for success.

2. Administrator (Secretary)

At the tip of the agency pyramid is the position of the administrator (or secretary) of food safety and defense oversight. The duties of the new administrator (secretary) will be true to the definition of both; that is—"an officer of the state that superintends a government administrative department; and one that executes management of their duties for the new agency" (Merriam-Webster, 2008a).

The focus of the single food safety agency away from the multiple agency system will require the person who occupies the position to be well-rounded in their understanding of the principles of food safety and administration of food safety programs. Unfortunately, the process of selection of individuals at this level tends to be political. The old saying that "you can't take the politics out of politics" generally holds true. However, it is hoped that the person chosen for the administrator position will be selected based on their experience and knowledge of food safety. There is a tendency, even in the current multiple food safety system, to select candidates based on a medical degree or a doctor of philosophy degree, with little background in the workings of food safety from the environmental and grass roots regulatory level. Advanced degrees add to an individual's body of knowledge, but experience specific to food safety and regulation should be a major consideration for appointments.

To safeguard the new system from too much emphasis on politics in the selection of an administrator within the framework at the top tier level of the agency, I propose in the conceptual framework that there be two deputy level positions. One deputy administrator can be appointed by the administrator, but should be required to be well versed in his or her knowledge of food safety. The second deputy will be chosen from the career ladder within the food safety regulatory system based on their previous performance and skill levels. A candidate for this position should be selected from the food safety regulatory community, with respected credentials and leadership skills, and experience in food safety over their career.

The requirements for selection, hopefully, should provide balance across the political and non-political spectrum from the outset, and present a well-rounded meta-leadership team focused on food safety and not on politics as usual. Figure 10 presents an image of the top tier (Marcus, Dorn, & Henderson, 2005). The administrator should also be receptive to communication channels throughout the tier system to provide transparency of the regulatory system. This communication aspect is an important component of the new regulatory system. The next tier level continues the overarching theme of communication with the liaison office tier.

Figure 10. Food Safety and Defense Administrator

3. Liaison Office

The second tier on the agency pyramid would be the liaison component of the agency structure. Liaison is defined as "communication for establishing and maintaining mutual understanding and cooperation" (Merriam-Webster, 2008c). The Liaison Office would establish and maintain communication with both the outside and inside worlds of food safety/defense. The five liaison positions would be the consumer and consumer group, industry, state and local, congressional, and homeland security components.

The liaison positions in the new food safety oversight agency are the communication conduit for information flow on food safety/defense, both outside and inside the agency. Communication of risk and transparent information exchanges are vitally important to success. In the comparisons made in Chapter V, established principles required for effective information sharing included the idea of being transparent in communicating risk. Two ways that the Merriam-Webster dictionary (2008b) defines communication are "1) a technique for expressing ideas effectively; and

2) a process by which information is exchanged between individuals through a common system of symbols, signs, and behavior." The liaison tier in the food safety administration is broken down as follows.

a. Congressional Liaison

- Directs communication to members and committees in Congress
- Provides presence for congressional issues on food safety and food defense/security questions
- Monitors legislation – both positive and negative to maintain the stability of the new food safety administration mission
- Champions agency position for fiscally responsible food safety resource requirements

b. Homeland Security Liaison to DHS

- Directs communication channel to DHS on issues affecting food and agricultural threats across the food supply chain
- Liaisons, along with food defense, intelligence, and law enforcement offices in the food oversight agency, to foreign governments regarding threats to the global food supply
- Responsible for communication to other agency liaisons in line with HSPD-9 to share information of threats to the food supply

c. Consumer Liaison

- Directs communication channel to consumers and consumer groups (consumer response will require technology bridges to be built to address concerns) on situational awareness
- Communicates concerns, questions, and answers for specific issues throughout agency departments from consumers and consumer groups
- Directs access to administrator level to communicate high level concerns
- Provides transparency through voice and messages of concerns

d. State and Local Liaison

- Directs communication channels to state and local regulatory agencies in all 50 states and territories. (While the state and local affairs office will also have a role in this communication, this will allow the administration to have direct access to state and local concerns)
- Advocates for state and local concerns by effect of federal mandates

e. Industry Liaison

- Directs communication channels for industry to regulatory on primary issues affecting the agricultural and food safety oversight of industry (industry can offer information on innovative processes)
- Communicates to other liaison positions on issues and information that industry may provide on issues of food security and regulatory concerns. (The linkage of communication between the consumer and consumer group liaison is also critical to the success of maintaining transparency and eliminating the appearance of industry favoritism. The net benefit, however, is that industry can provide valuable information to the success of the regulatory mission as an integral stakeholder in the overall protection of the food supply)

4. Risk Offices

While all tier offices in the administration would be important to establish a singular mission involving food safety and defense, the risk offices will occupy an important role in risk analysis (risk assessment, risk management, risk communication) of all food commodities. The research and finding that will come out of the risk offices will establish three primary items of importance on every food and agricultural community and the biological, chemical, radiological, and physical hazards associated with it. The three primary duties will be to provide information in a combined risk analysis of food and agriculture through the following.

- The **assessment** and identification of risk and hazards associated with all foods processed and unprocessed
- The **management** of all foods after risks are identified through development and use of appropriate codes, standards, and regulations as guidance to regulatory actions (preferably proactive and not reactive)
- The **communication** of risk to avoid lack of situational awareness

The separation of risk offices into a risk assessment office and a risk management office is purposeful. While there will be constant communication to achieve better transparency and awareness, the comparative analysis in Chapter V showed that there was concern among consumers in the countries analyzed for an open assessment of risk separate from risk management. The concern stemmed around the idea of government favoritism toward industry in promoting, for example, agricultural products for export. The concern grew from the idea that a direct link between an entity performing the assessment of risk and then also being responsible for direct management of risk (creation of standards, and regulations) would favor economic growth of the industry over protection of the consumer. While the conceptual model of a single oversight agency may seem to be a contradiction to achieving this separation, a division of roles between the two offices can be established to maintain transparency.

a. Risk Assessment Office

The risk assessment office will use science and knowledge of food and pathogens for the responsibilities of the following.

- Hazard identification
- Hazard classification
- Exposure assessment
- Risk categorization (Foodrisk.org, 2008)

The World Health Organization (WHO), Food and Agricultural Organization (FAO) (2004) in the Codex Alimentarius Commission Procedural Manual, Fourteenth Edition defines risk assessment as "a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization."

The risk assessment office would also serve as an outreach conduit for science, research, and risk analysis from the academic and private research done on food and agricultural processes. Information gathered via collaborative research can be tested to confirm risks, but the type of risk assessment information that can be provided through sharing information and research is immeasurable. This transparency of data across the

stakeholder sector specific to risks and hazards associated with food can be used to mitigate problems and create an atmosphere of trust by all stakeholders in food safety/defense initiatives.

b. Risk Management Office

The risk management office will use the information from the research performed by the risk assessment office to do the following.

- Develop statutes, standards, codes and regulations based on the assessed risks to the following
  - Reduce the impact of the risk
  - Reduce the likelihood of the risk
- Develop trade-offs of available options (for example, time temperature relationships using science and knowledge to manage risk) (Foodrisk.org, 2008)
- Apply the best practices to address risk (for example, the use of Precautionary measures until further risk assessment can be completed for unknowns)

The WHO/FAO in the Codex Alimentarius Commission Procedural Manual, Fourteenth Edition (2004), defines risk management as "The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options."[17]

The risk management office in a singular oversight agency would focus on reduction of multiple regulation, codes, and standards that have added to the confusion of regulatory oversight under the current system. For example, if three current regulations

[17] The only sticking factor in the definition of risk management from WHO/FAO is the possible favoritism and non-transparency created with the definition component, "for the promotion of fair trade practices." Risk management should focus on the risks and hazards for the protection of the health of the consumer and not on industry economics.

that were created by different statutes and mandates based on the same risk can be reduced to one, the benefit is immediately apparent from the cost savings from production of multiple documents alone.

c. Risk Communication

The WHO/FAO in Codex Alimentarius Commission Procedural Manual (2004) defines risk communication as "The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions."

Figure 11 depicts the importance of the risk offices and risk analysis as part of a continuous and circular process that will add value to protection of the food supply if the concept of the single food safety regulatory oversight is embraced.

Figure 11. Risk Offices Separate but Interlinked under the Food Safety Oversight Umbrella

5. Food and Agriculture Safety/Defense Offices

The consolidation of all food safety activities under a single agency umbrella will have benefits not only in increased standardization of the food safety system across all food commodities, but also in the increase the resources available to perform inspections of food at all levels, and should send a message of unity and consistency to consumers

and the industry. A clearer picture of a once larger-than-life maze of food regulatory agencies and standards should send a message of uniformity that has never been established across the U.S. food regulatory community.

a. Food Safety Office

The significance of a newly unified food safety office would be its charge to regulate, at the interstate and federal levels, the processing and preparation of all food commodities across the food supply chain, from farm to market. The revamping of antiquated statutes with the implementation of 21st century statutes that encompass proactive regulatory change can provide the consistency and a more definitive approach that food safety needs to keep up with increases in the size of the food supply chain. With the consolidation of the multiple food safety agencies and the reduction of statutes that are now being duplicated by multiple agencies with different standards, methods, and mandates, the food safety office and its personnel would be standardized across all food commodities.

With fewer but better-defined statutes and the consistency of inspection management tools, a baseline by the food safety office could now be established to monitor effectiveness of food safety inspections, basing frequency on risk factors. This will allow increased frequency of visits to facilities that may have fallen through the gaps because of limited resource factors and allow more flexibility in priorities associated with tracking sources of foodborne illnesses.

With consolidated resources, the food safety office could also be able to focus more resource and time on imported foods. Once again, the limits placed on inspections of imports based on multiple agencies would no longer be an issue. More time could also be placed on statutory change that should incorporate a certification system for foreign governments or food establishments wanting to import foods into the United States. Working with the agency liaison office and its protocols, the food safety office could also establish properly negotiated trade agreements with the industry and other parts of the U.S. government, with food safety as a top priority. Countries wishing to import into the United States would have to meet a standard format of requirements

and agreements through a single agency. Instead of working through several agencies with differing standards and protocols, there would be a straightforward and less confusing coordination of process.

As previously mentioned, a major component would be the establishment of trace-back and recall authority from point of origin to retail sale. The office of food safety, regardless of the commodity, would establish a protocol that can call on all resources available to manage the recall or trace back responsibly and correspondingly. This component alone is a large part of the recent sluggishness during the last few years to identify sources and food vectors of contamination in national outbreaks. Point-of-origin requirements would provide the food safety office with the ability to halt products responsible for contamination more quickly, even if only ingredient components of processed food products are implicated.

b. Food Defense Office

The food defense office would have responsibility over evaluating the readiness of the food/agricultural industry from a physical infrastructure, preparedness, and situational awareness perspective in reference to the possibility of intentional contamination of the food supply. There are concerns that in most cases it is hard to determine, from among the more than 250 foodborne diseases caused by a variety of bacteria, viruses, parasites, and toxins that can be associated with foodborne illnesses, whether a food contamination was unintentional or intentional (U.S. Centers for Disease Control, 2005). In harmony with the purpose of overall food protection and security, the food safety and defense offices are interlinked with each other. The food defense office would closely coordinate with the food safety office on standardization of mission, understanding that in case of a large unintentional contamination event, such as tornados, hurricanes, ice storms, and power failures, that the organizations that produce foods are prepared and would require immediate contact for protection of the food supply. The same process of food safety and food defense can be coordinated on both sides of the framework to work together for a common cause. The current system is not set up to use

the combined expertise needed to coordinate efforts, especially with the formation of several food defense offices in the various agencies that would be responsible for food safety and food defense.

While the probability of intentional contamination of the food supply is thought by some to be low, the fact remains that the food/agricultural infrastructure and food supply remain targets of interest for terrorist organizations. A survey by Stinson, Kinsey, Degeneffe, and Ghosh, (2007) published in the *Homeland Security Journal* showed a high percentage among U.S. respondents polled (4,260 persons), who said they were concerned about the possibility of deliberate contamination of the food supply from a terrorist attack. Table 2 shows some of the data from the survey specific to food.

Respondents Who Said They Were Concerned About *Deliberate* Chemical or Biological Contamination of a Common Food Product			
In Polled Persons Lifetime	In Next Four Years of Polled Persons Life	Allocation of Funds for Target Type – Food and Agriculture	Allocation of Funds If Post-Scenario Event
77 percent	44 percent	19.3 percent (Ranked Highest)	22.88 percent (Ranked Highest)

Table 2. National Survey of Attitudes of Terrorism (From: Stinson et al., 2007)

Preliminary results of a survey about perceptions that Americans have toward homeland security conducted by Stanford University and NPS/CHDS professor Jim Breckenridge (Breckenridge, personal communication, 2008), of 400 polled individuals, showed that 23.2 percent of the respondents polled saw contaminated food problems as a matter of great concern. The concern about protection of the food supply ranked third on a list of homeland security concerns that Dr. Breckenridge presented in the survey related to fears of attack by terrorists. These data provide evidence that the U.S. public will support the use of resources in the interlinked food safety and food defense offices within the framework. Food defense has been defined as “a collective

term to encompass activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering. This term encompasses other similar verbiage (i.e., bioterrorism, counter-terrorism, etc.) (FDA, 2008)."

6. Education and Awareness Office

With the many incidents of food-related illnesses in the last few years, the significance of education cannot be overemphasized. Awareness of the vulnerabilities and causes of food-related illnesses, in even general terms, can create a platform for growth of positive understanding of the nature of food and agricultural contaminants. Also, awareness provides a cadre of citizens who can be the extra eyes and ears that can help to protect the food supply from intentional contamination. Learning to recognize incidents and abnormal activities could have a positive affect on food safety/defense at all levels of the food supply chain. As knowledgeable consumers, citizens will know what to do to protect their health if natural disasters occur by knowing when foods could be a hazard and which foods are safe.

The education and awareness office would interlink with the other tier levels in the agency to promote a culture of innovative training and an educational opportunity to improve information sharing, both vertically and horizontally. The staffing and tools developed by the education and awareness office would be designed to take advantage of the latest techniques and technologies to enhance knowledge.

The education and awareness office would develop and deliver tools to do the following.

- Provide and communicate information on foodborne illness prevention strategies that is consistent, timely, and up to date
- Create technological learning portals for consumers, state and local regulatory employees (including law enforcement and first responders), and industry for assessment of their food safety and defense knowledge; create an interactive learning environment for a food safety/defense culture that is proactive and response driven (web sites, social networking system similar to Twitter, Facebook)
- Create a "take it on the road" campaign for all 50 states and territories on food safety education coordinated with state and local regulatory officials

- Provide staff in all 50 states that can help create food safety educational programs within their regulatory, industry, consumer, and academic communities. This will help establish consistent and collective education instead of separate conflicting education on food safety information. Again, this would bring proactive prevention through learning.
- Elevate food safety through use and partnership with the media throughout the country. This will help develop a consistent message through collaborative efforts.
- Create a system based on technology to monitor education and training efforts to create a database of learners and trainers who can monitor success of food safety and education across all stakeholder spectrums

The education and awareness office could create a new culture of food safety/defense in the United States. The old culture of selective education about food safety, based on budgets and selective grants only used by a few organizations affiliated with primary agencies, including the DHS Office of Health, would be a non-issue in the new agency. All funding and food educational efforts could be coordinated through the new agency office and with the interlinking system through the liaison office and other offices in the new structure to other agencies such as DHS for food defense studies.

7. Epidemiology and Surveillance Office

A new oversight agency office set up only for the purpose of food-related illness surveillance and epidemiology could provide a system of consistent and non-distracted focus on foodborne illness alone and a budget allocation to match. Interaction with state laboratories for testing, state and local food protection programs for investigation response, and surveillance for food-related problem patterns could be expanded. A dedicated office with sufficient budget and resource allocation to improve monitoring, surveillance, and epidemiologic capacity to assist federal, state, and local partners would address the national goal of reduction of foodborne illnesses. This should create the data necessary to drive a proactive prevention strategy that moves beyond the reactive and response-driven after-the-fact situations that often occur. The interaction and connectivity to education and awareness, risk assessment, risk management, and liaison offices can drive communication of risk and solution emphasis if adjustments need to be made to strategy. It would involve one agency rather than many.

The epidemiology and surveillance office would focus on the following.

- Increased connectivity with state and local agencies and their respective laboratories to increase data capacity through surveillance and epidemiological investigations (Technological bridges, web sites such as Twitter and Facebook to share information)
- Resource and budget allocations to help states and local systems increase capacity for surveillance, testing, and epidemiological investigations
- Standardization of methods that would be consistent throughout the nation and a movement away from different methodologies. (The new agency would coordinate with state and local agencies to develop a method that is productive and workable for all)

Legislation from Chapter VI under the section heading "Enhancing the Current Regulatory System—No Widespread Changes" entitled Food Safety Modernization Act [S. 3385] in the 110th Congress actually would, if modified to fit the proposed model, assist in increasing surveillance and epidemiology. It would be a good fit as far as legislation goes within the functioning of the epidemiology and surveillance office, and when considering the process model.

Identification of the cause of illnesses and vectors associated with food-related illness is important to reduce the incidence of foodborne illness outbreaks. Active surveillance is important to track the pathogens or chemicals responsible for an illness. Surveillance and epidemiologic evidence are important elements to prevent illness, and also to identify and stop the disease from spreading once it has started.

8. Intelligence and Law Enforcement Office

A single-focus agency would promote a unified approach to law enforcement and intelligence in relationship to food commodities. The new focus would allow for direct interactions by one agency, rather than several, on issues that involve intentional threats or investigation of unintentional contamination of food commodities, to partners in the state and local food regulatory community, the law enforcement and responder community, and the national law enforcement and intelligence communities.

The intelligence and law enforcement office in the food safety and defense oversight agency construct would do the following.

- Assist with intelligence gathering specific to food and agricultural products as subject matter experts for analysis of threats to the sector based on intelligence by
    - Directly interacting with the intelligence and law enforcement community, and regulatory community is the state and local offices
    - Providing continuous and coordinated links to subject matter experts in the risk assessment, education, and awareness, the epidemiologic and surveillance, liaison (communication and message delivery) offices, and the coordinating and state field and industry affairs community offices.
- Establish a single conduit for investigation of prohibited acts and penalties for food safety laws
- Assist with the enforcement of provisions established through new statutes for administrative detention, holds, and condemnation of food commodities

Enforcement, along with intelligence gathering and analyzing of different aspects of food safety data pertinent to the external and internal threat protection, security, and defense of food and agriculture, has been eclectic at best. Differing regulations, statutes, and codes have limited what has been done in this facet of the new order of food safety. Federal, state, and local law enforcement and responder communities are still not fully aware of their roles in defense of the food supply from intentional contamination.

A 2006-research report document reprinted in 2007 issued from the U.S. Department of Justice, Office of Justice Programs, National Institute of Justice, Research for Policy, entitled *Agroterrorism—Why We're Not Ready: A Look at the Role of Law Enforcement* touched on only one aspect of the food commodity spectrum. However, it touched on an issue that shows the confusion of the law enforcement community about what their role in food and agricultural security will be and should be. The report, in its conclusion, discussed creation of a coordinated national plan for law enforcement to prevent, respond to, and ultimately recover from an incident of agroterrorism (Schmitt, 2007). The role of law enforcement and intelligence gathers will go beyond agriculture to include all food commodities. The 2006 report was a beginning in addressing the concerns for law enforcement's role in food defense. It also brings the issue of food security/defense to the forefront, and shows the complications of strategy associated with

the law enforcement and intelligence communities and their roles in national security for the food/agricultural sector. The creation of a combined intelligence and law enforcement office would help bring clarity to this important security role in food protection.

9. State and Local Affairs Office

With field offices located in each state and territory, the state and local affairs office would have a direct link to the state and local inspection systems that oversee protection of most of the food supply that reaches consumers at the retail level. The interactive approach creates a linkage, as is the case with regional offices of the FDA and USDA that exist separately today, with the state and local offices on interpretation and standardization of food safety assessments and approaches to food safety inspections. At present, the safety and security of food is divided by agency interaction, retail to FDA, and agricultural wholesale tied to USDA and FDA, depending on food commodity type. It is often left up to the state retail inspection and agricultural wholesale inspection agencies to fill the divide created by federal mandates on commodity types that may fall through the gaps.

The state and local food safety affairs office would do the following.

- Guide standardization of inspections and statute interpretation, regardless of food commodity. Food safety risk factors and sanitation standards would be interpreted clearly for each food facility.
- Create a local link to the federal food safety network in the state-specific and dedicated only to food safety. (For example, the current FDA structure has limited regional staff dedicated to food safety. FDA consumer safety officers assigned to most states may have primary duties in medical device safety or other products regulated by FDA)
- Create a link between the federal food safety affairs office and the state and local offices on educational collaboration on education of food safety to consumers and the regulatory agencies on new information about food safety. This would be part of the collective effort and communication channels created up to the educational and awareness office.
- Provide an additional conduit for concerns that state and local agencies have regarding issues not addressed in the food safety system. Innovation on food safety can come from all levels. Efforts to improve food safety

through smarter practices need to have support along any access point within the food safety regulatory system to build true collective solutions and collaborative processes.

The food and agricultural industry office mission would be the focus it places on the industry and its delivery of safe food products. The men and women in the field would be the consistent link to the industry and its food safety programs of the facilities and states in which they are located. The industry affairs office also would act as the support and inspection mechanism for areas where ports of entry are located in the United States. The port inspections would focus a single agency on all points through which food and agricultural imported products enter and exported food products exit. This would also be an enhancement of the Department of Homeland Security's role in food defense with an increased presence of food safety and regulatory experts.

Also improved, similar to the state and local affairs office, would be the following.

- Standardization of inspections in industry processing and production plants to include increased or decreased inspection, depending on risk analysis. (Any decrease would be dependant on inspection history, potential risk or hazard of the food product itself, and the created ability to focus on more troubling problem facilities, for example, the peanut manufacturing facility responsible for the recent outbreak associated with the Georgia manufacturing plant)
- Increased education on food safety to industry, in conjunction with the food safety and defense education of the industry of each facility
- Increased inspection, assistance, and consistency with industry facilities in improvement of food defense plans
- In trace-back situations in foodborne illness outbreaks, working directly with food manufacturing plants in each state on evaluation of product, to eliminate or link like products and ingredients, to specific outbreak information. (Proactive response, instead of a reactive response, would also build trust of information sharing when contaminants found are not intentional.)

In times of crisis in a national outbreak, the use of staff from both the state and local affairs and industry affairs offices, which would be a shared location, could establish a cadre of staff that could be quickly combined for identifying food-related

contaminants. The relationships established with the state and local regulatory food safety systems could also lead to regular contact among the state, local, and federal regulatory system.

D. CONCLUSION

1. The Agency for Food and Agricultural Specific Oversight

A new food safety and defense oversight agency could establish a unified system that encourages replication of the system at the state and local levels. Replication of the new federal system would assist in a complete merger of the food safety regulatory system in the United States into a collective food safety culture. The mission of a single food safety and defense oversight system at the federal agency should lead to this unity of operation. A complementary food safety regulatory system at all levels—federal, state, and local—would enhance communication and create balance. Food safety codes, regulations, and inspections based on the same system would lead to consistency and streamlining and provide order to the complexity associated with multiple bureaucracies.

The new federal system would require innovative leadership and employees, each with a stake in the new concept's success. Regulations and standards at the federal level would require straightforward wording to avoid the complexities that often occur in the current system when regulations and code standards are forwarded to the states for consideration and adoption. The conceptual design framework presented in this chapter hopefully will stimulate the ideas of those with the power to produce the mechanism for innovative movement to see such a change occur. The advancement of food safety will never see its full potential unless a move to a single voice for food safety and security is formed. The concept framework presented would once again bring the United States forward as a society with a tradition of being innovative, progressive, and a world leader.

2. Why Should We Move Forward?

As stated in the book *MegaCommunities,* by Gerencser, Van Lee, Napolitano, and Kelly (2008), the concept of working together as a network is not to detract from the

individual, but to add strength to the collective when challenges need a larger set of resources and skills to solve problems that face the greater community. A move to a single agency would be a positive step toward building a megacommunity within a unified framework where the collective minds and skills of those dedicated to the food safety workforce could truly help and learn from one another.

All are charged, including the industry and academic research components of the infrastructure, in preventing illnesses and preparing for both the unintentional and possible deliberate attacks on our food and water supplies, and protecting our citizenry from harm. A unified system can be described as a smart practice. With that in mind, Eugene Bardach (2006) describes a "smart practice" as a practice that takes advantage of some latent potential in nature to achieve a goal at relatively low cost (pp. 28–47). The strategy of multiple organizations or agencies converted to a single agency for oversight of food safety exposes the latent potential for better collaboration and efficiency. It also creates an internal mechanism focused and coordinated towards food safety and smarter information sharing and food protection activity on a new level. A single agency can create this culture. The potentially lower cost of such a process makes it a smart practice because it allows redundancy among individual agency systems to be eliminated, at all times, but especially during national food-related illness outbreaks when coordinated efforts are needed to manage and respond to threats.

Bardach explains that an "interesting idea" in a practice is also considered a "smart practice." He prefers the term "smart practice" to "best practice" because any practice worth special attention should have something clever about it. It is the clever part of the practice that must been analyzed, characterized in words, and appraised as to its application to the situation (Bardach, 2005). The idea of a new organizational community for handling food safety creates an interesting idea and a clever strategy that merits the title "smart practice." The idea behind such a collaboration strategy identifies a system that would provide a single and proactive focus to all aspects of food safety/defense. This type of agency culture and the atmosphere created from a concept that is new and innovative would allow everyone involved to be on the same page and part of the creation of positive change.

C. F. Kurtz and D. J. Snowden (2003) in their article on sense-making provide a good descriptive lesson on the challenges faced when trying to describe and change organizational structures to be more effective. They called their sense-making model the Cynefin Framework. The framework consisted of ordered and unordered domains that challenged organizations. At present, each agency in the current system with food safety responsibilities has its own standard operating procedures (SOPs) within their field of expertise. Some of the discipline SOPs are *known* to work based on predetermined practice, while other SOPs *are knowable* in the sense that expert advice on the data being analyzed shows that a new SOP should work (Kurtz & Snowden, 2003). There can be an underlying sense that what is known or knowable should work in all situations as part of the *ordered* domain, and that a change to a new system would disrupt order in food safety. However, in the real world when an outbreak, a disaster, or threat occurs, one discipline may not have all the available resources and expertise to perform every function needed to handle the situation. In the domain of the *unordered* where *chaos* may rule the moment, quick, imaginative, and decisive decision-making may be necessary, which can be a decision that no one agency at present, based on differing statues alone, may be prepared or allowed to make such decisions (Kurtz & Snowden, 2003).

Also in the area of the *unordered* domain, which may play a part in a disaster or threat scenario, is the concept of *complex relationships*. Collaboration among multiple agencies can be a complex relationship. In these types of collaborations, there is often a feeling that “my way is better than your way,” while in fact, both ways may have merit. For example, collaboration especially during a chaotic situation, such as natural disasters like a hurricane or a tornado can be complex if the agencies or disciplines involved in response and recovery have not already agreed on how they will work together. As Kurt and Snowden reported in their studies on sense-making, this is the time to “stand still” (but pay attention) and gain new perspective on a situation instead of only relying on patterns of experience to determine response (2003). Kurt and Snowden also wrote that the domain of the *disordered*, the central space, is where individuals compete to interpret on the basis of their preference for action. While they may agree on the context, they are

considering from the four domains, this central area is where there can be contention (2003). A central food safety oversight agency will help move the food safety regulatory system out of this area of conflict or disorder.

Each existing agency will have something to contribute to the concept agency in building its initial structure. The people who make up the current agency workforce would become a part of the new agency. It is important for all to recognize that they will be involved in the success of the system as equal collaborators. The system that they collaborate to build can provide real examples of how effectively such a system can operate and how different disciplines can merge and work together to build better relationships and a smarter system. Such an agency can help close the gap in the disordered center space on the food safety/defense equivalent of the Cynefin framework; or at least, provide a bridge across the area of disorder into all four domains.

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VIII. CONCLUSIONS AND RECOMMENDATIONS

A. WHERE WE ARE NOW

An argument of some food safety leaders is that wholesale change is not needed under "my watch." Another argument is that each individual agency was given the responsibility for different aspects of the food supply for a statutory reason and therefore change is not immediately possible and is not necessary.

The observation by leaders and agencies is that with minor alterations to existing statutes and additional funding, they will be able to keep up with the challenges of protecting a food and agricultural food supply chain that has gone global. With consumer demand for more food product choices and seasonal fruits and vegetables year round, the daunting task of tracking and controlling the flow of food products is constantly growing. Protection of the food/agricultural supply and prevention of contamination along the global food supply chain is a monumental task that takes tremendous resources and open-minded leaders committed to a better system.

The current maze of departments and agencies consists of five executive branch departments and agencies, several primary and secondary agencies, and ancillary departments and offices under each of these executive branches. Looking back since 1862, each regulatory body was formed as a reaction to individual crisis and events, rather than proactive innovation. Decisions had to be made regarding how to protect food commodities in a changing environment. Food product distribution and demand once controlled in smaller rural markets were growing into larger urban and national markets. Food protection issues on food commodities changed in many ways. For example, increased quantities of potentially hazardous food commodities now in the supply chain were transported over longer distances to reach market, and there was increased handling of food products during processing and distribution.

The chances for food to be adulterated or become contaminated increased based on the variables of time, distance, and handling of products. The probability for increase in food-related illnesses created food safety and regulation issues and concerns from

citizens. Decisions were made for change in the regulation of food commodities related to sanitation and food safety based on what the leaders at the time perhaps deemed as necessary to stem the tide of probable increases in foodborne illnesses.

The policy for improvement in the food safety regulatory structure we see today has been forged from reactive responses and concern for the safety of the food supply, the citizens, and the vitality of the nation. Leaders and decision-makers have often expressed concerns for food safety issues and their effect on consumers and the nation. However, their reactions in most part are due to the effect of the outbreaks on the consumers and the nation at the moment a food-related outbreak occurs and the generated media coverage. However, as new regulations or statutes have been added, each new addition sometimes produces more layers of confusion as to how the government goes about addressing food safety. The country's leaders and lawmakers, when pressed to make changes, bring about milestones in the history of food safety laws, but no true forward-thinking change (U.S. Food and Drug Administration, 2005). However, the present regulatory structure and associated statutes to protect the food supply for different food commodities are the result of the reactive decisions of past leaders. The history of the food safety regulatory structure and the creation of our extensive web of agencies with regulatory authority in food safety show how complex a system can become with a purely reactive approach to food safety. Underlying all of the negative connotations of change are the many reorganizations that would be required, as shown in Chapter VI, if different components of various laws were to be passed and enacted into law. Chapter V indicated that restructuring a complex system into a more streamlined system is possible without a great deal of discourse if the path to change is a focused one. Positive cultural and structural change can be accomplished based on the strength of what is thought to be best for the country by informed and trusted leaders.

The possibility of consolidating food safety in the United States and centralizing regulatory management programs have been discussed by Presidents and their administrations since 1969 when the Nixon administration examined, but dismissed the

idea because of the maze of differing statutes and laws (Curran, 2003). Consensus about what is best for the food safety regulatory system has been difficult to achieve, but concern over food safety will continue until a better system is developed.

B. WHERE WE SHOULD GO

The overarching intent of this thesis is to stimulate discussion and prompt legislative debate toward the creation of a single food safety oversight agency. Based on comparisons discussed in this thesis and the conceptual model proposed, a single food safety agency with a dedicated and non-bifurcated system has been proposed. A single food safety agency would simplify the question of who ensures the safety of which food commodity and how those commodities are inspected. If food is imported from other countries, information about requirements and who oversees those requirements can be acquired without considering the specific ingredients or type of food that is involved.

Investigations of national food-related illnesses would be handled from a single agency with multiple resources available to trace back products and based on authority to require product tracking from the farm to the consumer. Research and information about threats to the food and agricultural system would be shared through open lines of communication and continuing education on biological, chemical, and radiological threats and how to manage and prevent threats. Responsibility for protection of the food supply is essential and should be required from all stakeholders, farm to table. Everyone, federal, state, and local regulators, industry, food science academic and private research groups, citizen groups, and citizens themselves, with the proper information should be part of enhancing the new system.

The concept of a single food safety system as presented would involve complex discussions, changes in laws, and a consensus among food safety organizations regarding effective legislation. The creation of the single food safety oversight agency would require intense and dedicated negotiation and commitment. Decision-makers would need to work with regulatory leaders at the executive branch and department levels at both the federal and state levels so that everyone understands why this change is necessary. These decision-makers must rely on valid research and innovative concepts that gather superlative information and focus toward the best interest of the nation, in terms of its

citizens, national security, and the sustainability of the vital resources within the food/agricultural infrastructure. It also requires Congress to establish a focused committee structure in both chambers of Congress (Senate and House), perhaps by a combined committee dedicated to all food issues. The result would be a more streamlined approach to food safety oversight from many committees to only one or two. Bipartisan and combined House and Senate committees should be included in these congressional committees. There is no reason for multiple committees on food safety/defense. Currently, hundred of pieces of legislation are presented during each session of Congress on food safety issues. The sheer volume of legislation leads to many pieces of legislation that are not acted on because they are lost in the mix of numerous proposals.

It is important to bring together the best components of the present food safety regulatory systems across agencies, to consolidate resources, and create a collective body that is under one organized oversight body. This would also help coordination of national efforts on food safety threats, whether intentional or unintentional, manmade or natural. This should, in theory, lead to a transparent organization that is more efficient while also providing accountability for food safety issues that arise.

Food products can be transported in a day's time to anywhere in the world. With its vast distribution network of growers, producers, processors, suppliers, and consumers, the U.S. food sectors are vulnerable to attack at any point in the supply chain.

The past few years of illness outbreaks related to food products contaminated from many sources and different pathogens should be a wake-up call for anyone concerned with food safety. Consolidations of food safety systems that have been accomplished in other countries give us models of what is possible. It would be a disservice to our citizens not to explore the concept of a single food safety agency.

C. A NEW START—PUTTING IT ALL TOGETHER

At a strategic level, there must be a starting point. It all could start with productive discussions about food safety/defense.

1. Baby Steps—A Beginning Through Dialogue

From the author's analysis, recommendations include an initial move toward passage of the "Food Safety Authority Modernization Act." Analysis shows this act to be part of a process that would be a smart practice in developing ideas toward gaining bipartisan and stakeholder support for the proposed Safe Food Act, which is in line with the model presented in this thesis. It would provide a forum to discuss and strengthen support for all around enhancement of a more modern food safety structure and more harmonious statutes. The next step in the process could be to consider the Safe Food Act, based on innovation and collaboration garnered from the bipartisan efforts of the Food Safety Authority Modernization Act discourse. It is important to build on and enhance ideas, as long as the movement is toward consolidation of the regulatory system. The author's recommendations, if acted on by Congress and signed into law by the President, it would set the course for modernization of the U.S. food safety system.

Progress will not take place unless someone steps forward with a plan and has the skills needed to form a collaborative structure to build innovative solutions. While an agreement to move to a single agency is the focus of the thesis, security of the food supply may require an initial first step prior to implementation of new statutes and a new agency. The role of the Department of Homeland Security could be part of that first step.

2. The First Step—Homeland Security and the Food Supply

The role of the Department of Homeland Security in food defense would be enhanced by a single food safety oversight agency, since issues affecting defense would be coordinated through this new agency instead of through several branch agencies.

Pending creation of a new food safety oversight agency, the concern for defense of the food infrastructure could find immediate benefit from passage of existing legislation in the Burr-Collins Senate Bill entitled, "National Food and Agricultural Defense Act." As described in Chapter VI, this act attempts to fill the gap about how we share information. It would create a consolidated national food defense plan for protecting our food infrastructure. In the author's analysis, there should be immediate

consideration of this legislation. While it would not create a single food safety agency and would maintain the existence of the USDA and the FDA, it would put greater emphasis on requiring these agencies to develop a coordinated national plan for food emergency preparedness, detection, response, and recovery. The act could also improve information sharing at national and state levels and in the public-private sector. Such a coordination plan would also be in line with Homeland Security Directive-9.

3. The Importance of Leadership and Seeing the Big Picture

Any move toward consolidation of the food safety regulatory system will take strong leadership and a desire for improvement. Strong leadership and the desire to protect citizens influenced the call for the food safety regulatory changes made in each country discussed in Chapter V. It will take a tremendous leadership effort outside the usual norms of traditional leadership, from the initial formation of a new food safety/defense oversight agency and beyond to create and operate the agency. It may demand what Marcus, Dorn, and Henderson (2005) loosely defined as "meta-leadership" in their article on national emergency preparedness and government connectivity.

Meta-leadership is a leadership type that focuses on the overarching "bigger picture." It involves leaders who see the need to cross-organizational lines, to step outside of the silos created by individual organizations. These meta-leaders can reach out and guide direction to develop a shared common vision, course of action, and focus necessary to maintain momentum (Marcus, Dorn, & Henderson, 2005). These meta-leaders can be found at the highest levels of government, but more significantly, at all stakeholder levels. From the fold, innovative, diverse, and critically thinking individuals who are needed to move the concept of a new agency forward will come. "Meta-leaders are those who encourage people and organizations to extend beyond their traditional scope of interest and activity (Marcus, Dorn, & Henderson, 2005, p. 46)." Marcus, Dorn, and Henderson defined these meta-leaders as having the skills and capabilities of the following.

- - courage
- - imagination
- - persuasion
- - crisis management
- - persistence and leadership as a valued effort
- - curiosity
- - organizational sensibilities
- - conflict management
- - emotional intelligence
- - leaders who see meta-

in leading the effort to make the situation better for everyone (pp. 48–53). Marcus, Dorn, and Henderson say, "the tendency for individual bureaucracies and their leaders to promote silo-based objectives and entrepreneurial interests above their mutual responsibilities for preparedness must be overcome" (p. 58). All leaders when advocating change to a complex system need to encourage collaboration among other leaders.

4. Time to Move Forward—Creating Positive Change for Resiliency

Throughout this thesis, we have discussed a move toward a single federal oversight food safety agency to look beyond the trepidations and multiple reasons usually given for not wanting to streamline the U.S. food safety regulatory system.

A more resilient national system can be built with the unwavering passion of everyone who believes in a vision of enhanced food safety. Chris Bellavita (2005) wrote in *Changing Homeland Security: The Issue-Attention Cycle*, "In the absence of an active national consensus that terrorists are a clear and present threat to the lives of average Americans, the dynamics of the Issue-Attention Cycle are as inevitable as the seasons" (Bellavita, 2005, p. 1). Bellavita based his Issue-Attention Cycle view and the homeland security implications on the writings of Anthony Downs. As Bellavita wrote:

> Downs argued that certain issues follow a predictable five stage process: pre-problem, alarmed discovery, awareness of the cost of making significant progress, gradual decline of intense public interest, and the post problem stage. (p. 2)

In reference to food-related illness outbreaks and calls for improvement in our food safety system, we have been, over the last few years, in a perpetual issue-attention cycle. We are now and once again somewhere between stages three and five of the issue-attention cycle. When thinking critically about the positive aspects of change, the

tendency is to focus on the negatives and the growing pains that come with change. Leaders, stakeholders, and citizens need to focus on what a new system will do for food safety in the country, and not on what it will take away from the old system.

The advocates for change to the system need to build a network of trust among all stakeholders. The advocates for change need to show the value in creation of a new system and the added value that even those who are opposed would contribute to shaping our new system. Consensus leads to a stronger system.

A focused food safety oversight agency can create an environment of prevention out of what William Pelfrey (2005) describes as, a "cycle of preparedness." Pelfrey, in his article, *The Cycle of Preparedness: Establishing a Framework to Prepare for Terrorist Threats*, (2005), used the word "cycle… as a proxy for a dynamic, flexible, and continuous process of interaction and integration, and functioning as a self-organizing mechanism that improves preparedness for anticipated events and for the unimagined events." He goes on to say that a "…'cycle' implies a repetitiveness, in sum as well as in parts, that is consistent with 'preparedness.' Preparedness cannot be proclaimed or finished; it is an ongoing process with constituent parts or phases working in, or being available to work in concert" (p. 5). A single food safety oversight agency can benefit from Pelfrey's description of a preparedness cycle. Pelfrey also acknowledges the great importance of "prevention" in preparedness, along with awareness, response and recovery as part of the four phases of the cycle (p. 4). The challenges for food and agricultural safety will continue to weigh toward prevention of food-related illnesses. Pelfrey goes on to identify collaboration and information as necessary elements for the application of prevention, even to the point of being the most essential parts of prevention (p. 7). The proposed change to a single food safety oversight agency and regulatory system will consolidate the principles of collaboration and information sharing through communication aimed at a smarter focus on prevention and preparedness.

5. Look Forward and Not Back

If we fail to provide the best protection to the food infrastructure because of fear of criticism, then we may fail to support the survival of our nation. We have continued

down the same path for more than 100 years. It is time for a paradigm shift to recreate the mold of food and agricultural safety oversight. A single structure formed from the smart practices of lessons learned and new ideas will encompass a path of focus, creativity, and innovation. Strong and innovative leadership is necessary for success of a new agency.

a. Strong and Innovative Leadership Required

Leadership is essential for change. In a complex system change, a single leader may not be able to handle all of the needed planning alone. It will take a cadre of leaders at all levels initially. John Bryson, in his book, *Strategic Planning for Public and Nonprofit Organizations* (2004), explains a collaborative type of leadership needed in strategic planning:

> The tasks of leadership for strategic planning are complex and many. Unless the organization is very small, no single person or group can perform them all. Effective strategic planning is a collective phenomenon, typically involving sponsors, champions, facilitators, teams, task forces, and others in various ways at various times. Over the course of a strategy change cycle, leaders of many different kinds must put together the elements we have described in such a way that organizational effectiveness is enhanced – thereby making some important part of the world outside of the organization noticeably better. (p. 316)

Once the new agency is formed, a new type of leadership philosophy would be necessary for success. Government organizations have always relied on a centralized type of leadership, and this may be hard to change completely in the early stages of a new system. However, while a centralized leadership with a single focus on food safety would need to be established at the top of the conceptual food safety pyramid structure, this author believes that there also needs to be a decentralization of the agency structure up and down the pyramid if the system is to be successful. Innovation and ideas need to flow from the bottom up to the top also. The creation of a combined system that allows communication and the talents of the whole organization will be essential to the success of the new agency. Innovative and collaborative leadership will help create a forward-reaching organization.

b. A New and Progressive Type of Organization

The type of organization the author envisions for the new regulatory agency is one that has been identified as a *hybrid organization* by authors Brafman and Beckstrom (2006) in their book, *The Starfish and the Spider* (2006). The organization is one that is a combination of both a centralized and decentralized organization. The hybrid organizational approach to the single food safety administration will allow for a flow of innovative ideas from within all areas of the agency. This is needed for complete success of the proactive concept. The concept will also complement the strengths that will be identified from the current regulatory structure that should be kept. The collaborative efforts in the new system will be at the heart of an organization that can be innovative and new, but melded from the smartest processes of the old system. Brafman's and Beckstrom's (2006) idea of a hybrid organization, if used in the new agency, will combine the bottom-up approach of decentralization and the structure, control, and resulting potential of centralization as they describe it, through positive and innovative collective efforts.

Brafman and Beckstrom identify the decentralized portion of a hybrid organization as similar to a starfish. The authors explain that if any of the five legs on a starfish are removed, a new starfish is created from the removed segment that is able to function on its own. However, in a decentralized structure, if the five legs are functioning together, the starfish becomes an unstoppable force. They identify the five legs to represent (*and the author relates these to the new food safety agency*) as follows.

- Leg 1—a circle (All parts of the new food safety agency form a collective component of the overall structure, each with the ability to be autonomous in their day-to-day activities)
- Leg 2—the catalyst (All parts of the new food safety agency contribute to the success of the whole. Innovation from anywhere in the structure gives the spark needed to improve the process, and then transfers back to the circle or agency as a whole)
- Leg 3—ideology (The guiding principle of food safety/defense built on a base statute that is strong and supported by all within the agency structure. The base of the structural foundation ideology is being proactive, and the glue that binds the structure and keeps it strong)

- Leg 4—the pre-existing network (The new food safety agency with new statutes will be built partly on strengths identified as smart practices of the old system)
- Leg 5—the champion (The new agency needs leadership that is vigilant and passionate about the new food safety/defense system. The leadership will keep a continuous, non-static, and proactive approach focused on food safety/defense. Once a new system is in place, the champion will campaign for permanent strength and support for food safety in the United States with no divisions to take away from the importance of the infrastructure)

Overall, the new food safety oversight agency should be built on the strength of the collective components of people inside and outside the agency.

D. FINAL THOUGHTS—IMPROVED FOOD SAFETY IS WITHIN REACH

The recommendation here is that **the United States should create a single food safety oversight agency (administration) at the Executive Branch, or as an alternative, established as an independent agency to create greater transparency**. Either approach can meet the design of the conceptual model. A single agency can become a reality—a well-led agency guided by well-planned regulations, where coordinated efforts eliminate gaps in regulatory service and communicate standards for sharing information and intelligence seamlessly throughout the food safety regulatory chain. The agency would collaborate with both public and private food and agricultural stakeholders, and craft solutions for problems created over the years.

This recommendation sounds simplistic and may give the impression that such a change can be made overnight. Of course, it cannot. However, until such a move is completed, there will continue to be breakdown in communication between the different layers of the food safety regulatory system and ever-branching regulations, statutes, and interpretation in the United States. The existing multi-dimensional regulatory system continues to cause confusion and has led to diminished consumer confidence in the government's abilities to protect the food supply. Also seen in the eyes of consumers is a lack of transparency of the food safety regulatory process. Outbreaks of bacterial contamination in different components of the nation's food supply during the last several years have led to this call for change to the U.S. food safety system.

A new single food safety/defense oversight agency could deliver long overdue change. With open communication, ideas will flow from all parts of the organization and each level will play a role in strengthening the system and provide continuous improvements that can benefit the whole and improve the food safety and now food defense system for years to come.

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