

**DECISION-MAKING APPLICATIONS IN FOOD SAFETY AND FOOD
DEFENSE**

by

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Abstract

The Department of Homeland Security recognizes the Agriculture and Food Sector as a Critical Infrastructure and Key Resource—critical to the health and wealth of the United States. When food safety (i.e., unintentional) or food defense (i.e., intentional) issues arise, those in the Agriculture and Food Sector must quickly and efficiently make decisions to ensure the safety of consumers. Decision-making is an essential element in critical infrastructure protection and response.

Naturalistic decision-making (NDM) explores how people make decisions in real-world settings. Eight factors characterize the task and setting in naturalistic environments and include the following: ill-structured problems; uncertain, dynamic environments; shifting, ill-defined, or competing goals; action/feedback loops; time constraints; outcome with high stakes; multiple players; and organizational goals and norms. This thesis explores whether or not food safety and food defense educational programs incorporate methods that help professionals make good decisions. To that end, this thesis first examines the decision-making environment in responding to incidents involving food safety and food defense. Four cases involving food safety and food defense reveal the presence of all eight factors. As these factors complicate the decision-making process, this thesis then evaluates whether or not prevailing educational programs and tools aimed at preparing for food safety and food defense issues (i.e., HACCP and CARVER plus Shock) directly address the eight factors characterizing NDM settings. This is explored by “following” a hypothetical student in a food safety and food defense course. The information presented to the student was analyzed and this analysis indicates that the eight factors characterizing NDM settings

were addressed albeit to varying degrees. HACCP addresses action/feedback loops, time constraints, outcome with high stakes, and multiple players. CARVER plus Shock addresses action/feedback loops, outcome with high stakes, and multiple players. While HACCP somewhat addresses ill-structured problems and organizational goals and norms, it fails to address uncertain, dynamic environments and shifting, ill-defined, or competing goals. CARVER plus Shock somewhat addresses ill-structured problems; uncertain, dynamic environments; shifting, ill-defined, or competing goals; time constraints; and organizational goals and norms. In light of this, new approaches to training are needed to fully incorporate all eight factors.

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List of Abbreviations

| | |
|---------|--|
| BT | Bioterrorism |
| CAC | Codex Alimentarius Commission |
| CCFH | Codex Committee on Food Hygiene |
| CCP | Critical Control Point |
| CDC | Centers for Disease Control and Prevention |
| CDG | Career Development Grant |
| CDT | Classical Decision Theory |
| cGMPs | Current Good Manufacturing Practices |
| CIKR | Critical Infrastructure and Key Resource |
| CT | Counter-terrorism |
| DHS | Department of Homeland Security |
| EIS | Epidemic Intelligence Service |
| EPA | Environmental Protection Agency |
| FAO | Food and Agriculture Organization of the United Nations |
| FDA | Food and Drug Administration |
| FMEA | Failure, Mode and Effect Analysis |
| FSIS | Food Safety and Inspection Service |
| FSWG | Food Safety Working Group |
| GAPs | Good Agricultural Practices |
| HACCP | Hazard Analysis Critical Control Point |
| HHS | Department of Health and Human Services |
| HS-STEM | Homeland Security-Science, Technology, Engineering and Mathematics |
| HSPD-5 | Homeland Security Presidential Directive-5: Management of Domestic Incidents |
| HSPD-7 | Homeland Security Presidential Directive-7: Critical Infrastructure Identification, Prioritization, and Protection |
| HSPD-8 | Homeland Security Presidential Directive-8: National Preparedness |
| HSPD-9 | Homeland Security Presidential Directive-9: Defense of the United States Agriculture and Food |
| HSPDs | Homeland Security Presidential Directives |
| IDR | Interdisciplinary Research |
| INS | Immigration and Naturalization Service |
| MOSPB | Microbial Outbreaks and Special Projects Branch |
| NACMCF | National Advisory Committee on Microbiological Criteria for Foods |
| NASA | National Aeronautics and Space Administration |
| NBP | National By-Products Inc. |
| NCFPD | National Center for Food Protection and Defense |
| NDM | Naturalistic Decision-making |
| NIMS | National Incident Management System |

| | |
|------|---|
| NIPP | National Infrastructure Protection Plan |
| NPG | National Preparedness Guidelines |
| NRF | National Response Framework |
| NRP | National Response Plan |
| OIM | Offshore Installation Manager |
| PFGE | Pulse-Field Gel Electrophoresis |
| RPD | Recognition Primed Decision Model |
| SA | Situation Awareness |
| SOP | Standard Operating Procedure |
| TCL | Target Capabilities List |
| U.S. | United States |
| USDA | United States Department of Agriculture |
| UTL | Universal Task List |
| WHO | World Health Organization |

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Chapter 1: Introduction

Deliberate contamination of the nation's food supply is a real possibility and the economic and psychological implications of an attack on the food supply are sobering. Some foods are more susceptible to deliberate contamination than others, but there is no practical way one can eliminate the possibility of being affected. Food terrorism utilizes a vector that affects everyone.¹

The agriculture and food industries are immense.² Global agriculture and food trade increased from \$138 billion in 1975 to \$436 billion in 2001.³ Despite this growth and the underlying importance of the agriculture and food industries, recent events

¹ Thomas F. Stinson et al., "Defending America's Food Supply against Terrorism: Who Is Responsible? Who Should Pay," *Choices* 2007. 67.

² The author of this thesis laments the confusion regarding the terms agriculture and food industries, agriculture and food system, Agriculture and Food Sector, and Food and Agriculture Security. "Agriculture and food industries" is used to describe all aspects of agriculture and food production including production, processing, storage, distribution, and sales. "Agriculture and food system" is a term used in Homeland Security Presidential Directive-9 (HSPD-9) and encompasses all stages of agriculture and food production. "Agriculture and Food Sector" is a term used in the National Infrastructure Protection Plan (NIPP) that identifies this sector as a Critical Infrastructure and Key Resource (CIKR). "Food and Agriculture Security" is a Department of Homeland Security (DHS) research area and encompasses academic disciplines including food science and technology, biological science, and chemical engineering. The term "Food and Agriculture Security" is preferentially adopted, as the author of this thesis is the recipient of a DHS Career Development Grant (CDG) through the University of Minnesota's National Center for Food Protection and Defense (NCFPD), a DHS Center of Excellence. Department of Homeland Security, "DHS Research Areas and Related Academic Disciplines" (paper presented at the HS-STEM Career Development Conference, Washington, D.C., 2008).

³ Jean C. Buzby and Laurian Unnevehr, "Introduction and Overview," in *Agriculture Economic Report Number 828: International Trade and Food Safety: Economic Theory and Case Studies*, ed. Jean C. Buzby (Washington, D.C.: United States Department of Agriculture: Economic Research Service, 2003).

show that there are lapses in the safety of agricultural and food products.⁴ These events—caused by unintentional contamination—have extensive effects on public health, on the profitability of food companies, and on future consumer purchases.⁵ The United States (U.S.) Centers for Disease Control and Prevention (CDC) estimates that foodborne illnesses in the U.S. are responsible for 76 million sicknesses, more than 300,000 hospitalizations, and 5,000 deaths annually.⁶ If even a portion of these illnesses were a result of intentional contamination, consumer uncertainty in the food supply would likely develop into a national crisis situation.⁷

⁴ Recent events include the 2008 outbreak of *Salmonella* serotype Saintpaul associated with jalapeño and Serrano peppers harvested and/or packed in Mexico. More than 1,400 individuals in 43 states, the District of Columbia, and Canada were affected by the outbreak strain. Initially, tomatoes were implicated as the source of the outbreak; however, this was later disproved. For more information, see: Centers for Disease Control and Prevention, "Investigation of Outbreak of Infections Caused by *Salmonella* Saintpaul," <http://www.cdc.gov/Salmonella/saintpaul/>. Additionally, a 2009 recall initiated by Peanut Corporation of America involved facilities in Blakely, Georgia and Plainview, Texas. Peanut products including peanut butter and peanut paste used as ingredients in cookies, crackers, cereal, candy, ice cream, pet treats, and other foods were recalled as they were possibly contaminated with *Salmonella* serotype Typhimurium. As of March 25, 2009, 3,859 different products were recalled. Nearly 700 individuals became ill and several died as a result. For more information, see: Food and Drug Administration, "Peanut Product Recalls: *Salmonella* Typhimurium," Department of Health and Human Services, <http://www.fda.gov/oc/opacom/hottopics/salmonellatyph.html#update..>

⁵ Barbara A. Rasco and Gleyne E. Bledsoe, *Bioterrorism and Food Safety* (Boca Raton, FL: CRC Press, 2005).

⁶ Centers for Disease Control and Prevention, "Foodborne Illness," Department of Health and Human Services, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm.

⁷ Stinson et al., "Defending America's Food Supply against Terrorism: Who Is Responsible? Who Should Pay."

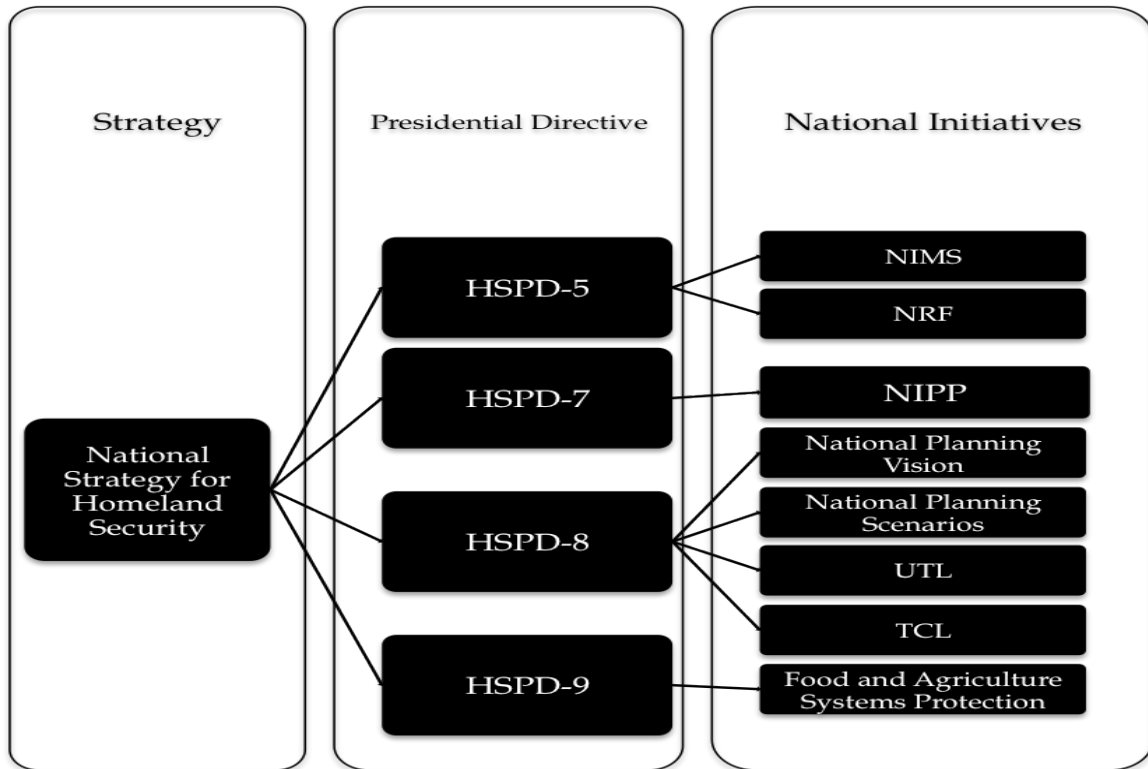
Critical Infrastructure Protection and Food and Agriculture Security

In recent years, protecting the U.S. infrastructure and its way of life has become a top priority and the focus of the Department of Homeland Security (DHS).⁸ Former President George W. Bush issued Homeland Security Presidential Directives (HSPDs) on areas associated with Homeland Security. Four HSPDs apply particularly to the Agriculture and Food Sector and each is discussed.⁹ Figure 1 depicts the relationship between HSPDs and the Agriculture and Food Sector.

⁸ Annette D. Beresford, "Homeland Security as an American Ideology: Implications for U.S. Policy and Action," *Journal of Homeland Security and Emergency Management* 1, no. 3 (2004).

⁹ Sharon R. Thompson et al., *Mgt 332: Agriculture and Food Vulnerability Assessment Training Course* (U.S. Department of Homeland Security, The University of Tennessee College of Veterinary Medicine, Western Institute for Food Safety and Security, New Mexico State University, Kirkwood Community College, Virginia-Maryland Regional College of Veterinary Medicine, The State of Tennessee, and Tennessee Office of Homeland Security, 2009).

Figure 1: National Strategy for Homeland Security¹⁰



Homeland Security Presidential Directive-5: Management of Domestic Incidents (HSPD-5) was issued on February 28, 2003, establishing a single National Incident Management System (NIMS) intended to prevent, prepare for, respond to, and recover from a terrorist attack, major disaster, or other crisis situation. This system allows for each sector of government to work together in an organized and constructive manner.¹¹

¹⁰ Adapted from: Stinson et al., "Defending America's Food Supply against Terrorism: Who Is Responsible? Who Should Pay."; Department of Homeland Security, "National Preparedness Guidelines," (Washington, D.C. September 2007). The presidential directives and national initiatives are discussed in subsequent sections of the thesis text.

¹¹ Department of Homeland Security, "Homeland Security Presidential Directive 5: Management of Domestic Incidents," http://www.dhs.gov/xabout/laws/gc_1214592333605.shtm.

Additionally, NIMS is the foundation for the National Response Plan (NRP), an all-hazards approach to domestic incident response.¹² The National Response Framework (NRF) replaced the NRP on March 22, 2008. The NRF explains how communities, tribes, states, the federal government, private-sector organizations and actors, and nongovernmental partners can collaborate to manage national response and outlines specific authorities and best practices for managing incidents.¹³

Homeland Security Presidential Directive-7: Critical Infrastructure Identification, Prioritization, and Protection (HSPD-7) was issued on December 17, 2003, creating a national policy to identify and defend the critical infrastructure and key resources (CIKRs) in the U.S. from terrorist attacks.¹⁴ Critical infrastructure, as explained in the National Infrastructure Protection Plan (NIPP) refers to “systems and assets, whether physical or virtual, so vital that the incapacity or destruction of such may have a debilitating impact on the security, economy, public health or safety, environment, or any combination of these matters, across any Federal, State, regional, territorial, or local jurisdiction.”¹⁵ Key resources, as explained in the *Homeland Security*

¹² Ibid. An all-hazards approach covers all conditions that can cause injury, illness, or death; harm or destruction of equipment, infrastructure, or property; or cause functional damage to social, economic, or environmental aspects of life.

¹³ Federal Emergency Management Agency, "National Response Framework," (Washington, D.C.: Department of Homeland Security, January 2008).

¹⁴ Department of Homeland Security, "Homeland Security Presidential Directive 7: Critical Infrastructure Identification, Prioritization, and Protection," http://www.dhs.gov/xabout/laws/gc_1214597989952.shtm.

¹⁵ ———, "National Infrastructure Protection Plan," www.dhs.gov/xlibrary/assets/NIPP_Plan.pdf. 109.

Act of 2002 include “publicly or privately controlled resources essential to the economy and government.”¹⁶ Table 1 summarizes identified CIKRs and Sector-Specific Agencies.

Table 1: Sector-Specific Agencies and CIKR Sectors¹⁷

| Sector-Specific Agency | Critical Infrastructure and Key Resource Sector |
|--|---|
| Department of Agriculture Department of Health and Human Services | Agriculture and Food |
| Department of Defense | Defense Industrial Base |
| Department of Energy | Energy |
| Department of Health and Human Services | Healthcare and Public Health |
| Department of the Interior | National Monuments and Icons |
| Department of the Treasury | Banking and Finance |
| Environmental Protection Agency | Water |
| Department of Homeland Security Office of Infrastructure Protection | Chemical Commercial Facilities Critical Manufacturing Dams Emergency Services Nuclear Reactors, Materials, and Waste |
| Office of Cybersecurity and Communications | Information Technology Communications |
| Transportation Security Administration | Postal and Shipping |
| Transportation Security Administration United States Coast Guard | Transportation Systems |
| Immigration and Customs Enforcement Federal Protective Service | Government Facilities |

The NIPP—in accordance with HSPD-7—outlines how CIKR protection activities should be implemented while recognizing and joining appropriate authorities, jurisdictions,

¹⁶ Ibid. 110.

¹⁷ Adapted from: ———, "Homeland Security Presidential Directive 7: Critical Infrastructure Identification, Prioritization, and Protection."

and rights of these partners. The Agriculture and Food Sector is one of eighteen identified CIKRs. The United States Department of Agriculture (USDA)—with jurisdiction over meat, poultry, and eggs—and the Department of Health and Human Services (HHS)—with jurisdiction over all food products other than those aforementioned—share responsibility for overseeing their respective CIKRs.¹⁸ Their plans, documented in May 2007, may be found in a multi-agency document entitled “Agriculture and Food: Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan.”¹⁹

Homeland Security Presidential Directive-8: National Preparedness (HSPD-8) was issued on December 17, 2003, establishing policies to enhance U.S. preparedness to prevent and respond to terrorist attacks, major disasters, and other crisis situations. HSPD-8 requires an all-hazards preparedness goal, with mechanisms for enhanced delivery of federal preparedness assistance to state and local governments. Procedures to improve preparedness capabilities of federal, state, and local entities are also included. HSPD-8 and HSPD-5 complement each other.²⁰ The final National

¹⁸ ———, "National Infrastructure Protection Plan."

¹⁹ Department of Homeland Security, Department of Agriculture, and Food and Drug Administration, "Agriculture and Food: Critical Infrastructure and Key Resources Sector-Specific Plan as Input to the National Infrastructure Protection Plan," (May 2007).

²⁰ Department of Homeland Security, "Homeland Security Presidential Directive 8: National Preparedness," http://www.dhs.gov/xabout/laws/gc_1215444247124.shtm#content.

Preparedness Guidelines (NPG)—released in September 2007—describe what preparedness for all hazards entails. Four components of the NPG are crucial:

1. ***National Preparedness Vision***: a concise description of the Nation's preparedness goal.
2. ***National Planning Scenarios***: a collection of 15 potential terrorist attack and national disaster scenarios intended for contingency planning for Homeland Security preparedness for government and the private sector.
3. ***Universal Task List (UTL)***: a list of 1,600 distinctive tasks that can assist efforts in preventing, protecting against, responding to, and recovering from events exemplified in the National Planning Scenarios.
4. ***Target Capabilities List (TCL)***: a list of 37 capabilities that communities, private sector, and government should have to adequately respond to disasters.²¹

Homeland Security Presidential Directive-9: Defense of the United States Agriculture and Food (HSPD-9) was issued on January 30, 2004, creating a national policy to ensure the safety of the U.S. agriculture and food systems. Terrorist attacks, major disasters, and other emergencies affecting the U.S. agriculture and food systems could have negative consequences on public health and the economy. HSPD-9 sets forth the following justification for this policy:

The United States agriculture and food systems are vulnerable to disease, pest, or poisonous agents that occur naturally, are unintentionally introduced, or are

²¹ ———, "National Preparedness Guidelines."

intentionally delivered by acts of terrorism. America's agriculture and food system is an extensive, open, interconnected, diverse, and complex structure providing potential targets for terrorist attacks. We should provide the best protection possible against a successful attack on the United States agriculture and food system, which could have catastrophic health and economic effects.²²

The seriousness of statements such as those quoted above has pushed those in the agriculture and food industries to allocate more time and money in efforts to ensure the safety of their products. To avoid confusion, definitions of food safety, food defense, food protection, and food security appear in Table 2. Worldwide, the U.S. government plays a key role in food safety and food defense efforts. These efforts include instituting safety standards, inspecting products, enforcing regulations, determining root causes of problems faced by those in the agriculture and food industries, and defending the U.S. food supply.²³

²² ———, "Homeland Security Presidential Directive 9: Defense of United States Agriculture and Food," http://www.dhs.gov/xabout/laws/gc_1217449547663.shtm#1.
1.

²³ International Food Information Council, "2007-2009 IFIC Foundation Media Guide on Food Safety and Nutrition. Backgrounder: Food Safety & Defense," <http://www.ific.org/food/safety/upload/foodsafetybackgrounder.pdf>.

Table 2: Terminology

| Term | Description |
|-----------------|--|
| Food safety | Food safety focuses on procedures and situations that protect food from incidental or unintentional contamination that can cause illness. ²⁴ |
| Food defense | “Food defense is the collective term used by the FDA, USDA, DHS, etc. 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 (BT), counter- terrorism (CT), etc.].” ²⁵ |
| Food protection | Food protection includes efforts that address both food safety and food defense issues to more effectively ensure a safe food supply. ²⁶ |
| Food security | Food security represents access to nutritious, adequate, and safe foods that meet the preferences and social standards of the consumer. ²⁷ |

Decision-making: An Essential Element in Critical Infrastructure Protection

When food safety and/or food defense issues arise, those in the agriculture and food industries must respond quickly and efficiently to ensure the safety of consumers.

Decision-making is an essential element of response. As stated by Hastie, three

²⁴ MedLine Plus, "Food Safety," U.S. National Library of Medicine and the National Institutes of Health, <http://www.nlm.nih.gov/medlineplus/ency/article/002434.htm>.

²⁵ Food and Drug Administration, "Food Defense Acronyms, Abbreviations and Definitions," <http://www.fda.gov/Food/FoodDefense/Training/ucm111382.htm>. 1.

²⁶ ———, "Food Protection Plan," U.S. Department of Health and Human Services, <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>.

²⁷ Economic Research Service, "Food Security in the United States: Measuring Household Food Security," United States Department of Agriculture, <http://www.ers.usda.gov/Briefing/FoodSecurity/measurement.htm#what>; J.R. Blanchfield, D. Lund, and W. Spiess, "Report on Food Security Forum," International Union of Food Science and Technology, Institute of Food Technologists, <http://www.worldfoodscience.org/cms/?pid=1004507>.

components comprise a decision: “(a) courses of action (choice options and alternatives); (b) beliefs about objective states, processes, and events in the world (including outcome states and means to achieve them); and (c) desires, values, or utilities that describe the consequences associated with the outcomes of each action-event combination.”²⁸

Some decisions faced by those in the agriculture and food industries are routine and require little deliberation. For instance, a food processing company accepts an incoming lot of ingredients when the product meets specifications set by company standards. Unfortunately, all decisions are not this simple. Consider the decisions that a food processing company would face when responding to a situation in which their product is contaminated with a pathogenic microorganism capable of causing severe illness and even death. Similarly, consider the decisions that a grain processing company must address if excessive pesticide residues in products were to threaten consumer safety. Likewise, consider the decisions that a meat processing plant makes when responding to potential glass contamination of their products. Decisions in such situations could drastically affect a company and, therefore, require much deliberation.

²⁸ R. Hastie, "Problems for Judgment and Decision Making," *Annual Review of Psychology* 52(2001). 656.

Decision-making is a complex and multifaceted field. The study of decision-making is rooted in the discipline of economics.²⁹ However, the field of decision-making has advanced and it is no longer the focus of just economists. Decision researchers span numerous academic disciplines including public policy, law, business, medicine, psychology, and engineering.³⁰

Aligned with the values of the *Frontier* program,³¹ this thesis uses interdisciplinary research (IDR) to evaluate the discipline of decision-making and its applicability to food safety and food defense. Researchers recognize that IDR is useful in bridging the gaps between multiple disciplines to help answer intricate questions, address bigger issues, solve complex problems faced by multiple disciplines and industries, and process large amounts of information to create a unified representation of situations.³² In utilizing an interdisciplinary approach, the balance of this introductory chapter discusses aspects of classical decision theory and challenges of the

²⁹ Mark R. Lehto and Fiona Nah, "Decision-Making Models and Decision Support " in *Handbook of Human Factors and Ergonomics*, ed. Gavriel Salvendy (Norwood, NJ: John Wiley & Sons, 2006).

³⁰ Terry Connolly, Hal R. Arkes, and Kenneth R. Hammond, *Judgement and Decision Making: An Interdisciplinary Reader* (Cambridge, UK: Cambridge University Press, 2000).

³¹ The author of this thesis is a research assistant with the *Frontier* program, an interdisciplinary program for the historical studies of border security, food security, and trade policy. In an ongoing cycle of research, the *Frontier* program encourages the values of sustained reflection, creativity, critical thinking, and attention to detail to approach IDR. For more information on the program, see: Justin Kastner et al., "Frontier Field Guide," <http://frontier.k-state.edu/ResearchAndAnalysis/UpdatesTools/FrontierFieldGuide2008-6-17.pdf>.

³² Julie Thompson Klein, *Interdisciplinarity: History, Theory, and Practice*, 3 ed. (Detroit, MI: Wayne State University Press, 1990).

same. This chapter also reviews literature from the field of naturalistic decision-making and previous findings in non-food settings (e.g., nuclear power plant emergency operations, battle command, offshore oil and gas industry, aviation, skilled fighter pilot, and fire fighting). This chapter concludes by posing an overall research question, a hypothesis, a subsidiary question, and a methodological approach rooted in IDR.

Classical Decision Theory

For the purpose of this thesis, classical decision theory (CDT) signifies “the collection of axiomatic models of uncertainty and risk (probability theory, including Bayesian theory) and utility (utility theory, including multiattribute utility theory), that prescribe the optimal choice of an option from an array of options, where optimality is defined by the underlying models and the choice is dictated by an explicit rule, usually some variant of maximization of (subjective) expected utility.”³³ Examples in which CDT has been applied include the decision an investor would face when deciding whether or not to invest in bond and the decision that a medical company would face when deciding whether or not to market a particular drug.³⁴

Mathematicians developed the numerical scale of probability for describing the likelihood of an event to occur. It is based on a scale of 0 to 1. A value of 0 indicates that

³³ Lee Roy Beach and Raanan Lipshitz, "Why Classical Decision Theory Is an Inappropriate Standard for Evaluating and Aiding Most Human Decision Making," in *Decision Making in Action: Models and Methods*, ed. Gary A. Klein, et al. (Norwood, NJ: Ablex Publishing Corporation, 1993). 21.

³⁴ For more detailed examples, see: James O. Berger, *Statistical Decision Theory and Bayesian Analysis* (Springer, 1985).

an event is not likely to occur at all; a value of 1 indicates that an event will definitely occur.³⁵ Three general approaches to probability include the following: necessary or logical, objectivistic, and personal. Probability—from a logical approach—involves the assessment of and application in the situation. Consider the chance of drawing an 8-card in a standard deck of cards. It is 1/13 in a logical sense. Probability—from an objectivistic approach—utilizes the relative frequency of the likelihood of an event to occur in an infinite number of times. The personal approach to relative frequency is the evaluation of an individual’s belief in a statement.³⁶ For reference, probability axioms are provided in Table 3.

Table 3: Probability Axioms³⁷

| Symbolic notation | Explication |
|--|---|
| Scale specific axioms | |
| $P(y \text{ or not-}y) = 1$ | The probability of y or not-y is equal to 1. |
| $P(y \text{ and not-}y) = 0$ | The probability of y and not-y is equal to 0. |
| $P(y) \geq 0$ | The probability of y is 0 or greater than 0. |
| Multiplication axiom $P(z \text{ and } y) = P(y) \times P(z y)$ | The probability of z and y is equal to the probability of y time the probability of z if y occurs. |
| Addition axiom $P(y \text{ or } z) = P(y) + P(z) - P(y \text{ and } z)$ | The probability of y or z or both occurring is equal to the probability of y plus the probability of z minus the probability of both y and z. |

Probability theory pertaining to decision-making, as explained by Roeckelein, is:

³⁵ John J. Horan, *Counseling for Effective Decision Making: A Cognitive-Behavioral Perspective* (North Scituate, MA: Duxbury Press, 1979). 50.

³⁶ Leonard J. Savage, *The Foundations of Statistics* (New York, NY: Wiley 1954).

³⁷ Adapted from “Table 4.1 Probability Axioms” in Horan, *Counseling for Effective Decision Making: A Cognitive-Behavioral Perspective*. 51.

The discipline within mathematics that deals with probability and forms the basis for all the statistical techniques of psychology where, given a relatively small number of observations in an experimental setting, one needs to make decisions about the likelihood of such observations in the long run.³⁸

Bayes' theorem, first explained by English clergyman Thomas Bayes in the eighteenth century, can be derived for the probability axioms in Table 3 and is a mathematical formula for computing conditional probabilities.³⁹ The equation is:

$$p(A|B) = p(B|A)p(A)/p(B).^{40}$$

From a philosophical standpoint, subjective value, commonly referred to as utility, is a measure of usefulness or value. Utility theory is concerned with individual preference or value and the assumptions about an individual's inclinations that permit them to be denoted in numerically practical ways.⁴¹ Utilities differ amongst people and situations;

³⁸ Jon E. Roedelein, *Dictionary of Theories, Laws, and Concepts in Psychology* (Westport, CT: Greenwood Press, 1998). 46.

³⁹ Horan, *Counseling for Effective Decision Making: A Cognitive-Behavioral Perspective*. Conditional probability is the probability of an event given that another event is true.

⁴⁰ Ward Edwards and Detlof von Winterfeldt, "On Cognitive Illusions and Their Implications," in *Judgment and Decision Making: An Interdisciplinary Reader*, ed. Terry Connolly, Hal R. Arkes, and Kenneth R. Hammond (Cambridge, UK: Cambridge University Press, 2000). $p(A|B)$ denotes the probability of A given that the probability of B is known. The probability of two mutually exclusive events will always sum 1. Bayes' theorem explains how you should revise your prior opinions [$p(A)$] taking into considerations the new evidence [$p(B|A)$].

⁴¹ Peter C. Fishburn, "Utility Theory," *Management Science* 14, no. 5 (1968); ———, *Utility Theory for Decision Making* (New York, NY: John Wiley & Sons, Inc., 1970). For a more thorough account of utility theory, see: Oskar Morgenstern and John Von Neumann, *Theory of Games and Economic Behavior*, 3rd ed. (Princeton, NJ: Princeton University Press, 1947/1980); Daniel Bernoulli, "Exposition of a New Theory on the Measurement of Risk, Comentarium Academiae Scientiarum Imperialis Petropolitanae,"

however, utilities can be measured and, when combined with probabilities, can describe how individuals should make decisions.⁴² Expected utility examines decisions under uncertainty wherein outcomes are analyzed into parts that relate to different states of the world. Hence, the overall utility of an option is the expected utility (figured by taking into account the utility in each possible state and constructing a weighted average, where the weights are the estimate of the probability of each state).⁴³

Traditionally, normative and prescriptive roles are attributed to CDT.⁴⁴ In its normative role, CDT is a theoretical organization of propositions that is intended to explain the alternative options presented to an ideal decision-maker, who is provided with exact details and assumptions of the decision task.⁴⁵ These details and assumptions allow the omniscient decision-maker to make rational decisions.⁴⁶ Additionally, normative models serve as a benchmark to evaluate whether or not individual's

Econometrica 22(1738/1954); W. Edwards, "The Theory of Decision Making," *Psychological Bulletin* 51, no. 4 (1954).

⁴² Horan, *Counseling for Effective Decision Making: A Cognitive-Behavioral Perspective*.

⁴³ Jonathan Baron, "Normative Models of Judgement and Decision Making," in *Blackwell Handbook of Judgement and Decision Making* ed. Derek J. Koehler and Nigel Harvey (Malden, MA: Blackwell Publishing, 2004).

⁴⁴ Beach and Lipshitz, "Why Classical Decision Theory Is an Inappropriate Standard for Evaluating and Aiding Most Human Decision Making."

⁴⁵ Ibid.

⁴⁶ David Over, "Rationality and the Normative/Descriptive Distinction," in *Blackwell Handbook of Judgment and Decision Making*, ed. Derek J. Koehler and Nigel Harvey (Malden, MA: Blackwell Publishing, 2004).

decisions are rational (i.e., based on theoretic axioms of rational behavior).⁴⁷ However, the normative role of CDT is hardly pertinent to real-world decision-making; decision-makers are rarely provided with complete information.⁴⁸ When CDT was applied to the discipline of psychology, the prescriptive role of CDT emerged. The prescriptive role of CDT incorporates normative principles into guidance provided to decision-makers on how they should make rational decisions (i.e., decisions that conform to normative models).⁴⁹ While CDT is useful and provides much information for decision-making researchers, it does not accurately describe how people make decisions.⁵⁰

Naturalistic Decision-Making

Traditional research analyzing the statistical and mathematical aspects of CDT typically focused on laboratory-based experiments. However, conditions found in laboratory settings often do not accurately portray conditions found in real-world settings. Naturalistic decision-making (NDM) aims to determine how humans actually make decisions in real-world settings. The Army Research Institute Office of Basic Research began a research program in 1985 that focused on planning, problem solving, and decision-making in hopes of making decision research more pertinent to applied

⁴⁷ Baron, "Normative Models of Judgement and Decision Making."

⁴⁸ Beach and Lipshitz, "Why Classical Decision Theory Is an Inappropriate Standard for Evaluating and Aiding Most Human Decision Making."

⁴⁹ Baron, "Normative Models of Judgement and Decision Making."

⁵⁰ For more information see: Daniel Kahneman and Alan Tversky, "Prospect Theory: An Analysis of Decision under Risk," *Econometrica* 47, no. 2 (1979); Daniel Ellsberg, "Risk, Ambiguity, and the Savage Axioms," *Quarterly Journal of Economics* 75(August 1961).

fields. In 1989, Klein Associates organized a meeting to record achievements and posed future research questions in the NDM field.⁵¹

Eight factors—often overlooked in CDT research—characterize the task and setting factors in naturalistic environments and appear in Table 4. While all eight factors may manifest themselves, they may be present at different intensities. NDM researchers suggest that pressures associated with these factors can increase difficulties in the decision-making task.⁵²

Table 4: Differences Between Naturalistic and Traditional Decision-Making Settings⁵³

| Naturalistic decision-making (NDM) settings | Traditional or classical decision-making (CDT) settings |
|--|--|
| Ill-structured problems | Precisely defined problems |
| Uncertain, dynamic environments | Relatively constant environments |
| Shifting, ill-defined, or competing goals | Single, well known goals |
| Action/feedback loops | Single decision event |
| Time constraints | Time for thoughtful reflection |
| Outcome with high stakes | Research subjects have little care for outcome of decision |
| Multiple players | Sole decision-maker |
| Organizational goals and norms | Individual inclinations |

⁵¹ Gary A. Klein et al., "Preface," in *Decision Making in Action: Models and Methods*, ed. Gary A. Klein, et al. (Norwood, NJ: Ablex Publishing Corporation, 1993).

⁵² Judith Orasanu and Terry Connolly, "The Reinvention of Decision Making," in *Decision Making in Action: Models and Methods*, ed. Gary A. Klein, et al. (Norwood, NJ: Ablex Publishing Corporation, 1993).

⁵³ Adapted from Ibid; Josephine M. Randel, H. Lauren Pugh, and Stephen K. Reed, "Differences in Expert and Novice Situation Awareness in Naturalistic Decision Making," *International Journal of Human-Computer Studies* 45(1996); R. J. Sternberg, "Teaching Critical Thinking, Part 1: Are We Making Critical Mistakes?," *Phi Delta Kappan* 67, no. 3 (1985); ———, *Intelligence Applied: Understanding and Increasing Your Intellectual Skills* (San Diego, CA: Harcourt, Brace, & Jovonovich, 1986).

Ill-structured problems

Real world decision problems are ill-structured. Decision-makers must exert much thought and mental processing to make sense of what is going on, to generate suitable responses, and to identify that a decision must be made. There are typically numerous approaches to solving a single problem and each may be equally acceptable. The decision-maker or group of decision-makers must evaluate the situation and proceed with a decision.⁵⁴

Uncertain, dynamic environments

Uncertain, dynamic environments are common in NDM settings; potentially, the environment can change rapidly thus affecting an individual or group of decision-makers. Information is rarely complete in real-world settings as presumed in CDT research; some parts may be missing or even inaccurate. This further complicates the process for those responsible for making decisions.⁵⁵

Shifting, ill-defined, or competing goals

In real-world situations, individuals and group decision-makers often struggle to define and understand goals. Tradeoffs, in which the decision-maker chooses one option over another, are used to opt between competing goals. Decisions are typically part of a

⁵⁴ Orasanu and Connolly, "The Reinvention of Decision Making."

⁵⁵ Ibid.

larger task or mission, which can assist those responsible for making decisions to better approach the situation.⁵⁶

Action/feedback loops

In NDM settings, a series of decisions—rather than a single decision event—addresses problems over time. Action/feedback loops are useful for decision-makers, as they allow them to address problems associated with a decision made in a previous step. On the contrary, action/feedback loops make it difficult to assign consequences to a decision because an action and its consequences can only be vaguely related.⁵⁷

Time constraints

In real-world settings, time is a major issue and source of stress. Individuals and groups face pressure to meet deadlines and move on to address additional problems. In some situations, action must be taken in a matter of seconds or minutes. Undoubtedly, this is a major source of stress for decision-makers and could result in decreased attentiveness and exhaustion. Time stress also has the potential to affect the decision-maker's reasoning strategy.⁵⁸

High stakes

Situations in NDM settings can have significant consequences on all individuals and groups involved. Consequences for an individual could include the loss of goods,

⁵⁶ Ibid.

⁵⁷ Ibid.

⁵⁸ Ibid.

life, or career. For a company, it could result in loss of business, financial stability, and ultimately the future.⁵⁹

Multiple players

In NDM settings, there is often not one decision-maker but rather a team of decision-makers working together. Individuals in the team each have their own ideas and coming to a consensus in the decision-making process can be difficult.⁶⁰

Organizational goals and norms

Lastly, NDM research maintains that decision-makers are often part of an organization with established goals and norms. Therefore, individuals cannot solely consider personal goals and norms when making decisions; rather, the goals and norms of the organization must be also be taken into account. The organization may react to the decision-maker's struggle by instituting broader goals or rules.⁶¹

Four central indicators for NDM research include the following: the task and setting factors (the eight characteristics of naturalistic decision settings previously described), the type of research participants (skilled decision-makers), the purpose of the research (how people truly make decisions), and the point of interest within the decision process (focusing not only the decision but the entire process, e.g., situation

⁵⁹ Ibid.

⁶⁰ Ibid.

⁶¹ Ibid.

awareness).⁶² Taking into account these four indicators, NDM researchers developed the following definition of NDM:

The study of NDM asks how experienced people, working as individuals or groups in dynamic, uncertain, and often fast-paced environments, identify and assess their situation, make decisions, and take actions whose consequences are meaningful to them and to the larger organization in which they operate.⁶³

NDM Findings in Non-Food Settings

NDM has been studied in diverse fields. A brief synopsis and the results and conclusions of selected studies are included below. In summary, these studies provide insight into how people in those specific situations actually make decisions.

Nuclear Power Plant Emergency Operations

Emergency situations in nuclear power plants present grave danger and warrant special attention. In an emergency situation, nuclear power plant operators are forced to abide by step-by-step procedures that describe what plant issues should be monitored, how the observed signs should be interpreted, and what responses should be taken. Such prescriptive procedures cause some to speculate on the cognitive activity necessary for operators to effectively manage an emergency situation. Researchers analyzed nuclear power plant operator performance in simulated emergencies that consisted of issues not completely covered in the step-by-step procedures. Researchers concluded

⁶² Caroline E. Zsombok, "Naturalistic Decision Making: Where Are We Now?," in *Naturalistic Decision Making*, ed. Caroline E. Zsombok and Gary Klein (Mahwah, NJ: Lawrence Erlbaum Associates, 1997).

⁶³ Ibid. 5.

that operators actively construct mental representations of the situation. Researchers also found that the usefulness of preplanned procedures (i.e., checklists, paper-based procedures, and conventional expert systems) is limited. Operators must still be able to actively assess the situation and develop response plans, particularly when faced with issues not covered in the step-by-step procedures.⁶⁴

Battle Command

Those who work in military command and control face numerous obstacles including complex problems, ambiguity, and fast-paced environments. “Battle command decision-making expertise” is essential.⁶⁵ Researchers describe it as the ability to make and execute decisions in an appropriate and proficient manner, often with incomplete information, in an unpredictable battlespace. In this study, researchers assessed battle command decision-making expertise and demonstrated that expertise could be brought forth in a laboratory-based, realistic setting. Research in battle command decision-making expertise is difficult; many have argued the method of assessing the level of expertise of individuals. However, domain experts were able to recognize command decision-making expertise while in a quasi-natural setting. Laboratory settings often neglect the ambiguity and complications of real-world

⁶⁴ Emilie M. Roth, "Analysis of Decision Making in Nuclear Power Plant Emergencies: An Investigation of Aided Decision Making," in *Naturalistic Decision Making*, ed. Caroline E. Zsombok and Gary Klein (Mahwah, NJ: Lawrence Erlbaum Associates, 1997).

⁶⁵ Term coined in Daniel Serfaty et al., "The Decision-Making Expertise of Battle Commanders," in *Naturalistic Decision Making*, ed. Caroline E. Zsombok and Gary Klein (Mahwah, NJ: Lawrence Erlbaum Associates, 1997).

problems. The results of this study are important to the NDM community, as researchers in this study were able to elicit expertise in a laboratory-based, realistic setting. Real-world incidents—in battle command and other complex fields—pose significant challenges and this study provided insight into the analysis of expertise in complex fields.⁶⁶

Offshore Oil and Gas Industry

The offshore installation manager (OIM) is responsible for daily operations and emergency management on oil rigs or platforms. Emergency response is very important in the offshore oil and gas industry, as emergency services often cannot respond immediately due to the remote location of the operation. The example of the Piper Alpha oil platform, which exploded in July 1988 and resulted in 167 deaths, highlights the importance of decision-making in such an industry. Researchers found that OIMs too use their previous knowledge to develop solutions to problems faced, similar to mental models used by battle commanders. Also, researchers noted that teamwork was an integral part of the industry and must be incorporated into training programs for these in the offshore oil industry.⁶⁷

Aviation

Flight-related decision-making by commercial airline pilots is particularly applicable to NDM researchers. Researchers set out to determine how flight crews

⁶⁶ Ibid.

⁶⁷ Rhona Flin, Georgina Slaven, and Keith Stewart, "Emergency Decision Making in the Offshore Oil and Gas Industry," *Human Factors* 38, no. 2 (1996).

effectively make decisions and what circumstances are present when poor decisions are made. Data from different sources, including simulator data, incident reports, and accident analyses, were examined. Unsurprisingly, researchers found that situation assessment, contingency planning, and task management were advantageous for efficient decision-making. Additionally, researchers found that successful flight crews were able to use different strategies to address problems faced in-flight. These strategies were diverse and depended upon specific decisions and the sequential development of problems. Study results suggested that flight-crew training programs would benefit from including methods that allow individuals to see the development of problems over time and modify responses accordingly.⁶⁸

Skilled Fighter Pilots

Fighter pilots seek to both defeat enemies and protect themselves from opposition. NDM researchers set out to determine the role situation awareness (SA) plays in skilled fighter pilot response and decision-making. SA, in this respect, is described as a pilot's constant awareness of himself or herself and the aircraft with regard to the shifting situation of flight, hazards, and task, and the ability to predict and complete tasks based on that perception. Results from the study indicated that successful fighter pilots demonstrated flight leadership, tactical mission planning, situation assessment, and decision-making skills. Researchers suggested that

⁶⁸ Judith Orasanu and Ute Fisher, "Finding Decision in Natural Environments: The View from the Cockpit," in *Naturalistic Decision Making*, ed. Caroline E. Zsombok and Gary Klein (Mahwah, NJ: Lawrence Erlbaum Associates, 1997).

simulations with ambiguity were useful in training fighter pilots; however, some aspects of the natural environment were not completely addressed in the simulations.⁶⁹

Firefighting

Researchers working with firefighters developed the recognition-primed decision model (RPD)—one of the nine models identified in the NDM community. This model explains how people use their previous experiences to form a catalog of patterns outlining aspects of the situation. These patterns focus on the most pertinent indicators, offer expectancies, pinpoint possible goals, and propose standard types of responses in that particular situation. Then, when a decision was required, individuals were able to match the situation to the patterns previously discovered. This allowed for rapid decision-making. Research with fireground commanders, who experience extreme time stress, found that mental simulation was used to imagine how a strategy or course of action would proceed given the current situation. If, mentally, the strategy worked, the commanders moved forward. However, if it did not work, the commanders adapted the strategy or considered others until they were comfortable with how they expected the situation to proceed.⁷⁰

⁶⁹ Wayne L. Waag and Herber H. Beel, "Situation Assessment and Decision Making in Skilled Fighter Pilots," in *Naturalistic Decision Making*, ed. Caroline E. Zsombok and Gary Klein (Mahwah, NJ: Lawrence Erlbaum Associates, 1997).

⁷⁰ Gary A. Klein, "A Recognition-Primed Decision (RPD) Model of Rapid Decision Making," in *Decision Making in Action: Models and Methods*, ed. Gary A. Klein, et al. (Norwood, NJ: Ablex Publishing Corporation, 1993).

Application of NDM to Food Safety and Food Defense

As decision-making is such an important aspect of food safety and food defense, the following overall research question has been posed: Do prevailing educational programs and tools aimed at preparing for food safety and food defense issues incorporate methods that help professionals make good decisions? To answer this overall research question, this thesis systematically seeks to do the following: (a) establish the nature of the decision-making environment in food safety and food defense settings (settings, this thesis hypothesizes, that are best characterized by the NDM factors) and (b) examine educational programs and tools aimed at preparing for food safety and food defense issues for their direct inclusion of the eight factors characterizing NDM settings. First, drawing on the insights provided by the field of NDM, the following hypothesis will be tested:

- The eight factors characterizing NDM settings (Table 4) are indeed present in responding to incidents involving food safety and food defense.

This hypothesis will be tested through a series of case studies.⁷¹ Past events where food safety and food defense issues have arisen will be analyzed to determine if the eight

⁷¹ Cases studies are commonly used in public health research. For examples, see: Justin J. Kastner, "Harmonising Sanitary Measure and Resolving Trade Disputes" (South Bank University, 1999); ———, "Sanitary Related International Trade Disputes: A Multiple-Factor Analysis Based on Nineteenth-Century Precedents" (The University of Guelph, 2003); David Salvesen et al., "Factors Influencing Implementation of Local Policies to Promote Physical Activity: A Case Study of Montgomery County, Maryland," *Journal of Public Health Management and Practice* 14, no. 3 (2008); Timothy L. Sellnow and Robert S. Littlefield, eds., *Lessons Learned About Protecting America's Food Supply* (North Dakota Institute for Regional Studies, 2005).

factors characterizing NDM settings were indeed present. The following cases will be evaluated:

1. *Salmonella* serotype Typhimurium in retail salad bars (1984; The Dalles, Oregon),
2. Pesticide in feed products (1996-1997; Berlin, Wisconsin),
3. *Salmonella* serotype Tennessee in peanut butter (2006-2007; Sylvester, Georgia), and
4. *Listeria monocytogenes* in deli products (2002; Camden, New Jersey and Franconia, Pennsylvania).⁷²

Second, this thesis will explore the following subsidiary question:

- Do prevailing educational programs and tools aimed at preparing for food safety and food defense issues (HACCP and CARVER plus Shock) directly include methods to address the eight factors characterizing NDM settings?⁷³

⁷² Events dealing with both food safety and food defense issues will be included in this thesis. The author originally intended to focus on food defense issues; however, there have been relatively few cases where food and agricultural products have been intentionally contaminated. Therefore, issues where lapses in food safety have occurred are used to draw relevant conclusions about food safety as well as food defense issues.

⁷³ The subsidiary question was developed after the author of this thesis read: Liz H. Mossop and Avril Senior, "I'll Show You Mine If You Show Me Yours! Portfolio Design in Two UK Veterinary Schools," *Journal of Veterinary Medical Education* 35, no. 4 (2008). In this article, the authors compare the portfolio systems of two veterinary schools in the UK. In veterinary curricula, portfolios can enhance a student's educational assessment and improve their critical reflection capabilities. Hence, portfolios can enhance professional development skills. Similarly in this thesis, educational programs and tools aimed at preparing for food safety and food defense

To address this question, a hypothetical student in a food safety and food defense course focusing on HACCP and CARVER plus Shock will “be followed.” A brief overview of the information presented to the student will be provided. The information will be analyzed to determine if it directly addresses the eight factors characterizing NDM settings.

This thesis is structured to systematically consider the overall research question, the hypothesis, and the subsidiary question. Chapter two explores each of the food safety and food defense case studies, focusing on the presence of the eight factors characterizing NDM settings. Chapter three follows the hypothetical food safety and food defense student and discusses how the eight factors were addressed. Chapter four features a summary of the findings of chapters two and three and offers recommendations useful for thought leaders in food safety and food defense addressing the Agriculture and Food Sector as a CIKR.

Researchers often seek to impact public policy and the author of this thesis seeks to accomplish the same. Recently, President Barack Obama created the Food Safety Working Group (FSWG) to assist in the development of contemporary food safety laws that draw together different government sectors as well as means of enforcement.⁷⁴ Past events in which food safety and food defense issues have arisen provide insight into the vulnerability and importance of the Agriculture and Food Sector in the U.S. The author

issues will be compared to determine their direct inclusion of the eight factors characterizing NDM settings.

⁷⁴ United States Department of Agriculture and U.S. Department of Health and Human Services, "President's Food Safety Working Group," <http://www.foodsafetyworkinggroup.gov/Home.htm>.

seeks to provide further insight on how characteristics present in these events can be incorporated into training professionals to better address problems faced in future situations. Decision-making is an essential component of the Agriculture and Food Sector and efforts to train professionals are necessary.

Chapter 2: NDM Task and Setting Factors in Responding to Incidents Involving Food Safety and Food Defense

Past incidents related to food safety and food defense provide useful insight on task and setting aspects common to the Agriculture and Food Sector. This chapter examines four cases related to food safety and food defense, followed by analyses determining the presence of the eight factors characterizing NDM. Table 5 summarizes the methods used to determine the presence of the eight NDM factors.

Table 5: Methods Used to Determine the Presence of the Eight NDM Factors

| NDM factor | Analysis parameters to determine presence |
|---|---|
| Ill-structured problems | Looked for evidence of ambiguity or confusion about the nature of the problem |
| Uncertain, dynamic environments | Looked for an environment that changed rapidly or evidence of missing, incomplete, or incorrect information |
| Shifting, ill-defined, or competing goals | Looked for evidence of shifting, ill-defined, or competing goals, rather than precisely defined goals |
| Action/feedback loops | Looked for evidence of a series of decision events, rather than a single decision |
| Time constraints | Looked for evidence of time constraints including a limited amount of time allowed for thoughtful reflection |
| Outcome with high stakes | Looked for evidence of personal high stakes (e.g., loss of goods, life, or career) and/or organizational high stakes (e.g., loss of business, financial stability, and ultimately the future) |
| Multiple players | Looked for evidence of different individuals or organizations involved in the case |
| Organizational goals and norms | Looked for evidence of organizational goals and norms rather than individual, personal inclinations |

Case 1: *Salmonella* serotype Typhimurium in retail salad bars (1984; The Dalles, Oregon)

Patrons, employees, and owners of Shakey's Pizza in The Dalles, Oregon unsuspectingly dined from the restaurant's salad bar on Sunday, September 9, 1984. Later that day, Dave Lutgens—an owner of Shakey's Pizza—developed symptoms that included stomach cramping, nausea, diarrhea, and vomiting. Within the next week, Lutgens' wife, thirteen of the restaurant's twenty-eight employees, and dozens of customers reported similar illnesses.⁷⁵ On September 17, 1984, the Wasco-Sherman Public Health Department began receiving reports of individuals who developed gastroenteritis after eating at one of two different restaurants in The Dalles, Oregon.⁷⁶ Within two days, a pathologist at Mid-Columbia Medical Center analyzed a patient's stool sample and determined that bacteria from the genus *Salmonella* was responsible for the illness. On September 21, the Oregon State Public Health Laboratory identified *S. Typhimurium* as the etiological agent. However, the specific strain of *S. Typhimurium* surprised public health officials, as it was not a common food poisoning agent.⁷⁷ Reports of individuals who worked at or ate at other restaurants in The Dalles suffering from

⁷⁵ Judith Miller, Stephan Engelberg, and William Broad, *Germs: Biological Weapons and America's Secret War* (New York, NY: Simon & Schuster, 2001); T. J. Török et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *The Journal of the American Medical Association* 278, no. 5 (1997).

⁷⁶ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

⁷⁷ Ibid; F. W. Brenner et al., "*Salmonella* Nomenclature," *Journal of Clinical Microbiology* 38, no. 7 (2000). *Salmonella* nomenclature is complicated and different systems are used. The formal name of the bacteria, using CDC nomenclature, is *Salmonella* serotype Typhimurium—abbreviated *S. Typhimurium*.

gastroenteritis increased. Carla Chamberlain, head of the county public health office, and her staff interviewed restaurant owners, employees, and those struck ill; many of those suffering from gastroenteritis reported eating food from salad bars.⁷⁸ All salad bars in The Dalles temporarily closed beginning on September 25, 1984.⁷⁹ Additionally, the Oregon Health Division requested assistance from the CDC and its Epidemic Intelligence Service (EIS).⁸⁰

Salmonellosis, an infection resulting from bacteria of the *Salmonella* genus, causes thousands of illnesses each year in the U.S.⁸¹ Individuals suffering from salmonellosis often experience diarrhea, fever, and abdominal cramping twelve to seventy-two hours after ingesting the bacteria; symptoms often subside within four to seven days.⁸² Immunocompromised individuals, including newborns, infants, and

⁷⁸ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

⁷⁹ Török et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars."

⁸⁰ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*. EIS was established during the Cold War to assist in the detection of a microbial attack on the U.S. At the time of this outbreak, EIS was made up of seventy doctors trained in epidemiology.

⁸¹ CDC Division of Foodborne Bacterial and Mycotic Diseases, "Salmonellosis," http://www.cdc.gov/nczved/dfbmd/disease_listing/salmonellosis_gi.html#2. Roughly 40,000 cases of salmonellosis are reported annually; however, some speculate that this number is possibly thirty times greater as less severe cases are not diagnosed or reported.

⁸² Ibid.

elderly individuals, are more inclined to develop salmonellosis than healthy adults.⁸³ Research suggests that ingesting as few as one to ten cells can cause infection.⁸⁴

Public health officials investigated The Dalles outbreak—interviewing patients and their families, checking water supplies, testing foods sold at restaurants, and using scores of other approaches to determine the source of the outbreak. *Salmonella* was found in coffee creamers at one restaurant and in the blue-cheese salad dressing at another. However, *Salmonella* was not found in dry mix used to make the salad dressing.⁸⁵

A case was defined as:

An illness with diarrhea and at least 3 of the following symptoms: fever, chills, headache, nausea, vomiting, abdominal pain, or bloody stools, or by a stool culture yielding *S. Typhimurium*.⁸⁶

Outbreak associated cases included cases where the appearance of symptoms or collection of *S. Typhimurium* occurred between September 9 and October 10, 1984, and

⁸³ Jean-Yves D'Aoust, "Salmonella," in *Foodborne Bacterial Pathogens*, ed. Michael P. Doyle (New York, NY: Marcel Dekker Inc., 1989); ———, "Salmonella Species," in *Food Microbiology Fundamentals and Frontiers*, ed. Michael P. Doyle, Larry R. Beuchat, and Thomas J. Montville (Washington, D.C.: ASM Press, 1997).

⁸⁴ Jean-Yves D'Aoust, D.W. Warburto, and A.M. Sewell, "Salmonella Typhimurium Phage-Type 10 from Cheddar Cheese Implicated in a Major Canadian Foodborne Outbreak," *Journal of Food Protection* 48(1985); G. Kapperud et al., "Outbreak of Salmonella Typhimurium Infection Traced to Contaminated Chocolate and Caused by a Strain Lacking the 60-Megadalton Virulence Plasmid," *Journal of Clinical Microbiology* 28, no. 12 (1990).

⁸⁵ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

⁸⁶ Török et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars." 390.

the affected person lived in or visited The Dalles during that period. Restaurant-associated cases included cases in which individuals ate at a restaurant in The Dalles within seven days of the appearance of symptoms or worked at a restaurant in The Dalles. Secondary infections included those that occurred in individuals who did not eat or work at a restaurant in The Dalles seven days before the appearance of symptoms, but were exposed to a case patient between September 9 and October 10, 1984.⁸⁷

Judge William Hulse suspected that a local religious commune caused this outbreak. The commune, led by Bhagwan Shree Rajneesh, lived on a remote ranch in Wasco County. In 1982, a group of his followers, referred to as Rajneeshees, moved into the adjacent town of Antelope where they gained control of the town council. With control of the town council, they developed the city of Rajneeshpuram complete with modern infrastructure. However, they faced zoning issues. Hulse, head of the county commission, was tasked with settling these zoning issues. Nearly a year before the outbreak, Hulse and another county commissioner visited the Rajneesh ranch for a routine inspection. When they returned to their car, they noticed a tire flat. Several Rajneeshees changed their tire and the commissioners drank water in paper cups offered to them by other Rajneeshees. Eight hours later, both commissioners were struck ill with symptoms that included stomach cramping, nausea, diarrhea, and

⁸⁷ Ibid.

vomiting . They suspected that the Rajneeshees tainted their water; however, they did not have proof and did not bother to further pursue the matter.⁸⁸

Upon hearing about the outbreak, Hulse became suspicious and related the story to Chamberlain. Chamberlain was aware that the Rajneeshees' medical laboratories were more sophisticated and better-equipped than those of the county; the Rajneeshees had access to the resources and facilities necessary to cause this outbreak. Hulse and Chamberlain concluded that it would be complicated to convince federal disease investigators that the outbreak was a result of intentional contamination by the Rajneeshees.⁸⁹

Over 1000 people reported symptoms; however, it is likely that more were affected because of The Dalles' location on a major interstate with high traffic.⁹⁰ The outbreak investigation identified 751 cases with 388 (51.7%) culture-confirmed cases and 363 (48.3%) clinical cases. Investigators discovered two different phases of illnesses: 88 cases (13%) from September 9 through September 18, peaking on September 15, and 586 cases (87%) from September 19 through October 10, peaking on

⁸⁸ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

⁸⁹ Ibid. Laurence R. Foster, then Oregon's most senior epidemiologist, was from the area and firmly believed that the Rajneeshees were being unduly tormented because of their unfamiliar religious conventions. Foster served as a mentor to Thomas Török, a lead EIS officer in the case.

⁹⁰ Rasco and Bledsoe, *Bioterrorism and Food Safety*.

September 24.⁹¹ Additionally, 692 (92%) cases were restaurant-associated, 11 (1%) cases were secondary, and 48 (6%) cases were of unknown origin because of inadequate information on restaurant exposure. Most cases were linked to ten restaurants and epidemiological studies concluded that eating from a salad bar was the major risk factor for infection. Foods affected on the salad bars varied between restaurants. Investigators did not identify a particular water supply, foodstuff, supplier, or distributor common to affected restaurants. Infected employees could have unintentionally spread the bacteria to food, but there was no indication that they were the source of the outbreak. Furthermore, improper chilling temperature and food rotation could have favored the growth of *S. Typhimurium*, but did not directly cause the outbreak.⁹²

The outbreak strain of *S. Typhimurium* was compared to other strains from national surveys and results indicated that the outbreak strain was not commonly found prior to the current outbreak. A strain from an animal isolate matched the current outbreak strain, but public health officials were not able to link it to The Dalles salad bars. Additionally, researchers matched the current outbreak strain to three other 1984 Oregon outbreaks, but officials were not able to find a relationship to The Dalles salad bars.⁹³

⁹¹ Török et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars." The date of symptom onset was known in 674 cases (90%); thus, those cases were included in the two waves of illness.

⁹² Ibid.

⁹³ Ibid.

Preliminary reports from the CDC and Oregon state officials concluded that the outbreak was caused by improper food handling; evidence failed to suggest that the outbreak was a result of intentional contamination. However, The Dalles residents and local law-enforcement thought the Rajneeshees were responsible and questioned the conclusions of public health officials.⁹⁴

On September 16, 1985, Bhagwan Shree Rajneesh, held a press conference in which he accused Ma Anand Sheela—his personal secretary and acting Rajneeshee leader—and her partners of poisoning locals and other attempts to sicken individuals. Bhagwan Shree Rajneesh requested a government investigation and state and federal police formed a task force with the Federal Bureau of Investigation (FBI), local and state police forces, sheriff's offices, Immigration and Naturalization Service (INS), and the National Guard.⁹⁵ The Rajneesh ranch served as headquarters for the investigation; however, Rajneeshees secretly tapped phone lines and destroyed relevant evidence. On October 2, 1985, search warrants were executed and investigators explored Pythagoras Medical Clinic and the Rajneesh Medical Corporation—both located on the Rajneesh ranch. Inside a laboratory, vials filled with *Salmonella* disks were found. Ma Anand Puja, a nurse, ordered the disks that were intended for use in diagnostic testing. Further analysis determined that this strain matched the strain from The Dalles salad bar outbreak the previous year. After this discovery, CDC scientist Robert V. Tauxe explained that investigators in the outbreak were fearful of wrongly accusing the

⁹⁴ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

⁹⁵ Ibid. Dave Fohnmayer, Oregon Attorney General, headed the task force.

Rajneeshees and evidence had not suggested intentional contamination. In the past, investigators had seen *Salmonella* cause larger outbreaks and were doubtful that anyone would deliberately harm the small town of The Dalles, Oregon.⁹⁶

As the investigation unfolded, David Berry Knapp, known as Krishna Diva or K.D., and Ava Kay Avalos, known as Ma Ava, complied with prosecutors and provided insider information about the Rajneeshees' biological capacity and efforts. Records showed that Puja ordered and received bacterial cultures from biologic companies including *Salmonella* serotype Typhi, *Salmonella* serotype Paratyphi, *Francisella tularensis*, and *Shigella dysenteriae*. During court hearings in the fall of 1985, K.D. and Ma Ava provided juries with a description of the Rajneeshees' activities from the past year. Rajneeshees tainted the lettuce at a local Albertson's grocery store with their blend of bacteria. Additionally, the two testified that other members went to restaurants and put *Salmonella* in coffee creamers, in blue-cheese dressing, and over fruits and vegetables at some salad bars. In their testimonies, K.D. and Ma Ava revealed that Shree and Sheela assured the Rajneesh community that sickening The Dalles community members would help protect the Rajneesh vision; this was a trial run and the real run would happen later that year when enough voters would be struck ill and the Rajneeshees could gain control of local government. Attempts to register homeless

⁹⁶ Ibid.

people to vote for similar purposes failed; consequently, their candidates lost the election.⁹⁷

Sheela and Puja, who had fled the U.S. to Germany, were extradited back to the U.S. and pled no contest to charges including attempted murder, illegal wiretapping, the poisoning of Judge Hulse, and causing the *Salmonella* outbreak in The Dalles. The two were sentenced to a maximum of twenty years in federal prison, and Sheela was fined \$400,000 and instructed to pay Wasco County \$69,353.31 in restitution. Both served less than four years in prison and were released early for good behavior. Oregon wanted to seek additional charges against the two, but they fled to Europe before the charges could be brought up. Bhagwan Shree Rajneesh received a ten-year suspended prison sentence, paid \$400,000, and fled the U.S.⁹⁸

The following section outlines the eight factors characterizing NDM settings and if, and when, they were present in the *S. Typhimurium* outbreak in The Dalles, Oregon.

Ill-structured problems

When reports of gastroenteritis arrived at the Wasco-Sherman Public Health Department, public health officials had to recognize that reported illnesses were out of the ordinary. Presumably, these illnesses could be non-related, common cases of foodborne illness; after all, each year foodborne illness affects 76 million people. As the epidemiological investigation progressed, restaurant salad bars were implicated as the

⁹⁷ Ibid.

⁹⁸ Ibid.

source of the outbreak and temporarily shut down. No food or water source was common to the salad bars, leading investigators to believe that improper food handling caused the outbreak. In retrospect, the ill-structured nature of problems in this outbreak was exemplified when the investigation revealed that Rajneeshees were actually responsible for the outbreak.

Uncertain, dynamic environments

Investigators did not determine that the *S. Typhimurium* outbreak in The Dalles, Oregon was caused by intentional contamination until more than a year after it happened. Public health researchers outlined nine reasons why they rejected the idea that the outbreak was a result of intentional contamination. These reasons exemplify the missing, incomplete, and incorrect information surrounding this case and include the following:

1. No one was thought to have a motive to intentionally contaminate the salad bars. Election fraud was taken into account; however, the outbreak occurred during months prior to the election.
2. No one admitted to contaminating the salad bars or asked for demands to be met. If the outbreak were a result of terrorism or extortion, an announcement would be likely.
3. Law enforcement officials investigated strange activities reported at different restaurants; a relationship between them was not determined.
4. Disgruntled employees were ruled out as the source of the outbreak.

5. The two waves of illnesses would require a reliable source of the bacteria and investigators believed that intentionally contaminating the salad bars more than once would be too risky for someone to attempt.
6. Some employees became ill before restaurant patrons did.
7. Intentional contamination of food was uncommon in the U.S.
8. Results of previous outbreak investigations provided justification on conclusions drawn by investigators.
9. The source of an outbreak may go unknown, as seen in other outbreak investigations.⁹⁹

Shifting, ill-defined, or competing goals

As salad bars were implicated as the source of the outbreak, they temporarily shut down to prevent additional illnesses. From the restaurants' perspectives, this represented a tradeoff; salad bars were temporarily losing revenue, as opposed to potentially causing illness. While restaurants aim to make a profit, the goal shifted towards protecting public health. When the true cause of the outbreak was determined, the goal shifted to prosecuting the individuals responsible for the outbreak.

Action/feedback loops

While investigating this outbreak, public health officials worked diligently to find the source of the outbreak. Dairy products and pond water from an uncertified dairy in Washington, local water systems, restaurant water, and products from area farms

⁹⁹ These nine reasons are adapted from: Török et al., "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars."

supplying restaurants in The Dalles were tested for the presence of *Salmonella*.¹⁰⁰ When test results came back negative, investigators looked into other possible sources of contamination. Indeed, the results of these tests and the failure to determine the food implicated from the salad bars represented action/feedback loops in this case. The true source of the outbreak was discovered only when Bhagwan Shree Rajneesh's claims were investigated.

Time constraints

Time stress was clearly an issue in this outbreak. Table 6 illustrates how quickly illnesses ensued and how rapidly public health officials, investigators, and restaurants responded to the outbreak.

Table 6: *S. Typhimurium* in Retail Salad Bars Outbreak Time Period (1984; The Dalles, Oregon)

| Date in 1984 | Event |
|---------------------|---|
| September 9 | Wave 1 illnesses began |
| September 15 | Wave 1 illnesses peaked |
| September 17 | Wasco-Sherman Public Health Department began receiving reports of gastroenteritis |
| September 18 | Wave 1 illnesses ended |
| September 19 | Wave 2 illnesses began <i>Salmonella</i> from stool sample isolated at Mid-Columbia Medical Center |
| September 21 | <i>S. Typhimurium</i> identified by Oregon State Public Health Laboratory |
| September 24 | Wave 2 illnesses peaked |
| September 25 | The Dalles salad bars temporarily closed |
| October 10 | Wave 2 illnesses ended |

¹⁰⁰ Miller, Engelberg, and Broad, *Germs: Biological Weapons and America's Secret War*.

Outcome with high stakes

Public health officials became concerned when reports of gastrointestinal illnesses increased. The etiological agent, side effects, and source of the agent were unknown. The agent could perhaps cause a serious or chronic disease. *S. Typhimurium*, though typically not fatal, can cause severe side effects. However, over 1000 people reported illnesses and there were 751 confirmed cases. When human health and life are threatened, high stakes are certainly present.

Multiple players

From a response standpoint, this outbreak involved numerous organizations including the Wasco-Sherman Public Health Department, the Oregon State Public Health Laboratory, the CDC, and the CDC's EIS working with restaurant owners and employees. Together, these teams determined the source of the outbreak and worked to prevent additional illnesses. When the criminal investigation began, teams from the FBI, local and state law enforcement teams, sheriffs' offices, INS, and the National Guard joined forces to determine the Rajneeshees' involvement in the outbreak. Additionally, all of the organizations involved included multiple individuals.

Organizational goals and norms

Local, state, and federal public health officials and investigators operate under their individual organizations—each with their own goals and norms. Carla Chamberlain, head of the county public health office, knew The Dalles area, the history of Rajneeshees, and the capacity of the Rajneesh medical laboratory. However, she and Judge Hulse feared negative responses from state and federal investigators when

suggesting that the Rajneeshees could be responsible for the outbreak. Their knowledge of the local community allowed them to logically consider all the possible sources of the outbreak. Public health officials and investigators from outside the community (i.e., state and federal investigators) were hesitant to accuse the Rajneeshees of intentionally contaminating salad bars, citing the fear of discriminating against the community. The fear of discriminating against the Rajneeshees ultimately delayed officials from correctly determining the source of the outbreak.

Case 2: Pesticide in feed products (1996; Berlin, Wisconsin)

Shortly after Christmas 1996, Berlin Police Department officials in Green Lake County, Wisconsin received an unusual letter from an unidentified person who alleged to have contaminated tallow with chlordane at the National By-Products Inc. (NBP) rendering plant.¹⁰¹ Chlordane is a man-made chemical that was utilized as a pesticide in the U.S. beginning in 1948. However, the Environmental Protection Agency (EPA) banned the use of chlordane in 1983 except to control termites due to its potential to harm the environment and human health. The use of chlordane for all purposes was eventually banned in 1988 as elevated levels of chlordane can negatively affect the nervous system and liver.¹⁰²

¹⁰¹ Richard P. Jones, "Product Recall in 4 States; Animal Feed Tainted in Act of Sabotage," *Milwaukee Journal Sentinel*, January 4, 1997.

¹⁰² Agency for Toxic Substance and Disease Registry, "Toxfaqs for Chlordane (Clordano)," (Atlanta, GA: Centers for Disease Control and Prevention, September 1995 (updated August 2008)).

The Wisconsin Department of Agriculture, Trade and Consumer Protection further investigated the letter and determined that the Berlin NBP plant supplied Purina Mills Inc. in Fond du Lac, Wisconsin with tallow used in mixed animal feed.¹⁰³ NBP recalled tallow shipped from December 12 to December 27, 1996, and thoroughly decontaminated the plant.¹⁰⁴ Feed tested positive for low levels of chlordane on January 2, 1997; Purina recalled feed shipped to farms in Wisconsin, Illinois, Iowa, and Michigan on January 3, 1997. Additionally, Purina stopped the shipment of nearly 300 tons of feed from the Fond du Lac mill and worked diligently to contact hundreds of dairy, beef, hog, and poultry customers affected by the recall.¹⁰⁵ The FDA's Minneapolis District Office, with the Center for Veterinary Medicine's Division of Compliance, assisted the Wisconsin Department of Agriculture, Trade, and Consumer Protection with the recall.¹⁰⁶ Before the recall was initiated, feed was shipped to around 4,000 farms in Wisconsin, Minnesota, Michigan, and Illinois. Milk from dairy cows that had consumed contaminated feed was shipped and intended for use in products including butter, ice cream, and cheese.¹⁰⁷ Fortunately, cattle ineffectively process chlordane and

¹⁰³ Jones, "Product Recall in 4 States; Animal Feed Tainted in Act of Sabotage."

¹⁰⁴ Fran Bauer, "\$10,000 Reward Offered in Feed Case: Anonymous Letter and Pesticide Presence Forced Recall at Berlin Plant," *Milwaukee Journal Sentinel*, January 27, 1997.

¹⁰⁵ Radford G. Davis, "Agroterrorism: Need for Awareness," in *Perspectives in World Food and Agriculture*, ed. Colin G. Scanes and John A. Miranowski (Ames, IA: Iowa State Press, 2004); Jones, "Product Recall in 4 States; Animal Feed Tainted in Act of Sabotage."

¹⁰⁶ Food and Drug Administration, "Animal & Veterinary: Tampering Conviction," *FDA Veterinarian Newsletter* XV, no. V (September/October 2000).

¹⁰⁷ Davis, "Agroterrorism: Need for Awareness."

the risk to humans posed by consumption of these dairy products was minimal. Despite the minimal risk, feed, milk and meat from cattle, hogs, and chickens on forty to fifty Wisconsin farms were tested for chlordane.¹⁰⁸ The Michigan Department of Agriculture and Wisconsin Agriculture, Trade, and Consumer Protection officials tested milk from cows suspected to have eaten chlordane-contaminated feed and results indicated that chlordane was not present because the initial level of contamination was so low.¹⁰⁹

The Food and Drug Administration (FDA) and their Office of Criminal Investigation, Chicago Field Office, were involved in the criminal investigation and conducted nearly 200 interviews and carried out three search warrants.¹¹⁰ A \$10,000 reward was offered for information leading investigators to the person responsible for contaminating the product.¹¹¹ The investigation identified two separate tampering incidents. The first incident involved hundreds of pounds of chlordane being placed in

¹⁰⁸ Jones, "Product Recall in 4 States; Animal Feed Tainted in Act of Sabotage."; Agency for Toxic Substance and Disease Registry, "Toxfaqs for Chlordane (Clordano)." The level of contamination in feed was one to two parts per million. For reference, FDA restricts the amount of chlordane and breakdown products in animal fat and fish to less than 100 parts per billion and less than 300 parts per billion in most fruits and vegetables.

¹⁰⁹ Journal Sentinel staff and The Associated Press, "Milk Tests Negative for Banned Pesticide," *Milwaukee Journal Sentinel*, January 7, 1997; Michigan Department of Agriculture, "MDA Investigates Possible Feed Contamination," *PR Newswire*, January 6, 1997.

¹¹⁰ Food and Drug Administration, "Animal & Veterinary: Tampering Conviction."; Jones, "Product Recall in 4 States; Animal Feed Tainted in Act of Sabotage."

¹¹¹ Bauer, "\$10,000 Reward Offered in Feed Case: Anonymous Letter and Pesticide Presence Forced Recall at Berlin Plant."

tallow and bone meal produced by NBP. The second incident involved the fungicide folpet being placed in grease containers owned by NBP.¹¹²

Investigators suspected that the perpetrator resented NBP—possibly a former, disgruntled NBP employee who wanted to damage the company.¹¹³ The investigation began focusing on Brian W. “Skip” Lea. Lea had previously worked with NBP, but this changed after business deals went bad. At the time of the contaminations, Lea and NBP were competitors.¹¹⁴ On September 14, 1999, Lea was indicted on two counts of product tampering in violation of Title 18, U.S.C., 1365(b); the charges were filed by the Office of the U.S. Attorney, Eastern District of Wisconsin, Milwaukee, Wisconsin. The trial began on April 3, 2000, and ten days later, the jury found him guilty on one count of product tampering stemming from the chlordane incident.¹¹⁵ Lea was found not guilty on charges stemming from the folpet incident.¹¹⁶ He was sentenced to three years in prison, followed with one year supervised release, and forced to pay \$2.2 million in restitution.¹¹⁷ NBP lost over \$2.5 million in the incident.¹¹⁸

¹¹² Food and Drug Administration, "Animal & Veterinary: Tampering Conviction.;" Gretchen Schuldt, "Man Indicted on Charges of Tainting Animal Feed; Berlin Plant Contaminated with Toxic Pesticide in 1996," *Milwaukee Journal Sentinel*, September 15, 1999.

¹¹³ Michigan Department of Agriculture, "MDA Investigates Possible Feed Contamination."

¹¹⁴ Rose J. Wesolek, "Man Convicted of Tampering with Byproducts in Animal Feed," *Milwaukee Journal Sentinel*, April 14, 2000.

¹¹⁵ Food and Drug Administration, "Animal & Veterinary: Tampering Conviction."

¹¹⁶ Wesolek, "Man Convicted of Tampering with Byproducts in Animal Feed."

¹¹⁷ Food and Drug Administration, "Animal & Veterinary: Tampering Conviction."

The following section outlines the factors characterizing NDM settings and if, and when, they were present in the pesticide in feed products case in Berlin, Wisconsin.

Ill-structured problems

When the Berlin Police Department received the anonymous letter in December 1996, officials were perplexed. The claims in the letter could have been a hoax, but the seriousness of such claims drove the department to take further action. The decision to pursue the claims in the letter could just as easily have been dismissed—there were no reports of suspicious behavior or other warning signs to concern them. The level of contamination was initially unknown—leaving those in the case wondering if the products were dangerous to animal or human health. When products tested positive for only low levels of chlordane, the risk to human and animal health was found to be only minimal. However, contaminated products had already been shipped and used in production; those who received these products then had to be informed of the potential danger of their products.

Uncertain, dynamic environments

An uncertain, dynamic environment was certainly exhibited in this case. When the anonymous letter was sent to the Berlin Police Department, information about the validity and the level of chlordane in the products. When only a low level of chlordane was found in products on January 2, 1997, officials were able to determine only

¹¹⁸ Davis, "Agroterrorism: Need for Awareness."; Food and Drug Administration, "Animal & Veterinary: Tampering Conviction."; Wesolek, "Man Convicted of Tampering with Byproducts in Animal Feed."

minimal—yet still significant—risk to animal and human health. Understandably, this drastically affected the environment surrounding the case.

Shifting, ill-defined, or competing goals

When the anonymous letter was sent to the Berlin Police Department, the main goal was to determine if the claims in the letter were factual. When chlordane was found in feed, the goal shifted to removing contaminated product from the market. This included ceasing shipment, recalling products, and contacting those who received affected products. The goal eventually shifted to determining who was responsible for tampering with NBP products; Lea was eventually prosecuted and sentenced in federal court.

As the claims in the letters were determined to be factual, companies enacted recalls to protect animal and human health. From their perspectives, this represented a tradeoff; the companies were temporarily losing revenue, as opposed to potentially causing animal and human illness.

Action/feedback loops

The problems associated with the chlordane in this case were addressed with multiple decisions from different organizations. Action/feedback loops were illustrated when the Berlin Police Department pursued the claims in the anonymous letter, NBP determined the claims were factual and recalled contaminated feed, and ultimately Purina recalled products associated with contaminated feed. When a joint investigation determined that Lea was responsible for the contamination, this information was ultimately used to prosecute him.

Time constraints

Indeed, time constraints played a crucial role in this case. The Berlin Police Department received the anonymous letter warning officials of the contamination shortly after Christmas of 1996. By January 2, 1997, NBP recalled products shipped between December 12 and December 27, 1996, and feed from Purina's Fond du Lac mill tested positive for the pesticide chlordane. The next day, Purina recalled affected feed and contacted customers. However, dairy products from cattle that were fed feed with low levels of chlordane had already reached consumers.

Outcome with high stakes

While chlordane posed only minimal risk to human health at the levels found in dairy products, criminal investigators and public health officials did not just ignore the case. The case affected thousands of farms and much effort was exerted in the investigation and response. From a financial aspect, NBP lost an estimated \$2.5 million. Lea, found guilty of product tampering in violation of Title 18, U.S.C., 1365(b), was sentenced to three years in prison, followed with one year supervised release, and forced to pay \$2.2 million in restitution.

Multiple players

Multiple organizations with multiple players were involved in the decision-making process of this case and include:

1. ***The Berlin Police Department***: it received the letter from an individual claiming to have contaminated NBP tallow with chlordane.

2. **NBP**: its tallow was contaminated with chlordane and the company made the decision to recall potentially contaminated tallow.
3. **Purina**: it received and used tallow contaminated with chlordane from NBP.
4. **Purina's customers and farms**: product was distributed to customers and farms in states including Wisconsin, Illinois, Iowa, Michigan, and Minnesota.
5. **State agriculture authorities**: these organizations were involved in recall efforts in their respective states.
6. **The FDA's Minneapolis District Office and the Center for Veterinary Medicine's Division of Compliance**: these organizations assisted in the recall.
7. **The FDA's Office of Criminal Investigations, Chicago Field Office**: it conducted the criminal investigation.
8. **The Office of the U.S. Attorney, Eastern District of Wisconsin, Milwaukee, Wisconsin**: the case was prosecuted under its jurisdiction.

Organizational goals and norms

Each player involved in the decision-making process of this case represented an organization with established goals and norms. All parties involved were required to consider these organizational goals and norms, rather than solely considering personal preferences in making decisions for their respective organizations.

Case 3: *Salmonella* serotype Tennessee in peanut butter (2006-2007; U.S.)

Throughout 2005 and most of 2006, PulseNet—a CDC-run organization of public health and food regulatory agency laboratories responsible for subtyping bacteria using

pulsed-field gel electrophoresis (PFGE)—received one to five reports of *S. Tennessee* a month. However, thirty reports were received in October 2006. Noticeably more reports of *S. Tennessee* led the CDC to investigate further.

OutbreakNet—a CDC team including local, state, and federal epidemiologists and public health officials that investigate foodborne illnesses—conducted interviews from November to December 2006; however, a common food exposure could not be found. In January 2007, OutbreakNet officials across the U.S. interviewed 26 patients using a standard survey instrument and found that 85% of patients had eaten peanut butter and 48% of patients had eaten turkey in the week prior to the onset of illness.

A multistate investigation from February 5 to February 13, 2007, with 65 patients and 124 controls, was used to determine the food responsible for the illnesses. A case was defined as infection with *S. Tennessee* matching the outbreak strain in a person age 18 years or older with a history of diarrhea. Individuals from the extended neighborhood of patients served as controls. Investigators associated illnesses with eating peanut butter (brands Peter Pan and Great Value) with the product code 2111.¹¹⁹

The CDC notified ConAgra Foods—producer of the implicated peanut butter—and they stopped production, destroyed remaining product, and recalled all Peter Pan and WalMart’s Great Value peanut butter with the product code 2111 on February 14, 2007. ConAgra worked with the FDA to ensure the safety of their products and offered

¹¹⁹ "Multistate Outbreak of *Salmonella* Serotype Tennessee Infections Associated with Peanut Butter-United States, 2006-2007," *The Journal of the American Medical Association* 298, no. 1 (2007).

full refunds to consumers.¹²⁰ Reports of illnesses decreased after the recall was enacted.¹²¹ On February 22, 2007, ConAgra confirmed that peanut butter manufactured in their Sylvester, Georgia plant had tested positive for *Salmonella*.¹²² Additionally, the outbreak strain of *S. Tennessee* was found in open and unopened jars of Peter Pan and Great Value peanut butter and in environmental samples from the Sylvester, Georgia plant.¹²³

A case was defined as,

Infection with *Salmonella Tennessee* with a PFGE pattern matching one of the three outbreak patterns in a person residing in the United States with symptom onset on or after August 1, 2006 (or, if onset date unknown, *Salmonella Tennessee* isolated on or after August 2, 2006).¹²⁴

¹²⁰ ConAgra Foods Inc., "Peter Pan Peanut Butter and Great Value Peanut Butter Products Beginning with Product Code 2111 Recalled for Possible *Salmonella* Contamination," <http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1008647&highlight=>.

¹²¹ "Multistate Outbreak of *Salmonella* Serotype Tennessee Infections Associated with Peanut Butter-United States, 2006-2007."

¹²² ———, "Conagra Foods Announces Test Finds *Salmonella* in Its Peanut Butter," Omaha, NE, <http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1008642&highlight=>.

¹²³ "Multistate Outbreak of *Salmonella* Serotype Tennessee Infections Associated with Peanut Butter-United States, 2006-2007."

¹²⁴ *Ibid.* 33.

The outbreak resulted in 714 cases in 48 states.¹²⁵ The recall—including the cost of the peanut butter, recovering it, and disposing it—cost ConAgra between \$50 million and \$60 million.¹²⁶

In a news release on April 5, 2007, ConAgra announced plans to renovate their Sylvester, Georgia plant in August 2007; the company assured consumers that renovations, including modern machinery, technology, and design, addressed all possible causes of the *Salmonella* outbreak. A plant investigation led ConAgra to believe that moisture, which accidentally entered the production line, provided conditions suitable for low levels of *Salmonella*, probably introduced from raw peanuts or peanut dust, to grow. Additionally, ConAgra created a position, vice president of Global Food Safety, and established a Food Safety Advisory Committee. To increase inventory, ConAgra contracted an approved co-manufacturer who produced Peter Pan peanut butter.¹²⁷

ConAgra's Peter Pan—the 3rd top peanut butter brand in the U.S.—reopened its Sylvester, Georgia plant in August 2007 and the top 30 grocery store chains restocked

¹²⁵ Robert V. Tauxe, "Real Burden and Potential Risks from Foodborne Infections: The Value of Multijurisdictional Collaborations," *Trends in Food Science and Technology* 19(2008).

¹²⁶ Marc Longpre and Hamilton Nolan, "Conagra Bolster Comms Amid Peanut Butter Recall," *PR Week* February 26, 2007.

¹²⁷ ConAgra Foods Inc., "Conagra Foods Announces the Renovation of Its Peanut Butter Plant and Enhanced Food Safety Measures," [http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1008473&highlight=.](http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1008473&highlight=)

their products.¹²⁸ ConAgra faced class action lawsuits that claimed injury and damages from eating tainted peanut butter.¹²⁹ A 2005 report had consumers questioning whether this outbreak was preventable. The report indicated that FDA inspectors investigated a suspected outbreak of *Salmonella* in peanut butter in October 2004 produced at ConAgra's Sylvester, Georgia plant. ConAgra acknowledged that it destroyed certain products in that time period; however, the company did not provide a reason why. ConAgra asked FDA inspectors for a written request for documentation to protect proprietary information; the written request was not provided and ConAgra dismissed the case. The FDA defended its actions and assured consumers that further action would have been taken if inspectors had found serious problems.¹³⁰

The following section outlines the eight factors characterizing NDM settings and if, and when, they were present in the *S. Tennessee* in peanut butter case from 2006 to 2007.

Ill-structured problems

In October 2006, an increase of reports of *S. Tennessee* alerted the CDC to a potential outbreak. However, determining the food responsible for the outbreak was

¹²⁸ Jen Haberkorn, "Peter Pan Tries to Recover from *Salmonella*," *The Washington Times*, April 9, 2007; Brad Dorfman, "Peter Pan Gets a Facelift," *The Montreal Gazette*, August 8, 2007.

¹²⁹ "Class Action Lawsuit Filed vs. Conagra over *Salmonella* in Peanut Butter," Progressive Grocer, http://www.progressivegrocer.com/progressivegrocer/eseach/article_display.jsp?vnu_content_id=1003567768.

¹³⁰ Elizabeth Williamson, "FDA Was Aware of Dangers to Food; Outbreaks Were Not Preventable, Officials Say," *The Washington Post*, April 23, 2007.

difficult. When ConAgra's peanut butter was implicated as the source of the outbreak, they responded by initiating a recall even though the presence of *S. Tennessee* in their peanut butter had not been confirmed. Peanut butter had rarely been implicated as a source of *Salmonella* and this confused public health researchers.¹³¹

Uncertain, dynamic environments

The environment in this case was unquestionably uncertain and dynamic. Public health officials were not able to implicate peanut butter as the source of the outbreak until February 13, 2007—although, additional reports of *S. Tennessee* were first noted in October of 2006. In that time period, information about the source of the illnesses was lacking. Additionally, the level of *Salmonella* in the products and the quantity of products that was distributed were unknown.

Shifting, ill-defined, or competing goals

When the outbreak investigation first began, researchers worked to determine the food responsible for the outbreak. When ConAgra peanut butter with product code 2111 was implicated, the goal shifted to preventing additional illnesses by initiating a recall. When recall efforts were finished, ConAgra aimed to reestablish itself as a top U.S. supplier of peanut butter by addressing issues uncovered in the recent outbreak

¹³¹ Elizabeth Weise, "Salmonella Outbreak, Rare in Peanut Butter, Stuns Health Officials," *USA Today*, February 16, 2007; S.L. Burnett et al., "Survival of *Salmonella* in Peanut Butter and Peanut Butter Spread," *Journal of Applied Microbiology* 89(2000). One outbreak of *Salmonella* in peanut butter, at that time, was known. The outbreak occurred in Australia in 1996. Researchers later found that the viscous and oily nature of peanut butter provides bacteria protection during pasteurization.

(i.e. renovating the plant, creating the position of vice president of Global Food Safety, and creating the Food Safety Advisory Committee).

Action/feedback loops

Initially, ConAgra recalled peanut butter as a precautionary step to protect the safety of consumers. Product testing results—confirming the presence of *S. Tennessee* in ConAgra peanut butter—served as action/feedback loops that allowed ConAgra to address problems that ultimately caused the contamination. Renovations including modern machinery, technology, and design were implemented to address the possible cause of the recent outbreak. The position of vice president of Global Food Safety and the Food Safety Advisory Committee were also created.

Time constraints

Time was certainly an issue in this case. When a multistate investigation from February 5 to February 13, 2007, implicated peanut butter produced by ConAgra with product code 2111 as the source of the outbreak, ConAgra was notified immediately. Within a day, on February 14, 2007, ConAgra recalled all peanut butter with the product code 2111, in an effort to ensure the safety of consumers. In making such a serious decision within less than 24 hours, time constraints undoubtedly stressed decision-makers at ConAgra.

Outcome with high stakes

When alerted by the CDC that their products were associated with a current *Salmonella* outbreak, ConAgra made decisions to prevent additional illnesses by initiating a recall. Certainly, personal high stakes were present; the outbreak strain of

Salmonella can cause serious illness. For the company, the decision to enact a recall was meant to limit the number of illnesses and reduce financial losses. The outbreak cost ConAgra more than \$50 million and, from a public health aspect, the outbreak resulted in at least 714 illnesses. Additionally, ConAgra faced class action lawsuits that claimed injury and damages from eating tainted peanut butter. Certainly, the outcome of these decisions had high stakes.

Multiple players

As ConAgra produced the contaminated peanut butter, it was their decision to stop production, destroy remaining products, and recall potentially contaminated products. Retailers who sold ConAgra's peanut butter also influenced ConAgra's decisions, since they were ultimately supplying consumers. ConAgra's decisions were influenced by other organizations including the CDC, the CDC's PulseNet, the CDC's OutbreakNet, and offices within the FDA who played specific roles in the case. Additionally, all of the organizations involved included multiple individuals.

Organizational goals and norms

Each player involved in the decision-making process of this case represented an organization with established goals and norms. All parties involved were required to consider these organizational goals and norms, rather than solely considering personal preferences when making decisions for their respective organizations.

Case 4: *Listeria monocytogenes* in deli products (2002; Camden, New Jersey and Franconia, Pennsylvania)

The Pennsylvania Department of Health received reports of twenty cases of *L. monocytogenes* from July to August 2002, with two cases resulting in death.¹³² This increase alarmed public health officials and the Pennsylvania Department of Health and the Philadelphia Department of Health began epidemiological and laboratory investigations on August 20, 2002. Lab samples collected from cases were sent to the CDC for additional testing.¹³³

Soil, water, and animals can be sources of *L. monocytogenes*. It has been found in raw foods including uncooked meats and vegetables and processed foods including soft cheeses and ready-to-eat meats (e.g., hot dogs and luncheon meats). Thorough cooking kills the bacteria; however, contamination in ready-to-eat meats commonly occurs after cooking but prior to packaging.¹³⁴ *L. monocytogenes* can survive cold temperatures and illness can occur days or even months after exposure.¹³⁵ Listeriosis, while rare, can develop after individuals eat food contaminated with *L. monocytogenes*. Typically affecting the elderly, pregnant women, newborns, and adults with weakened immune

¹³² Pennsylvania Department of Health, "Health Department Announces Investigation of *Listeria* Infections," <http://www.dsf.health.state.pa.us/health/cwp/view.asp?Q=232137&A=190>. The state typically received reports of fewer than two-dozen cases per year. However, 2002 was the first year *Listeria* became a reportable disease in Pennsylvania.

¹³³ Ibid.

¹³⁴ CDC Division of Foodborne Bacterial and Mycotic Diseases, "Listeriosis," http://www.cdc.gov/nczved/dfbmd/disease_listing/listeriosis_gi.html.

¹³⁵ J. M. Farber and P. I. Peterkin, "*Listeria monocytogenes*, a Food-Borne Pathogen," *Microbiology and Molecular Biology Reviews* 55, no. 3 (1991).

systems, symptoms initially include fever, muscle aches, and occasionally nausea and diarrhea. Infection can spread to the nervous system and cause headache, stiff neck, confusion, loss of balance, or convulsions. Symptoms in pregnant women may only include mild, flu-like illnesses; however, infection can cause miscarriage or stillbirth, premature delivery, or infection of the newborn.¹³⁶

On September 18, 2002, the CDC announced that 26 patients in Pennsylvania, New York, Maryland, Connecticut, and Michigan had contracted listeriosis from bacteria with a matching PFGE pattern (i.e., the outbreak strain); this suggested that a common food was responsible for the outbreak. The CDC and state health departments also investigated other listeriosis cases from strains not matching outbreak strain.¹³⁷ As the number of *L. monocytogenes* cases rose, health officials determined sliced turkey deli meat was likely the source of the outbreak; however, the manufacturer and brand were not yet known.¹³⁸

The USDA's Food Safety and Inspection Service (FSIS)—alongside the CDC, and state public health officials—worked to determine the cause of the outbreak. In Athens, Georgia, FSIS's Microbial Outbreaks and Special Projects Branch (MOSPB) laboratory

¹³⁶ CDC Division of Foodborne Bacterial and Mycotic Diseases, "Listeriosis."

¹³⁷ Centers for Disease Control and Prevention, "Update: Listeriosis Outbreak Investigation," <http://www.cdc.gov/media/pressrel/ro20918b.htm>.

¹³⁸ ———, "Update: Listeriosis Outbreak Investigation," <http://www.cdc.gov/media/pressrel/ro21004a.htm>. As of October 4, 2002, forty people contracted listeriosis from the outbreak strain. All of the said patients were hospitalized, seven died, and three pregnant women had stillbirths or miscarriages. *Listeria* strains, not matching the outbreak strain, from thirty other patients were also investigated.

tested more than 400 FSIS-regulated products. A sample collected on October 2, 2002, at a Pilgrim's Pride Corporation plant, conducting business as Wampler Foods Inc., in Franconia, Pennsylvania, tested positive for *L. monocytogenes*. However, the strain found did not match the outbreak strain. On October 9, 2002, USDA announced that Pilgrim's Pride was recalling approximately 295,000 pounds of fresh and frozen ready-to-eat turkey and chicken products that were possibly contaminated with *L. monocytogenes*. The products were produced on August 14, 2002, and sold to retail stores and other distributors and had the establishment code "P-1351" on the USDA inspection seal.¹³⁹

The FSIS collected additional product and environmental samples from the Franconia, Pennsylvania plant. Products manufactured on different days of production tested negative for *L. monocytogenes*, while environmental samples collected in the plant tested positive for the *L. monocytogenes* strain previously found in recalled products. With these findings, on October 12, 2002, the recall was expanded to include fresh and frozen ready-to-eat turkey and chicken products produced between May 1 and

¹³⁹ Food Safety and Inspection Service, "Pennsylvania Firm Recall Turkey and Chicken Products for Possible *Listeria* Contamination," United States Department of Agriculture, <http://www.fsis.usda.gov/OA/recalls/prelease/pr090-2002a.htm>.

October 11, 2002. Recalled products totaled approximately 27.4 million pounds.¹⁴⁰ At that time, this recall was the largest in USDA history.¹⁴¹

In an ongoing investigation, the CDC and FSIS tested product samples from Jack Lambersky Poultry Company Inc., conducting business as J.L. Foods Company Inc., in Camden, New Jersey. Some of these products tested positive for a strain of *L. monocytogenes* that was indistinguishable from the outbreak strain. On November 2, 2002, FSIS announced that Jack Lambersky Poultry Company was recalling 200,000 pounds of fresh and frozen ready-to-eat poultry products that were possibly contaminated with *L. monocytogenes*. The products were produced between June 27 and July 3, 2002, and sold to retail stores and other distributors.¹⁴² The recall was later expanded on November 20, 2002, to include products produced from May 29 to November 2, 2002. The products had the establishment code "P-4340" on the USDA inspection seal; product recall totaled approximately 4.2 million pounds.¹⁴³

¹⁴⁰ ———, "Pennsylvania Firm Expands Recall of Turkey and Chicken Products for Possible *Listeria* Contamination," United States Department of Agriculture, <http://www.fsis.usda.gov/OA/recalls/prelease/pr090-2002.htm>.

¹⁴¹ "Wampler Foods Recall Expanded to Record 27.4 Million Pounds," *Frozen Food Digest* 18, no. 2 (2002).

¹⁴² ———, "New Jersey Firm Recalls Poultry Products for Possible *Listeria* Contamination," United States Department of Agriculture, <http://www.fsis.usda.gov/OA/recalls/prelease/pr098-2002a.htm>.

¹⁴³ ———, "New Jersey Firm Expands Recall of Poultry Products for Possible *Listeria* Contamination," United States Department of Agriculture, <http://www.fsis.usda.gov/OA/recalls/prelease/pr098-2002.htm>.

Working together, USDA's FSIS and the CDC analyzed product and environmental samples from Pilgrim's Pride and Jack Lambersky Poultry Company plants. From the Franconia, Pennsylvania Pilgrim's Pride plant, two ready-to-eat turkey products and 25 environmental samples tested positive for *L. monocytogenes*. The CDC reported that the turkey products had *L. monocytogenes* strains that did not match the outbreak strain. Of the environmental samples analyzed, several samples had strains that matched the strains found in the turkey products and the strain found in two samples was indistinguishable from the outbreak strain. From the Camden, New Jersey Jack Lambersky Poultry Company plant, a number of ready-to-eat poultry products tested positive for a strain that was indistinguishable from the outbreak strain. One environmental sample tested positive for a strain that did not match the outbreak strain.¹⁴⁴ Researchers questioned how and why the same strain of *L. monocytogenes* was associated with product and environmental samples taken from geographically separate locations.¹⁴⁵

The *L. monocytogenes* outbreak strain was responsible for 53 cases of illness in nine states including Pennsylvania (15), New York (21), New Jersey (5), Delaware (4), Maryland (2), Connecticut (1), Michigan (1), Massachusetts (3), and Illinois (1). Males

¹⁴⁴ Centers for Disease Control and Prevention, "Update: Listeriosis Outbreak Investigation," <http://cdc.gov/media/pressrel/r021121.htm>.

¹⁴⁵ See: Phyllis Entis, *Food Safety: Old Habits, New Perspectives* (Washington, D.C.: ASM Press, 2007). Proposed reasons for this include laboratory error, raw poultry contamination, asymptomatic employee contamination, and used equipment contamination.

accounted for 32 cases, while females accounted for 21 cases. Table 7 summarizes the patient categories.¹⁴⁶

Table 7: *L. monocytogenes* Outbreak Strain Cases by Category (2002; Camden, New Jersey and Franconia, Pennsylvania)¹⁴⁷

| Categories | Number of patients |
|---|--------------------|
| Age 65 or above | 16 |
| Age 1 to 64 with immunocompromising medical condition | 17 |
| Pregnant | 8 |
| Neonates | 4 |
| Not pregnant or known to have an immunocompromising condition | 7 |
| No information available | 1 |

During the same time, 98 patients in the northeastern U.S. tested positive for different strains of *L. monocytogenes*, including 24 deaths. These are considered “background” intermittent illnesses probably from a variety of different foods.¹⁴⁸

The following section outlines the eight task and setting factors characterizing NDM settings and if, and when, they were present in the *L. monocytogenes* in deli products case in 2002.

Ill-structured problems

When increased reports of listeriosis began arriving at the Pennsylvania Department of Health, the department first had to decide if these reports were out of the

¹⁴⁶ Centers for Disease Control and Prevention, "Update: Listeriosis Outbreak Investigation."

¹⁴⁷ Table adapted from: Ibid.

¹⁴⁸ Ibid.

ordinary. These cases could be non-related, common cases of listeriosis; however, the department further investigated the potential listeriosis outbreak. Initially, Pilgrim's Pride products were implicated as the source of the outbreak. However, Jack Lambersky Poultry Company also recalled products for potential *L. monocytogenes* contamination. Investigators found a strain that was indistinguishable from the outbreak strain in environmental samples taken from the Pilgrim's Pride plant and from ready-to-eat poultry products from the Jack Lambersky Poultry Company plant. This created more ambiguity and difficulty for public health investigators because the same strain of bacteria is generally not isolated from product or environmental samples taken from geographically separate locations. There was also ambiguity associated with distinguishing listeriosis cases caused by the outbreak strain and other strains.

Uncertain, dynamic environments

Substantial information was missing during the outbreak investigation, which affected the environment. *L. monocytogenes* has a long incubation period and patients may not be able to recall what brand of poultry products or when they were consumed. This lack of information creates difficulty for public health researchers who are investigating the outbreak. Researchers confirmed that the *L. monocytogenes* outbreak strain caused 53 cases of illness, but other strains were responsible for 98 additional cases of illness. Researchers did not have all of the information about the cases and that certainly affected the environment.

Shifting, ill-defined, or competing goals

When the outbreak investigation first began, researchers worked to determine the food responsible for the outbreak. When sliced poultry products were implicated as the source of the outbreak, the goal shifted into preventing additional illnesses by removing potentially contaminated products from the market. Both Pilgrim's Pride and Jack Lambersky Poultry Company recalled products for potential *L. monocytogenes* contamination.

Action/feedback loops

Initially, Pilgrim's Pride recalled select turkey product as a precautionary step to protect the safety of consumers. Results from product testing confirmed the presence of *L. monocytogenes* and this led the company to include additional products in the recall. Results of microbial testing served as action/feedback loops because the information from previous product testing was utilized to address additional problems. A similar situation occurred when Jack Lambersky Poultry Company expanded their recall. Product and environmental testing results—confirming the presence of *L. monocytogenes* in Pilgrim's Pride and Jack Lambersky Poultry Company—served as action/feedback loops that allowed these companies to address problems that ultimately caused the contamination.

Time constraints

Time stress was, without doubt, an issue in this outbreak. Table 8 illustrates the time period in which public health officials responded and companies recalled products.

Table 8: *L. monocytogenes* in Deli Products Outbreak Time Period (2002; Camden, New Jersey and Franconia, Pennsylvania)

| Date in 2002 | Event |
|---------------------|--|
| July to August | The Pennsylvania Department of Health noticed a spike in reported cases of <i>L. monocytogenes</i> |
| August 20 | Epidemiological and laboratory investigation conducted by the Pennsylvania Department of Health |
| September 18 | The CDC announced that 26 patients in the northeastern U.S. had contracted listeriosis from the same strain |
| October 4 | Sliced turkey deli meat implicated as the source of the outbreak |
| October 9 | Pilgrim’s Pride recalled 295,000 pounds of poultry products that were potentially contaminated with <i>L. monocytogenes</i> |
| September 12 | Pilgrim’s Pride expanded their recall to include 27.4 million pounds of poultry products that were potentially contaminated with <i>L. monocytogenes</i> |
| November 2 | Jack Lambersky Poultry Company recalled 200,000 pounds of poultry products that were potentially contaminated with <i>L. monocytogenes</i> |
| November 29 | Jack Lambersky Poultry Company expanded their recall pounds of poultry products that were potentially contaminated with <i>L. monocytogenes</i> |

Outcome with high stakes

Listeriosis, while rare, can be fatal. When the risk of fatality is elevated, high stakes are certainly present. Pilgrim’s Pride and Jack Lambersky Poultry Company enacted recalls to ensure the safety of consumers and reduce financial losses. Still, these companies faced tremendous losses. Pilgrim’s Pride estimated that its turkey sales were negatively affected by \$145 million. Operating margins were estimated to be negatively affected by \$85 to \$95 million. The direct recall expense with the anticipated business interruption and product re-establishment costs was estimated at \$100 million; the

company's insurer paid \$50 million.¹⁴⁹ Individuals sued Pilgrim's Pride and Jack Lambersky Poultry Company for wrongful death and injury after eating contaminated products. Pilgrim's Pride settled several wrongful death and injury lawsuits. Pilgrim's Pride and Jack Lambersky Poultry Company paid Shakandra Hampton \$3 million after she contracted listeriosis and prematurely delivered a child with disabilities.¹⁵⁰ Certainly, the stakes were high.

Multiple players

Many organizations were involved in the outbreak investigation and contributed to the decision-making process. Health departments from states where illnesses were reported worked with the CDC to determine the source of the outbreak. The USDA's FSIS also helped determine the source of the outbreak and assisted in the recalls enacted by Pilgrim's Pride and Jack Lambersky Poultry Company. FSIS's MOSPB was also integral in the investigation, as they were responsible for testing products for *L. monocytogenes*. Additionally, all of the organizations involved included multiple individuals.

Organizational goals and norms

Each player involved in the decision-making process of this case represented an organization with established goals and norms. All parties involved were required to

¹⁴⁹ Pilgrim's Pride Corporation, "Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934," (Pittsburg, TX2005).

¹⁵⁰ Entis, *Food Safety: Old Habits, New Perspectives*.

consider these organizational goals and norms, rather than by solely considering personal preferences in making decisions for their respective organizations.

Discussion

As hypothesized, all eight factors characterizing NDM settings were indeed present in responding incidents involving food safety and food defense. That is, the four cases—collectively, representative of food safety and food defense settings—revealed the presence of ill-structured problems; uncertain, dynamic environments; shifting, ill-defined, or competing goals; action/feedback loops; time constraints; outcome with high stakes; multiple players; and organizational goals and norms. Table 9 summarizes the results of the analysis. As these factors complicate the decision-making process, it is important to determine if prevailing educational programs and tools aimed at preparing for food safety and food defense issues directly include methods to address the eight factors characterizing NDM settings. Chapter three explores this very question.

Table 9: NDM Task and Setting Factors in Incidents Involving Food Safety and Food Defense

| NDM Factors | Case | | | |
|--|---|--|--|---|
| | <i>Salmonella</i> serotype Typhimurium in retail salad bars | Pesticide in feed products | <i>Salmonella</i> serotype Tennessee in peanut butter | <i>Listeria monocytogenes</i> in deli products |
| Ill-structured problems | Illnesses could be non-related, common cases of foodborne illness No food or water source was common to the salad bars | Claims in the letter could have been a hoax If true, high levels of chlordane could be very dangerous to animals and humans | Peanut butter rarely implicated as a source of <i>Salmonella</i> and confused public health researchers | Ambiguity associated with two plants having the outbreak strain Ambiguity associated with distinguishing listeriosis cases caused by the outbreak strain and other strains |
| Uncertain, dynamic environments | Missing, incomplete, and incorrect information surrounding the cause of the outbreak | Missing and incomplete information about the validity and the level of chlordane in the products | Missing information about the source of the illnesses The level of <i>Salmonella</i> in the products and the quantity of products that was distributed were unknown | Information about the individual cases was often missing, incomplete, or incorrect |
| Shifting, ill-defined, or competing goals | Competing: public health versus restaurant profitability Shifting: determining the source of the | Shifting: investigating claims, removing contaminated product, and prosecuting the | Shifting: determining source of outbreak, preventing additional illnesses, recalling products, addressing | Shifting: determining source, preventing additional illnesses, and recalling products |

| | outbreak and prosecuting those responsible for the outbreak | perpetrator | problems that caused outbreak, and reestablishing the company in the market | |
|---------------------------------|---|--|---|--|
| Action/feedback loops | Investigating outbreak Environmental and product testing Interviewing patrons, employees, and restaurant owners Confession | Pursuing claims Recalling tallow Recalling feed Prosecuting perpetrator | Outbreak and recall ConAgra modernizing its plant | Both companies expanded recalls with results from product and environmental testing |
| Time constraints | Stress associated with responding to outbreak under time constraints | Stress associated with responding to claims under time constraints | Stress associated with responding to outbreak under time constraints | Stress associated with responding to outbreak under time constraints |
| Outcome with high stakes | Risk to health and life | NBP lost \$2.5 million Lea sentenced to three years in prison and forced to pay \$2.2 million | Risk to health and life Financial losses to ConAgra >\$50 million | Listeriosis poses exceptional health concerns Financial losses to Pilgrim's Pride >\$100 million |
| Multiple players | Wasco-Sherman Public Health Department Oregon State Public Health Laboratory CDC CDC's EIS Restaurants FBI Local and state law | The Berlin Police Department NBP Purina Purina customers and farms State agriculture authorities FDA's Minneapolis District Office, and | ConAgra Peter Pan Great Value Retailers CDC CDC's PulseNet CDC's OutbreakNet FDA | Pilgrim's Pride Jack Lambersky Poultry Company CDC USDA's FSIS FSIS's Microbial Outbreaks and Special Projects Branch |

| | | | | |
|--|---|---|--|--|
| | <p>enforcement INS National Guard</p> | <p>the Center for Veterinary Medicine's Division of Compliance FDA's Office of Criminal Investigations, Chicago Field Office The Office of the U.S. Attorney, Eastern District of Wisconsin, Milwaukee, Wisconsin</p> | | |
| <p>Organizational goals and norms</p> | <p>Federal and state officials versus local officials Unique to the different players</p> | <p>Unique to the different players</p> | <p>Unique to the different players</p> | <p>Unique to the different players</p> |

Chapter 3: NDM Task and Setting Factors in Prevailing Educational Programs and Tools Aimed at Preparing for Food Safety and Food Defense Issues

Prevailing educational programs and tools aimed at preparing for food safety and food defense issues include HACCP and CARVER plus Shock, respectively. This chapter will follow a hypothetical student, Shelly Smith, who is taking a food safety and food defense course that covers HACCP and CARVER plus Shock. While hypothetical, Shelly's experience is not far-fetched; indeed, food safety and food defense educational requirements often include HACCP and CARVER plus Shock.¹⁵¹ This chapter will analyze the information presented to Shelly to determine if it directly addresses the eight factors characterizing NDM settings.

Upon enrollment in KSU 949 "Food Safety and Food Defense Educational Programs and Tools," Shelly learns that the course will be split into two sections. The first is Introductory HACCP and the second section is CARVER plus Shock. The HACCP section received accreditation through the International HACCP Alliance. The International HACCP Alliance has established HACCP training program criteria and standards for program accreditation. Upon successful completion of the HACCP section

¹⁵¹ Food safety educational efforts often include HACCP. HACCP courses are offered worldwide and are often industry-specific. Food defense courses that include CARVER plus Shock are common. DHS sponsors an "Agriculture and Food Vulnerability Assessment Training Course" offered by the Center for Agriculture and Food Security and Preparedness and the course describes CARVER plus Shock in detail. Additionally, a Food Defense Training course offered in September 2009 by Purdue University, Kansas State University, and Indiana University-Purdue University Indianapolis included information on CARVER plus Shock.

of the course, participants like Shelly receive a certificate of completion indicating his or her successful completion of an accredited HACCP course.¹⁵²

Introductory HACCP

To be accredited by the International HACCP Alliance, an educational or training program must include established knowledge domains and learning objectives. Required knowledge domains and learning objectives taken directly from the International HACCP Alliance literature are provided in Appendix A. The eight knowledge domains covered in the HACCP modules are addressed in subsequent sections.

Recognizing the Relationship Between HACCP and Food Safety

Shelly's instructor first provided an overview of the course and expected learning objectives. She learns that the Pillsbury Company working with the National Aeronautics and Space Administration (NASA), U.S. Army Laboratories at Natick, and U.S. Air Force Space Laboratory Project Group initially developed the HACCP system to ensure the microbiological safety of food intended for the U.S. space program. HACCP, Shelly learns, is an acronym for the following elements:

- ***H***azard
- ***A***nalysis
- ***C***ritical
- ***C***ontrol
- ***P***oints

¹⁵² International HACCP Alliance, "International HACCP Alliance Accreditation Application for HACCP Training Programs Information Package," <http://www.haccpalliance.org/sub/accreditation.pdf>.

If foodborne illnesses were to affect astronauts in space, the mission could be compromised and this was not acceptable. HACCP was derived from the Failure, Mode and Effect Analysis (FMEA) engineering system.¹⁵³ When HACCP was introduced in the early 1960s, it was a novel approach to food safety and food quality; most efforts focused on end product testing, while HACCP offered a preventative program for the production of safe food.¹⁵⁴

As Shelly understood, the Pillsbury Company presented a basic HACCP system with three main principles in 1971 at the U.S. National Conference on Food Protection.¹⁵⁵ Since then, HACCP has advanced and many in the Agriculture and Food Sector utilize it. Crucial events in the progression of HACCP include the integration of HACCP principles into low-acid canned food regulations addressing *Clostridium botulinum* in 1973.¹⁵⁶ In 1992, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) endorsed HACCP as “an effective and rational means of assuring food safety from harvest to consumption” and provided a HACCP document in 1992.¹⁵⁷ NACMCF’s HACCP Working Group reviewed the document in 1995 to consider

¹⁵³ Tara Paster, *The HACCP Food Safety Training Manual* (Hoboken, NJ: John Wiley & Sons, Inc., 2007); Sara Mortimore and Carol Wallace, *HACCP: A Practical Approach* (London, England: Chapman & Hall, 1994). Prior to establishing control methods, Failure, Mode and Effect Analysis (FMEA) examines issues that could possibly arise at process steps and their causes and probable effects.

¹⁵⁴ Paster, *The HACCP Food Safety Training Manual*.

¹⁵⁵ Andrew Owen-Griffiths, *HACCP Works: Integrated Food Safety Management for Food Businesses* (Spinney Hill, UK: Highfield, 2005); Paster, *The HACCP Food Safety Training Manual*.

¹⁵⁶ Paster, *The HACCP Food Safety Training Manual*.

¹⁵⁷ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines," U.S.

HACCP guidance offered by the Codex Committee on Food Hygiene (CCFH). The CCFH provides the Codex Alimentarius Commission (CAC) with information regarding food hygiene.¹⁵⁸

In the U.S., HACCP is required for meat and poultry products; juices; and fish, shellfish, and fishery products.¹⁵⁹ However, the program is widely utilized by many in the Agriculture and Food Sector—from individual farms and ranches to retail establishments.¹⁶⁰ HACCP, when correctly utilized, allows for the production of safe food and decreases the risk of producing and selling unsafe food. Additional benefits to HACCP include improved product quality because of increased understanding of all

Department of Health and Human Services,
<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm>. 2. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is a committee housed under the USDA and includes members of the USDA's FSIS, the HHS's FDA, the HHS's CDC, the Department of Commerce's National Marine Fisheries Service, the Department of Defense's Office of the Army Surgeon General, academia, industry, and state employees. The Committee provides assistance and advice to the Secretary of Agriculture and the Secretary of Health and Human Services concerning microbiological food safety.

¹⁵⁸ Food Safety and Inspection Service, "Codex Alimentarius Commission," U.S. Department of Agriculture,
http://www.fsis.usda.gov/codex_alimentarius/Codex_CAC/index.asp. The Codex Alimentarius Commission (CAC) is an organization with more than 170 members and, under the regulations of the Joint Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), details food safety standards.

¹⁵⁹ For legislation regarding each, see: "Part 417-Hazard Analysis and Critical Control Point (HACCP) Systems," in *9CFR17* (U.S. Government Printing Office, 2008); "Part 120-Hazard Analysis and Critical Control Point (HACCP) Systems," in *2CFR120* (U.S. Government Printing Office, 2009); "Part 123-Fish and Fishery Products," in *21CFR123* (U.S. Government Printing Office, 2009).

¹⁶⁰ Mortimore and Wallace, *HACCP: A Practical Approach*.

hazards and participation of all HACCP team members.¹⁶¹ After a brief synopsis of food safety and HACCP, case studies highlighting the effectiveness of HACCP were reviewed.

Reviewing Good Manufacturing Practices

Shelly, unfamiliar with HACCP, learns that it is not a stand-alone food safety program, but requires prerequisite programs that impart conditions allowing for the production of safe foods. Federal, state, and local regulations and guidelines identify several of these.¹⁶² Table 10 identifies common prerequisite programs to HACCP cited by NACMCF.

¹⁶¹ Ibid.

¹⁶² National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines." Examples include Good Agricultural Practices (GAPs), current Good Manufacturing Practices (cGMPs), and the Food Code. For more information, see: Food and Agriculture Organization of the United Nations, "Good Agricultural Practices," http://www.fao.org/prods/GAP/index_en.htm; Food and Drug Administration, "Good Manufacturing Practices (GMPs) for the 21st Century - Food Processing," U.S. Department of Health and Human Services, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/ucm110877.htm>; Food and Drug Administration: Public Health Service, "2009 Food Code," U.S. Department of Health and Human Services, <http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/UCM189448.pdf>.

Table 10: Prerequisite Programs¹⁶³

| Prerequisite Program | Description |
|----------------------------------|---|
| Facilities | Sanitary design principles reducing the potential for cross-contamination should be considered when constructing an establishment. |
| Supplier control | Establishments should ensure that suppliers are reputable and have valid food safety programs. |
| Specifications | Written specifications for ingredients, goods, and packaging must be established. |
| Production equipment | Sanitary design principles should be considered when production equipment is installed in a facility. Additionally, equipment should be properly maintained and calibrated. |
| Cleaning and sanitation | Documentation of cleaning and sanitation operations should be recorded. |
| Personal hygiene | All those who enter the facility must maintain a level of personal hygiene. |
| Training | Records of employee training should be maintained. |
| Chemical control | Non-food chemical should be stored in a secure area and their use documented. |
| Receiving, Storage, and Shipping | Sanitary conditions should exist in receiving, storage, and shipping areas. |
| Traceability and recall | Lot-codes allowing for the traceability and recall of products should be utilized in case there is a need to recover products. |
| Pest control | Programs to ensure the management of pests should be utilized. |

In addition to the prerequisite programs described by NACMCF, Shelly learns about regulations regarding sanitation and sanitation standard operating procedures (SOPs) required for FSIS-inspected meat and poultry facilities. FSIS, in 9CFR416, addresses sanitation. Included in this, Shelly learns, are FSIS regulations on

¹⁶³ Table adapted from National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

establishment grounds and facilities; equipment and utensils; sanitary operations; employee hygiene; and tagging unsanitary equipment, utensils, rooms or compartments.¹⁶⁴ Sanitation SOPs explicitly describe specific tasks prior to and throughout a food processing operation that prevent adulteration or contamination of products. In developing sanitation SOPs, the person-in-charge should sign and date them—representing the implementation and maintenance of sanitation SOPs. It is also crucial for sanitation SOPs to include how often an SOP should be carried out and who is responsible for each SOP. The supervisor should include mechanisms for sanitation SOP implementation, maintenance, corrective actions, and record keeping.¹⁶⁵

Current good manufacturing practices (cGMPs), Shelly learns, are addressed by the FDA in 21CFR110. Using FDA definitions, a food is adulterated if it has been prepared, packed, or held under unsanitary conditions where it could have been contaminated with filth or under may have been rendered injurious to health. Specific regulations regarding personnel, buildings and facilities, equipment, and production and process controls can be found in 21CFR110.¹⁶⁶ While these regulations are not

¹⁶⁴ "Part 416-Sanitation," in *9CFR416* (U.S. Government Printing Office 2009). Included in the lecture on establishment grounds and facilities are specific sections addressing grounds and pest control; lighting; ventilation; plumbing; sewage disposal; water supply and water, ice, and solution reuse; and dressing rooms, lavatories and toilets. Included in the lecture on sanitary operations are specific sections addressing food-contact surface, non-food-contact surfaces, chemicals, and sanitary operations throughout the establishment. Included in the lecture on employee hygiene are sections on cleanliness, clothing, and disease control. The section on tagging unsanitary equipment, utensil, rooms or compartments includes an overview of tags used by FSIS employees that signify food produced under conditions not approved by the agency.

¹⁶⁵ *Ibid.*

¹⁶⁶ "Part 110-Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food," in *21CFR110* (Government Printing Office, 2009).

mandated by FSIS, they provide excellent guidance to meat and poultry producers under FSIS regulation.¹⁶⁷ After developing GMPs and SOPs, Shelly understands their importance as the building blocks of HACCP; a HACCP plan will not be effective unless prerequisite programs are established.

Identifying and Controlling Hazards

In this section of the course, Shelly is introduced to the concept of hazards. To effectively explore the concept of hazards, the food(s) produced must first be identified. A hazard is “a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.”¹⁶⁸ Biological, chemical, and physical hazards were further discussed, and they are explained below.

Shelly learns that biological hazards include bacteria, toxins formed by bacteria, viruses, and parasites capable of causing illness or injury. Foodborne disease caused by biological hazards results from the consumption of foods contaminated with living bacterial cells (or spores when referring to infant botulinum) or toxins produced by bacteria. The classification can be further broken down into three groups (e.g., intoxication, infection, and toxicoinfection).

Foodborne intoxication results from the ingestion of preformed bacterial toxin; living bacterial cells need not be present for illness to be present. Examples of foodborne

¹⁶⁷ University of Nebraska Cooperative Extension, "Good Manufacturing Practices (Gmp's)," University of Nebraska Lincoln, <http://foodsafety.unl.edu/haccp/prerequisites/gmp.html>.

¹⁶⁸ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines." 4.

intoxication include Staph poisoning resulting from *Staphylococcus aureus* and botulism from *Clostridium botulinum*.¹⁶⁹

Foodborne infection results from the ingestion of food contaminated with enteropathogenic bacteria; the bacteria must be capable of surviving processing and can potentially multiply in the digestive tract. Examples of microorganisms capable of causing foodborne infection include *Salmonella* spp., *Campylobacter* spp., enterohemorrhagic and nonhemorrhagic *Escherichia coli*, *Listeria monocytogenes*, *Shigella* spp., and *Vibrio parahaemolyticus* and *V. vulnificus*.¹⁷⁰ Monitoring and adjusting time, temperature, acidity, and water activity can often control these bacterial hazards.¹⁷¹

Toxicoinfection results from the ingestion of food contaminated with pathogenic bacteria that sporulate or die and release toxins that cause illness. Examples of microorganisms capable of causing foodborne toxicoinfection include *Clostridium perfringens*, *Bacillus cereus*, certain enteropathogenic and enterotoxigenic *E. coli* strains, and pathogenic strains of *V. cholerae*.¹⁷²

Viruses—another type of biological hazard—can rapidly reproduce on a host and cause illness. Examples include hepatitis A and E, rotavirus, norovirus, and reovirus.

¹⁶⁹ Bibek Ray, *Fundamental Food Microbiology* (Boca Raton, FL: CRC Press, Inc., 1996).

¹⁷⁰ *Ibid.*

¹⁷¹ Paster, *The HACCP Food Safety Training Manual*.

¹⁷² Ray, *Fundamental Food Microbiology*.

The spread of viruses is best controlled by proper hygiene including proper hand washing techniques and using gloves when touching ready-to-eat foods.¹⁷³

Parasites capable of causing foodborne illness—including, roundworms, flatworms, tapeworms, and protozoa—also require a host. Examples include *Trichinella spiralis*, *Taenia* spp., *Anisakis simplex*, *Toxoplasma gondii*, and *Giardia lamblia*. These organisms are often animal-host specific, but are capable of surviving in humans. The spread of parasites is best controlled by killing the organisms (e.g., thorough cooking and freezing).¹⁷⁴

Chemical hazards are chemicals capable of causing illness in humans. Examples include naturally occurring chemical toxins from certain fish, shellfish, mushrooms, plants, and beans. Specific control methods for the particular hazard and food are available.¹⁷⁵ Other potential chemical hazards include cleaning chemicals, pesticides, allergens, toxic metals, nitrates and nitrites, chemical additives, veterinary drug residues, plasticizers, and packaging materials. Controls methods to prevent chemical contamination are product specific.¹⁷⁶

Physical hazards are materials not normally found in foods that, if present, are capable of causing injury or illness. There are many examples of potential physical hazards; examples include glass, metal, stones, wood, bone, plastic, and pests (not

¹⁷³ Paster, *The HACCP Food Safety Training Manual*.

¹⁷⁴ Ray, *Fundamental Food Microbiology*; Paster, *The HACCP Food Safety Training Manual*.

¹⁷⁵ Paster, *The HACCP Food Safety Training Manual*.

¹⁷⁶ Mortimore and Wallace, *HACCP: A Practical Approach*.

disease-causing). Physical hazards can arise anywhere in production and many of the control measures may be addressed in prerequisite programs.¹⁷⁷

To identify hazards significant to an operation or facility, the HACCP team must identify hazards applicable to the specific product. This is done first by reviewing the ingredients used in the product, the production processes, the equipment used in production, the finished product, the method of storage and distribution, the intended use, and the intended consumer. Potential biological, chemical, and physical hazards are identified using that information. Questions developed by NACMCF can assist in the identification of potential hazards and are found in Appendix B. Information regarding past health-related events dealing with the product is also useful in identifying hazards. Next, the HACCP team decides what hazards should be addressed in the HACCP plan. To assess potential hazards, the HACCP teams looks at the severity (e.g., potential impact, magnitude, and duration of illness or injury associated with the hazard) and the likelihood of occurrence (e.g., experiential, epidemiological, and technical data). When the HACCP team finishes the hazard analysis, it records the hazards and methods to control them.¹⁷⁸ The following example is cited in NACMCF documents:

¹⁷⁷ Ibid.

¹⁷⁸ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

Table 11: Sample Hazard Analysis for Frozen Cooked Beef Patties¹⁷⁹

| Step | Potential hazard(s) | Justification | Hazard to be addressed in plan? Y/N | Control measure(s) |
|-------------|--|---|--|---------------------------|
| 5. Cooking | Enteric pathogens: <i>Salmonella</i> and verotoxigenic- <i>E. coli</i> | Enteric pathogens have been associated with outbreaks of foodborne illness from undercooked ground beef | Y | Cooking |

Presenting and Discussing the Principles of HACCP

Two weeks into the course, Shelly's instructor discussed some preliminary steps to HACCP including developing a HACCP team and creating a flow diagram. The HACCP team, ideally, includes individuals from different disciplines who can provide useful knowledge in the development of the plan. Team members can include subject matter and processing experts, operations personnel, and outside experts. The HACCP team should also develop a flow diagram that documents all steps in production or processing of the product in the facility. The HACCP team should verify the flow diagram by reviewing it to ensure that it accurately depicts the process. If necessary, modifications should be made.¹⁸⁰

The seven HACCP principles were then discussed. Shelly provided a summary of what was included in each principle; these appear below.

¹⁷⁹ Table adapted from: Ibid. 12.

¹⁸⁰ Ibid.

Principle 1: Conduct a hazard analysis

The HACCP team must conduct a hazard analysis, which includes identifying potential hazards and evaluating whether or not they should be addressed in the HACCP plan. When the HACCP team finishes the hazard analysis, the hazards and methods to control them should be recorded.¹⁸¹ Conducting a hazard analysis is directly related to the information regarding hazards discussed above.

Principle 2: Determine critical control points (CCPs)

Using the information from the hazard analysis, the HACCP team must determine control points and critical control points (CCPs). A control point is a step at which a hazard can be controlled. A CCP is a point, step, or procedure where a control can be employed to prevent or eliminate a food safety hazard or reduce the hazard to an acceptable level. CCPs address food safety issues; CCPs identified by the HACCP team could include a heat treatment at a specified temperature for a designated time. CCP decision trees, such as those in Appendix C, can be useful in identifying potential CCPs.¹⁸²

Principle 3: Establish critical limits

The HACCP team must then determine critical limits for CCPs. A critical limit is a measureable minimum and/or maximum value that must be satisfied to control CCPs. If applied, critical limits prevent or eliminate a food safety hazard or reduce the hazard to an acceptable level; critical limits should not be confused with operational limits, which

¹⁸¹ Ibid.

¹⁸² Ibid; Karen L. Hulebak and Wayne Schlosser, "Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview," *Risk Analysis* 22, no. 3 (2002).

address issues other than food safety. Critical limits should be scientifically based upon factors such as time, temperature, water activity, and pH. Documentation (citing regulatory resources, scientific literature, experimental results, and experts) of established critical limits is crucial.¹⁸³

Principle 4: Establish monitoring procedures

Monitoring procedures, such as observations or measurements, ensure that critical limits established for CCPs are met. Specifically, what factors are monitored, where they will be monitored, how they will be monitored, when they will be monitored, and who is responsible for monitoring should all be addressed in the HACCP plan.

Monitoring procedures fulfill three purposes. They include:

1. The tracking of the food processing operations,
2. The loss of control (i.e., not meeting established critical limits), and
3. The documentation of the operation used for verification.

If possible, monitoring procedures should be carried out on a continuous basis (i.e., capable of rapid results); however, some monitoring procedures such as microbial testing can take time and their usefulness in detecting contaminants is limited.

Therefore, adequate sampling plans and limitations of microbial testing must also be considered when determining monitoring procedures.¹⁸⁴

¹⁸³ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."; Hulebak and Schlosser, "Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview."

¹⁸⁴ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

Principle 5: Establish corrective actions

The HACCP program aims to prevent or eliminate food safety hazards or reduce the hazards to an acceptable level. However, this does not always happen. Therefore, the HACCP team must establish corrective actions. The corrective actions should include the following:

1. Find out and fix the reason why corrective action had to be taken,
2. Find out what happened to the affected product, and
3. Document the corrective actions taken.

Those responsible for corrective actions should be familiar with the production process, product, and the HACCP plan.¹⁸⁵

Principle 6: Establish record-keeping and documentation procedures.

Record-keeping and documentation procedures are of considerable importance to a HACCP system. Records should include a summary of the hazard analysis, the HACCP plan (including the HACCP team and responsibilities; description of the food, its distribution, intended use, and consumer; and verified flow diagram), and a HACCP summary table that addresses the seven HACCP principles.

Principle 7: Establish verification procedures

Verification procedures, as opposed to monitoring procedures, confirm that the HACCP plan is valid and that the plan is working effectively. Verification procedures include initial and subsequent validation of the HACCP plan, verification of CCP monitoring as explained in the HACCP plan, review of monitoring and correction action

¹⁸⁵ Ibid.

records to confirm alignment with the HACCP plan, and comprehensive HACCP system verification.¹⁸⁶

Implementing a HACCP Plan

Shelly's instructor further elaborates on the challenges to and tips for improving the successful implementation of a HACCP plan. First, senior management must stress the importance of food safety and convey this attitude to fellow employees. When an environment stressing food safety is enacted, a plan detailing how the HACCP plan will be developed and implemented can be established. Detailing realistic deadlines on HACCP implementation can be helpful initially. Timelines detailing the use of prerequisite programs such as SOPs and GMPs should always be included as a basis for HACCP.¹⁸⁷ Those in the Agriculture and Food Sector can look to industry trade groups, scholars, academia, and other thought leaders for tips for the successful implementation of HACCP.¹⁸⁸

Maintaining the HACCP Plan

Staff training is key to any successful HACCP plan. If not properly trained, employees are not able to effectively ensure the production of safe food. Training resources are available for companies to distribute to employees. Additionally,

¹⁸⁶ Ibid.

¹⁸⁷ Ibid.

¹⁸⁸ See: Vassilis Georgakopoulos, "Application of HACCP in Small Food Businesses," in *Food Safety: A Practical and Case Study Approach*, ed. Anna McElhatton and Richard J. Marshall (New York, NY: Springer, 2007).

management is key to maintaining the HACCP plan. The plan should be regularly updated and verified to ensure that food safety measures are enabled.¹⁸⁹

Recognizing Regulatory Issues Impacting the Implementation of HACCP

Shelly understands that, while HACCP is only mandated for select products, it is widely utilized and required by many organizations. It is the responsibility of processors to produce safe food. HACCP resources are widely available and even industry or product-specific resources can be found. In addition to HACCP regulatory requirements, other industry-specific regulatory requirement may be enforced. HACCP plans, mandated under U.S. regulations, are subject to verification and appropriate enforcement actions may be enacted in cases of noncompliance.¹⁹⁰

Establishing a Working HACCP Plan

After Shelly has absorbed all the information her HACCP instructor provides, she and her fellow classmates develop an actual HACCP plan. The HACCP instructor then provides the group feedback. Her instructor stressed that the HACCP principles must be tested and shown to prevent, reduce, or minimize identified hazards in real-world environments. After the successful completion of this, she is presented with a certificate of completion and the CARVER plus Shock portion of the course begins.

CARVER plus Shock

In an opening lecture, Shelly's instructor describes CARVER plus Shock as the following:

¹⁸⁹ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

¹⁹⁰ Ibid.

An assessment methodology that provides a consistent means for evaluating the consequences, vulnerability, and threat faced by assets, systems, networks, and functions in the Food and Agriculture Sector.¹⁹¹

In utilizing CARVER plus Shock, those in the Agriculture and Food Sector can assess vulnerabilities and concentrate on the most vulnerable points. CARVER, Shelly learns, is an acronym for the following elements:

- **Criticality**
- **Accessibility**
- **Recuperability**
- **Vulnerability**
- **Effect**
- **Recognizability**

Lastly, the “Shock” element is separate and estimates the health, economic, and psychological impacts of an attack.

Shelly’s instructor informs the class that there are five steps to conducting a CARVER plus Shock analysis; they are addressed in subsequent sections.

Step 1: Establish Parameters

Shelly learns that prior to scoring, parameters of what the decision-makers are aiming to protect and what they are aiming to protect it from must be established. These parameters include the following:

- What food supply, agricultural chain, or facility is going to be evaluated?

¹⁹¹ Department of Homeland Security, Department of Agriculture, and Food and Drug Administration, "Agriculture and Food: Critical Infrastructure and Key Resources Sector-Specific Plan as Input to the National Infrastructure Protection Plan." 69.

- Examples include a broad food supply chain from farm-to-fork such as milk or a specific establishment such as facility that produces snack cakes.
- What is the endpoint of concern?
 - Examples include foodborne illness or death in humans, plant or animal death, and economic impacts.
- What type of attacker and attack are you defending against?
 - Attackers could include disgruntled employees, terrorist organizations, or others wishing to harm a food supply, agricultural chain, or facility. In their vulnerability assessments, the FSIS and the FDA often assume that a top goal of terrorist organizations is to cause a large number of deaths by contaminating food products. Additionally, it can be helpful if the decision-makers select an attacker who has access to the facility (i.e., a trusted employee) as this individual is aware all potential vulnerabilities.
- What agent(s) may be used?
 - An attacker may use biological, chemical, or radiological agents. The properties (e.g., half-life, heat stability, and lethal dose) of the specific agent can determine the impact of an attack on the food supply. Additionally, it can be helpful if one selects an agent that can survive processing and remain toxic in the finished product as this helps to identify all potential vulnerabilities for assigning ordered risks and planning.¹⁹²

¹⁹² These parameters are adapted from: Thompson et al., *Mgt 332: Agriculture and Food Vulnerability Assessment Training Course*; United States Department of

Step 2: Assemble Experts

Shelly's instructor stresses the importance of assembling a multidisciplinary team of subject matter experts to conduct the CARVER plus Shock analysis. This may include production experts, food scientists, food toxicologists, epidemiologists, microbiologists, medical doctors, veterinarians, radiologists, risk assessors, intelligence or security professionals, and personnel or management directors. The team is then responsible for using the CARVER plus Shock method to assign a value for all elements of the food system infrastructure, based on the parameters established in the previous step.¹⁹³

Step 3: Detail the Food Supply Chain

Shelly's next lesson covers detailing the food supply chain. This includes describing the system or facility that is being analyzed. A flow chart of the system and its subsystem, complexes, components, and nodes should be created. The following example represents hot dog production:

- ***Subsystem:*** live animal production, slaughter/processing, and distribution.
- ***Complexes:*** slaughterhouse and processing facilities.
- ***Components:*** Raw materials receiving area, processing area, storage area, and shipping area.
- ***Nodes:*** Individual pieces of equipment.¹⁹⁴

Agriculture and Food and Drug Administration, "An Overview of the Carver Plus Shock Method for Food Sector Vulnerability Assessment," www.fsis.usda.gov/PDF/CARVER.pdf.

¹⁹³ Thompson et al., *Mgt 332: Agriculture and Food Vulnerability Assessment Training Course*.

¹⁹⁴ This example is provided by: Ibid; United States Department of Agriculture and Food and Drug Administration, "An Overview of the Carver Plus Shock Method for Food Sector Vulnerability Assessment."

Step 4: Assign Scores

Shelly learns that when the infrastructure is broken down into components and nodes, they can be scored for each of the CARVER plus Shock elements to calculate a score for the particular component or node. Those that have the highest overall score are those that are the most vulnerable. The logic behind the team's scoring should be documented. Shelly's instructors provided her the following tables outlining the CARVER plus Shock elements and scales.¹⁹⁵

Table 12: Criticality

Criticality: A target is critical when introduction of threat agents into food at this location would have significant health or economic impact. Example metrics are:

| Criticality Criteria | Scale |
|--|-------|
| Loss of over 10,000 lives or loss of more than \$100 billion (Note: if looking on a company level, loss of >90% of the total economic value for which you are concerned.*) | 9-10 |
| Loss of life is between 1,000-10,000 or loss of between \$10 billion and \$100 billion. (Note: if looking on a company level, loss of between 61% and 90% of the total economic value for which you are concerned.*) | 7-8 |
| Loss of life is between 100-1,000 or loss of between \$1 and \$10 billion. (Note: if looking on a company level, loss of between 31% and 60% of the total economic value for which you are concerned.*) | 5-6 |
| Loss of life is less than 100 or between \$100 million and \$1 billion. (Note: if looking on a company level, loss of between 10% and 30% of the total economic value for which you are concerned.*) | 3-4 |
| No loss of life or loss of less than \$100 million. (Note: if looking on a company level, loss of <10% of the total economic value for which you are concerned.*) | 1-2 |

*The total economic value for which you are concerned depends on your perspective. For example, for a company this could be the percent of a single facility's gross revenues, or percentage of a company's gross revenues lost from the effect on a single product line. Likewise, a state could evaluate the effect of the economic loss caused by an attack of a facility or farm by the proportion of the state's economy contributed by that commodity.

¹⁹⁵ Tables are taken directly from: United States Department of Agriculture and Food and Drug Administration, "An Overview of the Carver Plus Shock Method for Food Sector Vulnerability Assessment."

Table 13: Accessibility

| Accessibility: A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents. Example metrics are: | |
|---|--------------|
| Accessibility Criteria | Scale |
| Easily Accessible (e.g., target is outside building and no perimeter fence). Limited physical or human barriers or observation. Attacker has relatively unlimited access to the target. Attack can be carried out using medium or large volumes of contaminant without undue concern of detection. Multiple sources of information concerning the facility and the target are easily available. | 9-10 |
| Accessible (e.g., target is inside building, but in unsecured part of facility). Human observation and physical barriers limited. Attacker has access to the target for an hour or less. Attack can be carried out with moderate to large volumes of contaminant, but requires the use of stealth. Only limited specific information is available on the facility and the target. | 7-8 |
| Partially Accessible (e.g., inside building, but in a relatively unsecured, but busy, part of facility). Under constant possible human observation. Some physical barriers may be present. Contaminant must be disguised, and time limitations are significant. Only general, non-specific information is available on the facility and the target. | 5-6 |
| Hardly Accessible (e.g., inside building in a secured part of facility). Human observation and physical barriers with an established means of detection. Access generally restricted to operators or authorized persons. Contaminant must be disguised and time limitations are extreme. Limited general information available on the facility and the target. | 3-4 |
| Not Accessible. Physical barriers, alarms, and human observation. Defined means of intervention in place. Attacker can access target for less than 5 minutes with all equipment carried in pockets. No useful publicly available information concerning the target. | 1-2 |

Table 14: Recuperability

Recuperability: A target’s recuperability is measured in the time it will take for the specific system to recover productivity. The effect of a possible decrease in demand is considered in this criterion. Example metrics are:

| Recuperability Criteria | Scale |
|-------------------------|-------|
| >1 year | 9-10 |
| 6 months to 1 year | 7-8 |
| 3-6 months | 5-6 |
| 1-3 months | 3-4 |
| <1 month | 1-2 |

Table 15: Vulnerability

Vulnerability: A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker’s purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target (e.g., ease of introducing agents, ability to uniformly mix agents into target) and the characteristics of the surrounding environment (ability to work unobserved, time available for introduction of agents). It is also important to consider what interventions are already in place that might thwart an attack. Example metrics are:

| Vulnerability Criteria | Scale |
|--|-------|
| Target characteristics allow for easy introduction of sufficient agents to achieve aim. | 9-10 |
| Target characteristics almost always allow for introduction of sufficient agents to achieve aim. | 7-8 |
| Target characteristics allow 30 to 60% probability that sufficient agents can be added to achieve aim. | 5-6 |
| Target characteristics allow moderate probability (10 to 30 %) that sufficient agents can be added to achieve aim. | 3-4 |
| Target characteristics allow low probability (less than 10%) sufficient agents can be added to achieve aim. | 1-2 |

Table 16: Effect

Effect: Effect is a measure of the percentage of system productivity damaged by an attack at a single facility. Thus, effect is inversely related to the total number of facilities producing the same product. Example metrics are:

| Effect Criteria | Scale |
|--|-------|
| Greater than 50% of the system's production impacted | 9-10 |
| 25-50% of the system's production impacted | 7-8 |
| 10-25% of the system's production impacted | 5-6 |
| 1-10% of the system's production impacted | 3-4 |
| Less than 1% of system's production impacted | 1-2 |

Table 17: Recognizability

Recognizability: A target's recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components. Example metrics are:

| Recognizability Criteria | Scale |
|--|-------|
| The target is clearly recognizable and requires little or no training for recognition | 9-10 |
| The target is easily recognizable and requires only a small amount of training for recognition | 7-8 |
| The target is difficult to recognize or might be confused with other targets or target components and requires some training for recognition | 5-6 |
| The target is difficult to recognize. It is easily confused with other targets or components and requires extensive training for recognition | 3-4 |
| The target cannot be recognized under any conditions, except by experts. | 1-2 |

Table 18: Shock

Shock: Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. The psychological impact will be increased if there are a large number of deaths or the target has historical, cultural, religious, or other symbolic significance. Mass casualties are not required to achieve widespread economic loss or psychological damage. Collateral economic damage includes such items as decreased national economic activity, increased unemployment in collateral industries, etc. Psychological impact will be increased if victims are members of sensitive subpopulations such as children or the elderly. Example metrics are:

| Shock Criteria | Scale |
|--|-------|
| Target has major historical, cultural, religious, or other symbolic importance. Loss of over 10,000 lives. Major impact on sensitive subpopulations, e.g., children or elderly. National economic impact more than \$100 billion. | 9-10 |
| Target has high historical, cultural, religious, or other symbolic importance. Loss of between 1,000 and 10,000 lives. Significant impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$10 and \$100 billion. | 7-8 |
| Target has moderate historical, cultural, religious, or other symbolic importance. Loss of life between 100 and 1,000. Moderate impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$1 and \$10 billion. | 5-6 |
| Target has little historical, cultural, religious, or other symbolic importance. Loss of life less than 100. Small impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$100 million and \$1 billion. | 3-4 |
| Target has no historical, cultural, religious, or other symbolic importance. Loss of life less than 10. No impact on sensitive subpopulations, e.g., children or elderly. National economic impact less than \$100 million. | 1-2 |

Note: By definition, terrorists attempt to achieve strong emotional responses from their target audience. Aspects of targets that terrorists view as increasing a target’s shock value are symbolism (e.g., the Pentagon), large number of casualties, sensitive nature of facilities (e.g., nuclear facilities), and the ability to strike at core values and primal emotions (e.g., targeting children).

Step 5: Apply What Has Been Learned

Shelly learns that after the critical nodes are identified, countermeasures that lessen the attractiveness of the node should be put in place. Countermeasures are dependent upon the node, but may include increased physical security, personnel

security, and operational security. Specific strategies to harden targets (i.e., make them less attractive to potential attackers) were also provided by Shelly's instructor.¹⁹⁶

After covering the information presented above, Shelly's instructor informs the class that they will be using the CARVER plus Shock tool to assess potential vulnerabilities at several different establishments. The instructor provides background information on each establishment and the students work through the CARVER plus Shock analysis. In particular, they looked at a ham company and the following three nodes: mixing of the cure, drying of the ham, and packaging of the whole ham. Mixing of the cure scored 55, drying of the ham scored 42, and packaging of the whole ham scored 33. As the mixing of the cure had the highest score, this node has the highest potential vulnerability and was the focus of countermeasure efforts.¹⁹⁷ Mitigation strategies were discussed and developed.

Shelly has now completed KSU 949 "Food Safety and Food Defense Educational Programs and Tools." The following table outlines the information presented to Shelly in her course to determine if it directly addresses the eight factors characterizing NDM settings.

¹⁹⁶ Ibid.

¹⁹⁷ Example adapted from: Thompson et al., *Mgt 332: Agriculture and Food Vulnerability Assessment Training Course*.

Table 19: Do Prevailing Educational Programs and Tools Aimed at Preparing for Food Safety and Food Defense Issues Directly Address the NDM Factors?

| | Educational Programs and Tools | |
|---------------------------------|---|--|
| NDM Factors | HACCP | CARVER plus Shock |
| Ill-structured problems | Somewhat. In the course, Shelly learned that HACCP is a preventative food safety system. The HACCP team identifies hazards using scientific and historical data and information about the particular product. The severity and likelihood of occurrence are then utilized to determine if the particular hazard should be identified as a CCP. There is always potential for unconventional hazards to be introduced, which are not directly addressed by the HACCP plan. Rather, prerequisite programs are possibly utilized to address certain broader issues such as cleaning chemical contaminants. The hazards identified are reasonably likely or have occurred in the past. ¹⁹⁸ From this standpoint, HACCP does not directly address making decisions involving ill-structured problems. | Somewhat. Shelly’s course helped her understand the complexities and challenges of protecting the Agriculture and Food Sector. In utilizing a CARVER plus Shock analysis, it is suggested that the team approach attacks with the most ill-structured problems (i.e., the attacker has insider access and uses agents that cause the most harm). This approach highlights all possible vulnerabilities for planning purposes. These critical nodes can then be made less attractive to targets. However, making decisions in environments involving ill-structured problems is not completely addressed. |
| Uncertain, dynamic environments | No. Again, Shelly learned that HACCP addresses food safety issues likely to occur or that have occurred. When critical limits are not satisfied, corrective action is necessary. Corrective actions should include mechanisms for identifying the | Somewhat. In addressing the most ill-structured problems, a CARVER plus Shock analysis fails to address making decisions in environments involving uncertain, dynamic environment. Shelly learned that some of the uncertain, |

¹⁹⁸ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

| | | |
|--|--|---|
| | <p>reason or reasons why critical limits were not satisfied. However, it is a preventative system and does not directly address mechanisms to make decisions in an uncertain, dynamic environment.</p> | <p>dynamic environment is taken into account when assigning scores to components of the CARVER plus Shock analysis; but, she was not directly provided information on how to make decisions in an uncertain, dynamic environment.</p> |
| <p>Shifting, ill-defined, or competing goals</p> | <p>No. Shelly recognized that the primary goal of HACCP is to prevent food safety issues from arising. This is accomplished by applying the seven principles of HACCP. From this aspect, HACCP does not directly address shifting, ill-defined, or competing goals. However, shifting, ill-defined, or competing goals may be somewhat addressed when companies establish procedures to follow when critical limits are not met.</p> | <p>Somewhat. The CARVER plus Shock tool, as Shelly learned, assesses the vulnerabilities in a supply chain or facility. The scores tabulated in the assessment allow the team to rank the vulnerabilities. In this, it is assumed that the higher the score, the greater the risk. Hence, ranking the scores does somewhat address the competing nature of these goals. The countermeasures used to reduce the attractiveness of a node can also be looked at from a competing standpoint. Some countermeasures are inexpensive; however, others can be expensive. To determine realistic countermeasures, the team must utilize a cost-benefit analysis.</p> |
| <p>Action/feedback loops</p> | <p>Yes. After the course, Shelly recognized that when established processes do not occur, corrective action serves as action/feedback loops. The information as to why a critical limit was not achieved is used to address that problem in the future. In this sense, HACCP does address action/feedback loops.</p> | <p>Yes. Shelly learned that information from the critical nodes identified in CARVER plus Shock analysis can be used to harden the targets. These may include increased physical security, personnel security, and operational security. In this sense, CARVER plus Shock does address action/feedback loops.</p> |

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| Time constraints | <p>Yes. This course helped Shelly realize that an effective HACCP program includes monitoring procedures. However, continuous monitoring of procedures is not always possible; therefore, the frequency and reliability of the test becomes important. Some monitoring procedures allow for rapid results. Examples include pH, temperature, time, and moisture level. The NACMCF directly addresses the time constraints of microbial testing as a monitoring procedure in HACCP. Results from microbial testing can take time and the results may not always be accurate.¹⁹⁹ In this sense, HACCP does address some of the time constraints faced when dealing with the Agriculture and Food Sector.</p> | <p>Somewhat. In her course, Shelly’s instructor addressed time issues in three of the elements of a CARVER plus Shock analysis. They include:</p> <ol style="list-style-type: none"> 1. Accessibility: addresses time limitations that are faced when introducing a potential agent to a system or facility, 2. Recuperability: assesses the time required for productivity to recover after an attack is assessed, and 3. Vulnerability: addresses the time available for the introduction of a potential agent. <p>These components affect the final score in the analysis, but Shelly’s ability to make decisions under time constraints is not completely addressed.</p> |
| Outcome with high stakes | <p>Yes. Regardless of the food, consumers expect it to be safe. If it is not, companies and those involved with that product stand to lose a lot. Therefore, the stakes are high. Shelly’s instructors stressed that HACCP—through prevention—has significantly impacted the Agriculture and Food Sector. CCPs identified by the HACCP team that are not controlled are likely to cause injury or illness. Past and future research on the cost-benefit analysis of HACCP on particular foods serves as an illustration</p> | <p>Yes. Shelly’s instructor stresses each element of the CARVER plus Shock analysis (i.e., criticality, accessibility, recuperability, vulnerability, effect, recognizability, and shock). Inherently, the criticality component of CARVER plus Shock directly addresses the degree to which an outcome has high stakes.</p> |

¹⁹⁹ Ibid.

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| | into the usefulness and its potential effects on the outcome of an industry with high stakes. ²⁰⁰ | |
| Multiple players | Yes. Shelly's instructor stressed how NACMCF suggests that multiple players comprise a HACCP team. The team members may be from different disciplines including engineering, processing or production, sanitation, quality assurance, and food microbiology. In addition to company personnel, NACMCF recognizes the importance of outside experts; these experts can offer product specific knowledge regarding potential hazards. However, outside experts should not solely comprise a HACCP team. ²⁰¹ | Yes. Shelly learned that a CARVER plus Shock assessment should include multiple players. This may include production experts, food scientists, food toxicologists, epidemiologists, microbiologists, medical doctors, veterinarians, radiologists, risk assessors, intelligence or security professionals, and personnel and management directors. ²⁰² In this sense, this tool does address multiple players in the decision-making processes. |
| Organizational goals and norms | Somewhat. Food safety is the overriding goal of HACCP and it is only mandated for certain products in the U.S. For those mandated product, producers are required to meet governmental requirements that must be taken into account by the HACCP team. Each member or department of the HACCP team contributes something to the HACCP plan. The course helped Shelly realized that each may | Somewhat. Each expert participating in the CARVER plus Shock analysis contributes unique information. The course helped Shelly realize that each may operate under separate organizational goals and norms. This was not directly addressed; however, organizational goals and norms are expected when utilizing a |

²⁰⁰ Julie A. Caswell, Maury E. Bredahl, and Neal H. Hooker, "How Quality Management Metasystems Are Affecting the Food Industry," *Review of Agricultural Economics* 20, no. 2 (1998).

²⁰¹ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines."

²⁰² Thompson et al., *Mgt 332: Agriculture and Food Vulnerability Assessment Training Course*; United States Department of Agriculture and Food and Drug Administration, "An Overview of the Carver Plus Shock Method for Food Sector Vulnerability Assessment."

operate under separate organizational goals and norms. NACMCF does not directly address issues regarding organizational goals and norms; however, they do suggest utilizing a multidisciplinary HACCP team.

multidisciplinary group of experts.

Discussion

Prevailing educational programs and tools aimed at preparing for food safety and food defense issues including HACCP and CARVER plus Shock do, to varying degrees, address the following factors characterizing NDM settings: ill-structured problems; uncertain, dynamic environments; shifting, ill-defined, or competing goals; action/feedback loops; time constraints; outcome with high stakes; multiple players; and organizational goals and norms. For example, CARVER plus Shock clearly and directly addresses multiple players. However, CARVER plus Shock only somewhat directly addresses shifting, ill-defined, or competing goals. With HACCP, the results are also mixed. For example, while HACCP addresses action/feedback loops, it fails to address uncertain, dynamic environments. Indeed, the direct inclusion of these factors in prevailing educational programs and tools aimed at preparing for food safety and food defense issues could be improved. A summary of chapters two and three and recommendations follow in chapter four.

Chapter 4: Summary and Recommendations

Decision-making is an essential element to protecting CIKRs, including the Agriculture and Food Sector. This thesis aimed to determine if prevailing programs and tools cited in food safety and food defense educational settings incorporated methods that help professionals make good decisions. The following hypothesis was tested: The eight factors characterizing NDM settings are indeed present in responding to incidents involving food safety and food defense. The following subsidiary question was also explored: Do prevailing educational programs and tools aimed at preparing for food safety and food defense issues (i.e., HACCP and CARVER plus Shock) directly include methods to address the eight factors characterizing NDM settings?

NDM Task and Setting Factors in Responding to Incidents Involving Food Safety and Food Defense

The four cases studies included in this thesis help paint a picture of the decision-making environment in the Agriculture and Food Sector. The *S. Typhimurium* in retail salad bars case (1984; The Dalles, Oregon) highlighted the environment typical of retail food establishments. The environment seen in this case certainly complicated the decision-making process for all who were involved. Possibly, many of the problems faced by those involved in this case could have been minimized if effective training and/or educational programs had been effectively utilized. The pesticide in feed products case (1996; Berlin, Wisconsin) emphasized the interconnectedness common to farms and production agriculture. Not only did this case affect NBP, but all of the companies that utilized their products were also involved. The environment surrounding this case undoubtedly complicated the decision-making process for all that were involved. The *S. Tennessee* in peanut butter case (2006-2007; U.S.) and the *L.*

monocytogenes is deli products case (2002; Camden, New Jersey and Franconia, Pennsylvania) highlighted the decision-making environment common to the food industry. In both cases, investigators struggled to pinpoint the cause of the outbreaks. According to the four cases included in this thesis, all eight factors characterizing NDM settings are indeed present in responding to food safety and food defense issues. The presence of ill-structured problems; uncertain, dynamic environments; shifting, ill-defined, or competing goals; action/feedback loops; time constraints; outcome with high stakes; multiple players; and organizational goals and norms complicates the decision-making process. As these factors are present in responding to incidents involving food safety and food defense, it is important to determine if prevailing educational programs and tools aimed at preparing for food safety and food defense issues (i.e., HACCP and CARVER plus Shock) directly include methods to address the eight NDM factors.

NDM Task and Setting Factors in Prevailing Educational Programs and Tools Aimed at Preparing for Food Safety and Food Defense Issues

The eight factors—all of which were found to be present in responding to incidents involving food safety and food defense—ought to be addressed in educational programs and tools aimed at preparing for food safety and food defense issues. Chapter three revealed that two educational programs and tools do address the eight factors, albeit to varying degrees. HACCP addresses action/feedback loops, time constraints, outcome with high stakes, and multiple players. CARVER plus Shock addresses action/feedback loops, outcome with high stakes, and multiple players. While HACCP somewhat addresses ill-structured problems and organizational goals and norms, it fails to address uncertain, dynamic environments and shifting, ill-defined, or competing goals. CARVER plus Shock somewhat addresses ill-structured problems; uncertain,

dynamic environments; shifting, ill-defined, or competing goals; time constraints; and organizational goals and norms. To better prepare food safety and food defense professionals to make good decisions in “response” settings, the eight factors must be better incorporated into education and training.

Recommendations

The case studies included in this thesis revealed the presence of the eight NDM factors in responses to incidents involving food safety and food defense. Educational programs and tools (i.e., HACCP and CARVER plus Shock) are intended to prepare for food safety and food defense issues. As this thesis has demonstrated, these educational programs and tools do, to varying degrees, incorporate the NDM factors that characterize the decision-making challenges in a response and recovery context. To adequately train professionals in food safety and food defense, more emphasis on responding to and recovering from incidents is needed. One way to better emphasize response and recovery is to fully incorporate the eight NDM factors into education and training.

To that end, experiential educational programs and tools have much to offer. From an educational aspect, simulations can be very useful. They allow participants to improve decision-making, problem-solving, and communication skills.²⁰³ One experiential learning opportunity relevant to food safety and food defense is Purdue

²⁰³ Henry Ellington, Monica Gordon, and Joannie Fowlie, *Using Games & Simulations in the Classroom* (Routledge, 1998).

University's Food Defense Computational Simulation.²⁰⁴ This simulation incorporates real-world data and highlights the challenges surrounding the decision-making environment in food safety and food defense incidents. In participating in an incident simulation, the participants are able to gain a better understanding of the environment common to food safety and food defense. Participants can clearly see the eight factors and how their presence complicates the environment surrounding the simulation.²⁰⁵ Indeed, these simulations could supplement food safety and food defense programs and tools (i.e., HACCP and CARVER plus Shock) and better address the eight NDM factors—factors that reflect the real decision-making environment in which professionals operate.

²⁰⁴ Kansas State University, Purdue University, and Indiana University-Purdue University Indianapolis recently offered a workshop titled “Food Defense Training and Incident Simulation.” Appendix D provides a summary of the incident simulation that was included in the workshop.

²⁰⁵ Rich Linton, Personal communication, November 12, 2009. In a personal communication with Rich Linton, project leader of the workshop, he revealed that all the NDM factors are addressed.

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Appendix A: Knowledge Domains and Learning Objectives Required for an Introductory HACCP Course Approved by the International HACCP Alliance

The following knowledge domains and learning objectives are taken directly from International HACCP Alliance educational material.²⁰⁶

- I. Recognize the relationship between HACCP and food safety
 - a. Explain the relationship between HACCP and food safety.
 - b. Discuss the benefits of implementing a HACCP system which include motivating and selling the industry on HACCP and reviewing case studies.
 - c. Discuss HACCP and basic food safety principles.
 - d. Review what students will learn from the course.
- II. Review good manufacturing practices (not a part of the HACCP plan)
 - a. Define and develop SOPs.
 - b. Define and develop GMPs.
 - c. Discuss the importance of SOPs and GMPs.
 - d. Describe how SOPs and GMPs are necessary before developing a HACCP plan.
- III. Identify and control hazards
 - a. Identify food items that are produced.
 - b. Define a hazard(s).
 - c. Name the three hazard categories (biological, chemical, physical) as defined by the National Advisory Committee on Microbiological Criteria for Food (NACMCF).
 - d. Determine the significant hazards as described in Principle 1 of the NACMCF guidelines.
 - e. Explain control measures that prevent, reduce, or minimize hazards associated with foods.
- IV. Present and discuss the principles of HACCP
 - a. Develop a flow chart of the process and product.
 - b. Conduct a hazard analysis; prepare a list of steps in the process where significant hazards occur and describe the preventative measures.
 - i. Describe the product and intended use.
 - ii. Identify potential hazards at points where they enter the process/food or can be enhanced during the process.
 - iii. Evaluate the severity and risk of hazards.
 - iv. Document rationale for hazard selection.
 - v. Differentiate significant from non-significant hazards.
 - c. Identify Critical Control Points (CCPs) in the process.

²⁰⁶ See: International HACCP Alliance, "International HACCP Alliance Accreditation Application for HACCP Training Programs Information Package." 4-8.

- i. Define control point and critical control point.
 - ii. Identify CCPs by using valid scientific criteria (i.e., a decision tree).
- d. Establish critical limits for preventative measures associated with each Critical Control Point.
 - i. Define and determine critical limits and operational limits.
 - ii. Set critical limits that are relevant to product safety.
 - iii. Document the rationale for critical limit selection.
 - iv. Measure and document critical limits.
 - v. Explain how critical limits are used to reassure compliance within a HACCP plan.
- e. Establish Critical Control Point monitoring requirement and procedures for using the results of monitoring to adjust the process and maintain control.
 - i. Recognize the importance of monitoring.
 - ii. Identify factors to be monitored.
 - iii. Identify where measurements will be taken.
 - iv. Explain how monitoring is to be conducted.
 - v. Determine the frequency for taking measurements.
 - vi. Identify who is responsible for monitoring.
 - vii. Describe monitoring procedures, sampling plans and methodology used.
 - viii. Clarify the difference between monitoring and verification.
- f. Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit.
 - i. Develop corrective actions.
 - ii. Identify responsible authority for determining corrective action.
 - iii. Describe corrective actions in SOP documentation that are consistent with monitoring activities.
 - iv. Document corrective actions.
- g. Establish effective record keeping procedures that document the HACCP system.
 - i. Discuss the importance of record keeping for determined the effectiveness of the HACCP system and for documenting appropriate efforts to produce safe food.
 - ii. Identify what information should be included in records.
 - iii. Develop records for documenting HACCP activities.
 - iv. Develop simple, plant friendly records with clear instructions to be accessible at line worker level.
 - v. Recognize the importance of reviewing records before control of product is lost.
- h. Establish procedures for verification that the HACCP system is working correctly.
 - i. Recognize the importance of verification to support and assure the long term viability of HACCP in an organization.
 - ii. Discuss different activities that can be conducted as part of verification.

- iii. Reinforce the importance of record review before the control of a product is lost.
 - iv. Implement a HACCP plan review at regular intervals or when significant changes in equipment, ingredients or operating procedures occur.
- V. Implement a HACCP plan
 - a. Describe the commitment from upper management for food safety to succeed.
 - b. Determine the key factors for successful HACCP implementation.
 - c. Discuss the steps for developing and implementing HACCP in the production plant.
 - d. Develop implementation steps using GMPs as a foundation for HACCP.
 - e. Convey realistic expectations of time and commitment needed to be successful.
- VI. Maintain the HACCP plan
 - a. Establish a staff training program.
 - i. Recognize the factors that significantly impact employee job performance.
 - ii. Assess staff training needs using task analysis/SOPs.
 - iii. Develop written behavioral objectives for SOPs that impact employees' specific work responsibilities.
 - iv. Evaluate a variety of techniques and methods for delivering training to a diverse work force.
 - v. Evaluate the effectiveness of training programs by using objective and performance measurements.
 - b. Establish HACCP maintenance and measurement procedures.
 - i. Recognize that HACCP systems are dynamic and subject to change/updating.
 - ii. Identify change factors that significantly impact HACCP plans and require review of the system.
 - iii. Recognize support systems and measures for HACCP plans (management food safety objectives).
 - iv. Evaluate the appropriateness of different measurement tools that are operation/process specific for HACCP systems.
- VII. Recognize regulatory issues impacting the implementation of HACCP systems
 - i. Recognize that the establishment is responsible for producing a safe product and having/implementing a HACCP plan.
 - ii. Identify what assistance is available from FSIS/FDA or other regulatory agencies.
 - iii. Identify and recognize all regulatory requirements:
 - 1. Sanitation SOPs.
 - 2. Microbiological testing as a verification tool.
 - iv. Discuss how FSIS/FDA or other regulatory agency will verify that the HACCP plan is working satisfactorily.
 - v. Describe enforcement actions for noncompliance.
- VIII. Establish a working HACCP plan for the attendees.

Appendix B: Examples of Questions to be Considered When Conducting a Hazard Analysis

The following questions are taken directly from NACMCF material.²⁰⁷

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients

1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., *Salmonella*, *Staphylococcus aureus*); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
2. Are potable water, ice and steam used in formulating or in handling the food?
3. What are the sources (e.g., geographical region, specific supplier)

B. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.

1. What hazards may result if the food composition is not controlled?
2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

C. Procedures used for processing

1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?

D. Microbial content of the food

1. What is the normal microbial content of the food?

²⁰⁷ National Advisory Committee on Microbiological Criteria for Foods, "Hazard Analysis and Critical Control Point Principles and Application Guidelines." 23-26.

2. Does the microbial population change during the normal time the food is stored prior to consumption?
 3. Does the subsequent change in microbial population alter the safety of the food?
 4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?
- E. Facility design
1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
 2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
 3. Is the traffic pattern for people and moving equipment a significant source of contamination?
- F. Equipment design and use
1. Will the equipment provide the time-temperature control that is necessary for safe food?
 2. Is the equipment properly sized for the volume of food that will be processed?
 3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
 4. Is the equipment reliable or is it prone to frequent breakdowns?
 5. Is the equipment designed so that it can be easily cleaned and sanitized?
 6. Is there a chance for product contamination with hazardous substances; e.g., glass?
 7. What product safety devices are used to enhance consumer safety?
 - metal detectors
 - magnets
 - sifters
 - filters
 - screens
 - thermometers
 - bone removal devices
 - dud detectors
 8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
 9. Are allergen protocols needed in using equipment for different products?
- G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
 2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
 3. Does the package include instructions for the safe handling and preparation of the food by the end user?
 4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?

5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?
8. Are potential allergens in the ingredients included in the list of ingredients on the label?

H. Sanitation

1. Can sanitation have an impact upon the safety of the food that is being processed?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education

1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of food?

J. Conditions of storage between packaging and the end user

1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use

1. Will the food be heated by the consumer?
2. Will there likely be leftovers?

L. Intended consumer

1. Is the food intended for the general public?
2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
3. Is the food to be used for institutional feeding or the home?

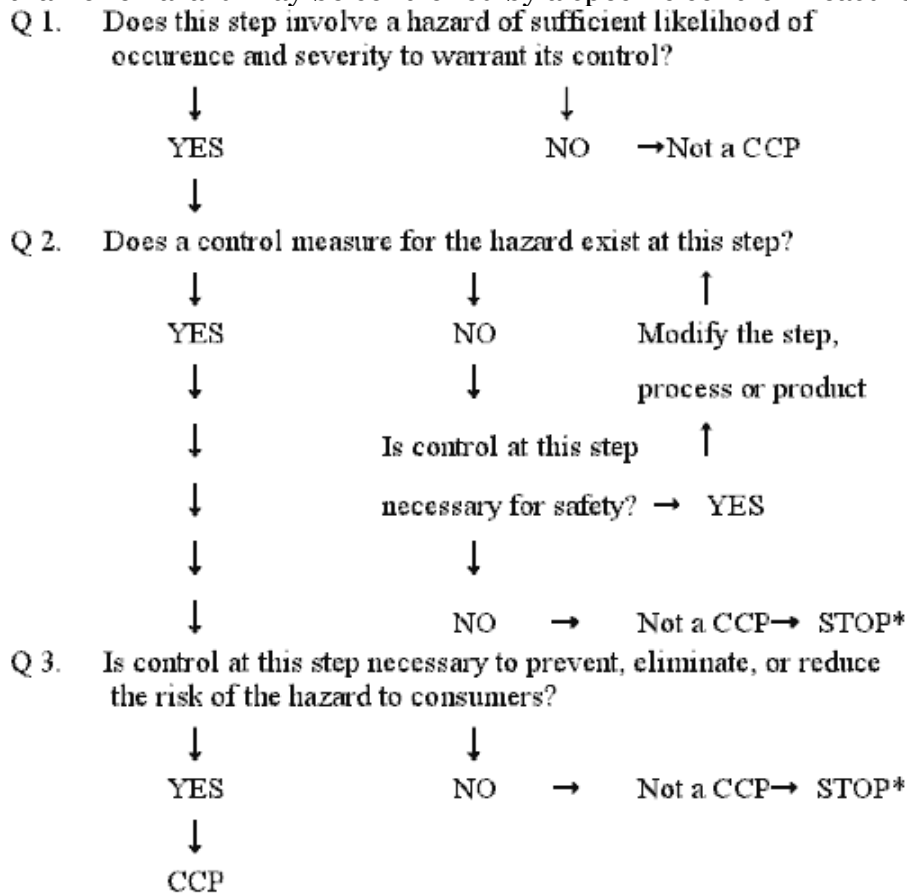
Appendix C: CCP Decision Trees

The following decision trees are taken directly from NACMCF material.²⁰⁸

Example I of a CCP Decision Tree

Important considerations when using the decision tree:

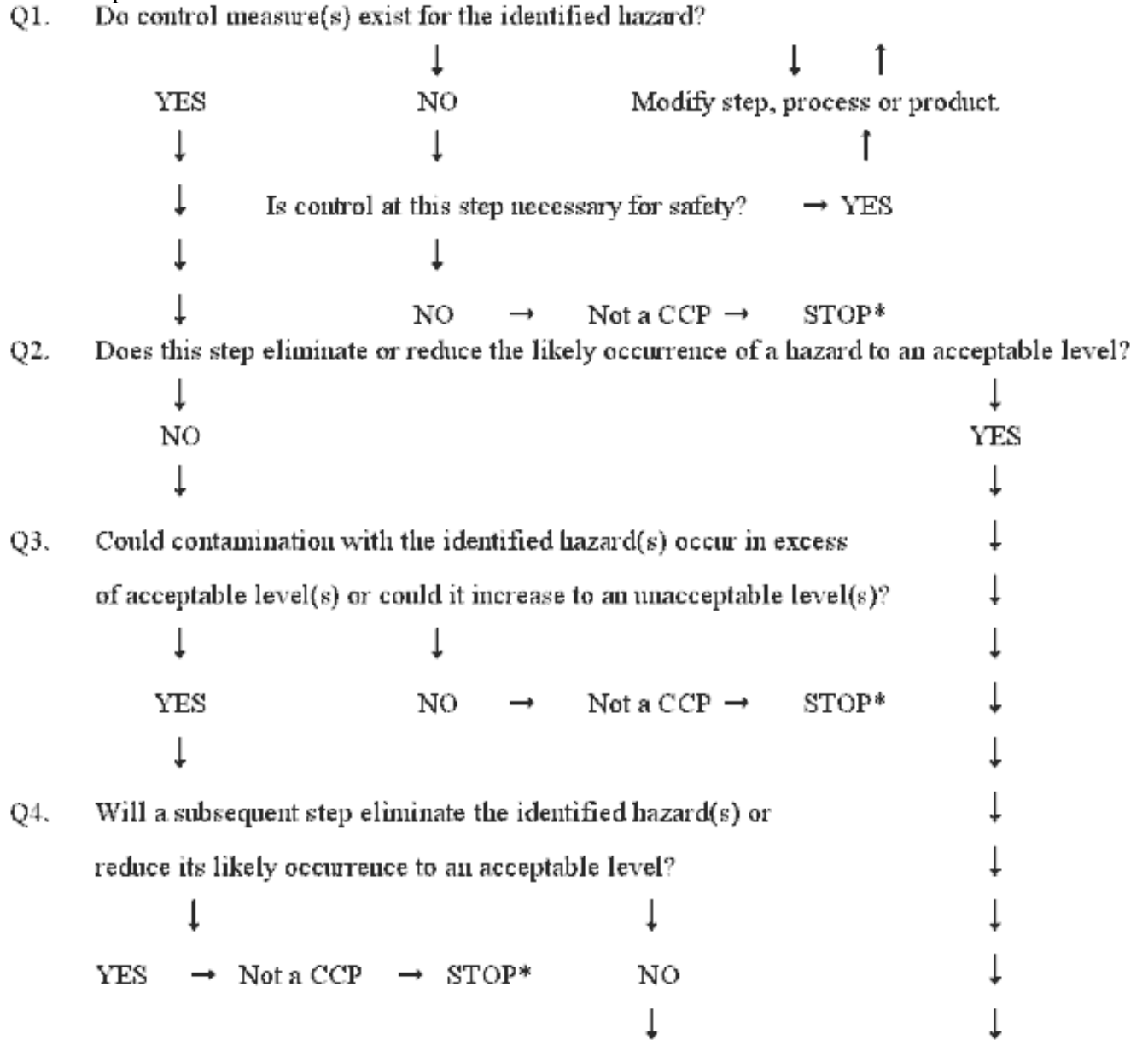
- The decision tree is used after the hazard analysis.
- The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan has been identified.
- A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.
- More than one step in a process may be involved in controlling a hazard.
- More than one hazard may be controlled by a specific control measure.



- Proceed to next step in the process.

²⁰⁸ Ibid. 28-30.

Example II of a CCP Decision Tree



CRITICAL CONTROL POINT

*Proceed to next step in the described process

Appendix D: Purdue University Food Defense Computational Simulation

The following information details the Purdue University Food Defense Computational Simulation.²⁰⁹

The Purdue University Food Defense Computational Simulation

Background

The Purdue Food Defense Computational Simulation (FDCS) was developed in 2004 by Purdue food scientists in collaboration with the Krannert School of Management and under the auspices of the Purdue Homeland Security Institute. It has been enhanced since by collaborations with Kansas State University, North Carolina State University, and Indiana University. The FDCS integrates input from stakeholders in food safety and food defense including government (federal, state, local), industry (production, distribution, manufacturing, retail, associations), public health and emergency management (police, healthcare, emergency management etc.), academia, media, and the public. To date, graduate students and faculty have logged over 2500 hours of data collection; the model then translates this "real world" data into the "virtual environment" used in the simulation.

The simulation was first used in May 2004 when Purdue University's Department of Food Science held the nation's first biosecurity simulation training for food companies. Forty representatives of the Department's Industrial Associates (corporate advisory board) along with USDA's Director of Homeland Security and Purdue internal media and faculty participated in the one-day program. Since that time, the FDCS has been conducted multiple times over the past few years, providing experience and training for dozens of participants.

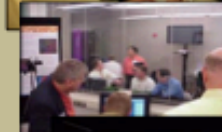
The Simulation Event

The simulation models the food supply chain from supplier to manufacturer to retailer—it includes data regarding products and their ingredients; geographic production, warehousing and shipping; quantities of production and sales; economic impacts of food product recalls, and public health impacts (illnesses, deaths, etc.) for each U.S. state. The simulation activity involves the introduction of a food contaminant (intentionally or inherently) at selected points in the food production chain. Teams of participants make decisions related to products and ingredients that may be affected, and are presented with resulting economic and public health impacts. The simulation is conducted in Purdue's state-of-the-art Envision Center allowing the "companies" to be placed in separate, soundproof rooms according to their place in the supply chain. Participants are provided data from the computer simulation model and from electronic reports of "government" teams and the "media."

Players participating in the simulation are divided into teams representing many different sectors. The simulation utilizes inputs from at least nine company-based teams (three bulk ingredient companies, three processors, and three retailers) and four additional teams (a first responder team, a USDA team, an FDA team, and a media team) that provide technical guidance throughout the exercise.



The evening prior to the one-day simulation event, participants receive preparatory training for the exercise. During the simulation, each team of 4-5 members is linked with at least one experienced graduate student and placed into a separate sound proof room. Using a computer interface, each team has the capability to gather information and make decisions during each round of the simulation.



For example, participants can obtain information related to the number of illnesses and deaths attributed to a specific food product, they can test products or ingredients for a long list of biological and chemical contaminants, then can hold or recall product, provide public announcements, and interact with government, industry, and the media.



During and after the simulation, teams join a series of after-action reviews where all simulation participants gather together in a common room to discuss the scenario and rationale for the decisions that they have made. The after-action reviews are facilitated by experts in Agrosecurity or Food Protection and provide a comfortable environment for all teams to openly discuss their actions and reactions to the fast-paced scenario.

²⁰⁹ Purdue University, Kansas State University, and Indiana University-Purdue University Indianapolis, "Food Defense Training and Incident Simulation Invitation," (2009). 2.