

**THE PROBLEM WITH PURITY:  
MARKET FAILURES, FOODBORNE CONTAMINATION, AND THE SEARCH FOR ACCOUNTABILITY  
IN THE U.S. FOOD SAFETY REGULATORY REGIME**

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**ABSTRACT**

One of the great myths of contemporary U.S. culture is that America's food supply is the safest in the world. Another is that government agencies have the ability and authority to guarantee food safety and to enforce accountability standards upon food producers, processors, and distributors. But the U.S. food safety regulatory regime is as it has been for more than a century: embedded in the notions of food *purity* and *wholesomeness* that framed the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act. Although changes in food production, processing, and distribution that occurred throughout the 20<sup>th</sup> century have rendered this regulatory regime ineffective and inefficient, efforts to amend its regulatory scope and power have been largely unsuccessful. Current proposals to transform this system, including the Food Safety Modernization Act of 2009 and the Food Safety Enhancement Act of 2009, however, would expand the power of government agencies to require process-based food safety systems, to test for contamination, to issue recalls, and to institute traceability protocols for all food products. Yet much of the economic literature critiques this top-down approach to regulation. Beginning with an overview of U.S. food safety and its regulation, this dissertation examines the relative effectiveness and efficiency of "top-down" "command and control" versus "bottom up" "market driven" regulatory regimes designed to resolve market failures and promote accountability relative to food safety. It includes an analysis of the impact and influence of food producing, processing, and distributing firms upon the policy process, examining when, why, and how large agri-food corporations support or oppose changes to the food safety regulatory regime and accountability framework, and concludes with an investigation of food safety crises as a catalyst for political change.

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**FOR MOM AND DADDY  
WITH AFFECTION AND GRATITUDE**

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## INTRODUCTION

### *FROM FOOD SAFETY TO ECONOMIC GOVERNANCE*

## CHAPTER 1

### FOOD SAFETY, MARKET FAILURES, AND THE NEED FOR REGULATORY GOVERNANCE

The University of Rhode Island's Department of Nutrition and Food Sciences defines *food safety* as the protection of the food supply "from microbial<sup>1</sup>, chemical<sup>2</sup>, and physical hazards<sup>3</sup> or contamination that may occur during all stages of food production and handling—growing, harvesting, processing, transporting, preparing, distributing and storing."<sup>4</sup> *Food Safety Online* refers to *food safety* as a "scientific discipline describing handling, preparation, and storage of food in ways that prevent foodborne<sup>5</sup> illness...this includes a number of routines that should be followed to avoid potentially severe health hazards."<sup>6</sup> Other sources, including many legal texts, limit the notion of *food safety* to conceptions of purity and wholesomeness, defining "safe food" as food free from adulteration or filth.<sup>7</sup>

These diverse definitions are representative of the regulatory history of the United States' food safety regime and indicate the analytical and popular confusion that often surrounds the problematization of "safe food." Understandings of food safety that are limited to notions of purity and wholesomeness are relics of a food safety regime established in the early 20<sup>th</sup> century when concerns centered upon food adulteration and the cleanliness of food processing facilities,

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<sup>1</sup> Such as *Salmonella*, *E. coli* O157:H7, and *Hepatitis* and a wide range of other bacterial, viral, and/or parasitic pathogens

<sup>2</sup> Such as agrochemicals, including, but not limited to, pesticides, insecticides, and herbicides; veterinary drugs; cleaning and/or sanitizing agents; and/or environmental contaminants including, but not limited to, arsenic, mercury, lead, and mycotoxins

<sup>3</sup> Such as rocks, dirt, glass, hair, paint chips, and/or machinery parts

<sup>4</sup> Rhode Island Food Safety Education, *Glossary*, University of Rhode Island, 2009 [available online: <http://www.uri.edu/ce/ceec/food/factsheets/glossary.html>].

<sup>5</sup> For consistency's sake, I have used "foodborne" rather than "food borne" throughout the entirety of the text.

<sup>6</sup> Food Safety Online, *Home*, 2009 [available online: <http://www.foodsafetyonline.org/>].

<sup>7</sup> Food adulteration is defined as the rendering of a food product unsafe or unwholesome through the addition of an extraneous or impure substance designed to make spoiled or otherwise inferior food look, feel, smell, or taste more acceptable. Early food adulteration consisted of economic adulteration; that is to say, the addition of adulterants that were not physically harmful but that cheated consumers out of their money. Economic adulteration at the beginning of the 20<sup>th</sup> century included the inclusion of dyes, fillers, or perfumes to food products in order to deceive customers into believing that the food was of a higher quality. The 1906 prohibition against food adulteration was as much about consumer protection in the face of false or deceptive advertising as it was about "food safety" per se. This concern is related to the issue of consumer information and misbranding; that is to say, there are those, particularly of the neo-liberal persuasion (Adler) who argue that consumers should have the right to purchase "lower quality" (implicitly "less safe") foods at lower costs so long as they have all of the relevant information about that food product and are not misled by adulteration or false advertising practices.

particularly slaughter houses. During this period “adulterators cheapened flour and sugar, chocolate and hone, beer, coffee, milk, tea, and wine;” as Young writes, American produced chocolate was heavily adulterated with a variety of substances including: wheat flour, potatoes, egg yolks, almonds, soap, and red oxide of mercury.<sup>8</sup> The prohibition against food adulteration was the cornerstone of both the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act. Together with their extensions and amendments, these laws established of the U.S. food safety regulatory regime, laid the groundwork for subsequent food safety statutes, including the food and color additive laws of the 1960s, and continue to govern the implementation of food safety regulatory policies throughout the United States. As a consequence of this focus on food adulteration, the U.S. food safety regulatory regime is statutorily obligated to guarantee food *purity* and *wholesomeness* and, in that context, the safety of food additives, but *lacks* a broad legislative mandate to regulate physical, chemical, and microbiological food *safety*. Although the FDA and USDA are nominally responsible for protecting public health by assuring the safety and security of the U.S. food supply, as later chapters demonstrate, attempts by these institutions to address food safety challenges beyond the scope of food *purity* test the boundaries of their statutory mandates, often rendering the regulatory regime inefficient, ineffective, and reactive to food safety threats, crises, or risks.<sup>9</sup>

To view food safety as a science is indicative of perspectives that grew out of the scientific revolution in food that occurred during the middle part of the 20<sup>th</sup> century. As the introduction to the 2009 documentary *Food, Inc.* emphasized, food production has changed more since the 1950s than it did in the 10,000 years from the beginning of the Neolithic revolution to that point.<sup>10</sup> Scientific advances in chemical science, germ theory, and toxicology precipitated a transformation in modern conceptions of both food and its safety. This combined with the industrialization, mechanization, and automation of food production, processing, transportation, and distribution that occurred during the same time period led to the construction of food safety as a *scientific* problem attached to notions of risk assessment, objective data, and unbiased

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<sup>8</sup> James Harvey Young, Pure Food: Securing the Federal Food and Drugs Act of 1906, Princeton, NJ: Princeton University Press (1989), pp. 31.

<sup>9</sup> Even the FDA’s Center for Food Safety and Applied Nutrition is primarily focused upon consumer information, industry guidance (rather than standards), food additives, food allergens, and food adulterants. Its food safety activities are focused upon high-risk specialty foods such as infant formula, seafood, and fresh juice.

<sup>10</sup> *Food, Inc.*, Directed by Robert Kenner, 2009.

research but divorced from the realm of politics, values, and subjective assessment. But as Nestle emphasizes, food safety is at its very foundation a political issue.<sup>11</sup> To attempt to define food safety in a way that removes political significance and relies exclusively on an ideology of “science,” ignores the fact that food production is a *business* controlled by a small number of very powerful, very influential corporations whose interactions with government agencies frame how food safety policies are written, implemented, and adjudicated.

It is thus the definition of food safety in terms of physical, chemical, and microbiological contamination linked to the “farm to fork” chain that is most applicable to an investigation of market failures, political economy, accountability, and the U.S. food regulatory regime. Because this definition incorporates physical, chemical, and microbiological contaminants, it encompasses aspects of food safety that were common at the beginning of the 20<sup>th</sup> century (physical), the middle of the 20<sup>th</sup> century (chemical), and the end of the 20<sup>th</sup> century (microbiological).<sup>12</sup> Moreover, this definition emphasizes the importance of the farm to fork chain thus eliminating the exclusive and myopic focus on consumer education that was commonly attached to 20<sup>th</sup> century conceptions of food safety.

#### Research Questions and Food Safety Case Studies:

This dissertation seeks to answer the following questions:

- How have changes in food production, food science and technology, and food politics over the course of the 20<sup>th</sup> century rendered the U.S. food safety regulatory regime ineffective and/or inefficient?
- What food safety scandals during the 20<sup>th</sup> and early 21<sup>st</sup> centuries transformed in the U.S. food safety regulatory regime either in terms of top-down hierarchical governance or bottom-up market-based coordination? What are the comparative

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<sup>11</sup> Marion Nestle, *Safe Food: Bacteria, Biotechnology, and Bioterrorism*, Berkeley: University of California Press (2003) pp. 1.

<sup>12</sup> When asked to rank their food safety concerns customers cite chemical contamination first followed by the safety of food additives and, increasingly in light of media coverage of recent outbreaks of foodborne illnesses and attention generated by the effects of *E. coli* 0157H7 on children, microbial contamination.

advantages and disadvantages of “top-down” and “bottom-up” food safety regulatory regimes?

- What do regulatory reform proposals currently before Congress indicate about changes in regulatory culture, consumer demands, or corporate interests relative to food safety? Why have these proposals come to the forefront *now* and why do they frame food safety as an issue of public, hierarchical, “command-and-control” economic governance?

Existing research on the food politics tends to focus on food security or on the safety of imported foods, Genetically Modified Foods (GMFs),<sup>13</sup> the use of animal growth hormones, or, increasingly, foods from cloned animals. Until recently food safety *writ large* was assumed to be a techno-scientific rather than a political problematic. With few exceptions—the most notable being Nestle’s Food Politics, Michele Morrone’s Poisons on Our Plates, and Ed Randall’s Food, Risk, and Politics—few scholars have examined the politics of food safety regulatory regimes. Moreover, while several scholars, including Hilt and Hawthorne, have studied the U.S. Food and Drug Administration, existing scholarship focuses on the regulatory oversight of “drugs” and, to a lesser extent, food additives. But no existing study examines the politics—past, present, and proposed—of the U.S. food safety regulatory regime.

This dissertation employs the logics of public policy analysis, political economy, and accountability to assess the U.S. food safety regulatory regime, particularly with respect to changes in food science, food production, and food politics throughout the course of the 20<sup>th</sup> century. It evaluates the efficiency and effectiveness—or lack thereof—of “command and control” as well as “marketized” food safety regulatory regimes. And it analyzes the effects of crises, scandals, and outbreaks on legal, administrative, corporate, and market food safety dynamics. To do so, it incorporates five food safety case studies. In each market failures, transaction costs, and crises combine to promote new accountability and regulatory approaches to food safety (See Table 1).

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<sup>13</sup> I have chosen not to analyze the politics of GMF safety for several reasons. First, it has been examined *ad nauseam* by scholars from many fields and from many different perspectives. But, more importantly, the US food safety regulatory regime relative to the safety of Genetically Modified Foods has been consistent since its decision to treat foods produced using modern biotechnologies no differently than foods produced using “traditional” agricultural techniques. David Vogel has written on the politics of this decision and I find it to be tangential to a more general discussion of the US food safety regulatory regime.

The first examines food adulteration, food impurity, and The Jungle. This focuses on the market failures and transaction costs that attended food production, processing, and distribution at the turn of the 20<sup>th</sup> century, the public scandal that attended Upton Sinclair's portrayal of turn of the century slaughter houses, and the regulatory framework established by the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act. The second addresses the market failures and transaction costs associated with the "Cranberry Crisis" of 1959 and mid-20<sup>th</sup> century regulatory emphasis on chemical contamination. The third assesses the market failures and transaction costs attached to the industrialization, automation, mechanization, and homogenization of food production, processing, and distribution during the mid-20<sup>th</sup> century. It analyzes the regulatory consequences, particularly the USDA Pathogen Reduction Program, of the emergence of *E. coli* 0157:H7 as a food-based pathogen.<sup>14</sup> The fourth analyzes the market failures and transaction costs associated with pathogen outbreaks in fresh produce and the establishment of the GAPs Initiative, the FDA's system of voluntary guidelines that acts as a "bottom-up" governance regime for fresh produce safety. Finally, the fifth examines the market failures and transaction costs associated with the 2008-2009 outbreak of *Salmonella* that was linked to peanut butter produced and distributed by the Peanut Corporation of America.

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<sup>14</sup> Throughout the text I refer to many microbial pathogens, including *Salmonella* and *E. coli*. I italicize foodborne pathogens. However, within quotations, I defer to the author's original text.

Table 1: Three Political Frames and Five Case Studies

	Food Adulteration and The Jungle—1906	Chemical Contamination of Cranberries—1959	Jack in the Box: E. coli 0157:H7 in Ground Beef	Cantaloupe, Spinach, Tomatoes, and Scallions: Pathogens in Fresh Produce	The Catalyst: Salmonella in Peanut Butter
Market Failures	Negative Externalities, Guile, and Structural Inequity	Opportunism, the Malevolent Side Effects of Corporate Decisions and the Risks of Interstate Commerce	Negative Externalities, the Power of Special Interests, and Oligopolistic/Monopsonistic Market Pressures	Negative Externalities and the Knowledge Gap Between Producers and Scientists	Guile, Opportunism, and the Malevolent Side Effects of Corporate Decisions
Transaction Costs	Fueled the Industrialization of Food Production, Processing, and Distribution According to Logics of Economies of Scale and the Rise of Corporate Agribusinesses	Cranberry market collapsed and producers lost millions of dollars but passed in part to the FDA which conducted product testing to certify “safe” cranberries	Managed by Large Agribusinesses through Vertical Integration and the Application of Fordism to an Industrialized and Concentrated System of Food Production, Processing, and Distribution	Passed from Processors to Producers in order to Promote Trust between Suppliers, Retailers, and Consumers	Passed from Processors to Government Regulatory Agencies to Enhance and Deepen Dynamics of Outsourcing and Horizontal Coordination
Regulation and Accountability	The 1906 Pure Food and Drug act and the 1906 Federal Meat Inspection Act	FDA monitoring and testing for chemical contaminants (the Total Diet Study) as well as FDA approval of products determined to be free of contamination	USDA Pathogen Reduction Program (command and control regime that requires that processors develop and implement HACCP Plans— pathogen testing requirements declared illegal)	GAPs Initiative (market-based regulatory regime predicated on voluntary compliance and Third Party Certification)	Ten Legislative Proposals including the Food Safety Modernization Act of 2009 and the Food Safety Enhancement Act of 2009

## A Changing Food System: Implications for Food Safety and Its Regulation

The industrialization of the U.S. food system during the course of the 20<sup>th</sup> century represents a convergence of the economic logics associated with Fordism<sup>15</sup> and scientific innovations that made large scale food production, processing, transportation, and marketing possible. As a consequence of this transformation, “new”<sup>16</sup> food production bears little resemblance to the small-scale, local system that fed the United States through the end of the Second World War. The industrialization of food production, catalyzed by the emergence and expansion of the “fast food” movement, the demand for homogenized products from large purchasers such as McDonald’s,<sup>17</sup> and the rise of supermarkets to replace small-scale food merchandisers transformed the “family farm” into the “corporate agribusiness.” In this context, the application of economies of scale, vertical integration, and the de-skilling of labor to food production combined with new processing techniques and inventions created a food production system more reminiscent of Ford’s automobile assembly line than of “traditional” agriculture.<sup>18</sup>

But despite enormous changes in food production, processing, and manufacturing, the U.S. food safety regulatory regime is as it has been for more than a century. Based upon the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act, this regulatory regime was designed to regulate food safety in the context of turn of the 20<sup>th</sup> century food production.<sup>19</sup> Thus its emphasis on adulteration and cleanliness, which was appropriate in the early 20<sup>th</sup> century, became increasingly outdated as food production became increasingly industrialized and food itself became increasingly processed. Although updates were made to the 1906 statute in 1938, regulatory changes focused on the pharmaceutical and cosmetic industries rather than food

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<sup>15</sup> Fordism is a method of industrial organization and production that derives efficiencies from economies of scale, mass production, mass distribution, Just-In-Case production, assembly lines methodologies, and vertical integration (see Chapter 4).

<sup>16</sup> Maxwell and Slater (2003) differentiate between “old” and “new” food systems as each concept relates to food policy. Their understanding emphasizes the distinctions between food production at the turn of the 20<sup>th</sup> century and food production at the turn of the 21<sup>st</sup> century within the context of food regulation.

<sup>17</sup> Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal*, Harper Perennial: New York (2002).

<sup>18</sup> This transformation created a food production system so complex that the History Channel has produced dozens of “Modern Marvels” episodes dedicated to its explanation. Many vividly portray “old” versus “new” production techniques and take the consumer inside production plants that process more food in a day than small-scale producers handle in a year.

<sup>19</sup> Early innovations in food production provided part of the impetus for the 1906 push for food safety regulation. The slaughterhouses described in The Jungle represented a relatively new form of food processing that justified a new kind of regulatory oversight. This linkage is expanded upon in the following chapter.

production and its regulation and safety. Throughout the remainder of the 20<sup>th</sup> century legislation enhanced the regulatory oversight of fragmented parts of the food industry,<sup>20</sup> but in the absence of a complete overhaul of the food safety regulatory regime. Attempts to adapt food safety regulations in the face of new production techniques and scientific understandings met with tremendous industry opposition. For example, attempts to require microbial testing and to mandate recalls of contaminated foods were challenged in federal court; the judges ruled that the U.S. government did not have the statutory authority to implement this plan thus effectively preventing U.S. food regulatory agencies from requiring that food producers take steps to prevent microbial contamination of food products (see Chapter 4). The food safety regime that regulates foods produced today, therefore, is largely based upon century-old problems, concerns, technologies, production methods, and scientific knowledge.

Changes, often constructed as “advances,” in food production have thus revolutionized the U.S. food system. But while “conventional” food production has become more industrialized, more uniform, and more processed, niche production has taken on an anti-industrial, and often anti-science,<sup>21</sup> flavor. In the late 20<sup>th</sup> and early 20<sup>th</sup> century three movements stood out: the organics movement, the “slow food” movement,<sup>22</sup> and the “local food” movement. The organic movement initially emerged from opposition to a new food technology designed to enhance the safety of food products—the pasteurization of milk. Thus “organic food” and “organic producers” do not represent a new phenomenon so much as a force that has promoted “traditional” agriculture and food production since the beginning of the 20<sup>th</sup> century. Pasteurization, food irradiation, the use of chemical fertilizers and pesticides—the organic movement has opposed almost all of the “advances” in food production that became “mainstream” over the course of the past 100 years, including the ones most of us take for granted today. But it was their opposition to chemical pesticides and fertilizers that gave organic

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<sup>20</sup> In 1957 the Federal Poultry Inspection Act gave the USDA similar regulatory authority in poultry as the 1906 Federal Meat Inspection Act gave it over meat. The 1970 Federal Egg Products Inspection Act further extended the USDA regulatory authority. For the FDA, however, advances were far more narrow and restrained. Legislation from the 1960s focused on the safety of food additives (including color additives) and food packaging. Legislation in the 1990s established regulatory frameworks for organic production and marketing, nutritional labeling, and health supplements. In 2002 food safety was contextualized against biosecurity, the need to protect the food supply from bioterrorism but, again, this legislation failed to address the regulatory deficits in the US food safety regulatory regime.

<sup>21</sup> Often constructed as “anti-modern.”

<sup>22</sup> As opposed to the “fast food” that attended the industrialization of food during the mid-20<sup>th</sup> century

producers a market advantage during the latter part of the 20<sup>th</sup> century. Consumers overwhelmingly cite the risk of chemical contamination as their primary food safety concern. This concern promoted organic production and transformed an anti-industrialized food movement into a marketing coup. Today the same large agribusinesses that dominate “conventional” food production dominate organic production. But as organic production became more attuned to consumer concerns and more dominated by large corporations rather than small farmers, concerns emerged over the labeling and marketing of “organic” foods. In 1990, therefore, national legislation prompted the establishment of the National Organics Program, a regulatory mechanism designed to ensure that “organic” foods are produced, packaged, and marketed in ways that are honest, standardized, and in the interest of consumer education.<sup>23</sup>

But it has been the growth of the “local food” movements that have introduced new and heretofore unaddressed regulatory concerns about food safety in the United States. “Local producers” establish themselves in opposition to the “industrial producers” that dominate the U.S. food system. They portray their products as more “traditional,” more ecologically sustainable, healthier, and, often, safer. And yet because the U.S. food regulatory regime excludes small-scale producers from its oversight and regulation, these claims are largely undocumented and unsubstantiated. But it is this “local food” movement that has captured the minds and emotional energies of many American consumers to the extent that it has eclipsed the organic movement in recent years. Books by Pollan, Kingsolver, and Salatin<sup>24</sup> demonize the industrial food system and represent “local food” as the ethical, environmentally responsible, and safe food choice.

The U.S. food regulatory regime has not created a system to hold most “local producers” accountable for the claims they make or the safety of the foods they produce. And many groups, including local producers associations and consumer advocacy groups, want to keep it that way.

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<sup>23</sup> Organic requirements are less about food safety than about truth in advertising. The NOP requires that organic foods be produced according to specific production methods, not because those methods necessarily enhance the physical, chemical, or microbiological “safety” of the food product, but so that consumers can make more informed choices and purchases.

<sup>24</sup> Whose book [Everything I Want to Do Is Illegal](#) makes it sound as though his adherence to “traditional” methods of food production are the subject of unreasonable discrimination by the US government until one evaluates just what it is that he wants to do in the context of scientific understandings about food contamination and its prevention. Salatin maintains that the “old way is the best way” but perpetuates the argument that local food is safe by virtue of its being local regardless of any and all evidence to the contrary.

Two of the proposals currently before Congress that would overhaul the U.S. food regulatory regime, the Food Safety Enhancement Act of 2009 and the Food Safety Modernization Act of 2009, would require that “local” producers meet the same burden of proof and adhere to the same safety standards as “conventional” producers. This is met with widespread opposition from local producers and their advocates; letter writing campaigns, blogs, and editorials have focused on the need to exempt “local” producers from the requirements of a new food safety regulatory regime. Should they be successful, even an updated regulatory regime would be characterized by a regulatory deficit in one of the fastest growing sectors of food production.

The current U.S. food regulatory regime, therefore, is characterized by a number of regulatory deficits: the failure to update the 1906 statutory authority of food regulatory agencies; the inability of regulators to safeguard food along the farm to fork chain; the powerlessness of government agencies to issue mandatory recalls of contaminated foods despite national distributions systems and new advances in traceability and outbreak monitoring; the exclusion of so-called “local” food producers from food safety regulation; and the overall focus, not on physical, microbiological, and chemical food safety, but rather on adulteration and the safety of food additives.<sup>25</sup> But as outbreaks of foodborne illnesses have become increasingly high-profile, as consumers have become increasingly concerned about the safety of their foods, and as corporate brand reputations have become dependent upon consumer perceptions of safety and wholesomeness, new systems of food regulation emerged in the late 1990’s. These innovations enhanced, and at times challenged, the regulatory effectiveness of the U.S. food safety regime relative, particularly, to consumer information and education. Often grounded in public or private Third Party Certifications, a system of food regulation that has become popular in Western Europe with measured success relative to food safety, these programs sought to fill the voids created by the antiquated U.S. food safety regulatory regime. These regulatory frameworks represent new “bottom-up” ways of looking at economic governance that stand in contrast to more familiar “top-down” methods of coordination.

One of the great myths in U.S. culture is that the food we eat is safe and that the government has the ability and authority to make sure that it is safe. Yet this is not the case. The

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<sup>25</sup> The FDA, which is responsible for regulating the vast majority of the US food supply, does not even have a standing committee devoted exclusively to food safety.

power of the U.S. government—either the FDA or the USDA—to regulate food safety, particularly microbiological food safety, is extremely limited. Moreover, many attempts to expand that power have been declared illegal given the statutory mandates of U.S. food regulatory agencies. Current proposals to change this system, including the Food Safety Modernization Act of 2009 and the Food Safety Enhancement Act of 2009, emphasize a top-down approach that would expand the power of government agencies to require process-based food safety systems, to test for contamination, to issue recalls, and to require traceability of food products. The relative effectiveness of top-down versus bottom-up regulatory regimes to resolve market failures and promote accountability relative to food safety is a topic of political economic, public policy, and food safety analysis that has yet to be examined.

### Research Justification: Theoretical Frameworks and Conceptual Linkages

The study of political economy in industrial economies converges on the study of governance and coordinating mechanisms.<sup>26</sup> Thus political economy stands at the intersection between economic principles, exchanges, choices, preferences, and efficiency standards and political structures, dynamics, procedures, institutions, structures, and values. Regulatory interfaces among economic coordinators such as governments, markets, and firms vary widely across industrial economies. They reflect the ways by and through which power, authority, legitimacy, and influence are mobilized and institutionalized as well as the ways by and through which values, preferences, and principles are advantaged or disadvantaged, legitimated or delegitimated, constructed and reconstructed. If, as *The Art of the Game* indicates, the policy process resolves fundamental tensions between rights and freedoms, pluralism and elitism, public and private, equality and justice, efficiency and effectiveness, it does so through the creation of a regulatory interface among mechanisms of economic coordination.<sup>27</sup> The negotiation of this regulatory interface is a political process involving many actors, agents,

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<sup>26</sup> My understandings of the conceptual linkages between specialization, risk, trust, governance, and economic efficiency as well as the governance capacities of and regulatory interface among governments, firms, and markets come from my work with Professor Weisband Edward in the development of his course, PSCI/IS/GEOG 2064: The Global Economy and World Politics.

<sup>27</sup> Stela Z. Theodoulou and Chris Kofinis, The Art of the Game: Understanding American Public Policy Making, Belmont, CA: Thompson-Wadsworth (2004).

interest, and institutions that determine how and when governments should intrude upon market dynamics, the degree to which markets should be free of centralized control or oversight, and the balance between individualism and the public interest, however conceptualized, relative to market failures, public good, and what Wolf calls “internalities.” But an understanding of food production and its regulation as a problematic in political economy requires an analysis of the linkages between economic efficiency, risk, trust, and governance.

Economic efficiency in industrial economies is grounded in specialized divisions of labor, task sharing, and mutual dependencies. But specialization and interdependence create risks—risks of promissory failure, of guile and opportunism, and of defection from standards. For this reason, political economists, public policy analysts, and accountability scholars recognize that specialization—and, by extension, economic gains derived from invention, innovation, productivity, and efficiency—cannot exist in the absence of trust. In industrial economies, or what Seabright called “societies of strangers,” trust is established through governance and operationalized by governments, markets, and firms as coordinating mechanisms.<sup>28</sup>

Governance can be conceptualized, therefore, either in terms of top-down (hierarchical, administrative, centralized) institutions or bottom-up (fragmented, market-oriented, dispersed) networks. To evaluate the efficiency and effectiveness of competing perspectives on regulation, its formation, and implementation, particularly in the context of food safety, one must consider the relative strengths and weaknesses of markets, governments, and firms. Although governance is typically conceptualized only in terms of centralized control, hierarchical authority, and public institutions, markets and market systems can be effective and efficient economic coordinators. As Linblom argues, the “market system” can act as a coordinator that regulates by virtue of purchases, sales, and choices rather than centralized decisions, directives, and mandates.<sup>29</sup> Known as “governance by small decisions,” markets allow consumers to express individual values, demands, and preferences in ways that have macroeconomic effects. Beholden to Adam

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<sup>28</sup> Paul Seabright, The Company of Strangers: A Natural History of Economic Life, Princeton, NJ: Princeton University Press (2005).

<sup>29</sup> Charles E. Lindblom, The Market System: What It Is, How It Works, and What To Make of It, New Haven, CT: Yale University Press (2001).

Smith's notion of the "hidden hand" and theories of Classical liberalism, markets promote economic efficiency by allowing economic decision-makers to guide production and pricing.

But the other side of market efficiency is the so-called "tyranny of small decisions." If left to their own devices, markets produce a set of intended—often undesirable—consequences known as market failures: guile, opportunism, negative externalities, malevolent side effects of business decisions, inequality, the power of special interests, and the concentration of economic power in monopolies and monopsonies. Contamination and outbreaks of foodborne illness can be understood in the context of market failures. As the recent outbreak associated with peanut butter revealed, guile and opportunism can undermine safety structures in the absence of third-party oversight with devastating results.<sup>30</sup> Authors including Schlosser and Spurlock have credited the monopsonistic purchasing power of McDonald's with changes in food production and processing techniques throughout the 20<sup>th</sup> century, many of which rendered the 1906 food safety regulatory regime antiquated and ineffective. Consumer activist groups allege outbreaks of foodborne illnesses are a malevolent side effect of corporations that elect to forgo pathogen testing and fail to implement HACCP Plans or Good Manufacturing Practices in the name of speed, cost savings, and profit maximization. Marion Nestle holds agribusinesses responsible for failures to update or modernize the 1906 food safety regulatory framework; she argues that agribusinesses constitute a special interest so powerful as to dominate the political process by and through which regulations could be reformed and transform corporate preferences into public policy. And Michael Pollan, an advocate of local and organic food production, argues that market structures and dynamics shift the risks of foodborne illness onto the poor who are more likely to purchase conventionally produced foods.

Food contamination and outbreaks of foodborne illnesses, along with their economic, health, and social consequences, can thus be understood as *negative externalities* of food production, that is, costs that are not covered in the market exchange between producer and consumer. These unintended consequences of the market system demonstrate that markets alone cannot satisfy the requirements of the public interest or collective good. The question thus becomes: who pays the price for foodborne illnesses, particularly when that price includes lost

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<sup>30</sup> In this case, producers "shopped around" for an inspection authority that would certify their product as "safe" despite positive pathogen tests for *Salmonella* and obvious cleanliness and sanitation violations.

merchandise (in the case of recalls), diminished productivity, sickness, and death?<sup>31</sup> The answer requires that we consider governments as alternative or complimentary mechanisms of economic coordination.

Governments regulate economic activity top-down through what accountability scholars call *public mechanisms* often associated with the allocation of *collective goods*. In the context of food security, the U.S. food safety regulatory regime can be understood as a collective good designed to promote the public interest by holding producers to a set of standards, evaluating their implantation of those standards, and imposing sanctions in cases of noncompliance. The question becomes, however, how is regulation justified, formulated, implemented, and assessed? If, as many argue, regulatory structures and demands impede upon the dynamics of invention and innovation in ways that impede economic efficiency, how much intrusion is too much? How is the effectiveness of a regulatory regime measured? What is the purpose of regulation; is it to protect consumers from “risks” or “dangers” or to provide consumers with the relevant information they need to make an informed market decision? What kinds of regulatory standards, dictates, and oversights are appropriate and how is regulatory authority structured, exercised, evaluated, controlled, or held accountable to the public writ large?

As Ebrahim and Weisband write in the context of accountability, government regulation and oversight are often seen as “cure-alls,” magic bullets able to remedy market failures, promote justice and equity, and advance collective welfare through the establishment of benchmarks, standards, and enforcement mechanisms.<sup>32</sup> Because accountability is often defined in terms of a hierarchical relationship in which one actor or institution has the power to hold other agents to a set of standards, to evaluate their actions, and to issue sanctions in the face of noncompliance, it is readily reduced to a set of technocratic mechanisms; when accountability breaks down, according to this logic, it is because of a problem in standard elaboration, evaluation, or oversight that can be corrected with better standards, evaluatory mechanisms, or oversight procedures. Such understandings of accountability focus on transparency,

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<sup>31</sup> The economic costs of foodborne illness outbreaks are estimated to be millions of dollars per year. Many costs, however, go unnoticed. For example, the long-term health costs associated with foodborne illness (kidney dialysis) and the allocation of public resources to those effected by foodborne illness (special education services, social security disability payments, emergency room care, etc.) are often excluded from these calculations.

<sup>32</sup> Alnoor Ebrahim and Edward Weisband (eds), Global Accountabilities: Participation, Pluralism, and Public Ethics, Cambridge: Cambridge University Press (2007).

answerability, compliance, enforcement, and sanctions and assume that these mechanisms are responsive to the “public interest.”

But, as Wolf observes, hierarchical governance mechanisms can produce their own set of failures, inefficiencies, and problems. Wolf calls these unintended consequences of centralized control “internalities” and warns that regulatory regimes must be assessed, adapted, reformed, and/or terminated if they fail to promote the public good or if they become rigid and inflexible in ways that restrict invention, innovation, and economic efficiency.<sup>33</sup> In the context of the U.S. food safety regulatory regime, some scholars argue that attempts to require that producers implement “command and control” safety systems (such as Hazard Analysis Critical Control Points [HACCP], Good Agricultural Practices [GAPs], or Good Manufacturing Practices [GMPs]) constitute an internality; although these process-based regimes may prevent contamination or outbreaks of foodborne illnesses, these scholars argue that they disadvantage small producers, inhibit innovation, and unnecessarily constrain producers. Instead, scholars such as Antle advocate for “performance-based” product standards and argue that regulators should have the authority to evaluate the only safety of end-use products, leaving process decisions to individual producers.<sup>34</sup> This question of the relative effectiveness and efficiency of process- versus product-based safety standards is of particular interest since the two major reform proposals currently before Congress include process-based requirements for all producers; competing interpretations of what is necessary, desirable, justifiable, effective, or efficient are thus currently being considered as part of the public policy process.

Although markets and governments represent two forms of economic coordination, an analysis of food safety and its regulation from a framework oriented to political economy would not be complete without an examination of firms. The industrial transformation of food production, processing, and distribution that characterized the 20<sup>th</sup> century concentrated these activities in the hands of a few powerful corporate agribusinesses. Dedicated to cost reductions, risk management, and profit maximization, these agribusinesses dominate the “farm to fork”

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<sup>33</sup> Charles Wolf, Jr., Markets or Governments: Choosing between Imperfect Alternatives, 2<sup>nd</sup> Edition, Cambridge, MA: The MIT Press (1993).

<sup>34</sup> John M. Antle, Choice and Efficiency in Food Safety Policy, Washington, DC: The American Enterprise Institute Press (1995).

commodity chain through which food is grown, processed, transported, distributed, marketed, and sold to consumers.

Coase's understandings of transaction cost economics answered the question "why firms not markets?"<sup>35</sup> In the early 20<sup>th</sup> century firms coordinated economic activity associated with new logics of efficiency, industrialism, and scientific management. Firms of that era vertically integrated the production process, internalizing specialization in an attempt to reduce the transaction costs associated with market interaction; vertical integration reduced information and bargaining costs, guaranteed access to specialized capital inputs, and allowed firms to reduce the risks of tort and liability. The industrialization of food production encouraged agribusinesses to apply the logics associated with Fordism to food processing: mass production, mass distribution, and mass marketing were promoted by economies of scale and assembly line technologies. As Schlosser observes, food production in the late 20<sup>th</sup> century was more akin to automobile manufacturing than to "traditional" forms of agriculture and food processing.<sup>36</sup>

As food production and processing became increasingly mechanized and industrialized, large firms were able to make capital and infrastructure investments designed to enhance productivity and efficiency; agribusinesses could afford new machinery, larger facilities, and computer systems that remained far beyond the reach of small producers. This competitive advantage enabled agribusinesses to control more and more of the food production and processing activities in the United States. When new economic logics and efficiency standards emerged to challenge the Fordist approach, agribusinesses adapted their methods, techniques, and orientation to one focused on economies of scope, niche marketing, brand image, and, to a lesser extent, horizontal coordination.<sup>37</sup> In the process, agribusinesses pioneered a new system of food safety regulation, one focused on private standard, voluntary compliance, and market dynamics rather than hierarchy, centralization, and administrative control.

As agribusinesses embraced outsourcing and subcontracting they began to use private regulatory frameworks to reduce the risks of food contamination. As a consequence, many

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<sup>35</sup> Ronald H. Coase, *The Firm, the Market, and the Law*, Chicago, IL: University of Chicago Press (1990).

<sup>36</sup> Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal*, New York, NY: Perennial (2002).

<sup>37</sup> Liability and tort risks continue to justify vertical integration for many agribusinesses. See Chapter 4 for more information.

producers and processors in the farm-to-fork chain must implement process-based safety systems and submit to inspections and oversight by third party certifiers, not as a consequence of government regulation, but to satisfy the demands of large firms further along the commodity chain. Even in the absence of public updates to the 1906 food safety regulatory framework, many producers use HACCP Plans, GAPs, and GMPs as well as traceability programs and inspection oversight in order to access new markets, protect their brand, and reduce the risks of liability and tort. In several European economies, this strategy—born of concerns about food imports from developing countries—has created what Vogel calls a “race to the top,” a system of food standards, benchmarks, and requirements that exceed government mandates in the name of consumer protection.<sup>38</sup>

With economic power came political influence and today many argue that agribusinesses dominate the U.S. policy process, particularly on issues of food safety and food regulation, in ways that advance their corporate interests at the expense of the “general welfare.” For many years agribusinesses opposed updates to the 1906 food safety regulatory framework. With regard to current proposals, however, they remain relatively quiet. The question, of course, is why? Perhaps it is because the transaction costs attached to the current proposals threaten the existence of small “local” food producers and thus may serve to eliminate market competitors; large agribusinesses can afford to implement the process-controls, testing, inspection, and traceability requirements that both major pieces of reform legislation include whereas many small producers cannot.<sup>39</sup> Perhaps it is because agribusinesses are looking to shift responsibility for outbreaks of foodborne illnesses onto government regulatory agencies in an attempt to protect their brands and avoid liability. Perhaps it is because firms hope that more stringent safety requirements will make them more competitive in international markets. Or perhaps it is because agribusinesses have learned that food safety is good for business. In any case, this focus on public reforms represents a change in the food safety regulatory dynamic that has existed for the past 100 years.

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<sup>38</sup> David Vogel (ed.), Dynamics of Regulatory Change: How Globalization Affects National Regulatory Policies, Berkeley, CA: University of California Press (2004).

<sup>39</sup> Or already are. This statement is not intended to suggest that all small producers *cannot* or *do not* implement process-based safety measures. To the contrary, some already adhere to much more stringent standards than required by federal law.

Thus the essential linkages between risk, trust, and governance teach us that production systems in advanced industrial economies operate on the basis of efficiency standards grounded in divisions of labor and input specialization. In this sense, an industrial economy can be understood as a network of interdependent agents and actors who work together, sometimes without their knowledge or without direct coordination, to produce end use products. This is true of food production in the United States. But while complex divisions of labor promote macroeconomic efficiency, they also generate risks of promissory failure, opportunism, and defection from standards. Economists argue that trust mechanisms counter the risks associated with economic exchange. The questions thus become: how is trust created and reinforced and what agents enforce sanctions against those who would violate that trust? From this theoretical perspective, one devoted to a political economy of governance associated with divisions of labor, interdependence, risk, and trust, comes an understanding of why industrial economies need accountability regimes to define and defend the “public interest.”

Keohane defines accountability as a hierarchical regime in which some actors have the right to hold others responsible to a set of standards, to evaluate their implementation of those standards, and to impose sanctions upon actors in the face of noncompliance. In this sense, accountability regimes may be understood as arrangements of transparency, answerability, compliance, enforcement, and sanction mechanisms. But as Ebrahim and Weisband emphasize, accountability should not be equated with managerialism and technocratic reductionism. For while many understandings of accountability focus on failures in oversight or compliance that may be easily corrected by the implementation of regulatory standards, such simplistic conceptions do not capture the cultural dimensions of accountability as it differs across economies, sectors, and industries relative to how political and economic power is distributed, legitimated, and exercised. If accountability is to be framed with reference to the “public interest,” an analysis of accountability regimes must take into account how the “public interest” is defined, by whom, and with what consequences.

Analyses of accountability in food production, safety, and regulation lend themselves to techno/administrative evaluations focused upon hazard analysis, pathogen control, good practices, and industrial design; in this context, problems are easily identified and solved through the application of scientific risk assessment and the application of technical expertise. And while

an examination of these technical accountability mechanisms would constitute an essential component of any attempt to explain the regulatory deficit that characterizes the U.S. food safety regulatory regime, such an examination would be insufficient and incomplete, creating more questions than it answered. For the regulatory deficit that exists in U.S. food safety relative to accountability practices is not the consequence of a failure of techno-scientific research and its unsuccessful application to food production. A more complete understanding requires an analysis of accountability and, by extension, food safety regulatory regimes as expressions of political values, products of competing demands, and reflections of power structures that serve some interests at the expense of others, legitimate some forms of knowledge while devaloring others, and include some actors in the policy-making process in ways that exclude others. Accountability frameworks must therefore be defined as more than a series of benchmarks, standards, and penalties; accountability must be understood as a participative, regulative, and constitutive process that both shapes and reflects how economic and political agents interact in an industrial economy.

Since 1906 the legal accountability framework for food safety and its regulation in the United States has focused issues of food *purity* (see Chapter 2). Thus the U.S. food safety regime is designed to prevent food adulteration (the addition of injurious or unwholesome substances to food products) and to promote the cleanliness of food production facilities. This focus reflects an early 20<sup>th</sup> century conception of the “public interest” focused on consumer education and market interactions; standards and regulations prevented producers adding dyes, perfumes, or fillers to inferior food products in an attempt to profit off of consumer deception. In this framework, accountability was narrowly constructed to address food purity and wholesomeness so that customers could make informed market decisions. The system was established, not to keep inferior products out of the market (although the sale of filthy or putrid products was banned by the 1906 framework), but to allow consumers to “vote with their food dollars” for higher or lower quality food products and to impose legal sanctions on producers who engaged in deception.<sup>40</sup>

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<sup>40</sup> Again, however, legal action against producers that deceived consumers or violated the purity standards that came out of the 1906 framework focused on consumer information; legal consequences did not always require that producers stop marking inferior products (though it did remove some dangerous products from the market) but instead that those products be clearly labeled.

Many scholars continue to argue that consumers should have the right to purchase inferior products or to pay less money in return for products that are “less safe” provided that they have the information necessary to make an informed decision. This neo-liberal reincarnation of the *laissez faire* economic culture of the early 20<sup>th</sup> century prompts fundamental questions about food safety—should safe food be a public good provided to all consumers at a potentially higher cost or should regulations focus only on consumer education so that individuals may make their own decisions relative to food purchasing habits? Intrinsic to this question are the tensions between equity and freedom, food security and food safety; a system that provides safe food to those who can afford it places some consumers at greater risk than others, but a system that requires that all food conform to high food safety standards may price some consumers out of the food market all together.

The question thus becomes: how are accountability regimes (in this case those designed to regulate food safety) created, implemented, and assessed by whom, for whom, how, and with what effects? What agents along the farm to fork chain are held accountable to whom and according to what standards or benchmarks?<sup>41</sup> How is food safety defined in ways that permit regulators to assess and control some risks but not others? What interests are served by the U.S. food safety accountability regime and why? Which actors are advantaged and which are disadvantaged by accountability frameworks currently at work in the U.S. food safety system? These questions and their answers reflect upon the regulatory culture of the United States, the structure of the food industry, and the ways that powerful corporate interests influence the regulatory policy process in ways that advance their own interests often at the expense of what others may call the “public interest.”

The United States food safety regime, past and presents, represents a set of regulatory policies designed to alter or restrict behaviors and practices ostensibly in pursuit of “public,” “collective,” or “general” welfare. It is a collection of actors, agents, institutions, and interests that reflect, reinforce, and sometimes reconstitute cultural values, economic paradigms,

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<sup>41</sup> Here an examination of private food safety regulatory regimes and accountability frameworks becomes possible and important. For while we tend to think of accountability only in the context of government agencies and market agents, the literature on private food safety standards and their implementation provides comparative lens through which constructions of accountability, appropriate accountability practices, and accountability narratives can be produced and perpetuated.

ideological attachments, and political preferences through the interaction of lawmakers, administrative officials, judges, industry lobbyists, the mass media, consumer interest groups, and science advisors. Grounded in the 1906 Pure Food and Drug Act, the 1906 Federal Meat Inspection Act, the 1938 Food, Drug and Cosmetic Act, the 1957 Poultry Products Inspection Act, and the 1960 Egg Products Inspection Act, the U.S. food safety regulatory regime is a complex network of actors, interests, and values, many that have been structurally entrenched and dominant for more than a century but currently find themselves challenged in the midst of transformation.

Public policy in the United States reflects cultural values attached to individualism, self-help, personal responsibility, and consumer sovereignty. And the U.S. food safety regulatory regime, a product of a Progressive Era when government activism began to challenge these cultural values, remains beholden to notions of consumer education, disclosure, and market choice. Since its inception this regulatory regime has been dedicated to preventing food adulteration. But this approach was not designed to protect the public from dangerous or harmful foods *per se*; it was to protect consumers from unwholesome foods that were deceptively packaged, marketed, or advertised. The ban on adulteration was designed to encourage the dynamics of rational choice in market exchange, dynamics that work only when consumers have all relevant information. Although the 1906 framework banned adulterated products that were dangerous or harmful to human health, therefore, its primary function was to help consumers make more informed market decisions so that the market could more efficiently and effectively self-regulate. This orientation has persisted for a century, throughout the entire history of U.S. food safety regulation. But in the aftermath of crises and scandals that have heightened public awareness of food safety issues grounded, not in adulteration, but in physical, chemical, and microbiological contamination, the cultural and ideological underpinnings of the U.S. food regulatory regime are facing a legitimacy crisis. Current regulatory proposals that would revolutionize this regulatory regime in the name of greater accountability, more stringent food safety standards from farm to fork, and “command and control” process based requirements rather than performance based product requirements for food products. This challenge to the statutory and regulatory legal frameworks upon which the U.S. food safety regime have relied since 1906 are best understood through an analysis of competing publics and the inner workings of politics in the U.S. public policy process.

US food safety regulation and its outputs outcomes may be theorized in the context of the policy process. But of particular interest is not the policy process itself but what that process reveals about political, cultural, economic, and social dynamics. What does government action or inaction indicate in the area of food safety indicate about U.S. economic values and preferences or the influence of specialized interests and powerful corporations? What has been the impact of the industrialization of food production on the U.S. food regulatory framework established in 1906? Who are the formal and informal players in the policy process and how do they influence the ways by and through which food safety regulation is framed, adopted, implemented, and assessed? How can alternative methods of food safety regulation be assessed and evaluated using comparative methods and case studies? What have been the intentional and unintentional outcomes of the U.S. food safety regulatory regime? How are risk and danger conceptualized, interpreted, or assessed in relation to food safety and its regulation? What values, beliefs, knowledge systems, or “publics” have been included or excluded, valued or devalued, legitimated or delegitimated in the U.S. food safety regulatory framework past and present and with what effects? These questions and their answers frame an understanding of food safety, food policy, and food regulation beyond technocratic or scientific standards, benchmarks, and measurements. They link food safety as a regulatory problem in political economy to a policy process in ways that reflect, represent, and help us to understand political influence, values, processes, and dynamics at a critical moment of transformation and change.

#### Research Methodology: Elite Interviews

Alongside a discourse and content analysis of primary and secondary legal, legislative, administrative, scholarly, and popular resources, this dissertation incorporates information gleaned from interviews with public officials involved with food safety governance. Manheim, Rich, Wilnat, and Brians write that “intensive interviewing techniques...are used, not to obtain precise measures of concepts for testing theories, but as a means of gaining *in-depth understanding* of a phenomenon and discovering aspects of that phenomenon that you did not

anticipate.”<sup>42</sup> In order to better understand the history of the U.S. food safety regulatory regime and the proposals currently before Congress from the perspectives of political economy, public policy, and accountability, I conducted an elite interview<sup>43</sup> with Lisa Shames, Director of Natural Resources and Environment at the U.S. Government Accountability Office.

Manheim, et. al. emphasize that elite interviews are often “unscheduled;” that is to say, the interviewer is often “guided only by a general objective...and has no predetermined set of question to ask...in elite interviewing the researcher is interested in learning what the respondent perceives as important and relevant to the research and lets the respondent’s observations suggest what questions should be asked in order to gain useful information.”<sup>44</sup> Thus elite interviewing is a “process of discovery...early interviews may teach us things that help us get the most useful information.”<sup>45</sup> In this case, elite interviews provided critical insights into the history and functioning of the U.S. food safety regulatory regime as well as current regulatory proposals.

### Conclusion:

Food safety is an issue whose “time has come.” For the first time in more than a century social, political, economic, corporate, and consumer interests have converged to make food production, processing, and distribution alongside food safety regulation high profile issues of debate, discourse, and contention. Public policy scholars are quick to emphasize that crises and scandals alone cannot provide the inertia necessary for a revolution of policy and regulatory structure. But crises and scandals—from outbreaks of foodborne illnesses to the emergence of new foodborne pathogens to the realization that guile and opportunism can and do undermine the very foundations of the U.S. food safety regulatory regime—can bring an issue to the forefront of political debate. Food safety is certainly there. This is a time when explorations of the food safety regulatory problem can focus on more than what has been and what is without treading unnecessarily into empty hypotheticals and spurious conjecture. Policy analysis requires the

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<sup>42</sup> Manheim, et. al. Empirical Political Analysis: Research Methods in Political Science, 6<sup>th</sup> Edition, New York: Pearson (2006): pp. 355.

<sup>43</sup> People are defined as “elite” if “they have knowledge...[and] access to information that can help answer a given research question.” (*Ibid*: pp. 355)

<sup>44</sup> *Ibid*, pp. 356.

<sup>45</sup> *Ibid*, pp. 358.

identification, evaluation, and assessment of alternatives including, in this context, and examination of the relative effectiveness and efficiency of different regulatory approaches to food safety.<sup>46</sup> For these reasons, an investigation of the politics of food safety regulation that incorporates understandings of accountability, political economy, public policy, and food science and technology can grant insight into what has been, what is, what could be, and what should be with respect to the U.S. food safety regulatory regime.

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<sup>46</sup>Such as the top-down administrative approach favored in the new legislation and the bottom-up market based approach implemented in the GAPs initiative.

**PART I:**  
**THE U.S. FOOD SAFETY REGULATORY REGIME**  
**FROM 1906 TO THE PRESENT**

**CHAPTER 2**  
**ESCAPE FROM THE JUNGLE:**  
**THE U.S. FOOD SAFETY REGULATORY REGIME**

The United States food safety regulatory regime rests upon “the authority of two laws enacted in 1906: the Pure Food and Drug Act and the Meat Inspection Act...The Pure Food and Drug Act was amended several times and in 1938 became the Food, Drug, and Cosmetic (FD&C) Act...[Since 1938) other laws dealing with the safety of such commodities as milk and water have been enacted by Federal, State, and local governments.”<sup>47</sup> Prior to 1906, food safety regulations within the United States were state and local laws and ordinances that “were motivated not by a desire to provide safe food to consumers, but rather out of foreign trade concerns.”<sup>48</sup> Massachusetts’s 1641 Meat and Fish Inspection Law, for example, was designed “to assure foreign trading partners that the colony produced high-quality food products.”<sup>49</sup> Because food production and distribution networks prior to the 20<sup>th</sup> century were, for the most part, intrastate, this decentralized framework appeared both appropriate and adequate. As food production and distribution changed, however, “the national scope necessitated national regulation.”<sup>50</sup>

*The 1906 Food Safety Revolution: From the Poison Squad to The Jungle*

Although national food purity bills have been debated since the 1890’s, 1906 was a watershed for U.S. food safety regulation. Widespread demands for change came following the publication of two investigative studies: the first, *A Popular Treatise on the Extent and Character of Food Adulterations* and, the second and far more infamous, *The Jungle*. Written by Dr. Harvey Washington Wiley and published in 1890, the pioneer of food chemistry who would go on to lead the Bureau of Chemistry (which would later become the Food and Drug Administration), *A Popular Treatise on the Extent and Character of Food Adulterations* warned

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<sup>47</sup> D. J. Wagstaff, *Public Health and Food Safety: A Historical Association*, Public Health Reports, Volume 10: Number 6 (November-December 1986), pp. 625.

<sup>48</sup> “Food Safety,” Food and Culture Encyclopedia, [available online: <http://www.answers.com/topic/food-safety>].

<sup>49</sup> *Ibid.*

<sup>50</sup> *Ibid.*

consumers that nearly every food they ate was either adulterated or misbranded. Building upon work by the federal government's "Poison Squad," a group of chemists employed by the U.S. Department of Agriculture, this report indicated that many of the chemicals used in food production, particularly those used as preservatives which included borax, boric acid, copper sulfate, potassium nitrate, saccharin, salicylic acid, salicylates, sulfuric acid, sulfites, benzoic acid, benzoates, and formaldehyde, were harmful to human health. Dr. Wiley's work prompted popular demands for federal food safety regulation, ultimately realized in the 1906 Pure Food and Drug Act, which prohibited the adulteration and/or misbranding of food or food products.<sup>51</sup>

But it was the 1906 publication of Upton Sinclair's *The Jungle*<sup>52</sup> with its "soaking disclosures of unsanitary conditions in meatpacking plants...[as well as] the filthy conditions and adulteration of meat that was common in the Chicago meat industry."<sup>53</sup> As Hilts writes, "particularly disturbing were the accounts of the workers, sick with tuberculosis, spitting onto the floor, then dragging butchered meat across it...there were tales of meat in storage rooms, rotting and covered with rat droppings, which was then made into sausage, detritus and all...there were even tales of workers who had fallen into the great acidic lard vat and become, after their bones had been fished out, a part of 'Durham's Pure Leaf Lard.'"<sup>54</sup>

Consumers, unable to stomach the graphic details of food production included in *The Jungle* launched a market response; within "weeks of the publication...the sales of meat fell by half."<sup>55</sup> Consumers demanded regulation and accountability in food production relative to food safety. Within weeks, Congress outlined the 1906 Federal Meat Inspection Act (FMIA), a consumer protection measure designed to assure that "meat and meat food products are wholesome, not adulterated, and properly marked, labeled, and packaged."<sup>56</sup> Comprised of four

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<sup>51</sup> Dr. Wiley is also the founder of one of the oldest systems of Third Party Certification in the United States. After leaving the Bureau of Chemistry in 1912 he became director of the Bureau of Foods Sanitation and Health for *Good Housekeeping* magazine where he developed the Good Housekeeping Seal of Approval.

<sup>52</sup> Although the book dedicated relatively little space to issues of food safety, the graphic descriptions were so heinous that several publishers refused to distribute the manuscript; readers were made physically ill by descriptions of rats being tossed into meat grinders and the unsanitary practices of workers in the slaughterhouses.

<sup>53</sup> "Food Safety," *Food and Culture Encyclopedia*, [available online: <http://www.answers.com/topic/food-safety>].

<sup>54</sup> Philip J. Hilts, *Protecting America's Health: the FDA, Business, and One Hundred Years of Regulation*, New York: Alfred A. Knoph (2003), pp. 49.

<sup>55</sup> *Ibid*, pp. 51.

<sup>56</sup> *Ibid*, 51.

primary requirements, the FMIA mandated: (1) inspections of all cattle, sheep, goats, horses, swine, and chickens before slaughter; (2) the postmortem inspection of each carcass; (3) the establishment of sanitary standards for slaughter houses and meat processing plants; and (4) the continuous monitoring and inspection of slaughter houses and meat processing plants by USDA officials. In addition, the FMIA gave the USDA the authority to remove its inspectors from a slaughter house or processing plant, effectively stopping operations and preventing the distribution of potentially adulterated or putrid meat products.

For Wiley, the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act represented the culmination of more than 25 years of efforts on the part of the pure-food lobby. Shortly before the publication of *The Jungle*, Wiley had “despaired of ever getting a [food safety] law” through the United States Congress.”<sup>57</sup> “Pure Food bills in the Senate had been regularly committed to the Committee on Manufacturers,’ he wrote, ‘much as an infant would be left to starve in a barren room.’”<sup>58</sup> But a combination of public demands, Presidential support, and mass media pressure pushed the 1906 legislation through Congress; as Hilt writes, “even the mainstream members of the industries to be regulated were asking for some bill that would save their hides from the constant flailing they were receiving.”<sup>59</sup> During debates on the bills, Senator Weldon of Idaho queried, “has there even been in the history of this country a more universal demand for action upon the part of Congress than the demand that has gone up from one end of the country to the other in regard to legislation upon the pure-food question?”<sup>60</sup>

But politics intervened and passage of the 1906 food purity legislation was anything but guaranteed. Congressman James W. Wadsworth, a cattleman who served as Chair of the House Committee on Agriculture, refused to bring the Federal Meat Inspection bill to a vote. When the meat industry offered a “compromise” measure, President Roosevelt declared it “so bad that in my opinion, if [the provisions] had been deliberately designed to prevent the remedying of the evils complained of, they could not have been made worse.”<sup>61</sup> He released the Neill-Reynolds

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<sup>57</sup>*Ibid*, 51.

<sup>58</sup>*Ibid*, 51.

<sup>59</sup>*Ibid*, 51.

<sup>60</sup>*Ibid*, pp. 51-52.

<sup>61</sup> Roosevelt may have begun his political career as a staunch *laissez faire* conservative but he ended his life as a progressive conservative that “wanted an adventurous, aggressive nation, as well as ne concerned about fairness for citizens” [*Ibid*, pp. 36]. While working as commissioner of police in New York City in 1895 Roosevelt faced

Report, a government investigation that confirmed even Sinclair's most scandalous observations about conditions in the meat processing and packaging industry, to the public. In the aftermath of the public outcry that ensued and for the sake of unity within the Republican Party, Congress passed the 1906 Federal Meat Inspection Act, sending it to the President for his signature.

The 1906 Pure Food and Drug Act faced a longer and more bitter political struggle. Not only would the Pure Food and Drug Act create the country's first regulatory agency, it would have to determine "safety" for hundreds of substances *and* confront questions of economic fraud as well. Capitulating to industry pressure, the bill relied on product labeling standards to prevent issues of economic fraud and purity requirements to prevent product adulteration. Under its provisions, food would be considered adulterated if it "was missing a key ingredient (such as flour in bread), or if its inferior quality was masked by coloring, powdering, coating, mixing, or staining."<sup>62</sup> Any food that was "filthy, decomposed, or putrid" or that included the addition of any "poisonous or other added deleterious ingredient which may render such article injurious to health" (such as preservatives investigated by the Poison Squad) would be considered adulterated under the 1906 law.<sup>63</sup>

The 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act may be understood as public interest legislation. "According to this view," write Coppin and High, "the leaders of the pure food movement, and Wiley in particular, are portrayed as morally upright, solicitous of the health and welfare of the consumer, and opposed to shoddy products and fraudulent labeling...those opposed to the act are portrayed as corrupted businessmen and politicians, including Nelson Aldrich and other Old Guard senators."<sup>64</sup> Another interpretation of the legislation is that "special interests captured it for their own purposes."<sup>65</sup> Donna Wood argues both laws can be understood as the product of conflicts "not between honest and

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"implacable political problems of corruption and conservatism" and used "progressive tactics—investigations and publicity about how unjust matters were—to combat them" [*Ibid*, pp. 37]. Experiences with the Rough Riders in Cuba convinced Roosevelt to join Dr. Wiley's campaign to establish minimum standards for food quality. As President, Roosevelt was a strong ally and proponent of the Pure Food Movement and, as Chapter 4 explains, a political force in the formation of the 1906 food safety regulatory regime.

<sup>62</sup> *Ibid*, pp. 54.

<sup>63</sup> *Ibid*, 54.

<sup>64</sup> Clayton A. Coppin and Jack High, The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy, Ann Arbor: The University of Michigan Press (1999), pp. 15.

<sup>65</sup> *Ibid*, pp. 15-16.

dishonest producers, as the public interest theory suggested, but rather between legitimate business interests that were intent on using regulation to gain an advantage over their competitors.”<sup>66</sup> Wood, who called this process “the strategic use of public policy,” argues that business conflict explains “the passage and early enforcement” of the 1906 Pure Food and Drug Act as well as the 1906 Federal Meat Inspection Act.<sup>67</sup> Coppin and High put forward a different interpretation. They argue that “the movement for a national food law came from food commissioners, agricultural chemists, manufacturers of expensive foods, representatives from rural agricultural states, and a small number of middle-class women...the rhetoric of regulation was ‘pure food for the mass consumer,’ but its impetus came from the professional classes.”<sup>68</sup> Each interpretation, discussed in greater length in later chapters, indicates that food safety is more than a scientific discipline; food safety and its regulation are inherently and intensely political issues.

As a consequence, therefore, the 1906 Pure Food and Drug Act was a vague statute replete with “weak language” and imprecise provisions. Moreover, the Bureau of Chemistry, the regulatory agency authorized to discharge the law, received no funds dedicated to its enforcement. As Hilt writes, “nor did [Congress] give the government the power simply to determine that the law was violated; it required that the government take each offender to court and prove that each particular food or drug was adulterated or mislabeled, and by what standards it was making the judgment.”<sup>69</sup> Therefore, although the law acknowledged “that there are instances, such as the ensuring of a supply of safe and wholesome food and medicine for the nation, in which the government must protect citizens against business,” its progressive principles would prove nearly impossible to enforce.<sup>70</sup> The law was a success but also a failure.

*Demands for an “Updated” Food Safety Regulatory Regime: American Chamber of Horrors*

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<sup>66</sup> *Ibid*, pp. 16.

<sup>67</sup> *Ibid*, pp. 16.

<sup>68</sup> *Ibid*, pp. 31.

<sup>69</sup> Philip J. Hilt, Protecting America’s Health: the FDA, Business, and One Hundred Years of Regulation, New York: Alfred A. Knoph (2003), pp. 54.

<sup>70</sup> *Ibid*, pp. 55.

Although revolutionary, the 1906 food safety framework consisting of the Pure Food and Drugs Act and the Federal Meat Inspection Act faced widespread criticism in the early decades of the 20<sup>th</sup> century. As food production, processing, and distribution became increasingly industrialized (see Chapter 3) and increasingly concentrated in the hands of a few large corporate agribusinesses (see Chapter 4), consumer activists and food chemists insisted that the 1906 framework failed to adequately protect consumers from food adulteration and misbranding. Framing their arguments in economic as well as public health terms, proponents of more stringent food adulteration prohibitions claimed that the 1906 regulations, particularly those contained in the Pure Food and Drug Act, were too broad and imprecise. Not only did the legislation fail to set standards for specific food commodities, thus leaving processors to determine what constituted “adulteration,” it required that government officials prove that producers *intended* for their products to deceive or harm consumers.

As in 1906, the final push for reform came in response to investigatory studies that alerted the public to potential dangers lurking in their foods. In 1933 Arthur Kallet and F. J. Schlink published *100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs, and Cosmetics*, which argued that widespread incompetence and inadequate regulatory authority prevented the federal government from protecting the public from adulterated, unwholesome, or putrid foods. At the same time, the newly created Food and Drug Administration, responsible for enforcing the 1906 Pure Food and Drug Act and for regulating all foods not specified in the Federal Meat Inspection Act, presented *American Chamber of Horrors: The Truth about Food and Drugs*. Published by FDA Chief Executive Officer Ruth deForest Lamb in 1936, this text chronicled hundreds of dangerous or misbranded products that remained legal under the 1906 framework. Primarily a response to the alliance of media outlets with food producers that opposed more stringent food safety standards and regulations, this “play to the populous” included exhibits, photographs, posters, and other promotional materials that were presented to women’s clubs, civic organizations, museums, and other public audiences in an attempt to illustrate the need for revised food safety laws. Noting that “the 1906 laws were outdated due to new modes of living, new kinds of products, new methods of manufacturing and selling, new tricks of sophistication, and new scientific discoveries, all demanding a more modern method of control,” the FDA, led by Dr. Wiley, led the public demand for a more comprehensive food safety regulatory regime.

*The 1938 Food, Drug, & Cosmetic Act and the 1967 Wholesome Meats Act*

By 1917 the USDA Bureau of Chemistry outlined the primary weaknesses of the 1906 Pure Food and Drug Act: (1) “the lack of legal standards (descriptions) for foods;” (2) “the lack of authority to inspect food and drug warehouses;” (3) “the inability to restrict the interstate shipment of a food that naturally contains poison;” (4) “the lack of jurisdiction over false or misleading claims made on food;” and (5) “the failure to address pesticide residue in foods.”<sup>71</sup> The 1938 Food, Drug, & Cosmetic Act (FD&CA) addressed, at least in part, these concerns by establishing a more precise and more inclusive food safety framework. The FD&CA’s provisions, which included (1) a prohibition against false food advertising, (2) the promulgation of definitions and standards for food that carried the force of law, (3) the establishment of safe tolerances for poisons added to foods (including pesticide residue limits), and (4) the extension of more severe penalties including criminal prosecution, injunctions, and seizure of goods, established “a catalogue of definitions elaborating two basic concepts: ‘adulteration’ and ‘misbranding.’”<sup>72</sup> As Hutt and Merrill write, “most of the Act’s operative provisions describe circumstances under which a food, drug, cosmetic, or device will be considered adulterated or misbranded under the law and thus subject to FDA enforcement action.”<sup>73</sup> Hutt and Merrill go on to explain that, “for example, section 402(a) of the Act does not forthrightly forbid the marketing of food that is decomposed or filthy; it specifies that food that is decomposed or filthy shall be ‘deemed adulterated.’ Then Section 301 enumerates a series of ‘prohibited acts,’ among them the shipment, distribution or sale of any adulterated food.”<sup>74</sup> “In short,” therefore, “much of the statute is devoted to ascribing the labels ‘adulterated’ or ‘misbranded’ to products whose composition, production, or labeling fails to meet substantive requirements that are the real focus of the law.”<sup>75</sup> This means, however, that “the Act’s basic format has not changed since 1906.”<sup>76</sup>

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<sup>71</sup> Patricia A. Curtis, Guide to Food Laws and Regulations, Ames, Iowa: Blackwell Publishing (2005), pp. 30.

<sup>72</sup> Peter Barton Hutt and Richard A. Merrill, Food and Drug Law: Cases and Materials, 2<sup>nd</sup> Edition, New York: The Foundation Press (1991), pp. 12.

<sup>73</sup> *Ibid*, pp. 12.

<sup>74</sup> *Ibid*, pp. 12.

<sup>75</sup> *Ibid*, pp. 12.

<sup>76</sup> *Ibid*, pp. 12.

Instead, “changes in the scope of FDA’s responsibilities have generally been reflected in the addition of new definitions of adulteration and misbranding.”<sup>77</sup>

The FD&CA has been amended many times since its passage in 1938, often in ways that “enlarged FDA’s substantive authority over products already within its jurisdiction.”<sup>78</sup> These amendments, including the Miller Pesticides Amendment of 1954, the Food Additives Amendment of 1958, and the Color Additives Amendment of 1960, did not change the fundamental character of the U.S. food safety regulatory regime; regulatory authority remained tethered to notions of “adulteration” and “misbranding.” Amendments, like the 1906 Pure Food and Drug Act and the 1938 Food, Drug, & Cosmetic Act, thus focused on the safety of food *additives* rather than the safety of foods themselves. As Hutt and Merrill write, “only in the last generation has FDA begun to act like a modern ‘regulatory agency’—a body responsible for routine monitoring of the operations of several industries and exercising comprehensive authority to prescribe how they must make and market products.”<sup>79</sup> But in its efforts to “adapt to contemporary problems” (see Chapters 5, 6, and 7), the FDA has to contend with the “problem of purity,” that is to say, the fact that its regulatory authority is tied to notions of food *purity* and *wholesomeness* rather than 20<sup>th</sup> century understandings of food *safety*. While the FDA “sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food-borne disease, to determine specific health impacts of hazardous substances in food and to develop methods for detecting them in foods; and maintains surveillance over foods through plant inspections, laboratory analyses, and legal action where necessary,” its regulatory operations are limited to food adulteration and misbranding. The FDA doesn’t even have a standing committee on food safety.<sup>80</sup>

Just as the 1906 Pure Food and Drug Act was updated and amended by the 1938 Food, Drug, & Cosmetic Act, the 1906 Federal Meat Inspection Act was updated and amended by the 1967 Wholesome Meat Act. The 1906 meat safety framework required that inspectors certify meat as healthy, clean, sanitary, wholesome (non-adulterated), and properly labeled. Designed to detect diseased or contaminated meat so that it could be destroyed, to assure clean and sanitary

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<sup>77</sup>*Ibid*, pp. 12.

<sup>78</sup>*Ibid*, pp. 13.

<sup>79</sup>*Ibid*, pp. 20.

<sup>80</sup>*Ibid*, pp. 21.

handling and preparation procedures, minimize the risks of microbial contamination of meat and meat products, prevent adulteration and/or the presence of chemical or drug residues, and prevent false or misleading labeling, the 1906 legislation afforded federal inspectors with the right to inspect meat processing facilities and to declare meat and meat products to be “USDA Certified.” Although it gave the USDA the authority to seize contaminated meat or meat products, it did not give the federal government the power to issue mandatory recalls of tainted meats. In practice, the USDA’s food safety activities focused upon three primary tasks: facility inspections, animal inspections, and product inspections. Facility inspections certify that “water supply, drainage, waste disposal, lighting, ventilation, refrigeration, [and] insect and rodent control” as well as worker operations satisfy regulatory specifications.<sup>81</sup> Although processors are no longer required to secure prior blueprint approval from federal authorities (see Chapter 4), meat processing plants “must be constructed so that they are clean and do not contribute to hazards in meat.”<sup>82</sup> In addition, USDA officials conduct antemortem, postmortem, and product inspections as well as laboratory determinations and assays.

The 1950’s and 1960’s were a time of transformative change for the USDA relative to the safety of meat and meat products. During this period, the USDA focused increasingly on meat wholesomeness and visible signs of contamination. During this period, concerns about the use of diseased animals as food diminished. A greater variety of meat products on the market, the industrialization of the food production process (see Chapter 3), the nationalization of food distribution networks, and the increased volume of processed meat products produced reframed concerns about mislabeling and adulteration. In response to rapid growth in the poultry industry during the post-World War II era, Congress passed the Poultry Products Inspection Act of 1957 as amended by the Poultry Products Inspection Act of 1968. And in 1967 the Federal Meat Inspection Act was amended as the Wholesome Meat Act that required states to conduct adequate inspections of the nation’s meat. As a consequence, the country’s meat and poultry inspection programs, which had emerged separately, were merged into a single program within the USDA’s Agricultural Research Service. In 1981 that program was christened the Food Safety and Inspection Service (FSIS), the branch of the federal bureaucracy that continues to

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<sup>81</sup> “Meat Inspection,” Texas A & M Meat Science, accessed November 23, 2009 [available online: <http://meat.tamu.edu/meatinsp.html>].

<sup>82</sup> *Ibid.*

administer regulatory functions and conduct all meat and poultry inspections in the United States. Since 1906, however, the USDA, like the FDA, has focused its efforts on the prevention of food adulteration. Although it enacted the Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) System in 1996<sup>83</sup> (see Chapter 6), accountability in food safety continues to be framed in terms of purity and wholesomeness rather than safety.

### *Divided Authority: the FDA and the USDA*

The U.S. food safety regulatory regime divides power, authority, and responsibility between two regulatory agencies—the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA). Under the authority of the 1906 Federal Meat Inspection Act, the 1957 Poultry Products Inspection Act (as amended), the 1967 Wholesome Meat Act, and the 1970 Egg Products Inspection Act, the USDA regulates the country’s meat, poultry, egg products, and processed meats (any food that contains greater than 3% raw meat or greater than 2% cooked meat). But by far, most of the country’s food supply is regulated by the FDA under the authority of the 1906 Pure Food and Drug Act and the 1938 Food, Drug, & Cosmetic Act (as amended). The FDA regulates everything *not* regulated by the USDA—including, but not limited to, imported foods, bottled water, infant formulas, foods derived from modern biotechnologies, fruits and vegetables, fresh and frozen seafood, and wines with less than 7% alcohol.<sup>84</sup> This divided authority, which grew out of the expansion of the federal bureaucracy over the course of the 20<sup>th</sup> century, represents a weakness of the U.S. food safety regulatory regime, particularly with respect to notions of accountability. As Lisa Shames, Director of Natural Resources and Environment for the U.S. Government Accountability Office stated, “the GAO put food safety on its high risk list [in 2007] and what we found...when we updated [that list] in 2009 was that the situation had actually gotten worse...[for example, the] USDA [now] has statutory responsibility for catfish [so] even seafood [regulation] is getting more fragmented...15 agencies oversee food safety and implement some 30 laws and this

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<sup>83</sup> The Pathogen Reduction and Hazard Analysis and Critical Control Point program instituted mandatory HACCP systems, microbial testing for *E. coli* and *Salmonella*, and sanitary standard operation procedures (SSOPs).

<sup>84</sup> The FDA also regulates drugs, medical devices, and a host of other consumer products.

fragmentation, based on 30 years of GAO review, led to inconsistent oversight, ineffective coordination, and an inefficient use of resources.”<sup>85</sup> The problem is not merely one of statutory mandate; it is also a problem of resource allocation. Continues Shames, “at the most macro level, USDA gets more of the federal food dollar than FDA but it's actually FDA that's responsible for more of the food...it's roughly an 80/20 split with USDA responsible for 20% of the food but getting 80% of the dollars and FDA responsible for 80% of the food but getting 20% of the dollars.”<sup>86</sup>

The FDA is the modern successor to the USDA's Bureau of Chemistry, the office led by Dr. Harvey Washington Wiley. Originally an agency of the Department of Agriculture, it now operates under the authority of the Department of Health and Human Services. It is, therefore, neither a Cabinet-level department (like the USDA) nor an independent agency (like the EPA). For this reason, as Hawthorne argues, the FDA lacks legitimacy and power relative to other federal agencies. Moreover, the FDA is a chronically underfunded regulatory agency. According to an advisory panel report, *FDA Science and Mission at Risk*, written by experts in academia, industry, and government officials, the FDA is so underfunded and understaffed that “the capacity of science to support the FDA mission is dangerously constrained” and “the nation's food supply is at risk.”<sup>87</sup> The report detailed a “plethora of inadequacies” including, as reported in the mainstream press: (1) “inadequate inspection of manufacturers;” (2) “a ‘badly broken’ food-import system and food supply ‘that grows riskier every year;” (3) “a depleted FDA staff;” (4) “a workforce with a ‘dearth’ of scientists who understand emerging technologies;” (5) high turnover rates in the scientific positions at the FDA; and (6) “an ‘obsolete’ information-technology system.”<sup>88</sup> These concerns have been echoed by officials at the Government Accountability Office, the investigative arm of Congress, as well as Congressional committees. In the past, reports indicated that “crises would arise if funding issues weren't addressed;” since 2007, “some of those crises are now realities, and American

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<sup>85</sup> Lisa Shames, interview by Courtney I. P. Thomas, 27 January 2010.

<sup>86</sup> *Ibid.*

<sup>87</sup> Gail Cassell, *FDA Science and Mission at Risk: Report of the FDA Science Board's Subcommittee on Science and Technology*, U.S. Food and Drug Administration, 25 February 2008, pp. 7 [available online: [http://energycommerce.house.gov/Press\\_110/022508.ScienceBoardReport.EstimatedResources.pdf](http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf)].

<sup>88</sup> Julie Schmit, *Report: FDA so underfunded, consumers are put at risk*, *USA TODAY*, 12/2/2007 [available online: [http://www.usatoday.com/news/washington/2007-12-02-fda\\_N.htm](http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm)].

lives are at risk.”<sup>89</sup> According to William Hubbard, a former FDA associate commissioner, the advisory panel “was supposed to look ahead to where the FDA needs to be [but] it came away concluding that ‘it cannot even do its job now.’”<sup>90</sup>

The USDA allocates food safety functions and responsibilities to the Food Safety and Inspection Service (FSIS). But, like the FDA, the FSIS has faced challenges in recent years, particularly with respect to its regulatory and inspection responsibilities. Although the Department of Agriculture’s FY 2010 budget includes a modest funding boost to the FSIS, “it appears the agency will be unable to close the gap in its inspection force responsible for policing the nation’s supply of meat and poultry.”<sup>91</sup> Because “the size of the [FSIS] inspectorate [must] be closely aligned to the size of the industry it regulates,” “funding and staff size are critical issues for FSIS.”<sup>92</sup> Population growth, an increased nationwide demand for meat and poultry products, and an increasingly complex food production system put pressure on the FSIS, a regulatory body which must inspect and approve *all* meat and poultry products *before* they are sold. Reports indicate that “in June 2007 the agency had a vacancy rate of 12.2 percent in its inspection force...as a result, the inspectors FSIS does employ are spread to thinly, and oversight of slaughterhouses and other facilities is insufficient.”<sup>93</sup>

Funding issues are not the only problems facing the USDA FSIS. Recent attempts to update the antiquated 1906 food safety framework for meat products have been struck down by U.S. courts (see Chapter 6). Moreover, the USDA, initially instituted to promote food *security* in the United States and only later to have a food *safety* function, has unusually close ties with the industry it regulates. Many argue that USDA (and the FDA) have been “captured” by the very interests they are supposed to regulate; the “revolving door” between large food producers and these regulatory agencies is well documented (see Chapter 4). For this reason, both the FDA and the USDA have been criticized as being “too friendly” to corporate interests and “hostile” to the

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<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> Matthew Madia, *USDA Budget Leaves Food Safety Agency Wanting*, OMB Watch, 10/14/2009 [available online: <http://www.ombwatch.org/node/10472>].

<sup>92</sup> *Ibid.*

<sup>93</sup> *Ibid.*

“public” interest.<sup>94</sup> As Wiley wrote in his *History of a Crime Against the Food Law*, “unscrupulous businesses such as the whiskey rectifiers, Coca-Cola, and Monsanto corrupted the secretary of agriculture and other powerful officials, who then thwarted congressional intent.”<sup>95</sup>

Although the USDA and the FDA dominate the food safety regulatory regime, they share power with state and local health departments and regulatory authorities, the National Institutes of Health, the Federal Trade Commission, the U.S. Trade Representative, and the Environmental Protection Agency, among others. One of the primary challenges facing the U.S. food safety regulatory regime, therefore, is one of *accountability*. As USDA Secretary Tom Vilsack commented in 2009, “the U.S. food safety system is divided by competing philosophies and a lack of accountability that make it harder to protect consumers.”<sup>96</sup> “It seems to me,” Vilsack continued in his testimony before a Congressional subcommittee that controls the USDA, that “today we have competing philosophies” with the USDA focused more on prevention while the Food and Drug Administration targets mitigation due to a heavy workload and limited staffing.<sup>97</sup> Vilsack, who supports a single food safety regulatory agency, concludes, “when you have [fifteen] separate agencies in the federal government responsible for some part (of food safety), you’ve got way too many...who do ‘you hold accountable when there is a problem?’”<sup>98</sup>

### *The Problem with Purity: The Food Safety Regulatory and Accountability Deficit*

Food adulteration is a problem as old as human civilization itself. Ancient texts, including Theophrastus’s (370-285 BC) botanical treatise *Enquiry into Plants* “discussed the use of artificial preservatives and flavors, such as balsam gum, that were added to many foods for

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<sup>94</sup> Some have argued that the close relationship between the USDA and food producers derives from the USDA’s mandate relative to food security. The USDA was established to enhance food security in the United States; that is, to make sure that citizens had access to an abundance of affordable food. To do so, USDA officials formed close working relationships with food producers. When the USDA was given food safety responsibilities, some argue, it continued to nurture those close relationships, allowing food producers to have a great deal of influence over the formulation and implementation of safety regulations.

<sup>95</sup> Clayton A. Coppin and Jack High, *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy*, Ann Arbor: The University of Michigan Press (1999), pp. 16.

<sup>96</sup> Christopher Doering, *USDA Chief cites problems in food safety system*, *Reuters*, March 31, 2009 [available online: <http://www.reuters.com/article/healthNews/idUSTRE52U7K920090331>].

<sup>97</sup> *Ibid.*

<sup>98</sup> *Ibid.*

economic reasons.”<sup>99</sup> And many experts agree that the world’s oldest food safety standard is the 1516 German (or Bavarian) Beer Purity Law or *Reinheitsgebot*. The *Reinheitsgebot* established standards for the sale and composition of beer, requiring that only water, barley, and hops be used in the production of German beer. This was, fundamentally, a prohibition against *adulteration*, that is, against the addition of any substance that would render the beer harmful, poisonous, or inferior. Designed in part to prevent the use of wheat or rye in beer, thus reserving those grains for bakers, the *Reinheitsgebot* was, as its name suggests, designed to guarantee that beer produced or sold within Germany would adhere to the highest standards of *purity*.

In the United States, the 1906 U.S. food safety framework, as amended, remains focused on notions of food *purity* and *wholesomeness*. But this emphasis on food *adulteration* and *misbranding* comes at the expense of a regulatory framework focused on more contemporary issues of food safety—including, for example, issues of microbiological contamination that currently stand at the forefront of food safety discourse. Legal regulatory and accountability frameworks designed to safeguard food safety in the United States remain largely based upon laws written at the turn of the 20<sup>th</sup> century continue to base their food safety activities upon the safety of food *additives*, substances which, if added to food products, may constitute adulteration under the 1906 framework’s prohibition against the addition of “extraneous” or “impure” substances to food products. The problem of purity, therefore, remains the foundation of both the U.S. food safety regulatory regime and the authority of federal regulators who enforce food safety standards and provisions.

Cultural and legal conceptions of food safety have changed dramatically since the first attempt by the U.S. government to regulate food production and safety in 1906. Comforted by government attempts to safeguard the purity of food and the cleanliness of food production and processing facilities, consumers in the post-World War II era focused their concerns on the chemical contamination of food products, particularly relative to the increasing use of pesticides and fertilizers in large-scale commercial agriculture.<sup>100</sup> As concerns about “conventionally”

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<sup>99</sup>Patricia A. Curtis, *Guide to Food Laws and Regulations*, Ames, Iowa: Blackwell Publishing (2005), pp. 25.

<sup>100</sup> Survey research indicates that consumer fears about “chemicals and novel processes generally outweigh concerns about foodborne illness of microbial origin” (M. S. Brewer and C. J. Prestat, *Consumer Attitudes Toward Food Safety Issues*, *Journal of Food Safety*, 22 (2002), pp. 68). According to survey research, most consumers “moderate” to “much” concern regarding “chemical issues” related to food safety: the use of artificial colors,

produced foods rose alongside the industrialization of food production (see Chapter 3),<sup>101</sup> consumers in the latter part of the 20<sup>th</sup> century became increasingly concerned about the safety (and environmental sustainability) of Genetically Modified Foods (GMFs) or so-called “Frankenfoods.” As trade liberalization opened U.S. food markets to imports, consumers questioned the safety of foods produced in other economies, particularly economies that did not have public institutions designed to ensure the “same level of food safety” the United States government provided. And, in recent years as food microbiology and medical science advances have provided insights into foodborne illnesses and mass media have sensationalized outbreaks, consumers report that they are concerned with microbiological food safety.<sup>102</sup>

These consumer concerns and conceptions have framed food discourse within the United States. Many consumers who were concerned with chemical contamination became proponents of organically produced foods. Reminiscent of the “pure foods” movement that supported the 1906 Pure Food and Drug Act, fears about the safety of “conventionally” (read “industrially”) produced foods have led to a local foods movement focused on small farms, farmer’s markets, and a return to “traditional” agriculture. And out of these concerns have come a myriad of food safety myths that have been popularized by specialized food interests and “naturalized” into the food discourse so thoroughly that they are no longer questioned.

Proponents of both organic and “local” foods, for example, argue that organically and/or locally produced foods are healthier, more ethical, and more environmentally sustainable than conventionally produced foods. More to the point, both argue that more “natural” foods are safer than industrially produced foods. And yet relatively little research has documented these claims. Many local producers offer no scientific evidence to substantiate their assurances that local food

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pesticide residues, hormones in poultry and meat, the use of preservatives, food irradiation, excessive processing of foods, hormones in milk, and the use of plastic packaging. Fewer consumers reported “much concern” over “microbiological” issues: restaurant sanitation, shelf-stable foods, pasteurized foods, refrigerated or prepared foods, improper food preparation, microbiological contamination, and nutritional imbalances. And of those who expressed concern over microbiological issues, 70% reported “moderate” or “much” concern about improper food preparation and about restaurant sanitation whereas only 55% of consumers expressed “moderate” to “much” concern about microbiological contamination in food.

<sup>101</sup> Approximately one-third of consumers believe that “food safety problems most likely occurred at food manufacturing [read: industrial] facilities” (M. S. Brewer and C. J. Prestat, *Consumer Attitudes Toward Food Safety Issues*, *Journal of Food Safety*, 22 (2002), pp. 77).

<sup>102</sup> Among their top concerns, consumers also report trepidation regarding the safety of food additives (including colors and flavors) and the nutritional quality of food.

is safer simply by virtue of its being local; they feed on the fear of the unknown, the paranoia about the power of large corporations that control the food supply, and widespread doubts about the effectiveness of the U.S. food safety regulatory regime.<sup>103</sup> But because most small-scale food production is exempt from regulation by the U.S. government, consumers have no way of knowing how “local” foods are produced.<sup>104</sup> And while there exists some evidence to suggest that organically produced foods have lower Pesticide Residue Levels than conventionally produced foods and thus there appears to be support for the assertion that organic foods have lower levels of chemical contamination, when consumers think about “food safety” they increasingly conflate the term with “microbiological food safety,” focusing their concerns about harmful pathogens that may cause foodborne illnesses. The comparative microbiological safety of conventionally versus locally or organically produced foods has not yet been adequately examined.

As Brewer and Prestat write “it is a paradox that, while consumers express high degrees of concern about specific elements, they generally believe that the food supply is safe. What seems to fluctuate with time is the relationship between the general level of concern about the safety of the food supply and the specific issue of concern (GMOs, pesticides, *Salmonella*, etc.)”<sup>105</sup> Thus despite widespread concerns about food safety, consumers overwhelmingly assume two things: that the food they eat *is* safe and that the U.S. government has the power to *make sure* that it’s safe. But neither assumption is logical given several facts about the legal regulatory and accountability food safety regime. First, neither the FDA nor the USDA has the power to conduct mandatory recalls of contaminated food products. Second, the FDA does not have the power to inspect farms because its regulatory authority is focused upon processors and retailers. Third, neither the FDA nor the USDA can mandate that producers follow Good Agricultural/Manufacturing Processes or, with limited exceptions, that they implement HACCP programs (see Chapter 6). Fourth, despite increasingly high profile outbreaks of foodborne

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<sup>103</sup> One local food producer with a background in food science and microbiology reported being appalled that consumers at farmers’ markets would eat fresh produce right off the stands without washing or otherwise processing them. He reports warning his customers that his organically produced fruit is not necessarily microbiologically safe.

<sup>104</sup> What pesticides or fertilizers were applied to the soil and at what levels; whether potable water was used for irrigation; whether “natural” fertilizers were properly composted; how products were picked, stored, and transported.

<sup>105</sup> M. S. Brewer and C. J. Prestat, *Consumer Attitudes Toward Food Safety Issues*, Journal of Food Safety, 22 (2002), pp. 67-68.

illnesses, the neither the FDA nor the USDA can mandate pathogen testing tied to mandatory recalls. As Chapter 6 explains, the pathogen reduction program instituted by the USDA in the 1990's was ruled by federal courts to overstep its statutory authority; the USDA is permitted to test for contamination but can use the results only to increase the frequency of inspections rather than to recall products or prevent the distribution of products *even if they are known to be contaminated*. Finally, the FDA and the USDA cannot mandate that food producers implement traceability systems that would facilitate food recalls or that would help to track outbreaks of foodborne illnesses. In short, the FDA and the USDA have virtually no power to regulate food safety as it is understood in the 21<sup>st</sup> century; the regulatory framework designed for the 1906 production and distribution system is woefully inadequate, inefficient, and ineffective when confronted with an industrialized food regime.

Instead, food safety regulatory authority is almost completely limited to two accountability mechanisms: consumer education and civil liability. There has been an emphasis throughout the 20<sup>th</sup> century, particularly in the latter part of the 20<sup>th</sup> century when political and economic ideologies aligned with neo-liberalism advocated the scaling back of government regulation and accountability, on consumer education with respect to food safety. Regulators have emphasized the importance of cleanliness and sanitation in home food preparation, the risks of cross-contamination, and the idea that the buyer must beware of the food products he procures, often at the expense of top-down, hierarchical, and centralized regulatory oversight of food producers, processors, and distributors. And when breakdowns in the food safety system have occurred, injured parties have turned to the courts to assess liability and damages. And while both are essential provisions of a food safety regulatory regime, each is a *reactive* as opposed to *proactive* approach to food safety.

But it is not as if proactive approaches do not exist. To the contrary, advances in food science and technology throughout the 20<sup>th</sup> century, particularly in the areas of toxicology, germ theory, microbiology, and chemical science, have produced a deep and complex understanding of food contamination, foodborne illness, and their prevention. Building upon a framework of scientific risk assessment involving risk analysis (the identification of risks), risk management (the neutralization of risks), and risk communication (producer and consumer education about risks, their effects, and prevention strategies), food safety systems are capable, not of completely

preventing 100% of food contamination and foodborne illness, but of enhancing the physical, chemical, and microbiological safety of food production, processing, and distribution.<sup>106</sup>

Among techniques developed to enhance food safety are *process-based approaches* including Good Agriculture/Manufacturing Processes (GAPs and GMPs), Hazard Analysis Critical Control Points (HACCP) plans, and the CARVER+Shock system<sup>107</sup> and *product-based*

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<sup>106</sup> Risk Assessment includes four steps:

- Step 1: Hazard Identification
  - *Define*: Hazard Identification determines the association between the disease and the presence of the pathogen in a specific food product. This step identifies the biological, chemical, and physical agents capable of causing adverse health effects and which might be present in particular foods or groups of foods.
  - *Importance*: Hazard identification examines the pathogen’s survival and growth in the food and incorporates previously collective data on epidemiological, surveillance, challenge testing, and studies of pathogenicity. The data collected during Hazard Identification are used later in the Exposure Assessment.
- Step 2: Exposure Assessment
- *Define*: The Exposure Assessment describes the pathways through which the pathogen population is introduced, distributed, and challenged in the production, distribution, and consumption of food. This step evaluates a particular food production pathway.  
*Importance*: An Exposure Assessment can examine the production pathway from farm-to-fork or it can evaluate each step of the production pathway separately. This step determines the key entry points into the food chain and tracks the pathogen to determine the likelihood that the pathogen will be ingested by the consumer.
- Step 3: Hazard Characterization
  - *Define*: Hazard Characterization describes the hazards associated with the pathogen.
- *Importance*: This is primarily a dose-response assessment that translates the exposure to a pathogen population into a health response in the population of consumers. This takes into account health populations as well as susceptible “at risk” populations. This step can be extremely difficult because of the shortage of data on pathogen-specific responses and because those responses depend on the immune status of the consumer.
- Step 4: Risk Characterization
  - *Define*: Risk Characterization integrates all of the information gathered in the previous steps to estimate the risk to a population, or to a particular type of consumer.
  - *Importance*: Risk Characterization allows you to change the parameters in the data to answer “what if” questions regarding the hazards associated with the pathogen.

<sup>107</sup> The CARVER + Shock System is a vulnerability assessment that is used to determine and establish specific vulnerabilities with a system or infrastructure in order to focus controls. This risk management tool is used “to identify the most vulnerable or ‘critical nodes’ within a food processing system, that is, the nodes that are the most likely targets for a terrorist attack” (CARVER + Shock Description, <http://www.fsis.usda.gov/PDF/CARVER.pdf>). In the CARVER + Shock method, “each node is rated on a scale of one to ten for the seven attributes represented by the acronym...the score for the seven attributes is summed and the nodes with the highest overall scores are considered to be the most vulnerable” and thus the focus for countermeasures (*ibid*). CARVER + Shock requires that investigators think like attackers in order to identify the most vulnerable areas or nodes of the food system in order to focus resources and take action on those most vulnerable points. The FDA and the USDA have used this

*approaches* including pathogen testing and control.<sup>108</sup> Although the economic literature on regulation and accountability expresses an overwhelming preference for product-based

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system to identify potential vulnerabilities for specific food products and specific facilities along the farm-to-fork chain. “Identifying critical nodes allows decision makers, industry, and others to focus the development of countermeasures at those sites that are the most vulnerable within a given system” (*ibid*). The acronym stands for:

- C= Criticality—Measure of public health and economic impacts of an attack
  - What is the significance of the health or economic impact of an attack?
  - What is the value of the target?
  - What are the critical nodes in the system where an attack could occur?
- A= Accessibility—Ability to physically access and egress from target
  - Can the attacker physically access the target in order to conduct the attack effectively and without detection?
  - What public information exists about the target
  - Is the target inside a building or a public area?
  - Is the target accessible by vehicle?
  - Is there surveillance in place?
  - Are there human barriers in place to prevent accessibility?
- R= Recuperability—Ability of system to recover from an attack
  - How much time would it take for the specific facility or system to recover productivity after the attack?
  - What is the length of time for necessary repairs or replacements?
- V= Vulnerability—Ease of accomplishing an attack
  - How easily could the threat agent be introduced in quantities that would be sufficient enough to achieve the attacker’s purpose?
  - If the system is vulnerable, what would the impact be to the system?
- E= Effect—Amount of direct loss from an attack as measured by loss in production
  - What is the percentage of a system’s productivity that would be damaged by an attack at a specific facility?
- R= Recognizability—Ease of identifying target
  - To what degree would the target be identified by an attacker without confusion if other targets or components existed?
  - Is the target recognizable under various conditions?
  - Does the target have additional significance?
- Shock = combined health, economic, and psychological impacts of an attack—the SHOCK attributes of a target
  - How strong would an emotional response to an attack be?

<sup>108</sup>Henson and Heasman specify of three kinds of food safety standards: (1) “target standards do not prescribe any specific safety standards for the supplier’s products or the processes by which they are produced, but impose criminal liability for prespecified harmful consequences which arise from their products,” (2) “performance standards require certain levels of safety to be achieved when the product is supplied but leave suppliers free to choose the mechanisms through which they meet such conditions,” and (3) “specification standards are applied both to products (product standards) and the processes by which those products are made (process standards) and can take both positive or negative forms—either compelling products to contain particular ingredients or the use of particular production methods or prohibiting the use of particular ingredients or production methods.” [Spencer Henson and Michael Heasman, *Food Safety, Regulation and the Firm: Understanding the Compliance Process*, Food Policy, Volume 23, Number 1 (1999), pp. 10.]

standards, arguing that they are less restrictive, more flexible, and thus more efficient, food scientists have demonstrated the comparative effectiveness of process-based food safety systems.<sup>109</sup>

While product-based standards focus only on the safety of the final product and do not regulate the process by and through which that product is produced, process-based systems imbue food safety strategies at every step along the farm to fork chain. HACCP, a safety technique that identifies hazards, evaluates critical control points, implements safety strategies, assesses the effectiveness of the system by testing the final product for contamination, and makes adjustments as necessary, was first developed to guarantee to the greatest extent possible the safety of foods sent into space.<sup>110</sup> Promoted by the Codex Alimentarius Commission, the international food safety agency, and adopted by numerous governments as *the* primary framework for food safety standard elaboration, HACCP systems are often portrayed as a kind of “middle ground” between product- and process-based standards: HACCP is flexible in the sense that each producer develops and implements the plan that best suits its needs but remains an effective food contamination prevention strategy.

Good Agricultural/Manufacturing Practices, many argue, are too stringent to be an efficient food safety prevention strategy. GAPs and GMPs break food production down into a series of individual steps and attempt to prevent contamination and enhance safety at every step. For years the FDA has recommended that producers adhere to GMP guidelines—the FDA publishes GMPs and many states require compliance, although there is no federal mandate to require food producers, processors, and distributors to do so. But beginning with the establishment of the GAPs Initiative for fresh produce in the U.S. in the late 1990s, the implementation of GAPs as a voluntary food safety strategy coupled with Third Party Certification has unfolded as an interesting experiment in food safety regulation and accountability (see Chapter 7). This market based, voluntary, bottom-up system standards, requirements, and benchmarks stands in contrast to the top-down model applied in other national

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<sup>109</sup> For this reason, Chapter 5’s analysis of both top-down and bottom-up regulatory regimes will focus on *process-based* mechanisms (Chapter 6, however, examines applications of *product-based* standards in the United States within the context of the USDA’s Pathogen Reduction Program).

<sup>110</sup> Foodborne illnesses are costly both in terms of lost productivity, lost product, and human health. But for astronauts, particularly those in the shuttles, food safety is absolutely essential to the successful completion of the mission.

food safety systems (including Great Britain and France) with efficient and effective results (see Chapter 9).

But despite research into the effectiveness of process-based food safety protocols, repeated outbreaks of foodborne illnesses indicate that the U.S. food safety regulatory regime is a system in crisis. There exists a regulatory deficit between what government agencies can do *legally* given the strictures of the 1906 framework and what they could do *realistically* to enhance U.S. food safety. The U.S. food safety regulatory regime is characterized by a near complete absence of accountability mechanisms that would hold food producers, processors, and distributors responsible for producing safe food. And whenever the FDA and the USDA have tried to issue rules and standards that would enhance food safety in accordance with scientific knowledge, discoveries, and assessments, they have faced corporate and interest group opposition and judicial censure. Although the FDA and the USDA are tasked with grounding their standards, regulations, and procedures in the best possible science available, many of the attempts made by these institutions to institute top-down, mandatory food safety systems *consistent with scientific understandings about food safety* have been unsuccessful. Of equal interest is the failure of proposals to enhance the legal food safety regulatory authority of the FDA and the USDA to make their way through Congress. For example, “Kevin’s Law,” named for a child who died after exposure to *E. coli* 0157H7, would extend the regulatory authority of the USDA and the FDA in ways specifically designed to enhance food safety and, in particular, microbiological food safety. Despite nearly a decade of lobbying by consumer groups, however, this legislation has never made it through the U.S. Congress.

The explanation for both of these failures to extend the food safety regulatory authority of the USDA and the FDA and to eliminate the regulatory deficit that characterizes the U.S. food safety regulatory regime lies, not in science, but in politics. For although risk assessment is a scientific strategy, risk interpretation is very much a political one. And entrenched producer interests that have become increasingly powerful throughout the course of the 20<sup>th</sup> century have framed the way that food safety legislation is written (or not written) and the way that food safety regulations are developed and enforced (or not developed and enforced).

What we see when we look at consumer perceptions about food safety against the backdrop of changes throughout the 20<sup>th</sup> century, therefore, appears to be more a conflation of

correlation with causation. Problems associated with food safety, and, in particular, the regulatory deficit that characterizes the U.S. food regulatory regime, are often associated with the industrialization of the food system. And yet, as Chapter 3 explains, industrialized processes do not make food unsafe; to the contrary, food science can develop process-based safety systems for large-scale, industrialized producers that are efficient and effective. The failure is not of scientific know-how, producer capacity, or technical feasibility. The problem is in the political processes by and through which food regulatory agencies are denied the authority to require that food safety systems be properly implemented. And that problem can be associated with a transformation that paralleled the industrialization of food production during the 20<sup>th</sup> century: the concentration of food production in the hands of a very small number of very powerful corporations.

### CHAPTER 3

#### THE INDUSTRIALIZATION OF THE U.S. FOOD SYSTEM AND THE COMMODIFICATION OF FOOD: IMPACTS UPON FOOD SAFETY REGULATION AND THE CASE OF CRANBERRIES

Over the course of the 20<sup>th</sup> century, the U.S. food system underwent a “modernizing” transformation associated with innovations in food technologies and the application of industrial logics attached to economies of scale, vertical integration, and assembly line manufacturing to food and its production. Whereas the U.S. food system at the end of the 19<sup>th</sup> century was characterized by small food producers, processors, and retailers and short food distribution lines, the U.S. food system at the turn of the 21<sup>st</sup> century is distinguished by the concentration of food production and processing activities in the hands of a few large agribusinesses with national (and international) distribution networks. At the same time, conceptions of “food” itself changed; the industrialization of the food system and the rise of the “fast food” culture transformed “food” into a set of highly processed, greatly homogenized, and heavily enhanced (what Harvey Washington Wiley may have even called “adulterated”) commodities. Over the course of the 20<sup>th</sup> century, food and its production became “modern marvels” of industrial innovation and design. As part of an effort to cut costs, add value, enhance efficiency, and raise productivity, food producers have mechanized food processing to guarantee that the end “products” taste, look, smell, and feel the same all the time, every time. Modern food producers seek to produce food quickly and cheaply in large quantities and for widespread distribution.

Early industrialization of food production and processing generated concerns about food adulteration and misbranding. The “Pure Food” movement that emerged catalyzed the formation of the 1906 food safety regulatory regime. And although an industrialized food system is often maligned as “unsafe,” “inherently risky,” or “dangerous,” this is not necessarily the case. As this chapter explains, advances in food science and technology allow so-called “modern” food systems to be organized, configured, and structured in ways that promote food safety. The U.S. food safety regime remains characterized by an accountability deficit, therefore, not because an industrialized food system *cannot* be made safe but because large and powerful corporations have perpetuated the regulatory focus on adulteration and misbranding that anchored the 1906 food safety framework.

*The Industrialization of Food Production, Processing, and Distribution*

Production systems in advanced industrial economies operate on the basis of efficiency standards grounded in divisions of labor and input specialization. In this sense, an industrial economy can be understood as a network of interdependent agents and actors who work together, sometimes without their knowledge or without direct coordination, to produce end use products. This is certainly true of food production in the United States. In accordance with industrial methodologies, today's food processors seek to control every step of the production process, either through vertical integration or through a complex system of producer chains; they provide the inputs (including seeds, immature livestock, fertilizers, and pesticides), establish their own sets of best practices and standards, and control marketing, advertising, and distribution to consumers.

Assembly line divisions of labor are efficient because they break large production projects into specialized component steps. These efficiencies, first enumerated in Adam Smith's explanation of the pin factory, were the foundation of the industrial revolution but have since been extended across economic sectors from agriculture to manufacturing to services and, most recently, to research and development. Perfected by Ford's automobile factories, assembly lines promote productivity and, subsequently, lower prices; the consequence is often that former luxury items, including, in the case of food, butter, white bread, and canned vegetables, are accessible to middle and working class consumers. Moreover, new production methodologies associated with mass production led to the rise of corporations which "grouped independent operations into one integrated multiplant corporation in order to address complicated problems of coordination....they brought together in one enterprise disparate activities----research, design, production, distribution, advertising---that had previously been carried out separately."<sup>111</sup> As "agriculture yielded to technology" in the late 1800's, assembly lines, which reduced both the

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<sup>111</sup> Jeffery Frieden, *Global Capitalism: Its Rise and Fall in the 20<sup>th</sup> Century*, New York, NY: W. W. Norton & Co., pp. 160.

time necessary to produce economic outputs as well as the costs of consumer goods across the economic spectrum, became the foundation of modern food production.<sup>112</sup>

Repetition and the de-skilling of labor are central to assembly line production. Because assembly lines break complex tasks, such as the assembly of an automobile or the slaughter of an animal, into a series of manageable steps, they eliminate the need for a skilled workforce. In this sense, Eric Schlosser is correct when he refers to industrial meat packers as “cogs in the great machine.” For years corporate agribusinesses have applied the logic of the assembly line to the slaughter of animals for human consumption, a production model Schlosser calls the “disassembly line.”<sup>113</sup> Like their predecessors in the manufacturing sector, these industrial food producers “[stand] in one spot along the line, performing the simple task over and over again, making the same knife cut thousands of times during an eight-hour shift.”<sup>114</sup> This “strict regimentation” creates “standardized products...it increases the throughput...and it gives [corporations] an enormous amount of power over their employees.”<sup>115</sup> As sociologist Robin Liedner noted, “when management determines exactly how every task is to be done...and can impose its own rules about pace, output, quality, and technique [it] makes workers increasingly interchangeable.”<sup>116</sup> Thus “the management no longer depends upon the talents or skills of its workers—those things are built into the operating system and machines.”<sup>117</sup> As Belasco writes, “the same gleaming artificiality, Fordist automation, and rapid turnover likewise underlay the emerging food system...[industrial food processors] perfected the ultra-Taylorist principles of KISS (Keep It Simple Stupid), which also guided the convenience food cuisine that would supposedly free women from effort and stress.”<sup>118</sup> Thus small scale producers that remain dependent upon specialized labor simply cannot compete with mass produced commodities; just as England’s textile factories eliminated small spinning enterprises and Ford’s automobile plants rendered entrepreneurial automakers obsolete, disassembly lines in animal slaughter decimated

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<sup>112</sup> Carol Simontacchi, The Crazy Makers: How the Food Industry is Destroying Our Brains and Harming Our Children, New York: Jeremy P. Tarcher/Penguin (2007), pp. 16.

<sup>113</sup> Eric Schlosser, Fast Food Nation: The Dark Side of the All-American Meal, New York: Perennial (2002), pp. 153.

<sup>114</sup> *Ibid*, pp. 153.

<sup>115</sup> *Ibid*, pp. 70.

<sup>116</sup> Quoted in Eric Schlosser, Fast Food Nation: The Dark Side of the All-American Meal, New York: Perennial (2002), pp. 70.

<sup>117</sup> Eric Schlosser, Fast Food Nation: The Dark Side of the All-American Meal, New York: Perennial (2002), pp. 153.

<sup>118</sup> Warren Belasco, Meals to Come: A History of the Future of Food, Berkeley: University of California Press (2006), pp. 197.

small, less efficient slaughterhouses and processing plants. But while complex divisions of labor promote macroeconomic efficiency, they also generate risks of promissory failure, opportunism, and defection from standards. Economists argue that trust mechanisms counter the risks associated with economic exchange. The questions thus become: how is trust created and reinforced and what agents enforce sanctions against those who would violate that trust? From this theoretical perspective, one devoted to a political economy of governance associated with divisions of labor, interdependence, risk, and trust, comes an understanding of why industrial economies need accountability regimes to define and defend the “public interest.”

Though initially applied to meat processing in the new slaughterhouses of the late 19<sup>th</sup> century, assembly line methodologies were soon applied to the production of other food commodities. By the dawn of the 21<sup>st</sup> century, mechanized food processing was the norm rather than the exception for nearly every food commodity. As Schlosser writes of potato processing in the late 1990’s, “inside the [production facility] a maze of red conveyer belts crisscrosses in and out of machines that wash, sort, peel, slice, blanch, blow-dry, fry, and flash-freeze potatoes...workers in white coats and hard hats keep everything running smoothly, monitoring the controls, checking the fries for imperfections,” all for less than 30 cents a pound.<sup>119</sup> Similar production processes give the modern consumer 1.9 million Hershey bars a day from the Hershey plant in Hershey, PA, 96 million pounds of mozzarella cheese each year from the Alto Dairy in Black Creek, WI, and 2000 pounds of pretzels an hour from the Snyder’s of Hanover plant in Hanover, PA. Everything from butter to potato chips to tomato sauce to ice-cream is now mass produced according to similar industrial logics—stainless steel machines, conveyer belts, and complex computers with commodity-specific software have automated food processing from the moment raw materials arrive from the farm to the moment finished commodities are packaged for distribution to wholesale or retail distributors.

Alongside the industrialization of food processing came the mechanization of food production. As Belasco writes, “in the opinion of many modernizers, the struggling, horse-powered, diversified small agricultural production units needed to be consolidated into highly mechanized corporate farms specializing in one or two commercial crops” such as corn,

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<sup>119</sup> Eric Schlosser, Fast Food Nation: The Dark Side of the All-American Meal, New York: Perennial (2002), pp. 111; 117.

potatoes, or wheat—the staples of the modern food system.<sup>120</sup> Today nearly all U.S. farmers vend the products of their labor in oligopolistic markets; others have sold their lands to corporate agribusinesses that substitute modern chemical inputs for intergenerational agricultural knowledge. Many of these farmers are encouraged to stay on the land as paid managers but are prohibited from farming according to traditional techniques; they are mandated instead to follow detailed corporate manuals so that their outputs are guaranteed to be homogenized agricultural commodities.<sup>121</sup> The “intensification dynamic—a reduction in genetic diversity and in the number of producers, at the cost of increased biological and social fragility—was widely duplicated” by agribusinesses in search of efficiency, productivity, and profitability in food production, processing, and distribution.<sup>122</sup>

Dominated by machines, controlled by computers, and dedicated to the production of a predictable product, industrialized processing plants depend upon uniform agricultural products in order to function efficiently. All commodities—including chickens, potatoes, milk, beans, and corn—must adhere to specific size and shape parameters for the mechanized processing system to maximize productivity. For this reason, chicken farmers contract with corporate agribusinesses that provide chicks, feed, and infrastructure along with detailed “care” instructions and timetables designed to guarantee that every chicken from every farmer satisfies the corporate demand for homogenous “inputs” into the industrialized food processing system. Similarly, french fry producers J. R. Simplot, Lamb Weston, and McCain insist that their suppliers provide them with starchy Russet potatoes of specific dimensions, perfectly designed to create crisp, flavorful fries. For this reason, nearly all potatoes grown in the United States are identical; biodiversity has been sacrificed on the altars of consistency and efficiency standards. As Belasco writes, this “modernist” revolution in food “celebrates purity, shortcuts, simplification, automation, and mass production while dismissing soil, sweat, labor,

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<sup>120</sup> Warren Belasco, Meals to Come: A History of the Future of Food, Berkeley: University of California Press (2006), pp. 175.

<sup>121</sup> The result is a new kind of alienation: the alienation of a farmer from his land. The consequences are fatal; “the suicide rate among ranchers and farmers in the United States is now about three times the national average” because “to fail several generations of relatives...to see yourself as the one weak link in a strong chain...is a terrible, and for some, an unbearable burden.” [Eric Schlosser, Fast Food Nation: The Dark Side of the All-American Meal, New York: Perennial (2002), pp. 146-147]

<sup>122</sup> Warren Belasco, Meals to Come: A History of the Future of Food, Berkeley: University of California Press (2006), pp. 195.

craftsmanship, and ornament...its favorite forms, tubes, beakers, buttons, domes, dials, and tunnels—the tools of engineering.”<sup>123</sup>

Thus it was during the late 1800’s and early 1900’s that U.S. food production, processing, and distribution became industrialized processes beholden to logics wholly distinct from those associated with “traditional” agriculture. As Belasco writes, “large firms that had integrated mass production with distribution had begun to appear in the late 1880s and 1890s; by 1900 mass distribution in the form of chain stores, which had grown up in the post-Civil War period, was well established.”<sup>124</sup> Fueled in part by the mass urbanization that followed the Civil War “the food industry in the United States [developed] new technologies and [produced] new goods,” particularly processed, canned, and otherwise preserved foods.<sup>125</sup> With their long shelf lives and widespread accessibility, these products transformed the American diet from one of staples to one of commodities.

### *The Commodification of Food: From Dietary Staples to Chemical Concoctions*

Food industrialization did not only change the processes by and through which foods were produced, processed, and distributed; it changed notions of what constituted “food” itself. As Schlosser writes, “the 1950s soon became ‘the Golden Age of Food Processing,’ in the words of historian Harvey Levenstein, a decade in which one marvelous innovation after another promised to simplify the lives of American housewives: frozen orange juice, frozen TV dinners, the Chicken-of-Tomorrow, ‘Potato salad from a package!,’ Cheese Whiz, Jell-O salads, Jet-Puffed Marshmallows, [and] Miracle Whip.”<sup>126</sup> As Belasco writes, “the processed meal certainly came of age in the 1950s and early 1960s...culinary historians differ on whether the most iconic representative of quick-and-easy cuisine was Miracle Whip, Crisp Vegetable Salad made with Jell-O, Cherry Coke Salad (also with Jell-O), California dip (made with dried onion

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<sup>123</sup> *Ibid*, pp. 166.

<sup>124</sup> *Ibid*, pp.18.

<sup>125</sup> *Ibid*, pp. 18.

<sup>126</sup> Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal*, New York: Perennial (202), pp. 113.

soup mix), the TV dinner, or Eight-Can Casserole.”<sup>127</sup> What is certain is that the 20<sup>th</sup> century became the Age of Processed Foods as “food manufacturers promoted canned meats, desiccated soups, evaporated milk, packaged gelatins, meat extracts, and Butterine, a new oleomargarine, as well as the synthetic lard substitutes Vegetole, Cotosuet, and Cottolene...[in addition] chemists offered tastes of ‘a wonderful chemical product called saccharine, derived from coal tar [and] 5000 times sweeter than sugar.”<sup>128</sup> So-called “modern” foods included “synthetic vegetables,” “‘beef’ broths manufactured from products that have never been near a cow,” “eggs made direct from grasses and cereals without calling in the aid of a hen.”<sup>129</sup> And let’s not forget the epitome of industrialized food production: the Twinkie™, a product whose ingredients are, as Ettliger discovered, “grown, mined (yes, mined), and manipulated...[as well as] crushed, baked, fermented, refined, and/or reacted into a totally unrecognizable goo or powder with a strange name—all for the sake of creating a simple snack cake.”<sup>130</sup>

The Chicago World Fair 1893 stood as a testament to these modern conceptions of food. As Belasco writes, “the same Agricultural Building that featured monumental pyramids of produce and temples of commodities also gave space to USDA experimental stations and laboratories promoting a more ‘scientific’ production of those commodities...Meat packers Swift and Armour [for example] showcased innovations in refrigeration, recycling, and mass disassembly that were making American an unmatched purveyor of cheap, if not always safe, animal products.”<sup>131</sup> Americans, particularly members of the working and middle classes, flocked to this food revolution; indeed, “everyone who faithfully followed a cooking school recipe’s precise measurements or attempted ‘gastric stimulation’ by floating raw vegetables in a gelatinous ‘perfection salad’ or replaced butter with Crisco—‘An Absolute New Product’ billed as ‘A Scientific Discovery Which Will Affect Every Kitchen in America’...was, in effect, helping to establish a new cuisine that reduced cooking to chemistry.”<sup>132</sup>

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<sup>127</sup> Warren Belasco, Meals to Come: A History of the Future of Food, Berkeley: University of California Press (2006), pp. 197.

<sup>128</sup> *Ibid*, pp. 168.

<sup>129</sup> *Ibid*, pp. 181.

<sup>130</sup> Steve Ettliger, Twinkie, Deconstructed: My Journey to Discover How the Ingredients Found in Processed Foods are Grown, Mined (Yes, Mined), and Manipulated into What America Eats, London: Hudson Street Press (2007).

<sup>131</sup> Warren Belasco, Meals to Come: A History of the Future of Food, Berkeley: University of California Press (2006), pp. 167-168.

<sup>132</sup> *Ibid*, pp. 172.

George Orwell critiqued the “world of synthetic foods” in 1937 writing of English consumers “it is the shiny, standardized, machine-made look of the American apple that appeals to them; the superior taste of the English apple is something they simply do not notice...or look at the factory-made, foil-wrapped cheeses and blended butter in any grocer’s; look at the hideous rows of tins which usurp more and more of the space in any food shop....look at the filthy chemical byproduct that people will pour down their throats under the name of beer...wherever you look you will see some stock of machine-made article triumphing over the old-fashioned article that still tastes of something other than sawdust.”<sup>133</sup> But although the “fake food” industry started off producing substitutes for “quality” products, they quickly became seen as superior alternatives to traditionally produced foods.

As processed food products began to dominate American food markets, concerns about adulteration and misbranding took on new dimensions. Color, texture, and smell greatly affect how taste is perceived; foods that don’t look, feel, or smell “right” are often rejected by consumers.<sup>134</sup> Processed foods thus became laden with “natural” and “artificial” colors and flavors, chemical additives that give most processed food its taste. As Schlosser writes, “the canning, freezing, and dehydrating techniques used to process food destroy most of its flavor...since the end of World War II, a vast industry has arisen in the United States to make processed food palatable.”<sup>135</sup> The additive industry is a highly secretive, precise science of flavor and color compounds; established brands are tested and adjusted and new concoctions developed by food scientists working for some of the largest and most powerful chemical corporations in the country. A typical artificial flavor, like the kind in a Burger King strawberry milkshake, may include such ingredients as “amyl acetate, amyl butyrate, amyl valerate, anethold, anisyl formate, benzyl acetate, benzyl isobutyrate, butyric acid, cinnamy isobutyrate, cinnamyl valerate, cognac essential oil, diacetyl, dipropyl ketone, ethyl acetate, ethyl amylketone, ethyl butyrate, ethyl cinnamate, etyl heptanoate, ethyl heptyl, ethyl lactate, ethyl methylphenylglycidate, ethyl nitrate, ethyl propionate, ethyl valerate, heliotropin,

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<sup>133</sup> George Orwell, *Coming Up For Air* (1937); reprinted Bee Wilson, *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*, Princeton, NJ: Princeton University Press (2008), pp. 214.

<sup>134</sup> “During one experiment in the early 1970s, people were served an oddly tinted meal of steak and French fries that appeared normal beneath colored lights. Everyone thought the meal tasted fine until the lighting was changed. Once it became apparent that the steak was actually blue and the fries were green, some people became ill.” [Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal*, New York: Perennial (2002), pp. 125.]

<sup>135</sup> Eric Schlosser, *Fast Food Nation: The Dark Side of the All-American Meal*, New York: Perennial (2002), pp. 120.

hydroxyphenyl-2-butanone...isobutyl anthranilate, isobutyl butyrate, lemon essential oil, maltol, 4-methylacetophenone, methyl anthranilate, methyl benzoate, methyl cinnamate, methyl heptane carbonate, methyl naphthyl ketone, methyl salicylate, mint essential oil, neroli essential oil, nerolin, neryl isobutyrate, orris butter, phenethyl alcohol, rose, rum, ether,  $\gamma$ -undecalactone, vanillin, and solvent.”<sup>136</sup>

The increasing popularity of processed foods and food products led to the need for flavors, colors, preservatives, and other additives—all of which could be called “adulterants” under the 1906 regulatory framework—that would extend shelf life, improve taste and texture, and give products a pleasing, uniform appearance. As Belasco writes, “because of the high temperatures at which foods were canned, most canned products were [commercially] sterile<sup>137</sup> and largely free from contamination...although preservatives usually were not used, many canners, particularly canners of fruits, did use large amounts of sugar as well as dyes, which made their products look fresh.”<sup>138</sup> Thus it was not only the industrialization and mechanization of food production, processing, and distribution that changed over the course of the 20<sup>th</sup> century; it was the very concept of food itself. No longer an agricultural staple, by the turn of the 21<sup>st</sup> century “food” had become defined as a highly processed, excessively commodified, chemically identified, and industrially homogenized product. The consequences for food safety, particularly given the stipulations against adulteration and misbranding that characterize the U.S. food safety regulatory regime, were vast.

### *The 1906 Framework: A Regulatory Interface for the Early 20<sup>th</sup> Century*

Coppin and High write that “the Pure Food and Drugs Act of 1906 reflected two broad trends of American life at the turn of the [20<sup>th</sup>] century: the move toward urban life and increasing federal regulation of the economy...the transformation of the United States from an

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<sup>136</sup> *Ibid.*, pp. 125-126.

<sup>137</sup> The term “sterilization” refers to the *complete* elimination of all microorganisms. However, some bacteria produce endospores of extremely high heat resistance that cannot be destroyed without rendering the product unmarketable. Thus the food industry uses the term “commercial sterilization” indicating that although a product may not be free of *all* microorganisms, those that survive the sterilization process are unlikely to grow during storage and cause product spoilage or human illness.

<sup>138</sup> Warren Belasco, *Meals to Come: A History of the Future of Food*, Berkeley: University of California Press (2006), pp. 20.

agrarian to an industrial society changed the way in which people ate...the combined effects of new technology, new food products, new competition, uncertain consumers, food experts, and government officials combined to produce the Pure Food and Drugs Act of 1906.”<sup>139</sup> But the 1906 regulatory framework also reflects two more specific, albeit related, trends in food production: the application of industrial logics to food production, processing, and distribution and the growth of an American processed food industry that infused food products with preservatives, dyes, fillers, flavors, and other chemical compounds. Together these dynamics fueled the Pure Food and Drug Movement, the late-19<sup>th</sup>/early-20<sup>th</sup> century social movement that generated popular and elite support for the implementation of the 1906 food safety regulatory regime.

As the United States became a more urban, industrialized society, fewer individuals and families lived “off the land.” During the mid-1800’s, 64%-69% of American laborers were farmers.<sup>140</sup> By the turn of the 21<sup>st</sup> century, only 1% of Americans claimed farming as an occupation and only about 2% of the general population actually lived on farms.<sup>141</sup> And because of the rise of mono-cropping over the course of the 20<sup>th</sup> century, very few of those farmers can be considered self-sufficient; even individuals and families who farm buy most of their food from the same corporate retailers that feed the rest of the country. Over the course of the 20<sup>th</sup> century, therefore, the vast majority of American consumers became progressively more distanced from the production and processing of the foods they ate. As the processed food industry became dominant and food additives became ubiquitous, some consumers became increasingly concerned and suspicious of food commodities. As Kruse writes, “before the mid-nineteenth century a large proportion of goods, especially consumables, were produced within the local communities where they were used, and peddlers who carried ‘foreign’ goods were viewed with great suspicion...the advance of wage labor and the rise of large national producers battered down such localism, but the fears and suspicions of goods made by anonymous

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<sup>139</sup> Clayton A. Coppin and Jack High, The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy, Ann Arbor: The University of Michigan Press (1999), pp. 18.

<sup>140</sup> *Growing a Nation: The History of American Agriculture: 1840* (accessed 27 November 2009) [available online: <http://www.agclassroom.org/gan/timeline/1840.htm>].

<sup>141</sup> Environmental Protection Agency, *Agriculture: Demographics*, 10 September 2009 (accessed 27 November 2009) [available online: <http://www.epa.gov/oecaagct/ag101/demographics.html>].

manufacturers, in far corners of the country, and in unknown conditions, remained.”<sup>142</sup> By the early 20<sup>th</sup> century, not only did many American consumers not know where their food came from or how it was processed (particularly as large agribusinesses replaced local butchers, bakers, mills, and retailers), they didn’t even know what ingredients were in it (and even after producers were required to include lists of ingredients on food labels, many descriptions were vague—such as “natural and artificial flavors”—while others—such as “sodium benzoate”—were categorically foreign).

In the late 19<sup>th</sup> century, therefore, the Pure Food and Drug Movement, dedicated to notions of consumer protection and food and drug purity, began organizing against the growing scale of industry and its increasing freedom from government control. An alliance between food chemists and middle-class women fueled popular demands for the implementation of a national food and drug regulatory regime. They were met, however, with organized opposition from food producers and processors. Thus although the 1892 Paddock Bill, which “prohibited some [food] additives and required accurate labeling,” passed the Senate, it failed in the House of Representatives.<sup>143</sup> Widespread support for federal food standards emerged, as Chapter 2 suggests, only after a series of investigatory studies alerted consumers to the dangers of food adulteration. The experiments conducted by Wiley’s “Poison Squad,” which demonstrated dangers of preservatives that were added to many popular food items, alongside a series of food adulteration exposés, increased support for federal action across a wide range of powerful interests and organizations including “the American Medical Association, the trade journal *American Grocer*, the newly formed National Consumers’ League, a number of influential food processors such as the H. J. Heinz Company, the very influential straight bourbon interests, and a number of western Senators finding political traction in condemning ‘eastern manufacturers.’”<sup>144</sup> It was, however, *The Jungle* that prompted a “split in the Republican Party between free-market stalwarts and regulation advocates” and resulted in the passage of the 1906 Pure Food and Drug Act and the 1906 Federal Meat Inspection Act.

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<sup>142</sup> Timothy Messer Kruse, *Pure Food and Drug Movement*, Dictionary of American History, The Gale Group Inc. (2003), *Encyclopedia.com*. (revised: November 27, 2009) [available online: <http://www.encyclopedia.com/doc/1G2-3401803469.html>].

<sup>143</sup> *Ibid.*

<sup>144</sup> *Ibid.*

Both laws emerged out of an alliance between seemingly contradictory political forces: “buyers initially made more literate by the periodical press [and] finally outraged by muckraking revelations and Wiley’s ‘Poison Squad’ reports [and] a congeries of managerial, marketing, and political changes [that] had brought major business elements to a conviction that a national law was desirable, or at least inevitable.”<sup>145</sup> Proponents demanded legislation that would require “shared rules, honesty, and integrity [in order to] reduce compliance costs, as well as to protect reputable manufactures from competitors lowering prices by using adulterants and deceitful labels.”<sup>146</sup> Established producers, “hoping to stifle producers of newer, cheaper goods,” favored “control over entry to the marketplace and restraint over substitute products by taxation and other means.”<sup>147</sup> Bowing to public and party pressure, opponents of federal regulation capitulated, casting their votes for a limited version of the federal purity standards advocated by food safety activists. Together business interests and producers “‘signaled Congress to act;’” “‘political resistance...dissolved’ and the food and drug law passed a Congress of special interests with only a modicum of opposition.”<sup>148</sup> As Young writes, “the 1906 laws ‘did seem to [be] a victory for all—except, of course, for adulterators, misbranders, and those whose newer products threatened the market positions of more established firms.’”<sup>149</sup>

It quickly became apparent, however, that although the regulatory focus on food purity was conceptually appropriate, the 1906 framework was far too vague and administratively weak to effectively and efficiently prevent food adulteration, let alone to promote more generalized conceptions of food safety. Although amendments and extensions—including the 1938 Food, Drug, and Cosmetic Act, the 1957 Poultry Products Inspection Act,<sup>150</sup> the 1958 Food Additives Amendment,<sup>151</sup> the 1960 Color Additive Amendment,<sup>152</sup> the 1967 Wholesome Meat Act, and the

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<sup>145</sup> James Harvey Young, Pure Food: Securing the Federal Food and Drugs Act of 1906, Princeton, NJ: Princeton University Press (1989), pp. 287-288.

<sup>146</sup> *Ibid*, pp. 287.

<sup>147</sup> *Ibid*, pp. 287.

<sup>148</sup> *Ibid*, pp. 288.

<sup>149</sup> *Ibid*, pp. 287.

<sup>150</sup> Which allowed the USDA to regulate poultry products in a way similar to that of the Federal Meat Inspection Act.

<sup>151</sup> Which required that new food additives be approved by the FDA and that their safety be proved by the manufacturer; also included the Delaney clause which prohibited the addition of any known carcinogen to food or food products.

<sup>152</sup> Which required manufacturers to demonstrate the safety of color additives to foods, drugs, and cosmetics.

1970 Egg Products Inspection Act,<sup>153</sup> strengthened prohibitions against adulteration, but did not alter the foundational regulatory approach of the U.S. food safety regulatory regime. Given the numerous criticisms of food safety and its regulation in the United States, it is, perhaps, easy to think of the 1906 food safety framework as a regulatory failure. To the contrary, however, prohibitions against adulteration and misbranding allowed the FDA and USDA to successfully navigate numerous food safety crises throughout the course of the 20<sup>th</sup> century. One example, the Great Cranberry Scare of 1959, demonstrates the strengths of both the 1906 food safety regulatory framework and the advantages of the industrialization of food production and processing relative to issues of food safety.

### *The 1906 Framework in Action: The Case of Cranberries*

Commercial cranberry farming “began in Massachusetts in 1816 when an enterprising farmer developed a technique for cultivating the berries in bogs covered with a thin layer of sand...as production increased, so did the popularity of the tart berries in the national diet...in 1930, three growers formed a farmer’s cooperative called Ocean Spray,” a corporation which still dominates cranberry production, processing, and distribution in the United States.<sup>154</sup> The 1959 cranberry crop set national records. The majority of the harvest would be transformed into cranberry sauce for Thanksgiving, Christmas, and New Years dinners; growers “were anticipating record sales when disaster struck.”<sup>155</sup>

On November 9, 1959, seventeen days before Thanksgiving, Secretary of Health, Education, and Welfare Arthur S. Fleming issued a warning to consumers that “two batches of Oregon and Washington cranberries had been found to be contaminated with the weed killer aminotriazole, a carcinogenic (cancer-causing) compound.”<sup>156</sup> He “urged Americans to ‘be on

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<sup>153</sup> Which gave the USDA the responsibility of regulating egg products.

<sup>154</sup> Edward T. O’Donnell, *The Great Cranberry Scare of 1959: 46 Years Ago*, *Hibernian Chronicle*, November 25-December 1, 2009 [available online: <http://www.irishecho.com/newspaper/story.cfm?id=17486>].

<sup>155</sup> *Ibid.*

<sup>156</sup> John E. Burris, *A Cranberry Affair of 1959*, Wisconsin Wetherby Cranberry Library Digital Collections [available online:

<http://content.wisconsinhistory.org/cdm4/document.php?CISOROOT=/cran&CISOPTR=1887&REC=8&CISOSHOW=1880>], pp. 1.

the safe side' and avoid consumer cranberries until the crop had been tested and deemed safe," a feat for which far exceeded the capacity and authority of a regulatory system designed to prevent food adulteration.<sup>157</sup> In the weeks that followed, government officials and cranberry growers developed a system of testing berries for aminotriazole so that safe berries could be identified, certified, labeled, and marketed. Unfortunately, despite the fact that Oregon and Washington produced only a small fraction of the country's cranberry crop, public panic and the inability of regulators to test all of the berries harvested in the year's bumper crop lead to near financial ruin for growers.

Aminotriazole is an "herbicide that is effective in controlling perennial weeds, such as white violets, panic grass, and rice cut grass, all of which are common to cranberry bogs."<sup>158</sup> The substance, which was an effective and inexpensive herbicide, allowed cranberries to grow normally but had been found to cause cancer in white rats.<sup>159</sup> Under the Delaney Amendment, a provision of the 1958 Food Additive Amendment to the FD&CA which prohibited the sale of any food shown to contain cancer-causing chemicals, the FDA had instituted a zero tolerance policy for aminotriazole; any food product found to contain even minute traces of the compound could not be sold in the United States.<sup>160</sup> The USDA had approved the use of the herbicide but only after the harvest of the cranberries.<sup>161</sup> During the 1959 season, however, some growers "failed to follow post-harvest directions and applied the spray in June before the harvest."<sup>162</sup> This attempt to increase the weed killer's effectiveness and to add to the growth of that year's berries resulted in the contamination of 3,000,000 pounds of Washington and Oregon

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<sup>157</sup> Edward T. O'Donnell, *The Great Cranberry Scare of 1959: 46 Years Ago*, *Hibernian Chronicle*, November 25-December 1, 2009 [available online: <http://www.irishecho.com/newspaper/story.cfm?id=17486>].

<sup>158</sup> John E. Burris, *A Cranberry Affair of 1959*, Wisconsin Wetherby Cranberry Library Digital Collections [available online:

<http://content.wisconsinhistory.org/cdm4/document.php?CISOROOT=/cran&CISOPTR=1887&REC=8&CISOSHOW=1880>], pp. 1.

<sup>159</sup> Although only when administered in very large doses over a long period of time.

<sup>160</sup> Scholars often categorize the United States food regulatory regime as inordinately "weak" compared to those implemented in European states. David Vogel, however, points out that the Delaney Clause represents a stringent application of the precautionary principle to an issue of food safety that far exceeds anything found in Western Europe during the same time period.

<sup>161</sup> In 1971 the Environmental Protection Agency (EPA) banned the use of aminotriazole on food crops.

<sup>162</sup> John E. Burris, *A Cranberry Affair of 1959*, Wisconsin Wetherby Cranberry Library Digital Collections [available online:

<http://content.wisconsinhistory.org/cdm4/document.php?CISOROOT=/cran&CISOPTR=1887&REC=8&CISOSHOW=1880>], pp. 2.

cranberries.<sup>163</sup> This opportunistic business decision led to disaster for the entire cranberry industry.

The problem was, of course, that no one knew which cranberries were safe; there was no way to identify growers that had violated the USDA protocols for the use of aminotriazole. FDA tests eventually found “four contaminated lots in Wisconsin, one from Washington, two from Oregon, and one from Massachusetts.”<sup>164</sup> In the meantime, all berries found to be uncontaminated were “labeled ‘Examined and passed by the FDA of the U.S. Department of HEW’ or ‘Certified safe under the plan approved by the U.S. Government for cranberries’ and then placed on the open market.”<sup>165</sup> The government’s failure to test and certify all berries in the year’s harvest, however, led cranberry growers to unleash fury upon the Department of Health, Education, and Welfare. Despite the fact that the Delaney Amendment *required that the Secretary remove berries contaminated with even trace amounts of known carcinogens*, growers insisted that the secretary had abused its regulatory authority. Claiming that there was no threat to public health, growers and their Congressional representatives demanded reparations. In the end, \$10 million was allocated to compensate growers of uncontaminated berries and cranberries were featured in school lunch programs and military meals.

Although the FDA developed a system of cranberry certification, the crisis highlighted a number of problems with food safety regulation within the United States forcing some observers to wonder if the FDA’s warning had been a strategic attempt to bring public attention to problems facing the U.S. food safety regulatory regime. An article in The New Republic indicated that Secretary Flemming “chose the cranberry industry as a painless way to point up several problems the FDA faced: 1. Authority was divided within the government between the FDA and the UDSA [and] 2. Recent additions to basic FDA laws were unworkable (in particular the Delaney Amendment.”<sup>166</sup> The willingness of the USDA to approve a chemical for which the FDA had set a zero tolerance level was indicative of the problems associated with divided authority. Moreover, Secretary Flemming’s strict interpretation of the Delaney Amendment did concentrate Congressional attention upon the risks of such inflexible applications of the

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<sup>163</sup> *Ibid*, pp. 2.

<sup>164</sup> *Ibid*, pp. 6.

<sup>165</sup> *Ibid*, pp. 6.

<sup>166</sup> “These Cranberries,” The New Republic, 30 November 1959, pp. 3.

precautionary principle to issues of food safety. Although Flemming's testimony in Congressional hearings indicated that he wanted producers, rather than government regulators, to have to prove that their products were safe before releasing them onto the market, it is also possible that his press release was designed to demonstrate how understaffed and underfunded, and thus unable to deal with a major food safety crisis, the FDA was.

The crisis generated a series of questions related to issues of accountability. Who was to blame for the crisis? Did the government overstep its regulatory authority? Were the growers that "cheated" on the use of aminotriazole legally and/or financially responsible for the collapse of the market? Should Secretary Flemming have given the industry time to prepare itself to rebut his accusations? Could the government have known that only a small percentage (0.3%) of cranberries were contaminated or was its blanket statement in the public interest? These questions would frame debates about food safety in the United States during the years that followed.

Concerns about carcinogens and chemical contaminants would grow throughout the rest of the 20<sup>th</sup> century. The 1989 scare over Alar in apples reminded consumers of the risks of chemical consumption and the organic food movement ultimately built its reputation upon lower pesticide residue levels. Eventually these concerns were eclipsed by something perceived as an even greater threat to the public interest: microbiological contamination. And if the risk of chemical contamination pushed the boundaries of the 1906 food regulatory framework, the dangers associated with microbiological contamination would render it nearly obsolete. The 1906 framework as amended by the 1938 FD&CA worked in the case of cranberries because the Delaney Clause established specific prohibitions against carcinogenic contamination; in this sense, the Delaney Clause was consistent with the general ban on food adulterants. But questions of traceability, industrial processing, national distribution, and accountability would come into sharper focus once food safety risks could no longer be classified as "adulterants."

### *The Food Safety Regulatory Deficit: Questions of Accountability*

The 1906 food safety regulatory regime created an accountability framework dedicated to the prevention of food adulteration and misbranding. Amendments to the 1906 framework have

perpetuated this narrow construction of “food safety.” As the case of cranberries demonstrates, the 1906 framework is not wholly ineffective; when the safety of a food or food product is compromised by an additive that can be legally classified as an adulterant, federal regulators have the power to protect public health and advance the public interest. But those powers remain limited. As the cranberry debacle of 1959 indicates, neither the FDA nor the USDA has the power to issue recalls of contaminated products; regulatory agencies must rely on processors and distributors to keep contaminated foods off the market.<sup>167</sup> Moreover, government officials, rather than food producers and processors, bear the burden of proof in cases of food adulteration. Food producers do not have to demonstrate that food additives are *safe*; federal regulators must prove that food additives violate regulatory provisions. Finally, regulators are limited to food safety concerns linked to *adulterants*; accountability in the U.S. food safety regulatory regime is constrained by the problem of purity.

Food scientists have come to advocate an accountability framework focused on scientific risk assessment, hazard analysis, and good practices designed to enhance food safety by reducing the risks of physical, chemical, or microbial contamination. In this context, food scientists have promoted the use of Good Agricultural and Manufacturing<sup>168</sup> Practices (GAPs and GMPs), the implementation of Hazard Analysis Critical Control Points (HACCP) Plans, and a holistic focus on physical, chemical, and microbiological food safety from farm to fork. This orientation has gained increasing legitimacy in the U.S. regulatory arena; regulators have recommended that processors implement GAP and GMP plans in all sectors and have required the use of HACCP Plans for specific food commodities. But although food regulatory agencies have tried to use administrative law to incorporate this scientific approach to accountability into the U.S. regulatory regime, federal courts have consistently ruled that attempts to go beyond the legal accountability framework focused on purity are unlawful; food regulators do not have the statutory authority to implement many of the accountability mechanisms recommended by the scientific community (see Chapters 5, 6, and 7).

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<sup>167</sup> In the case of cranberries, both processors and distributors prevented public consumption of cranberries. Ocean Spray kept many of the contaminated cranberries off the market completely. In response to the FDA warning, grocers pulled cranberry products off their shelves and restaurants removed cranberries from their menus. Nevertheless, the government did not have the power to *compel* growers, processors, or distributors to do so; each acted in accordance with what it perceived to be economic self-interest.

<sup>168</sup> The application of “good manufacturing practices” to food production is telling—it indicates that modern food processing is more analogous to industrial manufacturing than to traditional agriculture.

The United States' food safety problem is not one of technical capacity; even in an industrialized food economy, industrious applications of advances in food science and technology *can* enhance physical, chemical, and microbiological food safety from farm to fork (see Chapters 5 and 6). The fact that the U.S. food safety system has not been substantially overhauled or updated in more than 100 years reflects the political influence of food producers in the United States. For while European food safety regimes began to incorporate accountability practices grounded in hazard analysis, pathogen reduction, mandatory inspections, government recalls, and commodity traceability in the 1970's, attempts by U.S. regulatory agencies to do the same in the United States have met with opposition from food producers at every step of the policy process; producers lobby against legislative attempts to change the food safety regulatory regime, participate in the rule making process to prevent administrative efforts to impose new standards, and sue to prevent the implementation of policies that sneak through. As Chapter 4 demonstrates, systematic efforts on the part of food producers to perpetuate the limited 1906 food safety framework have largely succeeded.

Moreover, questions and misconceptions about who is accountable to whom in the current food safety regulatory framework persist. Consumers construct narratives about accountability practices that assume that federal agencies have the authority to require that food producers adhere to safety standards, particularly relative to microbiological contamination, to prevent the sale of contaminated products, to issue recalls when contamination is discovered, and thus to promote generalized notions of food safety. When outbreaks of foodborne illnesses occur, as they have recently in association with spinach, cookie dough, peanut butter, beef, tomatoes, and chicken, consumers assume that the USDA and the FDA have failed to fulfill their regulatory responsibilities.

This perception is amplified when outbreaks of foodborne illnesses are traced back to food products in ways that appear to be counter intuitive; consumers to some extent understand Salmonella outbreaks associated with chicken or egg products but when the Salmonella is in peanut butter they assume that there has been a catastrophic breakdown in the regulatory system. As Loader and Hobbs emphasize, "expect food safety to be 'provided'...they do not think it is something they have to worry about—'they' (the government in most cases) 'should ensure that

food is safe'...the majority [of consumers] feel that safety is a right rather than a privilege."<sup>169</sup> As a consequence of this misconception (for in fact the FDA and the USDA have a very narrowly defined authority relative to food safety) the FDA and the USDA are often blamed for situations wholly beyond their control. This may explain the efforts of regulatory agencies to update food safety standards but, as federal courts have ruled, consumer demands do not give regulatory agencies the power to go beyond their legislative mandates.

But public blame is not directed exclusively at federal regulatory agencies. In recent years, media coverage and the activities of consumer groups have focused consumer ire on food producers themselves. Despite the existence of "Veggie Libel Laws" that protect agribusinesses against "brand defamation," books, editorials, investigative reports, and documentaries have promoted the public perception that food producers have failed in their food safety responsibilities. Consumers are increasingly holding agribusinesses accountable for outbreaks of foodborne illnesses or other failures to promote food safety, not through public accountability frameworks, but through market accountability mechanisms. An outbreak of a foodborne illness, particularly one in which the corporation is perceived to have or found to have failed to do everything in its power to prevent the contamination, can be devastating for a food producer or processor (see Chapter 7).

In the aftermath of the 2009 peanut butter scandal (see Chapter 8), food producers are increasingly looking to tighten their control over food safety in efforts to meet consumer expectations and protect against liability and market damages. Some have argued that this new set of pressures has prompted food producers to support a government overhaul of the food safety accountability framework and regulatory regime so that they can pass responsibility and re-direct consumer dissatisfaction and wrath onto government agencies. This new dynamic may transform the role of the USDA and the FDA in managing food safety from farm to fork and may promote the development of new accountability frameworks and practices beholden to new political values associated with new conceptions of the "public interest." An analysis of the U.S. food safety accountability framework and regulatory regime from both a technoscientific perspective and a cultural/political orientation thus reflects the values, legitimacies, and

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<sup>169</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, *Food Policy*, Volume 24 (1999), pp. 693.

structures that ground conceptions of appropriate standards, the public interest, and power relationships as the U.S. food safety regulatory regime faces transformative revision for the first time since its creation more than a century ago.

**CHAPTER 4**  
**THE POWER OF CORPORATE AGRIBUSINESSES:**  
**WHERE FOOD REGULATION AND FOOD POLITICS COLLIDE**

Advances in food production and processing during the 20<sup>th</sup> century applied the industrial logics of Fordism to food production; because economies of scale reduced production costs and vertical integration reduced transaction costs, an industrialized food system produced vast quantities of inexpensive foods. At the same time, inventions and innovations in food science and technology developed preservatives, flavors, colors, and similar additives designed to extend the shelf-life of food products. As a consequence, the American diet became transformed over the course of the 20<sup>th</sup> century; “fast foods,” “pre-packaged foods,” and “processed foods” produced by corporate agribusinesses became dominant staples for the average American consumer.

In conjunction with a national transportation system that made it possible to produce or process vast quantities of food in a single location for national (or international) distribution, the enhanced efficiencies of industrialized food production fueled the concentration of economic power in the hands of a small number of corporate agribusinesses. Industrialized food production required ever larger infrastructure costs, particularly relative to mechanization and research and development; ultimately large corporate agribusinesses alone could afford the substantial investment in technology and machinery necessary to glean cost efficiencies from industrial productivity.

When the 1906 regulatory framework was created, food production was a dispersed operation. Whereas food production in the United States at the turn of the 20<sup>th</sup> century was characterized by many producers, many processors, many butchers, and many retailers, food production at the beginning of the 21<sup>st</sup> century was just the opposite. Today half a dozen agribusinesses,<sup>170</sup> each with very deep pockets, an army of lobbyists, and a staff of lawyers, dominate food production, processing, and distribution. They also dominate the policy process.

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<sup>170</sup> Four meat packers control about 80% of the U.S. meat industry: Tyson, Swift, Cargill, Smithfield, and National Beef. Nestle, Kraft, Sysco, Dole, PepsiCo, General Mills, Kellogg, and ConAgra not only dominate the U.S. food market but are also among the world’s largest food producers/processors.

As Nestle writes, food safety is inherently a political issue because large corporations dedicated to profit maximization, often at the expense of public health or consumer interests, have crafted the U.S. food safety regulatory regime; food safety “involves the interests of huge and powerful industries that use every means at their disposal to maximize income and reduce expenses, whether or not these means are in the interest of public health.”<sup>171</sup> Food producers and processors “lobby Congress to eliminate regulations perceived as unfavorable; they press federal regulatory agencies not to enforce such regulations; and when they don’t like regulatory decisions, they file lawsuits.”<sup>172</sup> Nestle explains, “the job of food lobbyists is to make sure that the government (1) does nothing to impede clients from selling more of their products and (2) does as much as possible to create a supportive sales environment...they accomplish this goal most effectively through personal contacts established through the revolving door, as well as through financial contributions.”<sup>173</sup>

Thus corporate agribusinesses often impede the policy process. When it advances their economic interests, however, food producers and processors can be powerful allies of the food safety lobby. In both 1906 and 1938 agribusinesses joined forces with advocates for federal food safety legislation. It was the support of agribusinesses, rather than popular outrage, which secured the passage of the 1906 Pure Food and Drug Act, the 1906 Federal Meat Inspection Act, and the 1938 Food, Drug, & Cosmetic Act. Similarly, during the 1958 Cranberry Crisis, cranberry producers and processors turned to federal regulators to certify “safe” cranberries and thus to prevent the complete collapse of the cranberry market (see Chapter 3). And in the aftermath of recent food safety crises, agribusinesses have shifted their support toward a new federal regulatory structure that would enforce higher accountability standards upon producers, processors, and distributors. The question, therefore, asks when, why, and under what circumstances corporate food producers and processors support rather than oppose changes to the U.S. food safety regulatory regime. An examination of food safety policy from 1906 indicates that corporate support for more stringent national regulatory standards emerges when the new regime will: (1) secure market share for existing agribusinesses; (2) help food producers and

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<sup>171</sup> Marion Nestle, Safe Food: Bacteria, Biotechnology, and Bioterrorism, Berkeley, CA: University of California Press (2003), pp. 1.

<sup>172</sup> Marion Nestle, Food Politics: How the Food Industry Influences Nutrition and Health, Berkeley, CA: University of California Press (2003), pp. viii.

<sup>173</sup> *Ibid*, pp. 110.

processors gain access to international markets; (3) prevent the collapse of a food sector or industry; and/or (4) re-direct consumer ire at government officials rather than food producers or processors.

### Regulation, Self-Interest, and the Impact of Firms on the U.S. Food Safety Regime

Firms internalized production, processing, and distribution in ways that reduced the risks of market failures, enhanced efficiency, and advanced profitability. Unlike markets, which act as *facilitators* of economic *exchange*, firms function as *agents* of economic *production*; they apply invention, innovation, and ingenuity to the production process in ways that reduce costs, increase profit margins, and generate competitiveness within an economic sector or industry (or, in the case of very large firms, many sectors and industries). More than this, however, firms act as economic coordinators and political advocates; not only do firms reduce risks and promote profitability, they champion and oppose a wide variety of public policy initiatives, not in the name of the *public* interest, but for the sake of their economic *self-interest*.

Public policy theories too often disregard the influence of firms in the policy making process. Theodoulou and Kofinis, for example, exclude firms from their analysis of policy-making actors. Even Sabatier's argument for "better theories of public policy" omits the importance of the firm in the policy process; he observes that "one of the conclusions emerging from the policy literature is that understanding the policy process requires looking at an intergovernmental policy community or sub-system—composed of bureaucrats, legislative personnel, interest group leaders, researchers, and specialist reporters within a substantive policy area....the traditional focus of political scientists on single institutions, or single levels of government...is usually inadequate for understanding the policy process over any length of time."<sup>174</sup> But without firms, an analysis of public policy remains incomplete.<sup>175</sup>

Where firms do feature prominently is in policy debates about the dynamics of "capture." As Kalt and Zupan write, "the tenor of economic ('capture') theories of regulation...suggest that

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<sup>174</sup>Paul A. Sabatier, *Towards Better Theories of Public Policy*, PS: Political Science and Politics, Volume 24, Number 2 (June 1991), pp. 148.

<sup>175</sup> The influence of firms cannot be reduced to the "interest group leaders" that represent some corporate interests in the policy making process.

the incidence of the legislation summarizes not only the economic but also the politics of the issue: narrowly self-interested [agents] capture policymakers at the expense of [other economic agents].”<sup>176</sup> They go on to explain that “probably the most basic proposition of economic, capture models of regulation is that the (sometimes implicit) assertion that the altruistic, publicly interested goals of individuals are such insignificant factors in the political process that they are empirically uninteresting and dispensable.”<sup>177</sup> The process instead favors concentrated, homogeneous groups with the resources necessary to wage a continuous war for or against specific policy proposals, initiatives, and movements. As Becker writes, “groups compete for political influence by spending time, energy, and money on the production of political pressure.”<sup>178</sup> But under what conditions do corporate interests support more stringent government regulations relative to food safety? Becker goes on to explain that “policies that raise efficiency are likely to win out in the competition for influence because they produce gains rather than deadweight costs, so the groups benefited have the intrinsic advantage compared to groups harmed.”<sup>179</sup> The bottom line for the corporation, therefore, remains *efficiency standards* that promote *profitability* and *competitiveness*. Regulations advancing what Croley calls the “public interest,” such as more stringent food safety standards, generate corporate support when they *simultaneously* advance the *corporate interest*.

But, in the context of food safety and its regulation, is there a unified “corporate interest”? Many authors like to talk about “corporate agribusinesses” as though all food producers, processors, and distributors shared the same policy goals, positions, and perspectives. Marion Nestle writes about “the food lobby,” Karl Weber of “Food, Inc.,” and Carol Simontacchi “the food industry.” Yet food producing, processing, and distributing firms vary widely in their interests, resources, and objectives. Rarely has “the industry” spoken with a single voice on issues relative to food safety and its regulation. Most of the time, as the case of 1906 and current food legislation debates indicate, food firms are divided; large, established agribusinesses are often at odds with their small, niche competitors. Thus to understand the

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<sup>176</sup> Joseph P. Kalt and Mark A. Zupan, *Capture and Ideology in the Economic Theory of Politics*, *the American Economic Review*, Volume 74, Number 3 (June 1984), pp. 280.

<sup>177</sup> *Ibid*, pp. 280.

<sup>178</sup> Gary S. Becker, *A Theory of Competition Among Pressure Groups for Political Influence*, *The Quarterly Journal of Economics*, Volume XCVIII, Number 3 (August 1983), pp. 377.

<sup>179</sup> *Ibid*, pp. 396.

influence of food firms upon the U.S. food safety regulatory regime, one must begin with the observation that the “food industry” does not present a unified front on issues of safety, regulation, and accountability.

Regulation during the Progressive Era was often portrayed as “government’s necessary and beneficial response to market failure...imposed on an unwilling business community by government officials committed to serving the public interest.”<sup>180</sup> Beginning in the 1960’s, however, “historians and economists began to doubt that public interest could adequately explain the emergence of regulation.”<sup>181</sup> In *Triumph of Conservatism* Gabriel Kolko argued that “the dominant fact of American political life at the beginning of [the 20<sup>th</sup>] century was that big business led the struggle for the federal regulation of the economy.”<sup>182</sup> This political phenomenon is explained by George Stigler’s commercial self-interest theory of regulation. As Stigler wrote, “regulation is acquired by the industry and is designed and operated for its benefit.”<sup>183</sup>

However, because regulation does not affect (or benefit) all firms within a sector or industry equally, not all firms will support regulatory provisions. Economists James Buchanan and Gordon Tullock explained regulatory conflict within an industry in terms of competitive advantage and market share. For example, “if regulation imposes more costs on inefficient firms than it does on efficient firms, then some inefficient firms will be driven out of business...fewer firms will mean less output and higher prices, which may benefit the firms who remain in business.”<sup>184</sup> In the case of food safety, regulations that increase transaction costs on small producers or processors advantage large food corporations; if large corporations can use federal regulation to force their competitors out of business, it is in their economic self-interest to do so. It is possible, therefore, for firms to use “regulation as a competitive weapon.”<sup>185</sup>

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<sup>180</sup> Clayton A. Coppin and Jack High, *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy*, Ann Arbor: The University of Michigan Press (1999), pp. 8.

<sup>181</sup> *Ibid*, pp. 8.

<sup>182</sup> Gabriel Kolko, *The Triumph of Conservatism*, New York, NY: Macmillan (1963), pp. 57-58.

<sup>183</sup> George J. Stigler, “The Theory of Economic Regulation,” *Bell Journal of Economics and Management*, 2 (1971), pp. 3.

<sup>184</sup> Clayton A. Coppin and Jack High, *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy*, Ann Arbor: The University of Michigan Press (1999), pp. 9.

<sup>185</sup> *Ibid*, pp. 11.

Economic self-interest is not always defined in terms of market share and competition. Under certain economic conditions, firms frame self-interest in terms of international market openness and access. In this case, national regulatory structures may serve to allow firms to access and operate within international markets. Consumers, particularly in advanced industrial economies, often report that concerns about the safety of food imports rank among their top food safety considerations. Throughout its history, the United States, a major agricultural producer and exporter, has fought to keep international food markets open and accessible to American producers and processors. Weaknesses in the U.S. food safety regulatory regime and the numerous food safety crises that have punctuated U.S. history have made this difficult to achieve; beginning in the late 1800's international concerns about the safety of U.S. food exports have led to protectionist embargos against U.S. food products. As this chapter will demonstrate with respect to the 1906 Federal Meat Inspection Act, agribusinesses have often demanded federal regulation in repose to international concerns about the safety of foods produced within the United State.

Although, as Sabatier argues, “the general public plays a more modest role in the formulation and implementation of governmental policy than in the [political scientist’s] research priorities,” market forces can compel firms to throw their support behind national regulatory proposals.<sup>186</sup> When market failures generate enough consumer backlash to threaten or undermine an entire sector or industry, firms will often champion federal regulatory standards designed to restore trust in the compromised system. For example, the collapse of U.S. meat markets in the aftermath of the publication of Upton Sinclair’s *The Jungle* prompted meat producers, processors, and packers to support the 1906 Federal Meat Inspection Act. Similarly, during the 1958 Cranberry Crisis, cranberry producers turned to federal regulators to certify safe cranberries in order to prevent a complete market collapse (see Chapter 2). The Good Agricultural Practices (GAPs) program emerged in the late 1990's with the support of fresh produce growers and processors (see Chapter 7). And in the aftermath of recent food safety crises and in the face of waning public confidence in the safety of the United States food supply, it appears that corporate agribusinesses are prepared to throw their support behind more stringent federal food safety regulations once again. Because food safety crises represent market failures,

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<sup>186</sup> Paul A. Sabatier, *Towards Better Theories of Public Policy*, PS: Political Science and Politics, Volume 24, Number 2 (June 1991), pp. 148.

corporate support for federal regulatory oversight and accountability mechanisms can be understood as economic self-interest.

### *Punctuated Equilibrium versus Incrementalism*

In his 1959 article *The Science of 'Muddling Through,'* Charles E. Lindblom argues that incrementalism in public policy formulation is the most efficient and effective way to affect policy change. Lindblom writes that, “incrementalism as a political pattern is easy to specify...it is political change by small steps.”<sup>187</sup> Lindblom explains, “incremental politics looks very good...it is intelligently linked with sequences of trial and error...it reduces the stakes in each political controversy, thus encouraging losers to bear their losses without disrupting the political system....moreover, incrementalism in politics is not, in principle slow moving...incremental steps can be made quickly because they are only incremental...they do not rock the boat, do not stir up the great antagonisms and paralyzing schisms as do proposals for more drastic change.”<sup>188</sup>

There are, certainly, some arguments for the efficiency of an incremental approach to public policy. As Lindblom writes, revolutionary public policy proposals face “too many conflicting interests pulling them apart;” because “an operative, integrated solution to a problem is a vast collection of specific commitments all of which are implemented...the odds of agreement among political elites or citizens...are extremely rare.”<sup>189</sup> Moreover, “incremental politics is also a way of ‘smuggling’ changes into the political system...important changes in

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<sup>187</sup> Lindblom explains in his companion article that incrementalism as policy *analysis* involves: (1) an “analysis that is limited to consideration of alternative policies all of which are only incrementally different from the status quo; (2) an “analysis marked by a mutually supporting set of simplifying and focusing stratagems” including the “limitation of analysis to a few somewhat familiar policy alternatives,” “a greater preoccupation with ills to be remedied than positive goals to be sought,” “a sequence of trials, errors, and revised trials,” and an “analysis that explores only some, not all, of the important possible consequences of a considered alternative; and (3) an “analysis limited to any calculated or thoughtfully chosen set of stratagems to simplify complex policy problems, that is, to short-cut the conventionally comprehensive ‘scientific analysis.’” [Charles E. Lindblom, *Still Muddling, Not Yet Through*, Public Administration Review, Volume 39, Number 6 (November-December 1979), pp. 517-518.]

<sup>188</sup> Charles E. Lindblom, *Still Muddling, Not Yet Through*, Public Administration Review, Volume 39, Number 6 (November-December 1979), pp. 520.

<sup>189</sup> *Ibid*, pp. 521.

policy and in the political system often come about quite indirectly and as a surprise to many participants in the system.”<sup>190</sup>

But an analysis of the U.S. food safety regulatory regime reveals that although incrementalism may be an *efficient* and *effective* method of public policy formulation (and analysis), it does not necessarily characterize the policy process. In the case of food safety, the theory of *punctuated equilibrium*, an alternative to incrementalism and a prominent tool for explaining policy change processes, emerges as relevant. As Robinson notes, “punctuated equilibrium theory is an account of policy change that predicts long-term policy equilibria that are infrequently, but dramatically, interrupted by periods of large change.”<sup>191</sup> This theory more accurately reflects the formation and transformation (or lack thereof) of the U.S. food safety regulatory regime. In 1906, and to a lesser extent 1938, dramatic, drastic changes occurred to revolutionize food safety and its regulation within the United States. But since that time, relatively little has changed, despite the fact that the 1906 framework is widely recognized to be antiquated, ineffective, and inefficient. Whereas European food safety regulatory regimes have been incrementally transformed throughout the course of the 20<sup>th</sup> century, attempts by U.S. food safety agencies to update their regulatory capacities, even in times of crisis (see Chapters 6 and 7), have largely failed.<sup>192</sup> But the equilibrium established in 1906 by the Pure Food and Drug Act and the Federal Meat Inspection Act appears increasingly fragile. For the first time since the turn of the 20<sup>th</sup> century, large, drastic changes are being considered by both houses of Congress. Two questions thus emerge: first, what sustained food safety equilibrium in the United States from 1906 to 2009; and, second, what catalyzed this current period of dramatic, transformative change? Both answers point to the power of food producers and processors in the U.S. policy formulation and implementation process; in order to understand the U.S. food safety regulatory regime, one must first understand the influence and impact of corporate agribusinesses on food safety policy beginning with the creation of the 1906 regulatory framework.

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<sup>190</sup> *Ibid*, pp. 521.

<sup>191</sup> Scott E. Robinson, *Punctuated Equilibrium*, Encyclopedia of Public Administration and Public Policy, 2<sup>nd</sup> edition, 15 April 2008 [available online: <http://www.informaworld.com/smpp/content~db=all~content=a792053393>].

<sup>192</sup> The identification of *E. coli* 1057:H7 as an adulterant under the 1906 Federal Meat Inspection Act (as Amended) is an exception to this rule. This will be discussed in detail in Chapters 5 and 9.

*The Impact of Agribusinesses on the Creation of the U.S. Food Safety Regulatory Regime*

The American food industry began a period of exponential growth around the turn of the 20<sup>th</sup> century. As food became increasingly industrialized and “as the American food industry grew, competition between food companies also grew...indeed, competition between national brands and local brands intensified throughout the Progressive Era.”<sup>193</sup> But because food safety standards of that era were *state and local* rather than *national*, local brands, which usually produced for small regions that covered only a few states, had a competitive advantage over national brands that struggled to satisfy the demands of a many different regulations and requirements. Thus “many national brands wanted national legislation because of the inconvenience caused by differing state laws [and because they ] hoped to use national legislation to gain a competitive advantage [over local producers].”<sup>194</sup> As Coppin and High write of the National Association of Cannrs and Packers, one of the leading forces in food production, “many canners, particularly those with [national] brand names, supported national food regulation...a national law that required purity would, they believed, benefit the image of their products.”<sup>195</sup>

Food firms split, however, in their assessment of the 1903 Hepburn-McCumber bill, a food safety measure that served as a predecessor to the 1906 Pure Food and Drug Act. Producers of national brands supported a pure food law, Coppin and High argue, “not out of concern for purity or health or the well-being of the working classes [but] for the competitive advantage that such legislation would provide...pure food legislation would hobble their lower-priced competitors.”<sup>196</sup> Representatives from the H. J. Heinz Company,<sup>197</sup> for example, argued in favor

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<sup>193</sup> Clayton A. Coppin and Jack High, *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy*, Ann Arbor: The University of Michigan Press (1999), pp. 22.

<sup>194</sup> *Ibid*, pp. 53-54.

<sup>195</sup> *Ibid*, pp. 21.

<sup>196</sup> *Ibid*, pp. 65.

<sup>197</sup> Heinz used that competitive advantage to gain predominance in the American ketchup market. More than 50% of the ketchup sold in the United States is produced by Heinz, a company that has become synonymous with what Jeffrey Steingarten calls America’s favorite condiment. Heinz used U.S. food law to gain a virtual monopoly in ketchup production. In his administration of the 1906 statute Wiley called for a ban on the use of preservatives, including benzoate of soda, a preservative frequently used in ketchup. Because Heinz was the only ketchup producer to develop a product that did not use benzoate of soda, it found this ruling particularly advantageous. Competing firms complained about the creation of a monopoly and called for an amendment to the 1906 statute that would create a committee of experts to determine standards for preservatives. The amendment was eliminated in

of national pure food legislation saying that “bargain counter mania” had given “the unscrupulous manufacturer a ready market for his products if he could sell them for a very low price...cheapness thus becomes the goal of his productive ambition, and this ambition [would be] realized and the goal reached by placing on the market products not containing the ingredients they were supposed to contain.”<sup>198</sup> But while Wiley, then leader of the USDA Bureau of Chemistry, “concentrated on making alliances with commercial interests that could benefit from his administration of a national food law” many food producers opposed the bill because they feared that Wiley<sup>199</sup> would use food purity legislation to “discriminate against their products.”<sup>200</sup> Thus although the Campbell Preserve Company, the straight whiskey industry, the National Association of Retail Grocers, and the Association of Manufacturers and Distributors of Food Products supported the Hepburn-McCumber legislation, opposition from the oleomargarine industry, the National Wholesale Liquor Dealers, the National Food Manufacturers’ Association, and glucose and saccharin producers, among others, killed the bill; the Senate adjourned in 1904 without considering the proposal.<sup>201</sup>

At the same time, U.S. meat producers and packers faced increasing pressures, both international and domestic. Beginning in 1879, European nations “increasingly came to fear Americana goods and started embargos against food, in particular meat.”<sup>202</sup> Although these

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conference committee giving Heinz a great competitive advantage in the production of ketchup, the effects of which remain evident today.

<sup>198</sup> Clayton A. Coppin and Jack High, The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy, Ann Arbor: The University of Michigan Press (1999), pp. 65.

<sup>199</sup> Some authors credit Wiley with the establishment of the U.S. food safety regulatory regime. This accolade is, to some extent, deserved. But Wiley, and his positions on issues of food adulteration, were so contentious as to split support for pure food legislation into two camps—one supporting his leadership of the food purity regime, one opposing his leadership, but both advocating for national food purity standards. Wiley was a true believer in the notion of food *purity*; he opposed all adulterants, whether harmful to human health or not, and advocated for “traditional” food products including sugar, butter, and whiskey. It may be said, therefore, that the 1906 Pure Food and Drug Act, not *because* of Wiley, but, at least in part, in spite of him.

<sup>200</sup> Clayton A. Coppin and Jack High, The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy, Ann Arbor: The University of Michigan Press (1999), pp. 56.

<sup>201</sup> Monsanto, the only U.S. producer of saccharine at the turn of the 20<sup>th</sup> century, explained that it favored national food safety regulation but opposed the Hepburn-McCumber bill because its provisions discriminated against saccharine in favor of sugar. In the same vein, the National Wholesale Liquor Dealers Association voted in support of pure food legislation at its 1904 meeting but opposed the Hepburn-McCumber bill because it discriminated against rectified whiskey. The margarine industry made similar arguments with regard to butter manufacturers.

<sup>202</sup> Philip J. Hilts, Protecting America’s Health: the FDA, Business, and One Hundred Years of Regulation, New York: Alfred A. Knopf (2003), pp. 30.

trade restrictions were partially protectionist—barriers against U.S. foods gave European food producers and manufacturers a hefty competitive advantage—rampant contamination of American products justified boycotts. Support for national food legislation that would restore confidence in American products in international markets thus began percolating in the meat processing industry in the late 1800’s. When the U.S. meat market collapsed in the aftermath of the publication of *The Jungle*, however, conditional support turned into outright demand;<sup>203</sup> where President Roosevelt “had been unable to get cooperation from packers unwilling to concede anything, he found them suddenly agreeing to some kind of federal inspection.”<sup>204</sup>

*The Jungle* provided the momentum the Pure Food and Drug Act needed to get through Congress. Fearful of a backlash from consumers, food producers and processors, even those opposed to Wiley’s definition of food “purity,” capitulated to public pressure. After years of debate, most food firms believed that a national purity law would serve their economic self-interest. As Wilson writes, “the new consumer awareness of pure food cut both ways...not only might consumer interests be opposed to business interests, business might also exploit the need to allay consumer anxieties.”<sup>205</sup> Thus “although some firms, such as Heinz or Royal Baking Powder or Old Taylor, received a competitive advantage from regulation, many firms simply wanted uniform regulations.”<sup>206</sup> Moreover, “the publicity resulting from the hyperbole of pure food propaganda was taking its toll on consumer confidence...the government’s stamp of approval on food products would help to restore confidence.”<sup>207</sup> The tides of economic self-interest had turned in favor of national food purity legislation. For the moment, at least, “noble

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<sup>203</sup> Packers did not agree, however, to proposals to nationalize the entire meat processing industry. Given the fallout that followed President Roosevelt’s release of the Neill-Reynolds Report, it is possible that the meat industry threw its support behind the 1906 Federal Meat Inspection Act, focused (as its name suggests) on federal inspections of meat processing, in an attempt to deflect attention away from calls to nationalize the industry.

<sup>204</sup> Philip J. Hiltz, *Protecting America’s Health: the FDA, Business, and One Hundred Years of Regulation*, New York: Alfred A. Knopf (2003), pp. 51.

<sup>205</sup> Bee Wilson, *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*, Princeton, NJ: Princeton University Press (2008), pp. 204.

<sup>206</sup> Clayton A. Coppin and Jack High, *The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy*, Ann Arbor: The University of Michigan Press (1999), pp. 82.

<sup>207</sup> *Ibid*, pp. 82.

purpose” and “self-interest” collided;<sup>208</sup> the creation of the U.S. food regulatory regime was the result.

*The Return of Economic Self-Interest: Agribusinesses and the 1938 FD&CA (as Amended)*

After the passage of the 1906 Pure Food and Drugs Act and the Federal Meat Inspection Act, producers built food empires upon the status of “pure food.”<sup>209</sup> As food firms developed advertising techniques designed to take advantage of consumer confidence in government “certification” of food products, “pure” food became synonymous with “healthy” food. Although demonstrable untrue in several cases and questionable in many more, this perception allowed food manufacturers to turn the 1906 food safety regime into a marketing bonanza that “appealed simultaneously to housewives frightened that they were poisoning their children and to grocers frightened that they might find themselves on the wrong side of the law.”<sup>210</sup> But as Wilson observes, this focus on food “purity” was so fixated on poisons that it missed the bigger picture; that is to say, issues food adulteration so completely dominated the U.S. food regulatory regime that legal definitions of food “safety” would remain tied to “purity” throughout the remainder of the 20<sup>th</sup> century.

The First World War, the Great Depression, and the Second World War created lucrative markets for inexpensive, largely adulterated, food products scientifically manipulated to be visually pleasing (if not palatable, healthful, or even safe). As Wilson writes, “substandard versions of regular goods posed a dilemma for government...technically, they were not allowed to be sold under the 1906 act...but without them, much of the already hungry population would starve.”<sup>211,212</sup> Rationing during the wars, poverty during the Depression, and even the rise of the consumption economy during the Roaring Twenties fueled the growth of the processed food industry.

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<sup>208</sup> Bee Wilson, *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*, Princeton, NJ: Princeton University Press (2008), pp. 208.

<sup>209</sup> *Ibid.*, pp. 209.

<sup>210</sup> *Ibid.*, pp. 208.

<sup>211</sup> *Ibid.*, pp. 223.

<sup>212</sup> The government responded with the 1931 Canner’s amendment which allowed substandard but wholesome canned goods to be sold provided they wore a black crepe label announcing their low quality.

But from the perspective of food purity, a greater problem arose with respect to so-called “imitation” foods. During the early 1930’s the market was flooded with new, cheap, imitation products: Peanut Spred™ that contained very few peanuts; Bred-Spred™ that contained pectin, sugar, water, and coloring but no fruit; American Cheese Food Product, natural cheeses blended with emulsifiers, colors, flavors, and preservatives to create a product with a lengthen shelf-life; and Maple Flavored Syrup that contained only 1.7% maple sugar by volume.<sup>213</sup> But the 1906 Pure Food and Drugs Act did not prevent such products from being sold. As long as they bore a “distinctive name,” they were not considered adulterated; “so long as Bred-Spred™ did not call itself ‘jam’ or ‘jelly,’” therefore, “it was entitled to contain as little fruit as it liked.”<sup>214</sup>

This loophole exasperated both the producers of “traditional” foods whose products appeared to be unnecessarily expensive compared to their imitation counterparts and federal regulators whose job it was to maintain food quality. As Lamb wrote in *American Chamber of Horrors*, “What is pepper? And who decides what constitutes maple syrup? The manufacturer of a commercial brand? The Vermont farmwife who boils down a syrup from sap she has collected from her own trees? The Department of Agriculture? Or the courts and juries? And who determines at what point chocolate loses its identity as its fat is removed during manufacture—or when an orange becomes ripe enough to eat?”<sup>215</sup> Similar questions plagued producers and regulators alike. Powerful food firms thus allied with regulatory officials to pressure Congress to amend the 1906 Pure Food and Drugs Act. The 1938 Food, Drug, & Cosmetic Act, therefore, abolished the distinctive name provision and established basic food composition standards. Gradually the FDA established enforceable standards for tomato products, milk, cream, fruit juices, canned tuna, canned vegetables, chocolate, flour, grains, cereal, mayonnaise, macaroni, and jelly. Most of these new standards favored “traditional” recipes; regulators identified ingredients that could be included in specific food products as well

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<sup>213</sup> Imitation food products continue to litter food markets. For example, many vegan alternatives to traditional foods, including “tofurkey” (not to be confused with the meaty TurDuckIn), Not Dogs™, Harvest Burgers™, Burger ‘n Loaf™ (original or Italian flavors), Chili Fixin’s™, Sloppy Joe Fixin’s™, and Taco Filling n’ Dip™, represent a new generation of imitation foods. Often consisting of small granules of concentrated soy protein with various flavor additives and preservatives, these food products are a “modern marvel” of food science and technology.

<sup>214</sup> Bee Wilson, *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*, Princeton, NJ: Princeton University Press (2008), pp. 223.

<sup>215</sup> Ruth de Forest Lamb, *American Chamber of Horrors*, New York, NY: Farrar & Rinehart (1936), pp. 143.

as minimum and maximum proportions. Armed with the FD&CA, producers of “genuine” foods, such as *Del Monte* and Heinz, held a competitive advantage against producers of “imitation” substitutes.

But producers of “imitation” foods fought back. In 1951 the FDA seized “Delicious Brand Imitation Jam,” a product that contained only 25% fruit (rather than the 45% required by law). Although the product was labeled as an “imitation,” the FDA argued that consumers would not know that it was not “real” jam as defined by U.S. law. In 1952, however, the United States Supreme Court ruled that Section 403(c) of the FD&CA declared that imitation foods were misbranded *unless* they were labeled as such; because Delicious Brand preservatives identified the product as an “imitation” on its label, it did not violate the terms of the U.S. food law. Although producers of “genuine” foods, such as the National Milk Producers, criticized the Court’s decision, this precedent was a victory for imitation food firms. As the United States entered its Golden Age of Processed Foods, federal regulators found it increasingly difficult to establish standards for specific food products; although regulators could argue that a product sold as “lemonade” should contain lemons, they were at a loss when confronted with “Tab.” Ultimately the 1952 Court decision would be the first of many attempts to “chip away” at the FD&CA. During the remainder of the 20<sup>th</sup> century, food producers would secure the right to “adulterate” foods with color and flavor additives as well as preservatives. Food laws would shift, therefore, from *consumer* protection to *corporate* protection, giving food manufacturers the right to create and sell “innovative” processed foods with impunity. Over time, producers of what had been called “imitation” foods came to dominate the market; their power to shape legislation and regulation dwarfed that of “traditional” food producers.

### *A Century of Equilibrium: Agribusinesses and Food Safety from 1938 to 2009*

Once Congress passed the 1958 Food Additive Amendment and the 1960 Color Additive Amendment and federal courts ruled that properly labeled “imitation” foods did not violate the FD&CA, the U.S. food safety regulatory regime entered a period of policy equilibrium. Although advances in food science, pathology, and microbiology expanded the parameters of “food safety,” legal and policy definitions remained tied to notions of food “purity” in ways

advantageous to the large firms that dominated the U.S. food supply. Throughout the 20<sup>th</sup> century, food firms seeking profit maximization, even at the expense of public health, systematically opposed attempts by regulators to “modernize” the food safety regulatory regime, particularly with respect to microbiological hazards.

This occurred despite the fact that food scientists developed process-based controls designed to enhance food safety. Initially created to secure the safety of the foods used by NASA on outerspace missions, scientists learned that the diligent application of HACCP Plans to food production and processing significantly reduced the risks of foodborne illnesses. Moreover, a pilot program conducted by the USDA demonstrated that HACCP based production systems were both effective *and cost efficient* (see Chapter 6). But the same program exposed something else, something equally important—it revealed that food companies would not implement or enforce pathogen reduction programs, regardless of their benefits for public health or corporate profit margins, unless forced to do so. And in an era dominated by neo-liberal economic ideologies that advocate the elimination of government regulatory programs, food producers have, for the most part, successfully prevented federal regulators from administering new regulatory standards or accountability frameworks.

But the influence of these large producers extends beyond attempts to lobby against food safety legislation and to argue in favor of more lenient product-based standards from the FDA and USDA. In many cases, administrators and directors of the FDA and USDA have close ties with the very industry they are tasked with regulating. The “revolving door”<sup>216</sup> that exists between agribusiness corporate boardrooms and regulatory agencies has been the subject of much critique and speculation, fueling the perception that federal food safety agencies have been “captured” by industry interests. Throughout the 20<sup>th</sup> century, therefore, food firms applied their own conception “public interest” to prevent regulators from “updating” or “modernizing” the 1906 food safety accountability framework to incorporate technoscientific constructions of “appropriate regulatory practices” because their conceptions of accountability and appropriate accountability mechanisms are contextualized against notions of cost reductions, value added profitability, and brand image. They argue that regulations stifle innovation, inhibit efficiency,

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<sup>216</sup> “Revolving door” is a concept used to describe a cycle in which employees move between roles in a regulated industry and positions in government agencies that regulate that industry. The “revolving door” is related to the idea of regulatory capture.

and unnecessarily constrain producers by forcing them to adhere to prescribed process-based safety regimes that do not adequately reflect the needs of individual processors. Thus, efforts by food firm lobbyists, lawyers, and employees-turned-administrators successfully tied the legal mandate of federal food regulatory agencies to conceptual understandings developed in the late 1800's.

### *Punctuated Equilibrium: A Time for Change*

As turn of the 20<sup>th</sup> century demands for national food purity legislation indicates, food safety crises tend to generate both public and corporate support for more stringent regulatory standards and accountability frameworks. During most of the 20<sup>th</sup> century, the food industry managed to redirect consumer concerns about food safety; U.S. food producers and processors so successfully argued that the U.S. food supply was the “safest in the world” that popular demands for greater food safety were successfully deflected. In the early 1990s members of Congress introduced more than thirty bills related to food safety; none passed. Although federal officials ranked microbial hazards first among food safety issues, consumer alarm over food imports, the use of antibiotics in meat and milk production, food irradiation, pesticide residues, mad cow disease, Genetically Modified Foods (GMFs), and bio-terrorism dwarfed concerns about physical, chemical, and microbiological food safety. And when outbreaks of foodborne illnesses forced consumers to consider the regulatory deficit that characterizes the U.S. food safety regime, ire was directed more upon government agencies than food producers. The public assumed that the federal government had the mandate and power to make sure that the foods produced, processed, and sold in the United States were safe; whenever this was demonstrably untrue, consumers took for granted that federal regulators had failed in their responsibilities.

But during the late 1990s and early 2000s, a series of very high profile crises, scares, and scandals disrupted the equilibrium that had characterized the U.S. food safety regulatory regime since the early 1900s. As Chapter 8 explains, these episodes, combined with media coverage and the activism of consumer groups, shifted consumer blame away from government agencies and onto food producing corporations. Despite the existence of “Veggie Libel Laws” that protect agribusinesses against “brand defamation,” books, editorials, investigative reports, and

documentaries have explained the limitations and challenges facing federal regulatory agencies and enhanced the public perception that food producers have failed in their food safety responsibilities. Thus consumers are increasingly holding agribusinesses accountable for outbreaks of foodborne illnesses or other failures to promote food safety, not through public accountability frameworks, but through market accountability mechanisms. An outbreak of a foodborne illness, particularly one in which the corporation is perceived to have or found to have failed to do everything in its power to prevent the contamination, can be devastating for a food producer or processor. In the aftermath of the recent peanut butter scandal, food producers are increasingly looking to tighten their control over food safety in efforts to meet consumer expectations and protect against liability and market damages.

Some have argued that this new set of pressures has prompted food producers to support a government overhaul of the food safety accountability framework and regulatory regime. But as in 1906, food firms are not united in support for new food safety legislation. In this instance, large “conventional” food producers and processors have voiced support for the 2009 Food Safety Modernization Act and 2009 Food Safety Enhancement Act whereas small “local” producers and processors have voiced virulent opposition (see Chapter 9). Small producers are currently exempt from federal food safety oversight. Proposed legislation would hold all food producers to the same standards, requiring that “local” producers implement the same safety measures and controls as large “industrial” firms. As Chapter 9 explains, the transaction costs of the current proposals are very high, so high, some argue, as to threaten the existence of small or “local” food producers. Although large agribusinesses can afford to implement the process-controls, testing, inspection, and traceability requirements that both major pieces of reform legislation include, many small producers cannot. Large food producing firms, therefore, may view the current proposals as a way to regain and retain their dominance in food markets.

Thus not only would new regulatory standards and accountability mechanisms help large, “conventional” food producers and processors restore consumer faith in their products, they would enhance the competitive advantage of industrialized food firms. Moreover, they would allow firms to pass responsibility for food safety crises onto government agencies and, as in 1906, replace a wide, disjointed array of state and local regulations with a single, federal framework. Alternatively, support may derive from the fact that food producers wish to protect

their brand image in the face of increasingly high profile outbreaks of foodborne illnesses and waning consumer confidence in the existing food safety regime. Or perhaps food producers have simply learned that food safety is good for business; it enhances efficiency and profitability by reducing the risks of market failure. Consumers have demonstrated their willingness to “punish” brands associated with food safety crises *as well as to* pay a premium for products that are produced according to higher food safety standards (see Chapter 7). For whatever reason, food producers appear to be adopting a new orientation to accountability. This alignment of food producers with regulatory agencies and the national legislature could generate new accountability norms and legitimate a new framework beholden to more “scientific” accountability practices as opposed to a narrow emphasis on food “purity.”

Thus large food firms have voiced their support for new federal food safety legislation (see Chapter 9). At this time there are at this time no less than nine proposals in Congress designed to enhance U.S. food safety regulatory authority and power. Two proposals, the Food Safety Enhancement Act of 2009 and the Food Safety Modernization Act of 2009, would revolutionize the accountability and regulatory framework as it applies to food safety (see Chapter 9). Among their provisions are the establishment of an independent Food Safety Agency,<sup>217</sup> requirements for HACCP implementation for all producers, mandatory inspections of all producers and processors by government officials or accredited third party certifiers, the power to conduct mandatory recalls or suspend production, traceability requirements, whistleblower protection, and criminal and civil penalties for those who violate food safety standards. Though some producers, such as the National Cattlemen’s Association,<sup>218</sup> have opposed these proposals, many producers see reform measures as both necessary and desirable.

As in 1906, this support, combined with public demand, may provide the inertia necessary to propel current proposals through Congress. It is possible that this dynamic will transform the role of the USDA and the FDA in managing food safety from farm to fork and promote the establishment of new accountability frameworks and practices beholden to new

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<sup>217</sup> Scholars that study the FDA often comment that it is structurally disadvantaged in the federal bureaucracy as it is neither a cabinet level department nor an independent commission. The proposed FSA would be an independent commission a move that some argue would in and of itself enhance the effectiveness of food safety regulation.

<sup>218</sup> In its press release the NCA emphasized that these proposals are unnecessary because “the US has the safest food in the world.”

political values associated with new conceptions of, not only the “public interest,” but the “corporate interest” as well. An analysis of the US food safety accountability framework and regulatory regime from both a technoscientific perspective and a cultural/political orientation is necessary as the values, legitimacies, and structures that ground conceptions of appropriate standards, the public interest, and power relationships are revised for the first time since creation of the food safety regulatory regime more than a century ago.

Consumer groups and the mass media have certainly encouraged this transformation. Their willingness to publicize accounts of the failures of the US food safety regulatory regime has raised overall awareness about the regulatory deficit that characterizes the current accountability framework and has prompted consumers to demand reform. As Ebrahim and Weisband argue, accountability can be transformative; it can reproduce, reinforce, reflect, reconfigure, or revolutionize power structures and relationships. For the last century the food safety accountability framework and the food safety regulatory regime have reflected, reinforced, and reproduced the power of food producers at the expense of consumer interests. The current proposals, it seems, have the potential to reconfigure and revolutionize contemporary understandings of accountability and accountability practices relative to the regulation of food, its production, and its safety. The question becomes: how is food safety best regulated? Are “top-down” so-called “command and control” systems, such as those included in the proposed legislation more effective and efficient than “bottom-up” so-called “market oriented” regimes? As we consider a new food safety regulatory regime and accountability framework for the 21<sup>st</sup> century, an analysis of the strengths and weaknesses of each approach, alongside case studies from U.S. history, provides necessary context for continuing public policy debates.

**PART II**  
**TOP-DOWN V. BOTTOM-UP:**  
**CRISES, SCANDALS, AND FOOD SAFETY REGULATION**

## CHAPTER 5

### ECONOMIC GOVERNANCE, REGULATORY REGIMES, AND ACCOUNTABILITY MECHANISMS

#### TOP-DOWN (PUBLIC) V. BOTTOM-UP (PRIVATE) FOOD SAFETY REGULATION

In his December 8, 2009 column for the *Washington Post*, Arthur Allen explored “the unusual suspects” responsible for outbreaks of foodborne illnesses in recent U.S. history. Allen writes, “whatever our politics, we increasingly eat for a communal kitchen...a steady roll call of food-borne illness outbreaks and recalls of contaminated products [since the Jack-in-the-Box crisis in 1996] have awakened consumers to the potential dangers of eating almost anything.”<sup>219</sup> Better detection and surveillance of foodborne illnesses, which make outbreaks more visible, alongside the wide range of the outbreaks themselves make “people realize how a trip to the supermarket can put them [at] the mercy of a dishonest or sloppy manager at a factory far away.”<sup>220</sup> Although Allen acknowledges that “the food supply is certainly safer than it was 100 years ago...and probably a bit safer than it was two decades ago...it could be a lot safer—and there are real reasons to worry.”<sup>221</sup>

This is a fact of which the 76 million Americans who suffer from foodborne illnesses each year are well aware. As Robin Dimock explained in the aftermath of her 5-year-old Brian’s near deadly fight with *E. coli*, contracted from unpasteurized apple juice, “when you lose trust in your food, you lost trust in a lot of things.”<sup>222</sup> The Dimocks retaliated against the Odwalla Company producer of the contaminated apple juice, with the virtually the only weapon available to consumers under the current food safety accountability framework—they sued. But although the lawsuit resulted in a settlement, it did little to re-establish the Dimocks trust, either in the safety of foods produced, processed, and distributed in the United States or in the federal regulatory regime charged, ostensibly, with promoting food safety. And although the last major outbreak, “in which *Salmonella* traced to two Peanut Corp. of America plants was responsible

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<sup>219</sup> Arthur Allen, *The Unusual Suspects*, *Washington Post: Health and Science*, 8 December 2009, pp. E1 and E6 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/04/AR2009120403633.html>].

<sup>220</sup> *Ibid.*

<sup>221</sup> *Ibid.*

<sup>222</sup> *Ibid.*

for nine deaths and about 700 illnesses” (see Chapter 8) “seems finally to have pushed Congress into action,” the question remains: what is the most effective and efficient way to restore trust relative to the safety of the U.S. food supply?<sup>223</sup> That is to say, *how* should Congress transform the U.S. food safety regulatory regime in order to reduce the risks of foodborne contamination and, in doing so, enhance *both* food safety *and* consumer confidence?

Regulation can operate top-down through administrative, centralized, public institutions or bottom-up through private, market-based dynamics. There are scholars who argue that top-down food safety standards and regulations constitute “paternalism” and that they inefficiently, inappropriately, and unreasonably diminish individual liberty in the name of “public security.” As Antle writes, “most food safety regulation is based on a paternalistic view of government—the view that government can make food safety choices better for people than they can make for themselves...this paternalism then becomes an excuse for inefficiency—people cannot choose for themselves, so it is better to have inefficient government regulations protecting people than to leave them at the mercy of the marketplace.”<sup>224</sup> There are others who argue that a public, top-down food safety regulatory regime based on process standards, inspections, and sanctions for noncompliance is desirable and necessary and that regulations are good for business because they promote both efficiency and equity and decrease the risks of market failure thus enhancing the public good. Still others argue that top-down regulation and public enforcement fail to satisfy efficiency criteria and should be replaced by private standards and third-party certification. But the question ultimately becomes: which form of regulatory governance most effectively *and* efficiently promotes physical, chemical, and microbiological food safety and *how*?

### *Markets, Market Failure, Public Goods, and the Search for Regulatory Governance*

Open markets allow “purchases and sales, not central authorities, [to] coordinate the society;” in other words, markets promote “a system of societywide coordination of human

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<sup>223</sup> *Ibid.*

<sup>224</sup> John M. Antle, *Choice and Efficiency in Food Safety Policy*, Washington, D. C.: The AEI Press (1995), pp. 2.

activities not by central command but by mutual interactions in the form of transactions.”<sup>225</sup> Because they govern by channeling the energies of a myriad of bottom-up decisions made at the margins of economic activity by many different self-motivated economic agents, markets tend to efficiently govern economic exchange. To view efficiency as an end in and of itself, however, represents a political philosophy known as neo-liberalism. Often associated with the “*laissez-fair*” doctrine attributed to the late Adam Smith, neo-liberalism is “a theory of political economic practices that proposes that human well-being can best be advanced by liberating individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets, and trade.”<sup>226</sup>

But left to their own devices unregulated markets generate social costs that are not priced into the exchange mechanism. Called “market failures,” the presence of these social costs—which include opportunism with guile, negative externalities, and the risks of product failure—suggests that markets alone are unable to satisfy the requirements of public interest and collective welfare. As Unnevehr and Jensen write, “private markets often fail to provide for adequate food safety because the safety is not readily apparent to consumers and it is often very costly to test for the safety of products...without the ability to fully capture returns to costly control of product hazard, firms lack incentive to implement controls for food safety.”<sup>227</sup> Those who would absolutize or universalize theories of market efficiency thus fail to recognize that regulatory policies can be justified to the extent that they reduce the risks of market failures or remedy the consequences of market failures without inordinately infringing upon the efficiencies of market exchange. Centralized economic coordinators are therefore necessary to respond to market failures on behalf of society as a whole; they do so by providing *collective goods*—provisions that are made available to all on a non-excludable basis in order to advance public welfare. Because outbreaks of foodborne illnesses can be understood as *market failures*, “food

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<sup>225</sup> Charles E. Lindblom, The Market System: What It is, How It Works, and What to Make of It, Yale University Press (2001), p. 4.

<sup>226</sup> David Harvey, A Brief History of Neo-Liberalism, Oxford University Press (2005), p. 2.

<sup>227</sup> Laurian J. Unnevehr and Helen H. Jensen, *The Economic Implications of Using HACCP as a Food Safety Regulatory Standard (Working Paper, Center for Agricultural and Rural Development, Iowa State University, Ames, IA)*, 15 December 1998, pp. 1.

safety standards [at least in principle] are considered public goods that are set and enforced by governments.”<sup>228</sup>

Economic governance, regulation, and accountability are often conceptualized only in terms of public, mandatory, top-down “command and control” policies, regimes, and mechanisms. But, as Wolf, who developed a theory of *internalities*<sup>229</sup> explains, this represents an incomplete understanding of economic governance—a hegemonic understanding, to be sure, but one whose efficiency and effectiveness must be evaluated against private, voluntary, or “bottom-up” alternatives. Moreover, as many European economies have discovered, regulatory effectiveness and efficiency can often be enhanced by a willingness to combine top-down, administrative efforts to reduce the risks of market failure with bottom-up, market-based endeavors to do the same.<sup>230</sup> France and Great Britain, for example, rely upon public, top-down, “command and control” food safety regulatory regimes to safeguard domestically produced and processed foods and food products, but turn to private, bottom-up, market-based regimes to enhance the safety of food imports, particularly from developing economies (see Chapter 9). Even the United States, confronted with the limitations of the 1906 food *purity* statutory framework and in an attempt to update or modernize its approach to food safety, has experimented with bottom-up, private, voluntary regulatory regimes, specifically for fresh produce (see Chapter 7).<sup>231</sup> As a preface to case studies focused upon the U.S. food safety regulatory regime and its attempts to resolve the risks of market failure relative to foodborne illness, this chapter examines the relative strengths and weaknesses of public, top-down versus

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<sup>228</sup> Spencer Henson and Thomas Reardon, *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*, *Food Policy*, Volume 30 (2005), pp. 245.

<sup>229</sup> See below.

<sup>230</sup> As Loader and Hobbs write, “if food safety is an important characteristic in a consumer’s purchasing decision, the consumer will incur high information or measurement costs in determining whether this characteristic is present...there are three possible solutions to this problem; they are not mutually exclusive...the first is a firm-level [bottom-up] response: the introduction of product certification or labeling to assure the safety and quality of the food...the second solution is legislative [top-down] protection in the form of labeling regulations and pathogen-reduction standards [as well as process-based requirements]...the third solution is to allow [top-down] tort liability law to create the incentives for firms to reduce food safety problems.” [Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, *Food Policy*, Volume 24 (1999), pp. 690.]

<sup>231</sup> Although the economics literature praises flexible *product-based* or *performance* standards, food scientists largely agree that *process-based* standards (such as HACCP, GMPs, and GAPs) more effectively reduce risks of foodborne illnesses. For this reason, this chapter will examine top-down and bottom-up *process-based* food safety regimes and will exclude an analysis of *product-based* standards.

private, bottom-up approaches to regulation as well as the indispensability of accountability mechanisms designed to strengthen and enhance regulatory regimes.

Regulatory Regimes, Accountability Mechanisms, and the Problematics of Economic Governance

Regulatory regimes represent coordinated efforts to resolve the risks of market failures. They may be public or private and may govern economic activity from the top-down through the activities of centralized administrative institutions or from the bottom-up through the dynamics of competitive markets. Regulatory regimes can exist nationally, as in the case of the U.S. food safety regulatory regime, internationally, as in the case of the Codex Alimentarius Commission, or transnationally, as in the case of the EUREPGAP Certification program. Moreover, regulatory regimes can function concurrently; within the broad framework of the U.S. food safety regulatory regime, for example, exists the GAPs Initiative, a bottom-up food safety regulatory regime designed to reduce the risks of physical, chemical, and microbial contamination of fresh produce (see Chapter 7). Thus regulatory regimes develop and implement mandates, standards, guidelines, controls, and other forms of regulation. In the context of food safety, as Henson and Caswell write, “public food safety regulation [often] takes the form of standards...in general, a target standard lays down the requirement that a food sold for human consumption must be safe, whilst a series of specification standards, covering both products and the processes by which they are manufactured, outline how this is to be achieved.”<sup>232</sup> These standards or regulations may extend either from a public statutory mandate, as in the case of USDA pathogen testing, or from a private market-based incentives, as in the case of GAPs.

But food safety regulatory regimes, whether public or private, cannot be effective or efficient unless they incorporate accountability mechanisms. As Starbird emphasizes, “food safety performance standards, in and of themselves, do not guarantee food processors will deliver safe food...in order to be effective, regulations designed to address food safety through

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<sup>232</sup> Spencer Henson and Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, Food Policy, Volume 24 (1999), pp. 596.

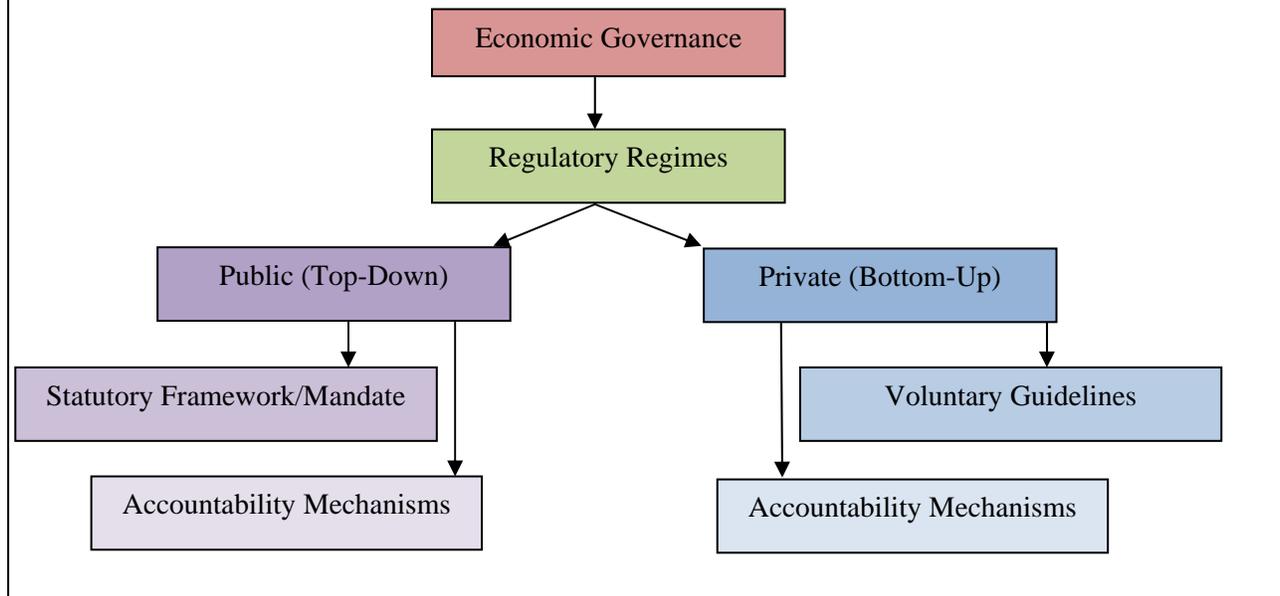
performance standards must include: (a) a quantifiable and measurable performance standard for the presence of contaminants, (b) a reliable inspection procedure for monitoring compliance to the performance standard, and (c) *an economic penalty for failure to comply with the performance standard.*<sup>233</sup> Accountability mechanisms ensure that the actors being held accountable “act in ways that are *consistent with accepted standards of behavior.*”<sup>234</sup> They hold actors to a set of standards or guidelines, monitor and assess their procedures and/or outcomes, impose sanctions if responsibilities have not been met, and certify their compliance when appropriate. In the context of food safety, accountability mechanisms can include: producer or processor registration; on-site inspections; product testing by public, private, or publically accredited private laboratories; oversight and surveillance; product traceability; public or third-party certification; reporting transparency requirements; mandatory recalls or seizures of contaminated foods or food products; civil and criminal penalties for noncompliance; and other techniques designed to ensure the safety of food product either by specifying how they must be produced and/or their final quality. In the absence of accountability mechanisms, a food safety regulatory regime cannot ensure that growers, producers, processors, and distributors implement standards, conform to regulatory requirements, or satisfy established benchmarks; it is, essentially, a hollow measure, doomed to be reactive at best and often incapable of preventing market failures associated with physical, chemical, or microbial food contamination.

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<sup>233</sup> S. Andrew Starbird, *Designing Food Safety Regulations: the Effect of Inspection Policy and Penalties for Noncompliance on Food Processor Behavior*, Journal of Agricultural and Resource Economics, Volume 25, Number 2 (2000), pp. 617, *emphasis mine*.

<sup>234</sup> R. W. Grant and R. O. Keohane, “Accountability and Abuse of Power in World Politics, International Law and Justice Working Paper: Institute for International Law and Justice, New York University School of Law (2004), pp. 3.

FIGURE 1: ECONOMIC GOVERNANCE, REGULATORY REGIMES, AND ACCOUNTABILITY FRAMEWORKS



Top-Down Governance: Public, Hierarchical, “Command and Control” Regulatory Regimes

In the aftermath of food safety crises or scandals, such as the 1906 publication of *The Jungle*, governments often implement public, top-down food safety regulatory regimes that are monitored by government agencies and enforced using criminal or civil sanctions in order to reduce the risks of market failure. As Henson and Reardon explain, “in many cases, standards [are] tightened on foods that have long raised safety concerns, while new standards [are] developed for previously unknown or unregulated hazards or to address the food quality concerns of consumers in order to provide a ‘level playing field’ on which quality-based consumption can take place.”<sup>235</sup> At the turn of the 20<sup>th</sup> century, when many industrial economies first implemented national food safety regulation, regulatory regimes focused on the prevention of food adulteration and misbranding, promoting food *wholesomeness* and *purity* rather than

<sup>235</sup> Spencer Henson and Thomas Reardon, *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*, *Food Policy*, Volume 30 (2005), pp. 243.

*safety*. These regulatory regimes incorporated two accountability mechanisms: civil liability for non-compliance and, primarily in the case of meat and poultry regulation, factory inspections designed to ensure that diseased animals were not slaughtered for human consumption.

Advances in toxicology, microbiology, and food science throughout the 20<sup>th</sup> century demonstrated that food *safety* differed from food *purity*. Many public food safety regulatory regimes throughout Europe responded by implementing product-based regulatory controls and accountability mechanisms designed to promote physical, chemical, and microbiological food safety producer/processor compliance with new statutory obligations. By the late 20<sup>th</sup> century, however, many governments recognized that “end-product testing is [often] and inefficient form of food safety control”<sup>236</sup> and took “a new approach to ensuring the safety of the food supply: mandated use of the Hazard Analysis Critical Control Point (HACCP) system in food industries.”<sup>237</sup> HACCP is “an effective approach to establish good manufacturing practices for the production of safe food” that has also been found to be a “cost-effective approach to food safety regulation.”<sup>238</sup> By the 1980s, food scientists, industry professionals, government regulators, and health officials alike understood HACCP to be “the most sensible and scientifically grounded approach to reducing the risks of [food] poisoning.”<sup>239</sup> This is, in part, because HACCP’s “preventative system of process control can and does prevent hazards that traditional reactive methods [such as visual inspection and pathogen testing] could not;” as Fortin writes, “HACCP prevents foodborne illness by applying science to identify risks through preventative controls...[it] is a complete system that includes corrective actions, record keeping, and verification, which increase the effectiveness and efficiency of both HACCP and conventional sanitation methods.”<sup>240</sup>

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<sup>236</sup> Spencer Henson and Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, Food Policy, Volume 24 (1999), pp. 596.

<sup>237</sup> Laurian J. Unnevehr and Helen H. Jensen, *The Economic Implications of Using HACCP as a Food Safety Regulatory Standard (Working Paper, Center for Agricultural and Rural Development, Iowa State University, Ames, IA)*, 15 December 1998, pp. 1.

<sup>238</sup> Spencer Henson and Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, Food Policy, Volume 24 (1999), pp. 596.

<sup>239</sup> Marion Nestle, Safe Food: Bacteria, Biotechnology, and Bioterrorism, Berkeley, CA: University of California Press (2003), pp. 71.

<sup>240</sup> Neal D. Fortin, Food Regulation: Law, Science, Policy, and Practice, New York, NY: Wiley (2009), pp. 242.

HACCP is an effective and efficient addition to a food safety regulatory regime because it *combines process-based standards* with broad *accountability mechanisms* that ensure that both producers/processors *and* regulators monitor compliance. Thus not only does HACCP create “a complete system to ensure food safety, which includes plans for corrective actions, record keeping systems, and verifications systems to ensure that potential risks are controlled,” it emphasizes “the industry’s role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.”<sup>241</sup> But it does not shift the responsibility onto producers and the processors at the expense of top-down, public monitoring and enforcement. To the contrary, as Unnevehr and Jensen write, HACCP “reduces the costs of regulatory enforcement”<sup>242</sup> and because it facilitates monitoring and enforcement at the level of the individual firm or plant.<sup>243</sup> Moreover, the regulatory imposition of top-down process-based standards on *processing* firms often leads to a “trickle down” effect throughout the industry. In the United States, for example, “the adoption of HACCP by meat, poultry, and seafood processors...increased pressure on producers to join on-farm HACCP-type systems for assuring quality and reducing food safety hazards.” In many of these cases, on-farm record keeping reduces information and monitoring costs, enhancing the ability of processing firms to comply with traceability requirements. Not only do these arrangements benefit “upstream” processing firms, “downstream firms have a clear strategic objective in encouraging closer supply chain relationships—they reduce the risk of losses from civil lawsuits by reducing the likelihood of a food safety problem.”<sup>244</sup> Thus regulatory regimes that mandate HACCP-based process controls enhance food safety throughout the farm-to-fork chain *while simultaneously* enhancing the ability of public officials to hold producers and processors accountable to standards and regulations.

Thus public, “top-down” regulatory regimes generally involve some degree of command and control (CAC) regulatory standards for performance and/or processing alongside government-coordinated accountability mechanisms, such as pathogen testing, inspections,

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<sup>241</sup> *Ibid*, pp. 242.

<sup>242</sup> Laurian J. Unnevehr and Helen H. Jensen, *The Economic Implications of Using HACCP as a Food Safety Regulatory Standard (Working Paper, Center for Agricultural and Rural Development, Iowa State University, Ames, IA)*, 15 December 1998, pp. 9.

<sup>243</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation, Food Policy*, Volume 24 (1999), pp. 688.

<sup>244</sup> *Ibid*, pp. 698.

information disclosure obligations, or traceability requirements, recall authority<sup>245</sup>, civil liability, and criminal penalties. These public mechanisms, however effective, remain expensive. And while governments often insist that food safety is a public priority, food safety agencies are often underfunded, understaffed, and overwhelmed. Moreover, although most scholars agree that top-down, particularly command-and-control, instruments *effectively* promote food safety, many argue that they fail to satisfy *efficiency* standards. As Loader and Hobbs write, “it has been argued that complying with food safety legislation which specifies ‘process’ rather than the measurement of ‘outcomes’ can impose extremely high costs on food firms...for example, legislation which specifies certain HACCP process for all firms regardless of size, product mix, or location may be forcing firms to adopt inefficient production processes by failing to allow for different circumstances between industries and between firms within an industry.”<sup>246</sup> The so-called “one size fits all” approaches to regulation and enforcement that characterize public, top-down regulatory regimes thus fall prey to the kinds of rigidity that inhibit economic efficiency. As Wolf explains, therefore, the *benefits* of top-down regulation must be assessed against the *costs* of public standard elaboration, monitoring, and enforcement.

*Public Regulatory Regimes and Externalities: the Risk of Nonmarket Failure*

Although top-down regulatory regimes can combat the risks of market failure, too often hierarchal government intervention is heralded as a “cure all” for all social ills attached to market failures. Thus while many scholars emphasize the risks of *externalities*, few consider the risks of what Wolf calls *internalities*, that is to say, the unintended side effects of *government intervention* in market dynamics. As Wolf explains, although “the principle rationale for public policy intervention lies in the inadequacies of market outcomes...this rationale is really only a necessary, not sufficient, condition for policy formulation...policy formulation properly requires

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<sup>245</sup> Recall authority is limited in its effectiveness. As Shames comments, “food recall authority is the action of last resort...by then the food is already out on the shelf and [the GAO has] found from prior work that FDA and USDA [have] not done a good job of making sure that contaminated food had been removed from the shelf; [thus] the risks that people would consume it and get sick or die are higher.” The GAO thus “feel[s] that a shift to prevention is a good way to go. We certainly have heard that from all of the food experts we have spoken to.” [Lisa Shames, Interview by Courtney I. P. Thomas, 27 January 2010.]

<sup>246</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, Food Policy, Volume 24 (1999), pp. 698.

that the realized inadequacies of market outcomes be compared with the potential inadequacies of nonmarket efforts to ameliorate them.”<sup>247</sup>

Wolf writes, “public policies intended to compensate for market inadequacies generally take the form of legislative or administrative assignment of certain functions to a government agency in order thereby to produce certain outputs, which are expected to redress the shortcomings of the market.”<sup>248</sup> But “nonmarket outputs are usually hard to define in principle, ill-defined in practice, and extremely difficult to measure independently of the inputs which produce them...[in addition] evidence of output quality is also elusive.”<sup>249</sup> To whom are government agencies held accountable? Who regulates the regulators? According to what standards of efficiency or effectiveness are agency performance and the performance of agency personnel evaluated? And if government regulatory regimes develop internalities that inhibit the public purpose they were designed to serve, the question becomes whether the risk *and costs* of internalities outweigh the risks and costs of externalities

The answer is not self-evident. Wolf does not go so far as to dismiss top-down government intervention as a mechanism to reduce the risks associated with externalities; public regulatory regimes, even those that produce internalities, can be, and often are, justified. Rather than demonize public regulation itself, Wolf emphasizes the need for critical evaluation of policy proposals, and, more importantly, of policy implementation. But beyond notions of policy *assessment* stands the concept of policy *alternatives*. Although an established part of the policy process, the elaboration of regulatory alternatives is often confined to an analysis of the comparative advantages and disadvantages of *public, top-down, administrative* regulations and accountability mechanisms.

But it is not sufficient to allow our understandings of the regulatory interface between markets and firms to become limited to cyclical arguments about externalities, government intervention, internalities, and externalities again. As Havinga writes, “traditional command-and-control regulation by the state is increasingly replaced in political theory as well as in

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<sup>247</sup> Charles Wolf, Jr., *A Theory of Nonmarket Failure: Framework for Implementation Analysis*, Journal of Law and Economics, Volume 22, Number 1 (April 1979), pp. 107.

<sup>248</sup> *Ibid*, pp. 113.

<sup>249</sup> *Ibid*, pp. 113.

practice by alternative, flexible, less state-centered forms of regulation, such as self-regulation, co-regulation, management-based regulation, and private systems of governance.”<sup>250</sup> This “shift of responsibility towards the private sector,” Martinez and Poole write, “has created a more complex and demanding ‘policy space’ involving public and private sector incentives and controls...the interaction between self-regulation and public regulation could provide a superior outcome” to traditional public interventions to improve food safety.<sup>251</sup> But in the absence of hierarchical regulation, oversight, and sanctions, can the risks of market failures be reduced? If we entertain the possibility that public, top-down, government intervention is not the answer, we must turn our attention back to markets themselves. Is it possible that private, bottom-up regulatory regimes based upon *market mechanisms* can more efficiently and effectively resolve the problem of market failures than their public, top-down counterparts?

#### *Bottom-Up Regulatory Regimes: Market-Based Regulation and Third-Party Accountability*

Private, bottom-up regulatory regimes may be national, international, or transnational. Because they are not tied to the regulatory standards of a particular state government, they may operate in ways that facilitate open trade among producers, processors, and distributors across many different economies, including those that do not have the the technical capital, economic resources, and/or political motivation to develop, implement, and enforce food safety standards. In addition, private regulatory regimes are not necessarily focused on food *safety*. Instead, “private standards, labels, and certification systems are crucial for providing information to stakeholders, allowing them to differentiate agrifood products by the attributes that concern them, such as animal welfare, environmental sustainability, and worker welfare.”<sup>252</sup> Thus as “consumers have focused on a broader array of product attributes when assessing product quality,” certification schemes have emerged to assess “the manner in which products are produced (for example, organic production and animal welfare concerns) and the make-up of

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<sup>250</sup> Tetty Havinga, *Private Regulation of Food Safety By Supermarkets*, Law and Policy, Volume 28, Number 4 (2006), pp. 515.

<sup>251</sup> Marian Garcia Martinez and Nigier Poole, *The Development of Private Fresh Produce Safety Standards: Implications for Developing Mediterranean Exporting Countries*, Food Policy, Volume 29 (2004), pp. 230.

<sup>252</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System*, Food Policy, Volume 30 (2005), pp. 357.

products (for example, pesticide residues), as well as the wider implications of the agri-food chain on the environment, global poverty, etc.”<sup>253</sup>

Bottom-up regulatory regimes assume a wide variety of forms and structures. They can be wholly private or semi-public, thoroughly detached from the activities of regulatory agencies or linked to public efforts to advance regulatory goals. For example, the Kosher foods regulatory regime operates wholly outside of the realm of public, government regulation and accountability (see Chapter 7). Alternatively, the GAPs Initiative emerged from public attempts to create an incentive-based regulatory regime for fresh produce “designed to induce either producers or consumers to identify and practice cost-effective methods that achieve improved food safety.”<sup>254</sup> Both represent bottom-up regulatory regimes for specific food commodities but each operates differently with respect to the U.S. food safety regulatory regime and its public agents, standards, regulations, and accountability mechanisms.

Often emerging in response to consumer concerns when public regulatory regimes fail to adequately promote food safety or quality, private standards, regulations, and accountability mechanisms confront public regulatory deficits and waning consumer confidence, frequently giving participating food producers and processors a competitive advantage over rival firms. As Henson and Reardon write, a “retail chain or processing firm has an incentive to implement private standard when there are missing or inadequate public standards...here private standards are a substitute for missing public institutions.”<sup>255</sup> Thus even when they are not forced to do so by public, top-down regulations, standards, or mechanisms, food producing and processing firms will often *voluntarily* enter into market-based, process-oriented, bottom-up safety assurance programs.<sup>256</sup>

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<sup>253</sup> Spencer Henson and Thomas Reardon, *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*, *Food Policy*, Volume 30 (2005), pp. 244.

<sup>254</sup> Laurian J. Unnevehr and Helen H. Jensen, *The Economic Implications of Using HACCP as a Food Safety Regulatory Standard (Working Paper, Center for Agricultural and Rural Development, Iowa State University, Ames, IA)*, 15 December 1998, pp. 7.

<sup>255</sup> Spencer Henson and Thomas Reardon, *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*, *Food Policy*, Volume 30 (2005), pp. 245.

<sup>256</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, *Food Policy*, Volume 24 (1999), pp. 698.

Like their public, top-down counterparts, private, bottom-up regulatory regimes elaborate and enforce process- and product-based food standards designed to safeguard food wholesomeness, purity, quality, composition, and/or safety. The standards established by private, bottom-up food regulatory regimes may be as stringent and expensive as those required by public regulatory agencies; in the case of the United States, where food safety regulatory deficits plague food production, third-party standards are often far more severe than their public equivalents. Private regulatory regimes often require that producers and processors upgrade plant facilities, purchase new technology and equipment, hire expert consultants to overhaul production processes, and employ additional workers to guarantee compliance. As Carl Tarabbio, Jr. of Tarabbio Farms reports, these demands transform the day-to-day operating procedures of producers and processors at every step of food production and processing; Mr. Tarabbio explains “they want the packing house to be enclosed so birds can’t fly in and possibly contaminate the containers or produce...they want our crates and boxes stored in concrete padded room...they want us to disinfect each basket after picking...they want us to disinfect the truck after each delivery.”<sup>257</sup>

There is nothing excessive about any of these requirements; to the contrary, they represent some of the best known ways to prevent foodborne contamination. One of the advantages of private, bottom-up food safety regulatory regimes is that they are easily modified to incorporate new scientific understandings of food safety. From a supplier’s perspective, however, the added expense, not to mention complexity, can be crippling. For this reason, private regulatory regimes, like government regulations, tend to advantage large food firms but to disadvantage small to medium sized producers and suppliers. In recent years, large, conventional food producers and processors have turned to private regulatory regimes, just as they supported the institution of the 1906 Pure Food and Drug Act because it would advance their corporate interests relative to their competitors. For many large food producers and processors, private regulations and standards represent process-and product-controls they have or would implement voluntarily in order to avoid civil liability and protect brand image. After all, it is in the firm’s self-interest to provide a safe supply of food, albeit “in the most cost-efficient and effective manner” possible. This is, in part, because “food manufacturers and food retail

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<sup>257</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System, Food Policy*, Volume 30 (2005), pp. 361.

outlets have a great deal of capital invested in their brand images...legal liability and loss of consumer confidence can have devastating effects on a company's market share and long-term survival prospects in a highly competitive market...this creates a clear incentive for firms to move toward closer strategic partnering relationships with suppliers."<sup>258</sup> Thus "businesses use private standards *strategically*, whether it is to gain access to new markets, to coordinate their operations, to provide quality and safety assurance to their consumers, to complement their brands, or to define niche products and markets."<sup>259</sup>

But, as Mr. Tarabbio explains, compliance costs are not the only fees associated with participation in private, bottom-up regulatory regimes; inspection, surveillance, monitoring, and enforcement costs constitute an additional burden upon food producers and processors. Private regulatory regimes, like their public counterparts, are ineffective without an enforcement or accountability mechanism. In public food safety regulatory regimes, government agencies are responsible for monitoring compliance with standards, regulations, and mandates; private regulatory regimes, on the other hand, must employ alternative methods of surveillance and enforcement. Some rely on self-regulation "where the company sets, monitors, and self-certifies the control parameters."<sup>260</sup> However effective self-regulation may be, and economists insist that it is, it remains inadequate because it fails to establish *accountability* in food production and processing; in the absence of *compliance mechanisms* private food safety regulatory regimes cannot compel food firms to make food safety a priority. For this reason, the rise of private regulatory systems has precipitated a shift in responsibility for monitoring and enforcement away, first, from government agencies and, moreover, from food firms to *third-party certifiers*.<sup>261</sup>

Third-party certification (TPC) represents an external form of monitoring, enforcement, and accountability. Third-party certifiers assess, evaluate, and certify safety and quality claims

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<sup>258</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, Food Policy, Volume 24 (1999), pp. 698.

<sup>259</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System*, Food Policy, Volume 30 (2005), pp. 356.

<sup>260</sup> Spencer Henson and Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, Food Policy, Volume 24 (1999), pp. 594.

<sup>261</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System*, Food Policy, Volume 30 (2005), pp. 355.

“based on a particular set of standards and compliance methods...certification provides assurances about a product to stakeholders by providing information about the commodity and its production process.”<sup>262</sup> Thus TPC is an accreditation mechanism that, as Hatanaka, et. al. write, represents a “key institution for enforcing private standards that is both independent from producers (who, by virtue of the qualities demanded, are not longer believed by consumers) and from governments (which have neither the flexibility nor the responsiveness now desired by all actors in the supply chain).”<sup>263</sup>

To become certified, a producer or processor must apply to a certifying agency, submit to a pre-assessment and documents review of its facilities and production operations, and undergo a field audit. Audits are designed to ensure that suppliers meet the technical specifications and adhere to the standards and regulations required by the private food safety regulatory regime. When compliance is verified, the producer or processor receives confirmation of its certification and is permitted to label and market its products accordingly. Producers and processors bear full financial responsibility for documentation, audits, monitoring, and inspections. Here too, large firms hold a lucrative comparative advantage since they are able to afford the costs associated with third-party certification.

Private, bottom-up food safety regulatory regimes are often associated with voluntary compliance and participation. However, although adherence to private quality and safety standards, compliance with monitoring, and submission to certification by parties outside the firm was once “voluntarily sought by the company,” it is increasingly becoming “required by those with whom [the producer or processor] does business.”<sup>264</sup> Although nominally optional and non-binding, supermarkets, restaurants, and other food retailers have systematically transformed many private, bottom-up regulatory regimes and standards from voluntary to compulsory. As Martinez and Poole write, “while the majority of private ‘codes of practice’ initiatives started as voluntary, they are becoming, or have already become, de facto

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<sup>262</sup>*Ibid*, pp. 355.

<sup>263</sup>*Ibid*, pp. 357.

<sup>264</sup> Spencer Henson and Julie Caswell, *Food Safety Regulation: An Overview of Contemporary Issues*, Food Policy, Volume 24 (1999), pp. 594.

mandatory.”<sup>265</sup> This is, in part, because “retailers’ bargaining power effectively enables them to impose their product specifications on the entire supply chain.”<sup>266</sup> For example, EUREPGAP, a private food safety regulatory regime for fresh produce in the European Union and its trading partners, was “developed by a consortium of leading supermarket chains, including Royal Ahold, Mars & Spencer, Tesco, Safeway, and Sainsbury’s...suppliers [which may be European, American, North African, etc.] who want to sell fresh produce to the European stores of these chains must be third-party certified against the standards established by EUREP.”<sup>267</sup> Within the United States a similar dynamic can be seen with respect to the GAPs Initiative. As Hatanaka writes, “a number of [American] restaurant chains have also begun to insist on TPC for their suppliers...for example, Subway now requires that their tomato, lettuce, and green pepper growers are audited by PrimusLabs.”<sup>268</sup> Thus, “as food retailing becomes more concentrated, large supermarket chains [and other food distributors] are better able to exert market power over upstream actors within the commodity chain and require that suppliers [comply with private standards and regulations]...in many instances, supermarkets [even] designate particular third-party certifies that their suppliers must use.”<sup>269</sup> From the perspective of many suppliers, therefore, so-called “voluntary” compliance with private standards differs only in name from “mandatory” conformity with public or government regulations. “As growing numbers of major retailers request certification,” therefore, “TPC may become less about gaining a competitive advantage and more about simply remaining in the marketplace.”<sup>270</sup>

This, again, advances the corporate self-interest of large food distributors and retailers. As Loader and Hobbs observe, “occasional supply chain relationships place high information and monitoring costs on retailers (and on processors) in identifying suitable suppliers and in monitoring those suppliers to prevent potential food safety problems.”<sup>271</sup> To minimize the risks of market failures and the transaction costs attached to them, food producing firms in the past

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<sup>265</sup> Marian Garcia Martinez and Nigier Poole, *The Development of Private Fresh Produce Safety Standards: Implications for Developing Mediterranean Exporting Countries*, *Food Policy*, Volume 29 (2004), pp. 234.

<sup>266</sup> *Ibid*, pp. 234.

<sup>267</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System*, *Food Policy*, Volume 30 (2005), pp. 359.

<sup>268</sup> *Ibid*, pp. 359.

<sup>269</sup> *Ibid*, pp. 359; 360.

<sup>270</sup> *Ibid*, pp. 361.

<sup>271</sup> Rupert Loader and Jill E. Hobbs, *Strategic Responses to Food Safety Legislation*, *Food Policy*, Volume 24 (1999), pp. 697.

were forced to rely either upon vertical integration, that is, the internalization of all production, process, and distribution functions, or upon “closer partnering arrangements with their suppliers” such as strategic alliances.<sup>272</sup> To some extent, participation in voluntary food safety regulatory regimes substitutes for the need for vertical integration and/or strategic alliances in food production and processing systems; they give firms “downstream” in the production or processing chain the risk reduction they seek but without the carrying costs associated with an internalized production stream or the rigidity that derives from long-term contractual attachments. Not only do private regulatory regimes make it easier for food producers, processors, and distributors to comply with due diligence requirements, it “allows retailers to offer guarantees to their customers with more confidence.”<sup>273</sup> Thus, TPC is a “regulatory mechanism that provides [food firms] with (1) the flexibility to differentiate agrifood products by the attributes that concern them, (2) ensures the consistent implementation of standards regardless of the product’s origin, while at the same time, (3) minimizing transaction costs and financial liability.”<sup>274</sup>

For these reasons, private regulatory regimes that include third-party certification as an accountability mechanism may be said to have at least seven advantages over public food safety or quality assurance regimes: (1) third-party certifiers assume responsibility for the monitoring of standards thus minimizing retailer responsibility for policing the safety or quality of their products; (2) liability shifts from retailers and producers to third-party certifiers; (3) the use of TPC allows retailers to shift the costs associated with food safety or quality monitoring to suppliers; (4) retailers can use TPC as a marketing tool; (5) TPC reduces transaction costs and risks of market failure by assuring higher levels of food safety or quality; (6) private standards are often more agile and thus more quickly aligned with technical knowledge and scientific discoveries while “government regulations are increasingly unable to keep pace with new developments and changing production practices;”<sup>275</sup> and (7) private regulatory regimes, which are not at the mercy of the politics that imbue the policy process, place few to no demands on the

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<sup>272</sup>*Ibid*, pp. 697.

<sup>273</sup> *Ibid*, pp. 697.

<sup>274</sup> Maki Hatanaka, Carmen Bain, and Lawrence Busch, *Third Part Certification in the Global Agrifood System, Food Policy*, Volume 30 (2005), pp. 359.

<sup>275</sup> *Ibid*, pp. 356.

public coffers.<sup>276</sup> Thus “it is private rather than public standards that are becoming the predominant drivers of agri-food systems.”<sup>277</sup>

*The Externalities Generated by Private, Market-Based, Bottom-Up Food Safety Regulation*

Many argue that private regulation is better, that is to say, more efficient and effective, than its public equivalent. In the absence of government monitoring structures, however, this claim can be difficult to substantiate. As Gunningham concludes in his analysis of environmental self-regulation in the chemical industry, “most documented cases of self-regulation are symbolic, meant to satisfy the public and to prevent government intervention.”<sup>278</sup> Neither is third-party monitoring and enforcement necessarily adequate, effective, or desirable. Part of the “problem,” for interpretation varies widely by supplier, is that third-party certifiers are often profit-seeking firms or supplier-funded government agencies. TPC is, therefore, neither free nor cheap and because compliance with private regulatory standards and submission to third-party inspection is often cost-prohibitive for small producers and processors it tends to advantage large corporate interests.<sup>279</sup> For this reason, large food producers and processors have become advocates of private regulatory regimes at the expense of public alternatives; this makes it unlikely that they will support reform proposals designed to transform the public, now antiquated, U.S. food safety regulatory regime.

But private food safety regulatory regimes have another problem: in the absence of public accountability mechanisms, the risks of market failures persist. As they exist today, third-party certifiers are *simultaneously* profit seeking actors *and* agents in the very market they are supposed to regulate. For this reason, they must be strict enough to establish their credibility as

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<sup>276</sup> *Ibid*, pp. 360.

<sup>277</sup> Spencer Henson and Thomas Reardon, *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*, Food Policy, Volume 30 (2005), pp. 242.

<sup>278</sup> Tetty Havinga, *Private Regulation of Food Safety By Supermarkets*, Law and Policy, Volume 28, Number 4 (2006), pp. 519.

<sup>279</sup> Some scholars, including Hatanaka, Bain, and Busch suggest that compliance costs may be minimized through the creation of certifying non-profit NGOs. These have been proposed particularly to help suppliers in developing countries achieve third-party certification so that they can export their goods to distributors in industrialized economies; producers in Ghana, for example, that have become EUREPGAP trained and certified have a great competitive advantage over other exporters, an advantage that encourages economic development beyond food producing and processing industries.

an accreditation agency and, at the same time, accommodating enough to attract customers (customers, of course, being food producers and processors seeking certification who will also bear the full cost of TPC services). Although critics of top-down food regulatory agencies often cite issues of industry “capture” and conflict of interest, very few proponents of bottom-up certification acknowledge this fundamental problem: third party certifiers and inspection agencies must “balance between being too cooperative and being too strict, between risking their reputation or accreditation and losing their clients.”<sup>280</sup>

As the 2008-2009 peanut crisis demonstrated, private accountability mechanisms, like the markets in which they operate, have a tendency to fail with catastrophic consequences (see Chapter 8). In the absence of public regulatory authority and sanctions, private test results can be falsified, ignored, or disregarded in favor of tests performed by a competing laboratory that produces a more desirable result. The question thus arises: in the case of third-party certification, the lynchpin of private regulatory governance, who watches the watchers? Who guarantees that certifications are extended only to those producers and processors that comply with privately elaborated standards? In a market where compliance and oversight expenses constitute a preponderance of production costs, what is to prevent producers and processors from “buying” certification in the absence of compliance as though it were a commodity “sold” by the third-party agency? And if the answer is, as it must be, “a government agency,” what benefit is derived from private regulation? Would it not be more efficient and effective to rely upon public, top-down regulatory and accountability mechanisms?

*An Accountability Deficit: The Need for Reformed Public, Top-Down Regulatory Governance*

The construction of a regulatory interface among governments, markets, and firms designed to enhance *both* “economic efficiency” and the “public good” is a *political* endeavor. How an economy chooses to regulate food safety, to what extent, through what mechanisms, and according to what standards is a fundamentally political question representative of what its participants believe and value. In theory, private food safety regulatory regimes reduce the risks

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<sup>280</sup> Tetty Havinga, *Private Regulation of Food Safety By Supermarkets*, Law and Policy, Volume 28, Number 4 (2006), pp. 526.

of market failure associated with food safety *while simultaneously* reducing the costs associated with externalities and government intervention in market exchange. But to understand why the U.S. food safety regulatory regime is in need of transformation, one must look beyond theories of top-down and bottom-up regulatory governance and instead examine their implementation. Only then can the weaknesses of the U.S. food safety regulatory regime, as well as the risks of private food safety regulatory governance, become apparent.

Unless standards, regulations, and accountability mechanisms change over time, adapting to new problems, challenges, and crises, a food safety regulatory regime is doomed to inefficiency and ineffectiveness. Grounded in a statutory mandate that is more than a century old, the U.S. food safety regulatory regime is nearly completely devoid of accountability mechanisms. U.S. food safety is thus besieged, not only by a *regulatory* deficit but by an *accountability* deficit as well; the latter inhibits the effectiveness of the *public* national regulatory regime *as well as* private regimes, such as the one governing fresh produce safety. As Chapters 6, 7, and 8 will demonstrate, bureaucratic attempts to “update” or “modernize” that mandate have consistently to accomplish what other advanced industrialized economies achieved decades ago: the institution of a public food safety regulatory regime equipped with the accountability mechanisms necessary to enforce producer and processor compliance with elaborated process- and product-based standards. But the next chapters will also demonstrate the inability of private food safety regulatory regimes to “fill the void” left by a century of legislative inaction. For although private regulatory regimes appear to combine standards with enforcement, regulation with accountability, in the absence of a “fourth party” agent empowered hold third-party certifiers accountable beyond the mechanisms market exchange, private regimes fall prey to the risks market failure. This is a period of regulatory transformation. And as legislators, consumers, interest groups, and corporations reconsider the role they want the national government to play relative to food safety, they must recognize that the United States needs a new public, top-down food safety regulatory regime suffused with accountability mechanisms designed to ensure producer and processor compliance with process-based standards.

## CHAPTER 6

### REGULATING BEYOND PURITY FROM THE TOP-DOWN:

#### *E. COLI 0157:H7, BEEF, AND THE USDA PATHOGEN REDUCTION PROGRAM*

The United States Department of Agriculture (USDA) receives its food safety mandate from the 1906 Federal Meat Inspection Act and the 1967 Wholesome Meat Act (as amended). Unlike the Food and Drug Administration, the USDA's statutory mandate includes accountability mechanisms that empower the USDA to conduct pre- and post-mortem inspections at slaughterhouses and processing facilities, to certify meat and poultry products before they enter the market, and to withdraw inspectors, thus closing a processing facility entirely, if necessary. For this reason, meat and poultry products sold in the United States carry a USDA certification that indicates that *the animal was healthy* prior to slaughter and that the meat was processed in a *wholesome and sanitary facility*. The USDA Food Safety and Inspection Service (FSIS) is "the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."<sup>281</sup>

Although it is responsible for regulating only 20% of the U.S. food supply, the USDA receives nearly 80% of federal food safety funding. These resources go, in part, to pay the inspectors that work on-site at slaughter and processing facilities throughout the country. But the USDA also funds scientific research, data collection, and analysis; emergency response and defense; inspector training and consumer education. For this reason, numerous offices, each existing for a specific food safety purpose, operate under the administrative structure of the FSIS. The National Advisory Committee on Microbiological Criteria for Foods "provides impartial, scientific advice to federal food agencies,"<sup>282</sup> including, when necessary, the FDA, while the Office of Public Health Service "provides expert scientific analysis, advice, data, and

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<sup>281</sup> Food Safety and Inspection Service, *About FSIS*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/index.asp](http://www.fsis.usda.gov/About_FSIS/index.asp)].

<sup>282</sup> Food Safety and Inspection Service, *About FSIS: The National Advisory Committee on Microbiological Criteria for Foods*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/NACMCF/index.asp](http://www.fsis.usda.gov/About_FSIS/NACMCF/index.asp)].

recommendations on all matters involving public health and science that are of concern to FSIS.”<sup>283</sup> The Office of Data Integration and Food Protection “coordinates all emergency response, food defense, and data analysis activities within FSIS.”<sup>284</sup> The Office of Field Operations “manages inspection and enforcement activities nationwide, ensuring that domestically produced meat, poultry, and egg products are safe, secure, wholesome, and properly labeled.”<sup>285</sup> The Office of Outreach, Employee Education, and Training “is responsible for directing outreach, education, and training programs designed to ensure public health and food safety through both inspection and enforcement”<sup>286</sup> while the Office of Public Affairs and Consumer Education “ensures that all segments of the farm-to-table chain receive valuable food safety information.”<sup>287</sup> Finally, FSIS coordinates numerous international food safety activities and houses the U.S. office of the Codex Alimentarius Commission.

Thus the USDA is better equipped institutionally to regulate and promote food safety, particularly microbiological and chemical food safety, than the FDA. In-house research facilities, more extensive resources, and broader statutory powers that include accountability mechanisms as well as regulatory authority give the USDA a distinct advantage over the FDA. But the USDA’s ability to safeguard the U.S. food supply remains limited by its early 20<sup>th</sup> century mandate and has, moreover, been diminished by concerted efforts by large meat and poultry producers since the 1970’s. With the help of several presidential administrations devoted to “small government” and the “free market,” pressure from agribusinesses has rendered the U.S. food safety regulatory regime for meat and poultry largely ineffective and inefficient. As Nestle writes, the USDA’s ability to regulate meat and poultry safety is limited by: “(1) the weaknesses—grounded in past and present history—of the current governmental oversight system; (2) the close personal and professional relationships of meat and poultry producers with

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<sup>283</sup> Food Safety and Inspection Service, *About FSIS: Office of Public Health Service*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/OPHS/index.asp](http://www.fsis.usda.gov/About_FSIS/OPHS/index.asp)].

<sup>284</sup> Food Safety and Inspection Service, *About FSIS: Office of Data Integration and Food Protection*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/ODIFP/index.asp](http://www.fsis.usda.gov/About_FSIS/ODIFP/index.asp)].

<sup>285</sup> Food Safety and Inspection Service, *About FSIS: Office of Field Operations*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/OFO/index.asp](http://www.fsis.usda.gov/About_FSIS/OFO/index.asp)].

<sup>286</sup> Food Safety and Inspection Service, *About FSIS: Office of Outreach, Employee Education, and Training*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/OOEET/index.asp](http://www.fsis.usda.gov/About_FSIS/OOEET/index.asp)].

<sup>287</sup> Food Safety and Inspection Service, *About FSIS: Office of Consumer Affairs and Public Education*, United States Department of Agriculture (2009) [available online: [http://www.fsis.usda.gov/About\\_FSIS/OPACE/index.asp](http://www.fsis.usda.gov/About_FSIS/OPACE/index.asp)].

officials of Congress and...the USDA; (3) the consistent and often successful efforts of these industries to block regulations that might adversely affect their commercial interests; (4) the industries' denial of responsibility for outbreaks of foodborne illness; and (5) their invocation of science as a means to prevent unwanted oversight.”<sup>288</sup> In the absence of *accountability mechanisms*, therefore, the “USDA certified” designation means very little; outbreaks of foodborne illnesses associated with meat and produce overwhelmingly originate with products certified by the USDA and although the label gives producers the right to sell their products, it does not assure the consumer that the product is safe.

In the aftermath of numerous crises and scandals in the latter half of the 20<sup>th</sup> century, the USDA sought to modernize its regulatory approach to meat and poultry safety and to “control microbial pathogens through development of the science-based preventative measures known collectively as *Pathogen Reduction: Hazard Analysis Critical Control Point (HACCP)*.”<sup>289</sup> The Pathogen Reduction Program, as conceptualized by USDA officials under the Clinton administration, would have instituted process-based food safety requirements for meat and poultry processing facilities *and* required pathogen testing as a condition of USDA certification. But this administrative attempt to update the USDA’s food safety authority challenged its statutory mandate. As a consequence, food science, food politics, and food law collided in a series of legal battles that would further erode the regulatory capacity of the USDA. Here again, attempts by the USDA to modernize its statutory mandate, particularly with respect to microbiological food safety, were thwarted by meat and poultry processors that, even in the wake of crises and scandals, prioritize *profits* over *safety*. For this reason, the USDA, like the FDA, needs a new statutory mandate with greater food safety, particularly microbiological food safety, authority.

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<sup>288</sup> Marion Nestle, *Safe Food: Bacteria, Biotechnology, and Bioterrorism*, Berkeley, CA: University of California Press (2003), pp. 63.

<sup>289</sup> *Ibid*, pp. 63.

*The Problem with Pathogens: APHA v. Butz (1974)*

Unlike fresh fruits and vegetables (see Chapter 7), raw meat and poultry products are expected to be contaminated by microbial pathogens. By the early 1970s, health officials, food scientists, industry representatives, legislators, and regulators were collectively aware of the dangers associated with pathogenic bacteria in raw meat and poultry. They also knew that the USDA's so-called poke-and-sniff inspection system, a relic of the early 20<sup>th</sup> century that relied upon sight and smell observations made by USDA inspectors but did not test for microbial pathogens, could not identify contaminated meat or poultry products. But the 1906/1967 statutory mandate did not specifically empower the USDA to regulate microbiological food safety.

In 1971 the American Public Health Association (APHA) attempted to force federal officials, barred from conducting pathogen testing on the products under their regulatory control, to warn consumers about the bacterial dangers associated with raw meat and poultry. The case, *American Public Health Association, et. al. v. Earl Butz, Secretary of Department of Agriculture (APHA v. Butz)*, was first argued in federal district court in the District of Columbia. There APHA alleged that the Secretary of Agriculture “was violating certain provisions of the Wholesome Meat Act, 21 U.S.C. §§ 601 et seq., and the Wholesome Poultry Products Act, 21 U.S.C. §§ 451 et seq....Specifically [by] refusing to affix to meat and poultry products, inspected by the Department of Agriculture, labels containing handling and preparation instructions to protect the consumer against food poisoning caused by Salmonellae and other bacteria.”<sup>290</sup> APHA stipulated that microscopic examination of all meat and poultry processed in the United States was neither feasible nor practical. For this reason, they did not seek a revision of inspection techniques and did not ask that the USDA be forced to supplement its inspections with pathogen testing. Instead, they argued that since Salmonellae are likely to be present in *all* meat and poultry, the certification labels used by the USDA afforded consumers a false sense of security. Thus, APHA asked that “the Secretary be enjoined 'from affixing the label 'U.S. Passed and Inspected' or 'U.S. Inspected for Wholesomeness' on meat and poultry unless it [was] accompanied by an adequate explanation to the consumer that the product may contain

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<sup>290</sup> *American Public Health Association et al., Appellants, v. Earl Butz, Secretary of Department of Agriculture, et al., (APHA v. Butz 1974)*, United States Court of Appeals, District of Columbia Circuit, [available online: <http://cases.justia.com/us-court-of-appeals/F2/511/331/399042/>].

organisms capable of causing food poisoning or infection which will multiply unless the product is properly handled and cooked,<sup>291</sup> along with proper instructions on how to minimize such risk.”<sup>292</sup> In the absence of such a disclaimer, APHA argued, the official inspection labels were false and misleading and thus constituted an illegal “misbranding” of meat and poultry products.

The USDA moved that the case be dismissed and the District Court agreed. APHA appealed to the United States Circuit Court of Appeals for the District of Columbia and on January 22, 1974 the appeal was considered before Circuit Judges Robinson and Robb and Senior District Judge for the United States District Court for the District of Columbia Matthews. The Appellate Court ruled that Congress intended to protect public health and consumer welfare and to prevent and eliminate burdens on commerce by assuring that meat and poultry products sold in the United States are wholesome and properly labeled. Thus Congress required that the USDA conduct inspections at meat and poultry packing plants and mandated that meat and poultry products that are found to be *unadulterated* be marked, stamped, or labeled “Inspected and Passed” prior to sale. The inspection procedures required by the Federal Meat Inspection Act and the Wholesome Meat Act (as amended) do not include “any investigation to detect the presence of *Salmonella* in meat and poultry.”<sup>293</sup> Although it recognized that *Salmonellae* bacteria are found in meats, poultry, eggs, and their products and that these pathogens can cause human illness and death, the Court noted that preventative measures, including care storage and preparation and proper cooking, reduces the risk of *Salmonella* poisoning. It also considered the USDA’s argument that, because a variety of foods and food products had been linked to outbreaks of *Salmonella*, it would be “unjustified to single out the meat industry and ask that the

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<sup>291</sup> APHA recommended the following disclaimers: “Caution: Improper handling and inadequate cooking of this product may be hazardous to your health. Despite careful government inspection, some disease-producing organisms may be present. Consult your local health department for information on the safe handling and preparation of this product” OR “WARNING: This product may contain bacteria which can cause food-poisoning. Refrigeration and adequate cooking will make it safe to eat. To keep bacteria from spreading to other foods: (1) Do not let other foods touch this uncooked product or the surfaces where it has been placed. (2) After handling, carefully wash your hands and all equipment which touched the raw product.”

<sup>292</sup> *American Public Health Association et al., Appellants, v. Earl Butz, Secretary of Department of Agriculture, et al.*, (APHA v. Butz 1974), United States Court of Appeals, District of Columbia Circuit, [available online: <http://cases.justia.com/us-court-of-appeals/F2/511/331/399042/>].

<sup>293</sup> *Ibid.*

Department identify its raw products as being hazardous to health...such an act would have to apply to any and all sources of Salmonellae in order to be fairly administered.”<sup>294</sup>

In its decision the Appellate Court ruled that “the American consumer knows that raw meat and poultry are not sterile and that, if handled improperly, perhaps could cause illness.”<sup>295</sup> It went on to say that the *Salmonella* problem could be handed most effectively at the *consumer level*, thus harkening back to the early 20<sup>th</sup> century tendency to shift food safety responsibility away from producers, processors, *and* regulators onto American consumers. Although the Court congratulated the USDA on its consumer education efforts, it ruled that any attempt to force the USDA to label meat and poultry with the APHA-recommended disclaimer, itself a consumer education instrument, would violate the statutory mandate of the USDA. Moreover, the Court ruled that the 1906 and 1967 laws (as amended) required that “meat ‘found to be not adulterated shall be marked, stamped, tagged, or labeled as Inspected and passed.’”<sup>296</sup> Therefore, unless the “presence of Salmonellae makes meat ‘adulterated,’” the certification label could not be considered not false or misleading; because the legal definition of “adulterated”<sup>297</sup> was directed

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<sup>294</sup> *Ibid.*

<sup>295</sup> The Court specifically said that American “housewives and cooks” are not “ignorant or stupid” and thus knew that raw meat or poultry could contain, if handled improperly, cause illness.

<sup>296</sup> *American Public Health Association et al., Appellants, v. Earl Butz, Secretary of Department of Agriculture, et al.* (APHA v. Butz 1974), United States Court of Appeals, District of Columbia Circuit, [available online: <http://cases.justia.com/us-court-of-appeals/F2/511/331/399042/>]

<sup>297</sup> 21 U.S.C. § 601(m) states that “**The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:**

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)

(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous

or added deleterious substance (other than one which is

(i) a pesticide chemical in or on a raw agricultural commodity;

(ii) a food additive; or

(iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical

which is unsafe within the meaning of section 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title:

Provided, That an

article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of

at poisonous or deleterious *additives* and filthy, putrid, or decomposed substances but did not include microbial pathogens, the Court determined that “the presence of *Salmonellae* in meat [did] not constitute adulteration within this definition” and that “Congress did not intend the prescribed official legends to import a finding that meat and poultry products were free from *Salmonellae*.”<sup>298</sup> The District Court ruling was affirmed and the case dismissed.<sup>299</sup> The decision, although contentious even at the time, would later be used to prevent the USDA from modernizing its food safety authority.

### *Scaling Back: Neo-Liberalism and the USDA’s Food Safety Mandate*

Beginning with the Reagan administration, neo-liberal economic policies designed to reduce the size and influence of the federal government undermined the USDA’s food safety authority and capacities. Both the Reagan and senior Bush administrations cut funding for

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the pesticide

chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments

at which inspection is maintained under this subchapter

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance. [Federal Meat Inspection Act, United States Department of Agriculture [available online: <http://www.fsis.usda.gov/Regulations/FMIA/index.asp>].

<sup>298</sup> *American Public Health Association et al., Appellants, v. Earl Butz, Secretary of Department of Agriculture, et al.* (APHA v. Butz 1974), United States Court of Appeals, District of Columbia Circuit, [available online: <http://cases.justia.com/us-court-of-appeals/F2/511/331/399042/>]

<sup>299</sup> Judge Robinson dissented with the Appellate Court’s decision to dismiss the case, not because he found the APHA arguments compelling, but because he found the Court’s logic debatable and concluded that the case should be remanded for trial.

USDA inspections and “staffed the [USDA] with officials far more interested in government deregulation than in food safety.”<sup>300</sup> The revolving door between business and industry rendered the USDA virtually indistinguishable from the industries it was supposed to regulate. For example, Reagan’s second Secretary of Agriculture (1986-1989), Richard Edmund Lyng, was the President of the American Meat Institute (formerly the American Meat Packers Association) from 1973 to 1979. Similarly, Reagan’s choice to command the USDA’s Food Marketing and Inspection Service was a vice president of the National Cattleman’s Association, one of the most powerful lobbies in Washington; President George H. W. Bush later appointed its president lead the USDA Food Safety and Inspection Service.

In 1986, the Processed Products Inspection Improvement Act of 1986 amended the USDA’s statutory authority to eliminate continuous on-site inspections of meat and poultry processing plants and instead allow the USDA to determine at its discretion how often facilities would be inspected. Armed with this revised mandate and operating under Lyng’s leadership, the USDA scaled back its inspection activities. It reduced the number of meat inspectors by half, eliminated the daily oversight of meat packing and processing facilities, and allowed plants to assume most of the food safety tasks, including inspections, originally left to regulators. In 1988, the USDA instituted the “Improved Processing Inspection” plan and the Streamlined Inspection System for Cattle (SIS-C) program. Cloaked in rhetoric about efficiency, “small government,” and the “free market” and purportedly designed to “modernize” the USDA’s inspection procedures, the SIS-C effectively removed the USDA’s only accountability mechanism—its on-site inspection authority—at five meat processing facilities across the country.

Implemented under the Senior Bush Administration, the SIS-C removed federal inspectors from meat processing plants across the country. In 1992, a USDA study determined that the pilot program was a success—SIS-C facilities were found to be “no dirtier” than others and the streamlined inspection system was extended to all U.S. meat processing facilities. An investigative report broadcast by ABCNews on April 30, 1992 revealed, however, that SIS-C facilities were only clean and sanitary when inspectors arrived for their pre-scheduled visits; as federal officials had previously reported in interviews, the *PrimeTime Live* exposé revealed that

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<sup>300</sup> Eric Schlosser, Fast Food Nation, New York, NY: Perennial (2002), pp. 206.

“the meat produced under the Streamlined Inspection System ‘had never been filthier’...at SIS-C slaughterhouses, visibly diseased animals—cattle infected with measles and tapeworms, covered with abscesses—were being slaughtered [while] poorly trained company inspectors [allowed] the shipment of beef contaminated with fecal matter, hair, insects, metal shavings, urine, and vomit.”<sup>301</sup> The program was slated for further review. But in 1993 the consequences of the SIS-C program would become strikingly apparent when meat processed at one of the five pilot facilities was linked to a nation-wide outbreak of *E. coli* 0157:H7.

*The E. coli 0157:H7 Crisis: Jack-in-the-Box Burgers and the Risk of Corporate Malevolence*

In January 1993, doctors in Seattle, WA began noticing that an unusual number of children were being admitted to hospitals with bloody diarrhea. Health officials traced the illnesses back to undercooked hamburgers served at local Jack-in-the-Box restaurants. Pathogen testing revealed that the meat was contaminated with *E. coli* 0157:H7, a bacterium that can cause abdominal cramps, mild diarrhea, vomiting, and, in about 4% of reported cases, hemolytic uremic syndrome, a previously rare disorder that damages the kidneys and that cannot be treated except with blood transfusions and dialysis. The meat, which had been supplied by one of Vons Companies, Inc.’s SIS-C facilities, sickened at least seven hundred people in at least four states. More than 200 individuals were hospitalized and at least four died; many of those sickened and all those killed were children.

*E. coli* 0157:H7 is a resilient and very infectious microbial pathogen. Generally associated with bovine manure, it is resistant to acid and salt. It can live in fresh or seawater and withstand freezing. It can survive in manure for up to ninety days, on surfaces for several days, and in moist environments for weeks. And an infection with *E. coli* 0157:H7 can be caused by exposure to as few as five organisms. People become contract *E. coli* 0157:H7 when exposed to contaminated water, fresh produce, raw milk, raw beef, or any other food product that comes into contact with bovine fecal matter. Moreover, because *E. coli* 0157:H7 can inhabit human excrement, people can transmit the pathogen to one another by practicing unsanitary hygiene practices.

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<sup>301</sup>*Ibid*, pp. 207.

The emergence and proliferation of *E. coli* 0157:H7 is often associated with the growth of large, commercial cattle feedlots.<sup>302</sup> Because *E. coli* 0157:H7 can replicate in feeding and watering troughs, many cattle are exposed to the pathogen through contaminated food and water. Moreover, feedlot diets contribute to the spread of disease; cattle in feedlots often consume a diet consisting of corn supplemented by chicken manure, itself saturated with microbial pathogens. But although it is often associated with packed feedlots, Allen writes that “0157:H7 seems to be out of the barn—and into the pasture [and] while it’s almost certain that the organism took off in crowded lots where cattle were being fed corn and other grains that seem to encourage its growth, studies have shown that ‘natural,’ grass-fed cattle are now also likely to carry it.”<sup>303</sup>

*E. coli* 0157:H7 is spread to meat during slaughter and processing, usually when animal hides and digestive systems are removed before the meat is processed. In modern slaughterhouses, animal hides are removed by large machines; if a hide has been inadequately cleaned, it can deposit chunks of manure onto the meat or onto processing equipment. Digestive systems are pulled from the carcass by hand; if this is not done properly, the contents of the stomach and intestines may spill onto the meat or the machinery. Moreover, *E. coli* 0157:H7 is generally associated with ground meat; because the meat passes through mechanical grinders, contaminated meat can pass the bacteria onto the machinery which can then infect all the meat processed on it until its next cleaning. If it is then cleaned improperly, the contamination can remain or spread to other equipment and other meat products.

A government investigation of the Jack-in-the-Box crisis found that the restaurants had been cooking their hamburgers to 140 degrees F, a temperature that would not kill *E. coli* 0157:H7 but that met federal guidelines. Nevertheless, consumer complaints about raw or undercooked hamburgers going back six months from the beginning of the outbreak indicated that, *in practice*, Jack-in-the-Box often failed to satisfy federal requirements; documents prove that the restaurant chain considered consumer complaints, as well as a memo from a restaurant employee who was concerned that the cooking practices left the burgers undercooked, and made

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<sup>302</sup> There is a growing perception that *E. coli* 0157:H7 can *only* be found in cattle that have been held on large feedlots; for this reason, some argue that drinking raw milk is “safe” as long as the cows have not been exposed to feedlot conditions.

<sup>303</sup> Arthur Allen, *The Unusual Suspects*, Washington Post: Health and Science, 8 December 2009, pp. E1 and E6 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/04/AR2009120403633.html>].

a conscious decision against making changes its standard operating procedures.<sup>304</sup> Moreover, Jack-in-the-Box knew about, but chose to ignore, Washington state regulations requiring that raw hamburger be cooked to at least 155 degrees F, a temperature that would have likely eliminated the *E. coli* 0157:H7 threat.<sup>305</sup> Although Jack-in-the-Box insisted that, legally, the federal standard superseded the state requirement, the company explained in an internal document filed in court that “if patties are cooked longer...they tend to become tough.”<sup>306</sup> *Taste*, it appears, was a higher priority than *safety* and the consequences were disastrous.

This malevolent decision was not made by all fast food restaurant chains. *E. coli* 0157:H7 was noticed in the food supply for the first time in 1982 when a number of illnesses were traced back to McDonald’s hamburgers. McDonald’s hired Michael Doyle, director of the Food Safety Center at the University of Georgia, to help eliminate the risk of *E. coli* 0157:H7 contamination in its hamburgers. Doyle “told the company that one way to be sure to kill 0157:H7 was by heating their hamburgers to at least 155 degrees.”<sup>307</sup> As Allen explains, “McDonald’s officials grumbled that they would lose customers, but they did what [Doyle] told them.”<sup>308</sup> They began cooking their hamburgers to at least 155 degrees F, 15 degrees higher than FDA guidelines. Most other chains, however, “kept cooking at lower temperatures in order to produce juicier burgers that attracted customers who didn’t like the ‘hockey pucks’ being served at McDonald’s.”<sup>309</sup> That choice cost Jack-in-the Box legally, economically, and publicly.

In the aftermath of the crisis, food safety reform came quickly, not from federal regulatory authorities, but from Jack-In-the-Box itself. Although the president of Foodmaker, Inc., Robert Nugent’s, first instinct was to “blame the chains’ ground beef supplier<sup>310</sup> and Washington State health officials,” he ultimately admitted that “Jack-in-the-Box bore some

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<sup>304</sup> Elaine Porterfield and Adam Berliant, *Jack in the Box Ignored Safety Rules*, The News Tribune (16 June 1995) [available online: [http://www.marlerclark.com/case\\_news/detail/jack-in-the-box-ignored-safety-rules](http://www.marlerclark.com/case_news/detail/jack-in-the-box-ignored-safety-rules)].

<sup>305</sup> *Ibid.*

<sup>306</sup> *Ibid.*

<sup>307</sup> Arthur Allen, *The Unusual Suspects*, Washington Post: Health and Science, 8 December 2009, pp. E1 and E6 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/04/AR2009120403633.html>].

<sup>308</sup> *Ibid.*

<sup>309</sup> *Ibid.*

<sup>310</sup> The beef supplier thereafter reported that it had complied with federal regulations and that USDA officials had inspected the meat, thus passing blame onto the federal government; this strategy was not successful. Foodmaker, Inc. did sue Vons Companies, Inc. for its role in the outbreak. Blame ultimately rested, however, with Jack-in-the-Box since it did not cook its hamburgers to an adequate internal temperature to kill *E. coli* 0157:H7.

responsibility for the illnesses.”<sup>311</sup> Nugent then recruited David M. Theno, a prominent food scientist, to reduce the risks of another outbreak. Theno was an advocate of the HACCP system (see Chapter 5). Realizing that Jack-in-the-Box had relied exclusively upon the safety standards of its suppliers, Theno “created the first HACCP plan in the fast food industry, a ‘farm-to-fork’ policy that scrutinized threats to food safety at every level of production and distribution.”<sup>312</sup> Moreover, he “insisted that every Jack-in-the-Box manager attend a food safety course, that every refrigerated delivery truck have a record-keeping thermometer mounted inside it, that every kitchen grill be calibrated to ensure an adequate cooking temperature, and that every grill person use tongs to handle hamburger patties instead of bare hands.”<sup>313</sup> But, as Schlosser writes, it was an “almost fanatical devotion to microbial testing [that] became the key to Theno’s food safety programs.”<sup>314</sup> He quickly “discovered that the levels of contamination varied enormously in ground beef supplied by different meatpacking companies...some slaughterhouses did a fine job; others were adequate; and a few were appalling.”<sup>315</sup> Thus he instituted mandatory testing requirements for all Jack-in-the-Box suppliers. The companies that supplied Jack-in-the-Box were required to test their beef for a wide range of microbial pathogens, including *E. coli* 0157:H7, every fifteen minutes. The companies that failed to meet pathogen testing benchmarks were eliminated as suppliers. The entire system, which processors at the time claimed radically increased costs and inhibited efficiency standards, increased “the cost of the chain’s ground beef by about one penny per pound.”<sup>316</sup> But although effective and efficient, these reforms represented a limited success at best; they constituted a private regulatory regime designed only to protect Jack-in-the-Box consumers from contaminated beef rather than a public transformation designed to protect Americans writ large.

While implementing changes at Jack-in-the-Box, Theno recommended that the entire meatpacking and processing industry adopt a system of “performance-based” grading. According to this system, “slaughterhouses that produced consistently clean meat would receive a grade A...plants that performed moderately well would receive a grade B, and so

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<sup>311</sup> Eric Schlosser, *Fast Food Nation*, New York, NY: Perennial (2002), pp. 208.

<sup>312</sup> *Ibid.*, pp. 208.

<sup>313</sup> *Ibid.*, pp. 208.

<sup>314</sup> *Ibid.*, pp. 208-209.

<sup>315</sup> *Ibid.*, pp. 209.

<sup>316</sup> *Ibid.*, pp. 210.

on...microbial testing would determine the grades, and the marketplace would reward companies that ranked highest.”<sup>317</sup> Essentially, he suggested that the meat industry implement a private, bottom-up, market-based, voluntary food safety regulatory regime that would allow consumers operating in open markets to choose the level of food safety they desired and to pay accordingly. Similar to the GAPs Initiative (see Chapter 7), this approach is characterized by at least one fundamental flaw: it assumes that purchasers are committed to food safety. Despite the potential public backlash against companies associated with outbreaks of foodborne illnesses, food producing, processing, and distributing firms have demonstrated over and over again that they are committed first and foremost to cost efficiencies; firms that can increase profit margins by purchasing beef from a “lower-grade” and thus less safe facility cannot be trusted not to do. The very presence of lower-grade suppliers represents a market failure in the making. Thus it is unlikely that the industry would have adopted Theno’s proposal on a voluntary basis. Industry-wide reform would require public action from the USDA. But the meat processing industry, as it had since the turn of the 20<sup>th</sup> century, elected to fight the imposition of top-down federal regulation with every weapon in its political arsenal. And, despite the USDA’s efforts, the industry ultimately won.

*From APHA v. Butz to Texas Food Industry Association v. Espy*

In the aftermath of the Jack-in-the-Box crisis, the USDA instituted process-based pathogen reduction measures tied to top-down, command-and-control accountability mechanisms. On September 29, 1993, the Food Safety and Inspection Service announced that the USDA would consider *E. coli* 0157:H7 to be an illegal food adulterant under the Federal Meat Inspection Act; ground beef found to be contaminated with *E. coli* 0157:H7, regardless of the level of contamination, would thus be classified unsafe, adulterated, subject to enforcement action, and prohibited from sale or distribution. Pursuant to this declaration, the USDA began random microbial testing of ground beef in meat processing facilities so that *E. coli* 0157:H7 contaminated product could be removed from the nation’s food supply. This represented a radical divergence from the food safety activities of the USDA under previous administrations;

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<sup>317</sup>*Ibid*, pp. 209.

not only did the USDA discontinue the “Improved Processing Inspection” initiative, it instituted *pathogen* inspections that went far beyond the traditional methodologies of FSIS officials.

In response, industry representatives including the American Meat Institute, the National Cattlemen’s Association, and the Texas Food Industry Association sought an injunction in federal court to prevent the re-definition of “adulteration” and the implementation of pathogen reduction measures.<sup>318</sup> In *Texas Food Industry Association v. Epsy* (1994), food producers and processors argued that the precedent set in *APHA v. Butz* prevented the USDA from classifying *E. coli* 0157:H7 as a food adulterant. Siding with FSIS Director Michael R. Taylor’s assertion that *E. coli* 0157:H7 constituted a “poisonous or deleterious substance which may render [food] injurious to health” and citing the administrative Procedures Act, which permits an agency to issue interpretive rules, general statements of policy, and rules of agency practice, Judge James R. Rowlin of the U.S. District Court for the Western District of Texas dismissed the industry’s request and allowed the USDA to proceed with its pathogen reduction plans. Although the policy was limited to one pathogen, *E. coli* 0157:H7, and one product, ground beef,<sup>319</sup> it was a revolutionary step toward modernizing the 1906 framework in ways designed to reduce the risks of microbial contamination.<sup>320</sup>

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<sup>318</sup> Many were particularly opposed to the categorization of *E. coli* 0157:H7 as an adulterant in ground beef alone since *APHA v. Butz* presumably protected the poultry industry from similar measures involving *Salmonella*; they argued that the new rules unfairly targeted the beef industry.

<sup>319</sup> The USDA later attempted to extend the definition of “adulterated” to other non-intact meat—meat, for example, that had been pounded, tenderized, or injected—since those procedures can introduce bacteria into the interior of meat where they are unlikely to be cooked to as high a temperature as bacteria on the outer surfaces. The USDA remained unconcerned about intact meat since cooking the surface of the meat generally kills bacterial pathogens and continued to limit its definition of “adulterated” to *E. coli* 0157:7, refusing, for example, to extend it to *Listeria* or *Salmonella*.

<sup>320</sup> Given the precedent set in *Supreme Beef v. USDA* (see below), it is possible that a federal court would reverse the District Court ruling in *Texas Food Industry Association v. Epsy*. Although the classification of *E. coli* 0157:H7 has not been further challenged in federal courts, most likely because the USDA was not permitted to institute mandatory *E. coli* 0157:H7 testing as part of its Pathogen Reduction Program (see below), it is unlikely that the *E. coli* 0157:H7 classification would withstand further judicial review, particularly given that the *Epsy* decision occurred at the District court level whereas *Salmonella* decisions occurred at the Circuit Court level. Moreover, given the changes in the federal bench since the early 1990’s, it is more likely that federal judges would stand by precedent and rule that the classification of microbial pathogens as adulterants violates a plain text reading of current food safety legislation. To make such a classification, therefore, the USDA and FDA legislative mandates would have to change. Current proposals resolve this issue by specifically and legally classifying microbial pathogens as adulterants (see Chapter 9).

### The USDA Pathogen Reduction Program

In 1996 the USDA attempted to take this new regulatory approach even further. It proposed the *Pathogen Reduction: Hazard Analysis Critical Control Point (HACCP)*<sup>321</sup> Program, a new safety initiative that would implement mandatory process-based food safety regulations designed to supplement pathogen testing and inspection procedures. Recognizing that “centralization doesn’t necessarily mean less-safe food” and that “a well-run centralized industry is arguably easier to police and control than a more decentralized one,”<sup>322</sup> the USDA proposed that all meat producers and processors be required to (1) implement a government-approved HACCP plan *and* (2) submit meat to the USDA for microbial testing.<sup>323</sup>

Citing the success of Theno’s reforms at Jack-in-the-Box, advocates of HACCP saw the USDA’s proposal as a transformative approach to meat and poultry safety. However, industry representatives, despite the fact that “USDA economists calculated that the economic benefits of Pathogen Reduction [and] HACCP would outweigh [their] costs even under the most conservative estimates,” saw it as a fundamental attack on their profit margins.<sup>324</sup> Despite the “almost complete unanimity among scientists that properly developed HACCP plans could reduce pathogens” the regulated industry claimed that “HACCP was an imperfect system that did not address the real problem—consumer education”—and sought to prevent this expansion of

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<sup>321</sup> See Chapter 5 for more information on HACCP.

<sup>322</sup> One potential advantage of industrial processing is its concentration. Throughout the United States, food production, processing, and distribution operate in an hourglass configuration: animals come from numerous farms and feedlots to centralized processing facilities and, after processing, are distributed to many different restaurants, grocery stores, and consumers. Although this means that food products contaminated at the processing facility are then pushed into nation-wide distribution networks, extending the scale and scope of foodborne illness outbreaks, it also means that the implementation of HACCP mechanisms at that centralized point can promote food safety throughout the rest of the farm-to-fork chain. Another advantage derives from the vast resources commanded by large agri-firm processors. Large meat processors, unlike their small counterparts, have the resources necessary to design facilities and train personnel in ways that reduce the risks of contamination; they can build slaughterhouses, purchase equipment, and require employee sanitary regimens that enhance food safety according to the best available technical research. As Theno demonstrated in the aftermath of the Jack-in-the-Box crisis, the implementation of HACCP procedures in conjunction with microbial testing can dramatically enhance the safety and quality of the meat processed in a given facility, even a large, industrial facility, all for mere pennies on the pound.

<sup>323</sup> Arthur Allen, *The Unusual Suspects*, Washington Post: Health and Science, 8 December 2009, pp. E1 and E6 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/04/AR2009120403633.html>].

<sup>324</sup> Marion Nestle, *Safe Food: Bacteria, Biotechnology, and Bioterrorism*, Berkeley, CA: University of California Press (2003), pp. 71; 96.

USDA food safety authority.<sup>325</sup> During the rulemaking process, the proposal underwent dramatic revision; by the time negotiations with the meatpacking industry and members of Congress were complete, the Pathogen Reduction Program was, like the 1906 Federal Meat Inspection Act, a hollow shell of the initial proposal. The end result was “HACCP without pathogen reduction,” a regulatory approach that would placate the public but fail to enhance food safety.<sup>326</sup>

The Pathogen Reduction Program that emerged shifted food safety tasks *away from* federal authorities and onto company employees, much as Improved Processing Inspection under the Reagan and Senior Bush administrations had done a decade earlier; HACCP plans would be developed, administered, and evaluated by facility employees *rather than* approved and overseen by federal inspectors. Moreover, processors would *not* be required to test for *E. coli* 0157:H7; instead, facilities could elect to test for a wide range of pathogens to determine levels of fecal contamination. And, according to the revised policy, those test results were to be used evaluate the success of preventative measures *only*; processors did not have to release test results to government officials and, with the exception of ground beef contaminated by *E. coli* 0157:H7, meat *that had been found to be contaminated during the process of microbial testing* could still be sold to the public.

But the meat processing industry did not settle for a weaker Pathogen Reduction program. Instead, it went to federal court to force the USDA to adhere to the *original intent* of the 1906 Federal Meat Inspection Act: to protect the public against sick animals and unsanitary conditions *rather than* bacterial pathogens. Although the USDA had not secured the right to require pathogen testing for *E. coli* 0157:H7, it had been permitted required mandatory testing for *Salmonella*; no more than 7.5% of the sampled product could contain *Salmonella*. When Supreme Beef’s ground beef exceeded this 7.5% benchmark for the third time, the USDA withdrew its inspectors and forced the plant to close. Supreme Beef sued the USDA asserting that asserting that (1) the USDA “did not have the legal authority to regulate *Salmonella*” and that (2) “because cooking kills *Salmonella*, [the] bacteria do not threaten public safety and

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<sup>325</sup>*Ibid*, pp. 91.

<sup>326</sup>*Ibid*, pp. 91.

cannot be considered adulterants.”<sup>327</sup> The USDA countered claiming that Supreme Beef’s repeated failure to meet *Salmonella* performance standards proved that the ground beef from its facility was processed under insanitary conditions in violation of the 1906 and 1967 statutes (as amended).

Supreme Beef requested an injunction that would prohibit the USDA from closing its facility. In *Supreme Beef v. USDA*, a federal district court granted the injunction and, furthermore, ruled that the *Salmonella* regulations were beyond the authority granted the Secretary of the USDA by the Federal Meat Inspection Act. In December 2001, the 5<sup>th</sup> Circuit Court of Appeals ruled that *Salmonella* could not be classified as an adulterant because it is naturally present in raw meat and poultry products. Referencing *APHA v. Butz* as precedent, *Supreme Beef v. USDA* “essentially overturned the pathogen reduction portion of HACCP.”<sup>328</sup> The USDA was thus legally obligated to certify *Salmonella* contaminated beef as “USDA Inspected and Passed” so that it could be sold to consumers. Although the USDA could use pathogen test results to assess the effectiveness of a plant’s food safety plan and as the basis for more stringent inspection and oversight, it could not use them as the basis for plant closure or product seizure. Thus the industry: (1) secured the right to develop and implement HACCP plans without federal oversight; (2) prevented pathogen testing for *E. coli* 0157:H7, and (3) barred the USDA from classifying *Salmonella* as an adulterant for purposes of inspection and certification.

### Opposition from Within

But industry officials were not the only ones that opposed the Pathogen Reduction Program. By 1997, USDA inspectors, claiming that the new system undermined their authority to promote food safety by forcing them to examine paper rather than animals, voiced strong opposition. Although meat inspectors recognized that traditional inspection methods cannot adequately prevent foodborne illnesses, they insisted that it “worked well at accomplishing what

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<sup>327</sup> *Ibid*, pp. 104.

<sup>328</sup> *Ibid*, pp. 106.

it was designed to achieve—cleaner food produced in more sanitary conditions.<sup>329</sup> Admitting that HACCP’s “preventative nature may be its most significant design achievement,” they warned that HACCP systems are only useful if they are implemented properly; in the absence of an industry-wide commitment to food safety, HACCP requirements were largely ceremonial and, as later outbreaks would demonstrate, disastrously ineffective.<sup>330</sup> They thus argued that it was better for federal inspectors to continue with traditional methods rather than to abdicate their food safety responsibilities to industry personnel.

Concerned inspectors, alongside their union and the Community Nutrition Institute, thus filed a motion in federal district court to enjoin the new inspection procedures. While a lower court supported FSIS and the HACCP-Based Inspection Models Project (HIMP), the U.S. Circuit Court of Appeals for the District of Columbia in *American Federation of Government Employees, AFL-CIO, et al. v. Daniel R. Glickman, Secretary of the U.S. Department of Agriculture, et al.* overturned the district court ruling in 2002. Stating that HIMP’s practice of freeing inspectors for their traditional carcass inspections violated U.S. law, the Appellate Court ruled that federal meat inspectors could not fulfill their statutory duty to inspect meat and poultry products by watching company personnel perform food safety tasks. As Judge Randolph said, “[one] might as well say that umpires are pitchers because they carefully watch others throw baseballs.”<sup>331</sup> Therefore, the National Joint Council of Food Inspection Locals secured the right for federal inspectors to personally inspect each animal before, during, and after slaughter. In doing so, however, they legally reasserted the early 20<sup>th</sup> century food safety authority of the USDA; its attempt to modernize its mandate was once again undermined.

### “Tweaking” the Legislative Mandate: Pathogens and the Problem with Purity

Although the USDA under the Clinton administration tried to reform the USDA’s food safety authority and approach in the wake of the Jack-in-the-Box crisis, what limited progress

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<sup>329</sup> Neal D. Fortin, *Food Regulation: Law, Science, Policy, and Practice*, New York, NY: Wiley (2009), pp. 241.

<sup>330</sup> *Ibid.*, pp. 241.

<sup>331</sup> *American Federation of Government Employees, AFL-CIO, et al. Appellants v. Daniel R. Glickman, Secretary of the U.S. Department of Agriculture, et al., Appellees*, U.S. Circuit Court of Appeals for the District of Columbia, June 30, 2000.

that remained after the Pathogen Reduction Plan was diluted, first, during the rulemaking process and, later, by lawsuits, was then undermined by the newly elected George W. Bush administration that took office in 2001. Like Republican presidents before him, Bush appointed over a half-dozen meat industry executives to high-ranking positions in the USDA. For example, Charles Lambert, formerly from the National Cattleman's Beef Association, became the deputy undersecretary for the USDA's marketing and regulatory programs; his work prevented mandatory *and voluntary* testing for Mad Cow Disease within the United States. Throughout the eight years of the Bush administration, food safety analysts report, the USDA backed away from pathogen testing all together. Outbreaks of foodborne illnesses associated with meat and poultry products continued, sickening thousands and killing hundreds. By the late 2000's, the Bush administration was accused of knowingly and negligently eroding the food safety authority and capacity of the USDA (and FDA) in ways that undermined public health. By the end of President Bush's tenure in office, public demands for a more modern, stringent food safety regulatory regime had come to the forefront (see Chapters 8 and 9).

But history indicates that a new food safety regulatory approach cannot originate within the USDA. Instead, the agency needs a new statutory mandate. Grounded in the 1906 Federal Meat Inspection Act (as amended), the USDA's current food safety mandate relies heavily on early 20<sup>th</sup> century inspection techniques rather than process-based controls or pathogen testing. Outbreaks of foodborne illnesses have repeatedly demonstrated that inspections alone are inadequate and ineffective in the face of 21<sup>st</sup> century food safety challenges. Moreover, the USDA lacks any practical form of recourse: it cannot stop production lines *if a food safety hazard occurs in front of its inspectors*, it cannot prevent the distribution of contaminated meat or poultry products, it cannot initiate a mandatory recall or force food processing firms to do so, and it cannot remove its inspectors from a facility on the basis of microbial testing. Without the power to hold meat and poultry processors to accountable for the safety of the foods they produce, the USDA cannot effectively promote food safety.

Thus the USDA cannot rely upon administrative efforts to incorporate modern food safety challenges into a century-old framework. To protect the public against microbial contamination of meat and poultry products, the USDA needs a new mandate. This mandate must go beyond early 20<sup>th</sup> century notions of "adulteration" and "cleanliness," beyond consumer

education, and beyond traditional carcass-by-carcass inspections. Because the problem is not that food producers, processors, and regulators *cannot* reduce the risks of microbial contamination of meat and poultry products—the problem is that food producers and processors have *chosen* to prioritize *profits over food safety* and regulators have no way to *mandate* that they do otherwise. The challenge is to convince meat and poultry producers and processors that it is in their best interest to support a new, more stringent federal regulatory regime.

Historically, the meat and poultry industry have opposed every attempt to impose top-down standards upon its operations. Federal legislation emerged in 1906 only after the public scandal associated with *The Jungle* and even then represented a weak compromise between regulatory advocates and industry officials that gave oversight authority to a federal agency that enjoyed close industry ties and was responsible for the *marketing* of meat products, a goal that many would argue conflicts with its food safety mandate. And today, the meat industry continues to oppose the Food Safety Modernization Act of 2009 despite the fact that the proposed legislation *in no way alters the regulatory mandate of the USDA* (see Chapter 9). To transform the U.S. food safety regulatory regime for meat and poultry, therefore, federal officials and legislators must find a way either to *overcome* or to *co-opt* a hostile and politically powerful industry. And it must do so in a way that allows regulators to address 21<sup>st</sup> century problems armed with a 21<sup>st</sup> century legislative mandate.

## CHAPTER 7

### A BOTTOM-UP REGULATORY REGIME:

#### FRESH PRODUCE CONTAMINATION AND THE GOOD AGRICULTURAL PRODUCTS (GAPs) INITIATIVE

Unlike top-down forms of centralized coordination, bottom-up regulatory regimes rely upon voluntary compliance, market dynamics, and third party certification (TPC) to regulate economic activity and reduce the risks of market failures. Although only recently applied to food safety, voluntary compliance and third party certification have a long history in the United States beginning, one might argue, with kosher food certification. According to Jewish religious tradition, kosher foods must be produced according to specific methods of processing and handling, and must adhere to explicit compositional standards.<sup>332</sup> As supermarkets became the largest and most common food merchandisers, consumers determined to adhere to kosher standards required detailed information about food products that far exceeded government labeling requirements or provisions. Thus emerged private, religiously accredited certification systems designed to ensure that consumers could trust that certified-Kosher products satisfied necessary compositional and processing standards. The Orthodox Union (OU) is the largest and best known third-party certifier of kosher products. Employees for the OU examine the food inputs, the production processes, and the packing of a variety of food products from beef to butter and from natural cheeses to breakfast cereals to ensure that they fulfill kosher requirements.<sup>333</sup> Products that pass designated by the OU symbol (Ⓞ), a message to consumers that the product is “safe” to consume. As this non-profit’s website explains, “for over 80 years the Orthodox Union has maintained the highest standard of kosher certification...today, the OU

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<sup>332</sup> Kosher standards are not food *safety* standards. Nevertheless, a study by Mintel demonstrated that consumers who bought kosher products cited “food quality,” “general healthfulness,” and “food safety” as their top reasons for buying kosher. “I follow kosher religious rules” came in sixth in the survey. [Nina Shen Rastogi, *Kosher and Halal Meat is No Safer or Better for the Environment than Other Meat*, Washington Post, 2 February 2010 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2010/02/01/AR2010020103209.html>].

<sup>333</sup> Kosher guidelines are exacting, precise, and comprehensive. For example, Kosher standards prohibit adherents from eating insects. Many popular food dyes (legally labeled only as “natural and/or artificial colors or by their patent names), however, contain insect parts. The OU examines each product *as well as each component or additive* to make ensure that they meet Kosher requirements.

supervises more than 400,000 products, making it the world's most recognized and most trusted kosher symbol.”<sup>334</sup>

In recent years, as Muslims have comprised a larger part of the U.S. population, similar organizations have emerged to certify foods as “halal”<sup>335</sup> or in adherence to Muslim dietary requirements (including the prohibition of alcohol, even as a food additive or flavor carrier).<sup>336</sup> Organizations such as the Islamic Food and Nutrition Council of America subject food products to rigorous testing and analysis to determine their status under Islamic law and recommend that consumers avoid foods that are “questionable” or uncertified as they may not satisfy halal standards. Food producing firms seeking to attract Muslim consumers submit to product testing and, when necessary, often alter their production processes to guarantee that their outputs can be certified “halal.” As a consequence, the halal food market in the United States has grown into a multi-billion dollar industry.

Though neither kosher nor halal certification systems represent a food *safety* regulatory regime (as their concerns are about *religious* standards rather than food *safety*), the ability of private, third-party institutions, such as the Orthodox Union, to provide consumers with accurate information, to regulate food according to a prescribed set of standards, and to establish trust in an industrialized food production system confirms that food regulation need not *necessarily* derive from top-down “command and control” regulatory structures. Kosher and halal certification systems fulfill an important governance function, obviously for religiously-motivated consumers, but also for food producers. Not only do TPCs allow food firms to sell their goods in niche markets without having the “in house” expertise necessary to determine

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<sup>334</sup> OU Kosher.org, *Welcome*, accessed 14 December 2009 [available online: <http://www.oukosher.org/>].

<sup>335</sup> According to Islamic Dietary Laws, there are three categories of food for Muslims: *halal*, *haram*, and *mushbooh*. Halal describes foods that are lawful for Muslims to consume, according to Islamic dietary laws found in the Quran, Hadith (sayings of the prophet Muhammad) and in the fiqh (jurisprudence) of the Muslim jurists. All foods are halal except for those that are specifically haram or mushbooh. Haram foods and food products, such as pork or alcohol, are unlawful and prohibited for Muslims. Mushbooh foods are questionable (see F351) and should, therefore, be avoided.

<sup>336</sup> A 2008 controversy focused on the use of alcohol as a flavor carrier in Doritos™. Assumed to meet Islamic dietary standards, the chips were sold in halal grocery stores. The discovery that they were, in fact, haram caused an uproar in the Muslim community. It is important to note, however, that the chips were not *certified* halal by a TPC; they were *assumed* to be “safe” by merchandisers and consumers whereas they should have been considered mushbooh. The breakdown, therefore, was not in the TPC system; in fact, had the chips been subject to third-party examination, the presence of alcohol would likely have been noted and the controversy averted.

which of their food outputs meet Kosher or halal requirements, it is the TPC, rather than the food producer that is held accountable for false advertising if a certified food is found to be in violation prescribed dictates.

Third-party food certification in the United States extends beyond religious mandates and often builds upon public initiatives designed to reduce risks of market failures relative to specific food safety or quality concerns. For example, widespread concerns about misbranding<sup>337</sup> and “organic” food production led to the establishment of the National Organic Program (NOP) in 2002.<sup>338</sup> In the interest of consumer protection, the NOP established truth and transparency in “organic food” advertising as well as market consistency. This legislation and its accompanying administrative regulations outline the production, handling, and labeling standards under which organic agricultural products are produced and sold, as well as a verification system that certifies organic agricultural producers, processors, and products and permits the accreditation of private certifying agencies.<sup>339</sup> Food producers or processors who market their products using the USDA Organic Seal must be certified by a public institution, such as the USDA Organic Growers Program or a state counterpart, or by a *publically accredited private agency*.<sup>340</sup> To fulfill the

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<sup>337</sup> Before the implementation of the National Organic Program (NOP) the designation “organic” had no established meaning. Thus consumers had no way of knowing, therefore, what differentiated “organic” products from their “non-organic” counterparts.

<sup>338</sup> Organic food sales in the United States reached \$14 billion in 2005 and continue to grow at a rate of approximately 20% per year. Consumers cite the avoidance of pesticides, freshness, and health benefits as their primary rationales for organic food purchases. The increasing tendency of food producers and distributors to market foods as “organic,” the public health perceptions associated with organic diets, and the lack of specific standards for “organic” foods prompted Congress to pass the Organic Foods Production Act of 1990. This legislation required the USDA to develop national standards for organically produced agricultural products to assure consumers that agricultural products marketed as organic meet consistent, uniform standards. In 2002 the Department of Agriculture implemented the National Organic Program.

<sup>339</sup> Both the NOP and GAPs initiative require that certifiers be accredited by the government. This is a vital component of a food safety regime because in the absence of this accountability mechanism, TPCs are vulnerable to guile and opportunism. For example, in the recent foodborne illness outbreak associated with peanut butter, the producer was aware of the contamination and went to three separate certifying agencies until it found one willing to certify what was undoubtedly an unsafe product. As explained in Chapter 5 private, certifiers are hired by producers and thus walk a fine line; if they are too lenient, they threaten the entire regulatory framework but if they are too strict they lose customers and go out of business. Not only must producers be held accountable, therefore, so also must certifiers be subject to accountability mechanisms.

<sup>340</sup> Several private agencies, such as Primus Labs, are permitted to certify growers, producers, and processors under the NOP system. Those private agencies, however, must be accredited and subject to reaccreditation by the USDA. In the NOP, therefore, the USDA “watches the watchers” to ensure that private certifying agencies (1) hold producers and processors accountable to NOP standards and (2) are themselves accountable to NOP requirements.

certification requirements, producers must keep meticulous records of their production processes, supply those records to the inspectors who conduct on-site investigations, and alter their production or processing systems as necessary. Once a producer's compliance with government standards for organic foods is documented, that producer may use the USDA Organic seal (  ) to market its products.

However, food producers and processors are not the only parties subject to transparency requirements according to the dictates of the NOP. Private certification agencies (TPCs) are also required keep records of their activities and submit to government review and inspection; only accredited certifiers may contract with growers or producers. Although concerns about the effectiveness of government oversight persist, this requirement fosters trust organic food markets by eliminating a fundamental risk of third-party certification—the risk that private, particularly profit-seeking, certifiers will fail to hold producers and processors to appropriate standards and thereby undermine the “organic” designation. Thus the NOP attaches what began as a marketing technique to a series of benchmarks and standards<sup>341</sup> in ways that allow certified producers to operate within organic markets *and* provide consumers with reliable information so that they can make more informed market choices.<sup>342</sup>

But the organic program is not a food safety regulatory regime. It is not designed to guarantee the *safety* of organic foods but instead dictates the *methods* by and through which they must be produced or processed. The NOP did, however, serve as a model for private, bottom-up food safety governance in the United States. In the wake of rising concerns about the safety of fresh produce, the FDA launched the Good Agricultural Practices (GAPs) Initiative, a program

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<sup>341</sup> Specific standards have been developed and are updated and implemented by the United States Department of Agriculture's Agricultural Marketing System in cooperation with the fifteen-member National Organic Standards Board, which includes representatives from farmers/growers, handlers/processors, retailers, consumers/public interest groups, environmentalists, scientists, and certifying agents. Together the rules and regulations regarding organic food production, labeling, and certification comprise the National Organic Standards. These standards regulate crop production, wild crop harvesting, livestock management, and the processing and handling of organic foods; in addition, they address the methods, practices, and substances used in production and handling of crops, livestock, and processed food products. The requirements thus apply to the way that the food is *created* rather than its composition or safety.

<sup>342</sup> Growers and producers that report less than \$5000 per year in organic food sales are not required to have their products certified by the USDA; they may label their products as “organic” but their products may not use the “USDA Organic” seal. This may be seen as a “loophole” in the NOP framework. Nevertheless, the NOP establishes a civil penalty of \$10,000 per offense for the knowing sale or labeling as organic a product that does not meet the NOP regulations; there are no criminal consequences.

designed to enhance the safety of fresh fruits and vegetables that stands as one of the country's only *public food safety* systems attached to *private* third party certification and *voluntary* compliance with food safety *guidelines* (rather than *regulations*).

### Fresh Produce Crises in the Pre-GAPs Era

According to the Centers for Disease Control and Prevention (CDC), up to 12% of foodborne illness outbreaks reported in the 1990s were linked to fresh produce. Asparagus, broccoli, cauliflower, celery, lettuce, pepper, spinach, green onions, mushrooms, parsley, potatoes, cabbage, cilantro, chicory, eggplant, radishes, tomatoes, artichokes, beet leaves, cantaloupe, chilies, endive, fennel, strawberries, watermelon, basil, raspberries, and blackberries were each associated with outbreaks of a foodborne illness during that decade.<sup>343</sup> *Cryptosporidium*, *Cyclospora*, *Giardia*, *Toxoplasma*, Hepatitis A and E, norovirus, *Salmonella*, *Shigella*, *Staphylococcus*, *Vibrio cholerae*, *Listeria monocytogenes*, *E. coli* 0157:H7, *Clostridium botulinum*, *Campylobacter jejuni*, *Bacillus cereus*, and *Aeromonas hydrophilla* associated with soil and water contamination, animal and human fecal contamination, and improper sanitation and handling practices contributed to thousands of illnesses, hundreds of deaths, and millions of dollars in economic losses.<sup>344</sup>

In most of these cases, the market failure was not a consequence of guile or opportunism, the malevolent side effects of business decisions or the concentrated power of large agribusinesses; instead the failure can be understood as a knowledge gap between food scientists and food producers and processors. For example, in 1996 an outbreak of *E. coli* 0157:H7 was linked to contaminated mesclun lettuce mix that “was grown on a farm located near a cattle operation and a free range chicken farm...the outbreak was traced back to poor agricultural

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<sup>343</sup> Amy Simone, *Principles and Practices of Food Safety for Vegetable Production in Florida*, University of Florida: IFAS Extension [available online: <http://edis.ifas.ufl.edu/cv288>].

<sup>344</sup> The CDC reports that *Salmonella* and *E. coli* 0157:H7 are the most common foodborne pathogens associated with fresh produce outbreaks. This makes sense given that both agents live in the intestinal systems of animals (including chickens, birds, and cows) and, more importantly, in their manure. Run-off, contaminated water during planting, growing, irrigation, harvesting, or processing, direct contamination, and fertilizing practices can bring untreated animal manure in contact with fresh produce thus increasing the risk of *Salmonella* or *E. coli* contamination.

practices and improper handling of the lettuce after harvest.”<sup>345</sup> As researchers at Cornell University observe, this outbreak “could have been prevented with the use of good agricultural and management practices.”<sup>346</sup> Thus the problem was not that producers and processors *willfully* or even *knowingly* failed to follow Good Agricultural Practices; the problem was that most producers or processors did not understand the technical particularities associated with fresh produce safety and thus *could* not implement the necessary safety protocols or mechanisms.

A food safety regulatory regime to enhance the safety of fresh produce, therefore, had to develop a way to provide growers, handlers, and processors with the information they needed to prevent outbreaks; it could not merely establish benchmarks for pathogen levels or institute top-down systems of surveillance and traceability. And given the particular challenges associated with fresh produce safety, the creation of such a system would stretch the capacities and resources of the U.S. Food and Drug Administration. As Robert F. Stovicek, President and Chairman of the Primus Group, Inc., one of the country’s largest private third-party certifying agencies, reported in his testimony before the House Horticulture and Organic Agriculture Subcommittee, “implementing a food safety program is [a] major expenditure [with] actual audit costs [as] a fraction of the food safety investment.”<sup>347</sup> “As the federal agency principally responsible for regulating the safety of the majority of the food supply, including produce,” therefore, the “Food and Drug Administration (FDA) [was] prepared to lead the effort to achieve [a] reduction” in outbreaks of foodborne illnesses associated with fresh fruits and vegetables.<sup>348</sup> “Realistically, however,” the FDA recognized that this task would “require a collaborative effort by the FDA, its federal food safety partners such as the CDC and the U.S. Department of Agriculture (USDA), FDA’s counterparts in foreign governments, state and local agencies, the

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<sup>345</sup> Anusuya Rangarajan, Elizabeth A. Bihn, Robert B. Gravani, Donna L. Scott, and Marvin P. Pritts, *Food Safety Begins on the Farm, A Grower’s Guide: Good Agricultural Practices for Fresh Fruits and Vegetables*, GAPsNET, Cornell University Department of Food Science [available online: <http://www.gaps.cornell.edu/Educationalmaterials/Samples/FSBFEngLOW.pdf>].

<sup>346</sup> *Ibid.*

<sup>347</sup> Robert F. Stovicek, *Testimony Before Congress*, House Subcommittee on Horticulture and Organic Agriculture, 14 May 2009 [available online: <http://agriculture.house.gov/testimony/111/h051409/Stovicek.doc>].

<sup>348</sup> Food and Drug Administration, *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption*, U.S. Department of Health and Human Services (October 2004) [available online: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/ProduceSafetyActionPlan/ucm129487.htm>].

private sector (including relevant trade associations, academia, and consumers.”<sup>349,350</sup> Understaffed and underfunded, the FDA looked to private bottom-up regulatory alternatives to a public top-down regime. Its efforts would bring researchers, land grant universities, private certifying agencies, federal officials, and industry representatives into the process of enhancing fresh produce safety in the United States.<sup>351</sup>

### *The Food Safety Challenge Presented by Fresh Produce*

Fresh produce has long been considered a necessary component of a healthy diet. And most of the fresh fruits and vegetables consumed in the United States are “wholesome and free of microorganisms that could result in illness under common and sensible handling and food preparation practices.”<sup>352</sup> Moreover, “many fruits and vegetables have natural barriers that minimize the chance that any surface contamination could be transferred to the internal edible portions, up to the point of harvest...these same barriers may also increase the effectiveness of removal of contamination during washing combined with light to vigorous brushing.”<sup>353</sup> However, corruption by physical, chemical, or, more frequently, microbial contaminants can occur at any point along the farm-to-fork chain. During the early 1990s, foodborne illness outbreaks linked to the consumption of imported<sup>354</sup> and domestically produced fresh produce,

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<sup>349</sup> *Ibid.*

<sup>350</sup> Note that producers and processors are conspicuously absent from that list.

<sup>351</sup> Although the FDA has provided the framework for GAP guidelines and training materials, a great deal of the progress made toward the widespread development and implementation of Good Agricultural Practices and toward the reduction of foodborne illness outbreaks associated with fresh produce could not have been accomplished absent the contributions of faculty employed by four major research universities, each of which is also a land grant institution: Cornell University, the University of California-Davis, Virginia Polytechnic Institute and State University, and North Carolina State University. These institutions conduct necessary food safety research, develop and publish training manuals and commodity-specific GAPs protocols, and help growers and processors implement GAPs so that they can become GAPs Certified.

<sup>352</sup> Center for Food Safety and Applied Nutrition, “Good Agricultural Practices: A Self-Audit for Growers and Handlers,” U.S. Department of Health and Human Services: Food and Drug Administration (1998) [available online: <http://ucce.ucdavis.edu/files/filelibrary/5453/4362.pdf>].

<sup>353</sup> *Ibid.*

<sup>354</sup> Consumers and public officials often focus their attention on *imported* fresh produce, assuming that fresh produce produced outside of the United States is more likely to be contaminated in ways that might cause a foodborne illness. The Centers for Disease Control and Prevention, however, report that more than 75% of fresh fruit and vegetable outbreaks in the United States are traced back to domestically grown produce. [Anusuya Rangarajan, Elizabeth A. Bihn, Robert B. Gravani, Donna L. Scott, and Marvin P. Pritts, *Food Safety Begins on the*

positive detection of pathogens in randomly sampled fresh produce, and research documenting the potential for internalization of pathogens during post-harvest handling contributed to consumer and industry demands for more stringent food safety standards for fresh produce. As Stovicek emphasized, “few industries have gone through as radical a change as the fresh produce industry in the past 10 to 15 years...fresh produce’s image as the most wholesome of the food categories has evolved to one that is repeatedly associated with disease outbreaks.”<sup>355</sup> As the FDA explains, “as the fresh-cut produce market continues to grow, the processors of such produce are faced with the challenge of processing an increasing variety and volume of products in a manner that ensures the safety of this produce...from 1996 to 2006, seventy-two foodborne illness outbreaks were associated with the consumption of fresh produce...of these produce related outbreaks, 25 percent (18 outbreaks) implicated fresh-cut produce.”<sup>356</sup> For these reasons, consumer, industry, Congressional, and regulatory focus shifted from pathogen reduction in the meat industry to fresh produce safety.

From a food science perspective, the safety of fresh fruits and vegetables is particularly hard to guarantee. “Grown in a natural environment” and “often consumed raw without any type of intervention that would reduce, control, or eliminate pathogens prior to consumption,” the Centers for Disease Control and Prevention report that fresh produce is linked with at least 12% of the foodborne-outbreak-associated illnesses identified in the United States each year.<sup>357</sup> Fresh produce can be contaminated at numerous points along the farm to fork chain from growing to harvesting to processing to transportation and distribution. Crop water, soil quality, irrigation design, well construction, topographical features, run-off from nearby fields (animal fecal contamination), the application of manure or municipal biosolids as fertilizer, composting

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*Farm, A Grower’s Guide: Good Agricultural Practices for Fresh Fruits and Vegetables*, GAPsNET, Cornell University Department of Food Science [available online: <http://www.gaps.cornell.edu/Educationalmaterials/Samples/FSBFEngLOW.pdf>].

<sup>355</sup> Robert F. Stovicek, *Testimony Before Congress*, House Subcommittee on Horticulture and Organic Agriculture, 14 May 2009 [available online: <http://agriculture.house.gov/testimony/111/h051409/Stovicek.doc>].

<sup>356</sup> Center for Food Safety and Applied Nutrition, “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,” U.S. Department of Health and Human Services: Food and Drug Administration (February 2008) [available online: <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm#ch1>].

<sup>357</sup> *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption*. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition. Available Online: <http://www.cfsan.fda.gov/~dms/prodpla2.html>.

practices, worker health and hygiene, the availability and adequacy of field facilities, pest and animal control, the design of the packing and processing facilities, wash water and methods, transportation cleanliness, equipment sanitation, and post-harvest temperature and storage contribute to the safety and quality of the final product. Fresh-cut produce, that is, fruits and vegetables that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming prior to being packaged for use by the consumer, present additional risks. As the FDA explains, “processing fresh produce into fresh-cut produce [such as shredded lettuce, sliced tomatoes, salad mixes, peeled baby carrots, broccoli florets, cauliflower florets, cut celery stalks, shredded cabbage, cut melon, sliced pineapple, or sectioned citrus]increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce...the release of plant cellular fluids provides a nutritive medium in which pathogens, if present, can survive and grow.”<sup>358</sup>

But, as food scientists discovered, produce does not have to be cut, shredded, or otherwise processed to present a food safety risk. A close investigation of whole, intact produce gave researchers insight into the limitations surface decontamination strategies (including the use of chemical sanitizers). They discovered that bacteria can enter fresh produce even when the flesh remains unbroken. First, pathogens found in contaminated soil or water can transfer to “internal locations in plant tissue and [thus be] protected from the action of sanitizing agents by virtue of its inaccessibility...experiments demonstrate[d] that *E. coli* O157:H7 [for example] can enter [a] lettuce plant through the root system and migrate throughout the edible portion of the plant.”<sup>359</sup> Moreover, fresh fruits and vegetables can become internally contaminated during the cleaning process. Research found that when warm produce is placed in water that is more than ten degrees cooler than its flesh, it can create negative pressure and pull contaminated water from the dump tank directly into its flesh through the stem scar. As a consequence, the inside of the

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<sup>358</sup> Center for Food Safety and Applied Nutrition, “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,” U.S. Department of Health and Human Services: Food and Drug administration (February 2008) [available online: <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm#ch1>].

<sup>359</sup> Ethan B. Solomon, Sima Yaron, and Karl R. Matthews, Transmission of *Escherichia coli* O157:H7 from Contaminated Manure and Irrigation Water to Lettuce Plant Tissue and Its Subsequent Internalization, Applied Environmental Microbiology, Volume 68, Number 1 (2002) [abstract available online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC126537/>].

fruit becomes contaminated despite the fact that the fruit or vegetable remains undamaged. The fact that pathogens infiltrate the fruit or vegetable via this process demonstrates that surface decontamination is not sufficient to completely ensure the safety of fresh produce; surface sanitation does not kill pathogens that have been internalized by a fruit or vegetable. To reduce the risks of pathogen internalization, producers must implement Good Agricultural Practices for fresh fruits and vegetables.

Fresh produce safety is thus a complex problematic. From growing to handling to transportation to storage to processing to packaging, food firms must rely upon care, attention, and planning to prevent microbial contamination. But this requires the application of a great deal of specialized, technical expertise. Moreover, “fresh produce operations are complex organizations consisting of numerous independent firms...any brand may have dozens or even thousands of growers...commonly, the brand owner will subcontract with an independent harvesting company to harvest, and then with another independent firm to cool and provide cold storage...last, an independent trucking company is hired to transport the fresh produce to the retail or food service distribution center...each of these operations has the potential to contribute to an adverse event...finding and acting to prevent a contamination in such a complex system is a challenge.”<sup>360</sup> To enhance the safety of fresh produce, therefore, regulators had to find a way to develop Good Agricultural Practices based upon the best available technical research, to communicate that information to growers and processors, and to establish an accountability framework that would include oversight, inspections, and traceability. And they had to do all of this without overstepping the legal mandate established by the 1906 Pure Food and Drug Act and the 1938 Food, Drug, and Cosmetics Act (as amended). For, as the GAO observed, existing food safety statutes “do not specifically authorize the FDA or USDA to require food processors to implement any type of security measures designed to prevent the intentional contamination of the foods they produce.”<sup>361</sup> Although the FD&CA provides the FDA “with tools to adopt measures to control insanitary preparation, packing, and holding conditions that could lead to unsafe food; detect contamination of food; and control contaminated food,” counsel in the

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<sup>360</sup> Robert F. Stovicek, *Testimony Before Congress*, House Subcommittee on Horticulture and Organic Agriculture, 14 May 2009 [available online: <http://agriculture.house.gov/testimony/111/h051409/Stovicek.doc>].

<sup>361</sup> *Food-Processing Security: Voluntary Efforts are Under Way, But Federal Agencies Cannot Fully Assess their Implementation.*” GAO, (2003) [Available Online: <http://www.gao.gov/new.items/d03342.pdf>].

Department of Health and Human Service's Office of the Assistant Secretary for Legislation advised that the "FDA's food safety authorities do not extend to the regulation of physical facility [safety] measures."<sup>362</sup> Thus the FDA and USDA developed a systematic, process-based approach to fresh produce safety that incorporated pest management, soil management, water management, and sanitation/hygiene management based on voluntary, non-binding guidelines rather than mandatory government regulations.

### *The GAPs Initiative: Structure, Dynamics, and Implementation*

In October 1997, President Clinton announced the creation of an "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables." As part of this initiative, "the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fruits and vegetables."<sup>363</sup> In response to this directive, the FDA and USDA issued *Guidance for Industry—Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. This document "addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form...this voluntary, science-based guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce."<sup>364</sup>

The GAPs Initiative represents a semi-public, bottom-up, market-oriented regulatory system in which producers and processors conform with federal guidance on a voluntary basis and, in doing so, secure the right to market their produce as "GAPs Certified." It is designed "to minimize the incidence of foodborne illness associated with the consumption of fresh produce"

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<sup>362</sup> *Ibid.*

<sup>363</sup> Center for Food Safety and Applied Nutrition, "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables," U.S. Department of Health and Human Services: Food and Drug administration (February 2008) [available online: <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm#ch1>].

<sup>364</sup> *Ibid.*

by preventing contamination, minimizing the public health impact when contamination of fresh produce inadvertently occurs, improving communication with producers, preparers, and consumers about fresh produce, and facilitating research relevant to fresh produce.<sup>365</sup> Although compliance is not mandated by the federal government (as it is in the case of the USDA Pathogen Reduction Program for the meat industry), fresh produce growers are increasingly choosing to participate in the USDA GAPs Certified Growers Program. That is to say, they are electing to implement Good Agricultural Practices; to document their irrigation, fertilization, planting, harvesting, and other production practices; and to submit to inspections so that their products may be designated “GAPs Certified.”

Good Agricultural Practices for fresh produce “are analogous to hazard analysis critical control point (HACCP) systems analysis for processed foodstuff...[however] while HACCP as a quality control/assurance system has long been in place for processed items, no similar system existed for fresh produce [until the] FDA’s publication of the Guide instituted a marked change in how fresh commodities moved in commerce.”<sup>366</sup> Willing to collaborate with agents at all parts of the farm-to-fork chain and maintaining that “each entity involved in the producing, packing, processing, transporting, distributing, or preparing fresh produce has a responsibility to conduct its activities so as to reduce, control, or eliminate microbial contamination of produce,” the FDA’s approach is designed to “ensure maximum progress toward the goal of reducing the incidence of foodborne illness associated with the consumption of fresh produce” and to “target microbial food safety hazards (such as bacteria, viruses, and parasites) in or on produce consumed in the U.S., whether produced in the U.S. or abroad.”<sup>367</sup>

Thus the *Produce and Imported Safety Initiative* represents the single most aggressive program dedicated to the safety of fresh produce in U.S. history. But Good Agricultural Practices were established as *voluntary guidelines* rather than as *binding standards*; while GAPs represent the FDA’s official regulatory recommendations regarding fresh produce safety, they are not enforceable upon producers or distributors of fresh fruits and vegetables. This regulatory

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<sup>365</sup> *Ibid.*

<sup>366</sup> Dennis J. Osborne, et. al., *Gaining Producer Buy-In for Food Safety and Security in the United States*, HortTechnology, October-December 2006, 16(4), pg. 563-565.

<sup>367</sup> *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption*. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition. Available Online: <http://www.cfsan.fda.gov/~dms/prodpla2.html>.

emphasis on *guidance* and *collaboration* as opposed to *enforcement* and *public mandates* indicates that the FDA is more interested in the regulatory “carrot” than the authoritarian “stick” relative to fresh produce safety; rather than burden growers with binding requirements and oppressive oversight, the FDA and its public and private sector collaborators, including state agencies, land-grant universities, advocacy groups, and food firms, have endeavored educate growers on the importance of Good Agricultural Practices and to thereby encourage them to become GAPs Certified.

The GAPs initiative requires that growers develop their own food safety plans based upon expert advice. But producers may become GAPs Certified must submit to external, third-party review, either by public officials from the USDA or a state agency or by private, third-party certifiers.<sup>368</sup> The certification process verifies that food safety practices implemented on the farm minimize microbial contamination in the production of fresh fruits and vegetables. A GAPs audit includes General Questions, Farm Review, and Field Post-Harvest Review; “the General Questions are constructed to verify the implementation of a basic food safety program...the Farm Review questions verify that hazards associated with land use and water are mitigated, and the Field Harvest and Field Packing questions verify the implementation of precautions and practices that mitigate microbial contamination during harvest and field packing...GAP certification audits are conducted during harvest when harvest crews are operating.”<sup>369</sup> A Good Handling Practices (GHP) Certification verifies that practices in the handling and packing operations minimize microbial contamination in fresh fruits and vegetables. A GHP audit verifies “compliance with four sections of the USDA Federal/State Audit Checklist: General Questions, House Packing Facility, Storage and Transportation and Traceback...the General Questions are constructed to verify the implementation of a basic food safety program on the farm...the House Packing Facility questions verify that hazards associated receiving and packing product are mitigated, the Storage and Transportation questions verify the implementation of precautions and practices that mitigate microbial contamination

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<sup>368</sup> If a grower sells to multiple buyers, it may be required to be certified by more than one third-party auditor. For example, some buyers prefer that the certification come from the USDA while others prefer Primus Lab certification. This requirement can create a problem for growers because, if nothing else, it increases the cost of GAPs compliance.

<sup>369</sup> ODA Commodity Inspection Division, *GAP/GHP Certification*, Oregon Department of Agriculture (April 2009) [available online: [http://www.oregon.gov/ODA/CID/ghp\\_gap.shtml](http://www.oregon.gov/ODA/CID/ghp_gap.shtml)].

during storage and transportation, and the Traceback section checks the lot identification system and that product is traceable one step forward and one step back in the food supply chain...GHP audits are performed when the packing operation is running and workers are present.”<sup>370</sup> Private GAPs auditors must themselves submit to external review by government officials. These officials “watch the watchers” in order to ensure that third-party firms hold growers and processors to the high standards required by the GAPs initiative.

Thus as Virginia Tech Extension Specialist Tony Bratsch writes, “GAPs is industry versus regulatory<sup>371</sup> driven...in the produce business, the buzz words growers are starting to hear are ‘third-party inspections’...that is, buyers will not buy product from a commercial producer unless the farm has undergone an independent (and usually annual) inspection for GAPs compliance, and has been certified as a state operation.”<sup>372</sup> Although, “from a buyer’s standpoint, liability and product traceback is [th] greatest concern,” Bratsch warns that “it has been reported that GAPs requirements have been used by buyers to ‘weed out’ smaller, less dependable, and less traceable producers in favor of larger operations—who can afford third-party inspections and deliver consistent quantity and quality.”<sup>373</sup> It appears, therefore, that the GAPs initiative, like regulatory efforts of the past, may disadvantage small, “local” producers while giving large, “corporate” producers a useful competitive advantage. Either way, Bratsch argues that “from the grower’s perspective, [GAPs requirements are] a new hoop to jump through, a learning, time, and dollar commitment to implement [Good Agricultural Practices]” and “a considerable expense to pay for third-party inspection,” particularly because “few pass an audit the first time, meaning they will have to pay for it again until they do.”<sup>374</sup> But as many state departments of agriculture choose to initiate on-farm inspection services at a fraction of the cost required by private firms and extension efforts provide training to growers so that they are better prepared to pass GAPs audits, GAPs may become less of a burden and more than just “a

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<sup>370</sup> *Ibid.*

<sup>371</sup> The GAPs Initiative represents a food safety regulatory regime for fresh produce; Bratsch’s statement substitutes “regulatory” for “public” or “government.”

<sup>372</sup> Tony Bratsch, *GAPs: Common Sense for Fresh Produce Growers*, Virginia Vegetable, Small Fruit and Specialty Crops, (2004) [available online: <http://pubs.ext.vt.edu/2906/2906-1359/2906-1359.html>].

<sup>373</sup> *Ibid.*

<sup>374</sup> *Ibid.*

good common sense program to implement;” it may become a “strong marketing and promotional tool” for small and large producers alike.<sup>375</sup>

Top-Down v. Bottom-Up: Standards v. Guidelines and Regulation v. Voluntary Compliance

Critics of the FDA’s approach to fresh produce safety have focused on the fact that the GAPs framework is comprised of voluntary guidelines rather than binding standards. According to Caroline Smith DeWaal, Food Safety Director of the Center for Science in the Public Interest in Washington, “the FDA could do a better job [at protecting consumers from foodborne illnesses associated with fresh produce] if it [had] ‘proactive authority,’ much like the Agriculture Department, which conducts mandatory inspections at meat facilities every day...the underlying problem is that the FDA doesn’t have the authority to actually go into the farm.”<sup>376</sup> Her sentiment is echoed others who concern themselves with the political, economic, and public health implications of fresh produce safety in the United States including, but not limited to, members of the United States Senate. In a letter to the FDA, the USDA, and the CDC that “urged [these] agencies to convene a multi-agency task force and to develop recommendations on how to address the problem of foodborne illness associated with fresh produce,” Senators Lautenberg, Durbin, Schumer, Clinton, and Menedez asserted that “while the FDA has issued voluntary food safety guidance to the produce industry over the years...recent outbreaks indicate that this voluntary approach may be insufficient to protect public health...we need to do more to reduce the risks of foodborne illness in our country.”<sup>377</sup> The U.S. Government and Accountability Office (GAO) has adopted a similar perspective; in its 2003 report on the effectiveness of food safety guidelines, the GAO reported that “voluntary efforts are underway, but federal agencies cannot fully assess [the] implementation [of non-binding regulations].”<sup>378</sup> Representative of a body of criticism published in journals, public statements, and mass media

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<sup>375</sup> *Ibid.*

<sup>376</sup> Jane Zhang, *Politics & Economics: Food Safety Concerns Extend Beyond California: Regulators Still Struggle to Discover the Cause of Spinach E. coli Outbreak*, The Wall Street Journal (Eastern edition), New York: NY, September 18, 2006, pp. A6.

<sup>377</sup> Lautenberg, et. al, *Letter of December 12, 2006*, Reproduced: *Fresh Produce Food Safety: An Introduction to GAPs*, Robert Williams, Virginia Tech.

<sup>378</sup> *Food-Processing Security: Voluntary Efforts are Under Way, But Federal Agencies Cannot Fully Assess their Implementation.*” GAO, (2003) [Available Online: <http://www.gao.gov/new.items/d03342.pdf>]

reports throughout the past years, these voices express an obvious public doubt in the ability of the current regulatory framework to successfully reduce the risks of foodborne illness outbreaks associated with fresh produce; indeed, it seems that there is no one in the current public administration and policy literature who is willing to speak on behalf of the possibilities represented by the *Produce and Imported Safety Initiative*.

However, these critiques ignore a number of challenges faced by the FDA relative to fresh produce safety. First, fresh produce safety initiatives require that regulators seek to understand and control a wide range of complex dynamics, interactions, and processes; the many vectors for contamination and cross contamination make it difficult for a regulatory agency to enforce what would inevitably be draconian standards. Moreover, fresh produce safety guidelines must necessarily “focus on risk reduction, not risk elimination, since current technologies cannot ensure the elimination of all potential food safety risks associated with fresh produce”<sup>379</sup> In addition, GAPs implementation tends to be costly; binding standards would be cost prohibitive, placing new demands upon growers who are already buckling under the pressures of an increasingly expensive and risky industry. Finally, the FDA faces structural challenges that prevent it from establishing a command-and-control safety regime for fresh produce. First, the resources it would take to create let alone enforce a framework of binding standards are simply unavailable and despite willingness of lawmakers to posture for constituents, demanding that binding standards replace the ineffective voluntary framework currently in place, recent rounds of budget negotiations indicate that funding for the FDA is unlikely to increase no matter how dire the situation appears to be.<sup>380</sup> More importantly, the FDA’s legal mandate does not provide for on-site inspections or mandatory recalls. In the absence of these accountability mechanisms, the FDA would be unable to enforce binding standards; any attempt to do so would violate the legal framework of the U.S. food safety regulatory regime. When one considers these regulatory realities, the FDA’s decision to promote voluntary guidelines rather than binding standards can be framed as responsible governance. However, when one also takes into account the ability of markets and firms to provide economic

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<sup>379</sup> L.R. Howard and A. R. Gonzales, *Food Safety and Produce Operations: What is the Future?*, Hort Sci, 36 (2001), pp. 33-39.

<sup>380</sup> Peter Romeo, *Regulators, Consumer Advocates Lament Gaps in U.S. Food Safety Inspections as Imports Increase*, Nation’s Restaurant News, 42:6, February 11, 2008, pp. 4.

governance beyond the institutional hierarchy represented by the FDA, the potential of the *Produce and Imported Safety Initiative* to successfully advance the cause of fresh produce safety comes becomes apparent.

The ability of growers to become certified by the USDA's 'GAPs Grower Certification Program' or by a third-party auditing process that comes with the designation 'GAPs Certified' creates new "market opportunities for growers of all scale...[allowing] even the smallest scale grower [to] be 'USDA Certified' and to use such designation as a marketing tool."<sup>381</sup> Increasingly, although certification is not required by law, the GAPs "designation [is] increasingly demanded by buyers of fresh produce."<sup>382</sup> These buyers have, in essence, transformed *de jure* voluntary guidelines into *de facto* standards by requiring that growers be GAPs certified in order to sell in fresh produce markets. To protect their brands, reduce the risks of food contamination, meet the demands of due diligence, and satisfy consumer preferences, large purchasers—including agribusinesses, grocery chains, and the U.S. government—are increasingly purchasing produce *only* from "GAPs Certified" growers.<sup>383</sup> The GAPs initiative seeks the reduction of instances of contamination and foodborne illness through the establishment of a process-based system of food safety for fresh produce. Like the NOP, the GAPs Initiative seeks to transform food *production* but, in this case, with a specific safety objective grounded in the most current scientific knowledge available. As with organic foods, the advantages benefit both producers and consumers; consumers that purchase "GAPs Certified" produce know that it has been held to rigorous safety standards while producers can

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<sup>381</sup> Dennis J. Osborne, et. al., *Gaining Producer Buy-In for Food Safety and Security in the United States*, HortTechnology, October-December 2006, 16(4), pp. 563-565.

<sup>382</sup> *Ibid.*, pp. 563-565.

<sup>383</sup> GAPs/GHPs certification gives many growers and processors three of the four advantages that, as Chapter 4 explained, have historically encouraged food firms to support more stringent regulatory structures: (1) GAPs/GHPs certification appears to give large food producers a comparative advantage over their smaller counterparts thus securing market share for established agribusinesses; (2) GAPs/GHPs certification allows U.S. food producers and processors to more effectively sell their products in international markets; (3) the GAPs Initiative has helped to restore consumer confidence in fresh produce, particularly in the wake of highly publicized outbreaks of foodborne illnesses. However, because GAPs/GHPs certification is based upon a system of voluntary, non-binding guidelines, the initiative does not re-direct consumer ire at government officials; it does, however, shift some of the legal responsibility for outbreaks of foodborne illnesses to the certifying agencies, thus giving large distributors a degree of security from the risks of market failures that particularly attach to horizontal purchasing chains. This may explain why many large purchasers have decided to purchase exclusively from GAPs/GHPs certified producers and processors.

market their products more effectively, particularly since consumers are willing to pay a premium for “GAPs Certified” produce. The GAPs Initiative has thus emerged as a private, market-based governance mechanism designed to reduce the risks of market failure in an increasingly horizontal, post-Fordist economic system and can illustrate the relative strengths and weaknesses of bottom-up food safety regulatory regimes.

Firms and government agencies that purchase fresh produce from growers in open markets leverage enormous influence over growers, forcing them to adhere to GAPs guidelines simply by refusing to do business with them otherwise; therefore, “although HACCP programs are not currently mandatory for growers of fresh produce, several buyers [including the United States government and its requisitioning agencies] are requiring that growers implement HACCP plans to ensure food safety practices for growing, harvesting, postharvest handling, and transporting fresh produce”<sup>384</sup> Moreover, retail firms, such as Wal-Mart and its competitors, have announced that they will only purchase produce from suppliers accredited either by government agencies or by private inspection offices.<sup>385</sup> Finally, intermediate producers that purchase fresh produce from growers and then package and sell that produce under their own brand name are insisting that the suppliers adhere to GAPs guidelines lest they face the catastrophic economic consequences of a foodborne illness outbreak; having witnessed the devastation that can befall a brand or industry in the aftermath of a foodborne illness outbreak, firms have begun to recognize that their economic self-interest is linked to fresh produce safety and, by extension, to GAPs compliance.

The ability of large scale purchasers to in effect force growers to become GAPs compliant indicates that the non-binding framework of the GAPs program has not rendered it unable to promote fresh produce safety. However, firms and government procurement agencies are not the only market agents interested in promoting fresh produce safety. Individual consumer choices can similarly influence producer behaviors. In the case of fresh produce safety, consumers report that they are willing to pay more for GAPs Certified produce; 84% of the respondents to a consumer survey conducted during June 2001 in the New England states

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<sup>384</sup> L.R. Howard and A. R. Gonzales, *Food Safety and Produce Operations: What is the Future?*, Hort Sci, 36 (2001), pgs. 33-39.

<sup>385</sup> John W. Miller, *Private Food Standards Gain Favor: Wal-Mart, McDonald's Adopt European Safety Guidelines*, Wall Street Journal (Eastern Edition), New York, NY, March 11, 2008 (pg. B1).

indicated that they would be willing to pay a \$0.50 premium for a “produce basket from a GAP-certified farm;” 71% indicated that they would pay a \$1.00 premium.<sup>386</sup> These data indicate that there is a market opportunity open for growers who want to sell directly to consumers at a premium price; because most fresh fruit and vegetable producers “engage in the activity for profit,” it stands to reason that growers would be more inclined to participate in programs in the pursuit of profit than in programs cast only in terms of regulation.<sup>387</sup> Thus consumer preferences for GAPs Certified produce has the potential to encourage growers to adhere to GAPs guidelines, not because they are required to do so by law, but because they can generate higher profits from their sales.

Moreover, the GAPs Initiative has brought technical experts together with growers and processors to collapse the knowledge gap between scientists and food producers. As Cassidy writes, “a highly important public good that largely escaped the attention of economists until pretty recently is scientific knowledge.”<sup>388</sup> This is particularly important with regard to fresh produce safety since safe fresh fruit and vegetable production and processing presents, as Brasch explains, a “steep learning curve” that requires extensive scientific and technical knowledge and skill.<sup>389</sup> But the FDA, unlike the USDA, does not have an internal research branch; while the USDA can call upon the technical and scientific expertise of its Agricultural Research Service, the FDA must find marshal external resources in order to contribute to scientific knowledge as a public good. Through the GAPs Initiative, however, industry representatives, university faculty, and trade groups have collaborated to develop commodity-specific guidance documents designed to assist growers with GAP/GHP implementation.<sup>390</sup> Guidance documents are already available for leafy greens, tomatoes, and melons. This information is provided free of charge to growers

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<sup>386</sup> L.F. Pivarnik, et.al., *New England Consumers’ Willingness to Pay for Fresh Fruits and Vegetables Grown on GAP-Certified Farms*, Food Protection Trends, 2005, Volume 25, Number 4, pgs. 256-266.

<sup>387</sup> Dennis J. Osborne, et. al., *Gaining Producer Buy-In for Food Safety and Security in the United States*, HortTechnology, October-December 2006, 16(4), pg. 563-565.

<sup>388</sup> John Cassidy, *How Markets Fail: The Logic of Economic Collapse*, New York, NY: Farrar, Straus, and Giroux (2009), pp. 135.

<sup>389</sup> Tony Bratsch, *GAPs: Common Sense for Fresh Produce Growers*, [Virginia Vegetable, Small Fruit and Specialty Crops](http://pubs.ext.vt.edu/2906/2906-1359/2906-1359.html), (2004) [available online: <http://pubs.ext.vt.edu/2906/2906-1359/2906-1359.html>].

<sup>390</sup> Ken Petersen, *USDA 3<sup>rd</sup> Party Audit Verification Program*, USDA Agricultural Marketing Service, Fresh Products Branch: Good Agricultural Practices and Good Handling Practices Program [available online: [http://www.gaps.cornell.edu/Eventscalendar/USDA\\_3rd\\_Party\\_Audit\\_Verification\\_Programs.pdf](http://www.gaps.cornell.edu/Eventscalendar/USDA_3rd_Party_Audit_Verification_Programs.pdf)].

and processors so that they may develop better food safety plans and align their production practices with GAPs requirements.

Therefore, fresh produce safety is a case in which voluntary compliance market mechanisms are able to accomplish what public regulatory agencies could not. Because consumers, large and small, are increasingly willing to demand that their suppliers achieve and maintain GAPs Certification, allowing markets to function can effectively promote fresh produce safety, public health, and economic profitability. By operating within open markets, firms, government agencies, and consumers are, despite or perhaps on account of their “growing fears about food safety and impatience with government response,” able to “provide a rapid response to things [that consumers] care about in a way that governments can’t provide” by transforming a set of voluntary food safety guidelines into a new kind of food safety standards.<sup>391</sup>

*A Critique of GAPs: On-Going Fresh Produce Crises and the Question of Regulatory Effectiveness*

The FDA released its *Guide to Minimize the Microbial Food Safety Hazards for Fresh Fruits and Vegetables* in 1998 and the final draft of its *Guide to Minimize Food Safety Hazards of Fresh-Cut Fruits and Vegetables* in 2007; both contained non-binding recommendations and guidance designed to prevent contamination of fresh produce. Since that time, however, several high-profile outbreaks of foodborne illnesses linked to fresh produce have raised questions about the effectiveness of the GAPs Initiative. In 2000 an outbreak of *Salmonella* in bean sprouts from Pacific Coast Sprout Farms caused 67 illnesses and 17 hospitalizations from Oregon to Massachusetts. In 2003, an outbreak of *Hepatitis A* linked to green onions infected consumers in Pennsylvania. In 2006 a nation-wide outbreak of *E. coli* 0157:H7 linked to bagged spinach packaged by Natural Selection Foods left three dead and nearly 200 sickened across 25 states. And in 2008 an outbreak of a rare strain of *Salmonella*<sup>392</sup> infected more than 1000 people in 41 states. Initially linked to fresh tomatoes, the outbreak was later traced back to contaminated Serrano peppers imported from Mexican grower. The outbreak caused at least one death,

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<sup>391</sup> John W. Miller, *Private Food Standards Gain Favor; Wal-Mart, McDonald's Adopt European Safety Guidelines*, Wall Street Journal (Eastern Edition), New York, NY, March 11, 2008 (pg. B1).

<sup>392</sup> The Saintpaul serotype of *Salmonella enteric*

hundreds of hospitalizations, and millions of dollars in economic damages, particularly to the tomato industry which, in the end, had nothing to do with the outbreak. These crises prompted FDA to warn several sectors of the fresh fruit and vegetable industry, notably melon, tomato, and lettuce producers, that their failure to improve food safety on a voluntary basis would force the FDA to institute legally-binding regulations for fresh produce. They also generated concerns about the bottom-up approach to fresh produce safety adopted by the GAPs Initiative.

Critics maintain that a bottom-up approach to food safety is characterized by a “lack of regulatory rigor when it comes to protecting the public from food safety threats.”<sup>393</sup> This criticism focuses overwhelmingly on the non-binding nature of the GAPs Initiative and on the fact that the FDA does little to monitor the on-farm implementation and effectiveness of the GAPs program, but also on the inability of public regulatory agencies to issue mandatory recalls to minimize the public health impact when outbreaks occur. At present, the FDA, like the USDA, cannot recall contaminated food products; it can merely advise consumers to avoid the product and ask producers to issue a recall. As Morrone writes, “until the U.S. government has the authority to issue food recalls as it does when it comes to drugs and consumer products, we will have to wonder about the rue magnitude of the food safety problem.”<sup>394</sup>

But this criticism is not of the GAPs Initiative, but of the U.S. food regulatory regime as a whole; government regulators simply do not have the legislative mandate necessary to enact the legally binding “command-and-control” regulatory mechanisms and accountability frameworks that critics advocate. Unless the legislative mandate changes (see Chapter 9), the FDA’s options remain limited to market-based initiatives. For, unlike the USDA, the FDA does not even have the authority to institute mandatory inspections of food processing facilities, let alone farms. Nor can it recall contaminated food products, impose criminal penalties for non-compliance with food safety recommendations, or require that producers and processors implement process-based safety systems. The GAPs Initiative, for all of its shortcomings, represents the FDA’s best effort to reduce the risks of fresh produce contamination given its limited mandate relative to food *safety*, particularly *microbiological* food safety. To institute a public, top-down regulatory regime, the FDA would need a radically revised mandate.

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<sup>393</sup> Michele Morrone, Poisons on Our Plates: The Real Food Safety Problem in the United States, Westport, CT: Praeger (2008), pp. 41.

<sup>394</sup> *Ibid*, pp. 43.

**PART III**  
**A NEW REGULATORY REGIME FOR THE 21<sup>ST</sup> CENTURY**

## CHAPTER 8

### DISRUPTED EQUILIBRIUM:

#### THE SEARCH FOR ACCOUNTABILITY IN THE AFTERMATH OF THE 2008-2009 PEANUT BUTTER CRISIS

In late 2008, a food safety crisis associated with peanuts catapulted food safety regulatory reform onto the national policy agenda. A product of corporate guile, deceit, and opportunism, this crisis affected Americans across many demographics and necessitated the largest food recall in U.S. history. More importantly, it demonstrated the weakness, not only of the U.S. food safety regulatory regime and its statutory mandate, but of private, non-accredited, third party certification as an accountability mechanism. In the aftermath of the 2008-2009 Peanut Crisis, citizens, legislators, and regulators alike embarked upon a search for accountability in food safety and its regulation and, finding none, sought the transformation of the U.S. food safety regulatory regime away from notions of food purity and wholesomeness and, furthermore, away from bottom-up, market-based approaches to regulatory governance.

The Peanut Corporation of America (PCA) was a peanut-processing corporation founded in the late 1970's and headquartered in Lynchburg, VA. For thirty years it provided processed peanut products, such as peanuts, peanut butter, peanut meal, and peanut paste, to a variety of food producers and processors for inclusion in a wide range of products including cookies, crackers, snacks, candies, and ice creams.<sup>395</sup> The company manufactured approximately 2.5 percent of the United States' processed peanuts. And despite a number of previous lawsuits<sup>396</sup> and concerns about sanitation at the facility dating back to the mid-1980's, PCA did \$25 million in sales in 2008.

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<sup>395</sup> As well as dog biscuits. In fact, the first confirmed case of the PCA strain of *Salmonella* was found in a dog that had eaten contaminated biscuits.

<sup>396</sup> In 1990 the American Candy Corporation sued PCA after the FDA determined that PCA peanut butter exceeded the FDA tolerance level for aflatoxin, a toxic mold product. In 1991, PCA was sued by Zachary Confections, Inc. after a shipment of its product was found to have an unacceptably high level of aflatoxin.

But in February 2009, the Peanut Corporation of America ceased to exist. Laboratory testing by state officials, the FDA, and the CDC confirmed that an outbreak of *Salmonella typhimurium* was caused by peanut butter, peanut paste, and peanut meal produced by PCA at its processing plant in Blakely, GA. The outbreak, which killed 9 and sickened at least 691,<sup>397</sup> prompted the largest and most extensive food recall in U.S. history; more than 350 companies voluntarily recalled nearly 4,000 products that were manufactured using PCA ingredients. Consumers, schools, food pantries, and agrifirms were forced to discard millions of pounds of food for fear of contamination. And although the outbreak was never linked to major-brand peanut butter, many consumers, perhaps because of the 2007 outbreak of *Salmonella* attributed to Peter Pan™ and Great Value™ peanut butters, stopped eating peanut butter and peanut butter products altogether; in all, the outbreak is estimated to have caused \$1 billion in damages.

Though it followed on the heels of numerous other high profile outbreaks of foodborne illnesses, the 2008/2009 peanut butter crisis was unique. A combination of corporate guile and opportunism alongside the failure of third-party certifiers to enforce food safety standards highlighted numerous weaknesses in the U.S. food safety regulatory regime. As government officials across numerous states and jurisdictions confronted the outbreak and its consequences, the ineffectiveness and inefficiency of voluntary recalls became increasingly apparent. Complicated by the fact that the outbreak was linked to an *ingredient* used in many food products produced by numerous different corporations, the scandal captured the attention of candidates in the 2008 Presidential election creating, for the first time in more than 100 years, a state of disrupted equilibrium. The consequences have the potential to revolutionize the U.S. food safety regulatory regime (see Chapter 9).

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<sup>397</sup> Likely far more; the CDC estimates that for every reported case of *Salmonella*, another 38 cases go unreported. [Paul S. Mead, et. al., *Food-Related Illness and Death in the United States*, Centers for Disease Control and Prevention, 1999 [available online: <http://www.cdc.gov/ncidod/eid/vol15no5/mead.htm>].]

*Opportunism and the Malevolent Side Effects of Business Decisions: Market Failures & PCA*

Once the outbreak was traced back to the Blakely plant, PCA Owner and President Stewart Parnell announced that “we deeply regret that this has happened...out of an abundance of caution, we are voluntarily withdrawing this product and contacting our customers...we are taking these actions with the safety of our consumers as our first priority.”<sup>398</sup> This generated some of the last good press PCA would receive. On January 15, 2009, for example, Dan Hicks, senior consultant with the Institute for Crisis Management, praised PCA for “doing a very good job” in managing the peanut butter crisis.<sup>399</sup> Hicks explained that the “Peanut Corporation of America...voluntarily recalled peanut butter produced in its Blakely, Georgia processing facility because it may be contaminated with Salmonella.”<sup>400</sup> He went on to write that “the company stepped up and took aggressive action and accepted responsibility.” But after federal officials subpoenaed PCA’s internal documents, it became apparent that not only had the company knowingly and intentionally *failed* to prioritize the safety of its consumers, it had acted *irresponsibly* since 2007, refusing to “step up and take aggressive action” to prevent the contamination of its products. Thus the 2008-2009 peanut butter scandal, unlike other recent food safety crises, achieved infamy because it was the result of guile, opportunism, and corporate malevolence.

PCA plants had been cited for sanitation violations since the 1980’s. In the aftermath of the crisis, federal inspectors found that the Blakely plant had mold growing on its ceilings and walls, foot-long gaps in its roof, a roaster that was not properly calibrated to kill deadly microbial pathogens, and dead insects near its peanut products. The processing equipment was improperly cleaned and maintained, the peanuts improperly stored and separated, and the workforce was improperly trained to prevent microbial contamination of its outputs. The *New York Times* reported that the Georgia plant “was cited repeatedly in 2006 and 2007 for having dirty surfaces and grease residue and dirty buildup throughout the plant...inspection reports from 2008 found

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<sup>398</sup> David Hicks, *Peanut Butter Recall is Being Handled Responsibly*, [Communicating Through Crisis](http://crisisexperts.blogspot.com/2009/01/peanut-butter-recall-is-being-handled.html), 15 January 2009 [available online: <http://crisisexperts.blogspot.com/2009/01/peanut-butter-recall-is-being-handled.html>].

<sup>399</sup> *Ibid.*

<sup>400</sup> *Ibid.*

the plant repeatedly in violation of cleanliness standards.”<sup>401</sup> Inspections by state officials “found areas of rust that could flake into foods, gaps in warehouse doors large enough for rodents to get through, unmarked spray bottles and containers, and numerous violations of other practices designed to prevent food contamination.”<sup>402</sup> Inspectors report that “the food-contact surfaces...were not properly cleaned and sanitized;” two reports from 2008 “found the plant out of compliance with practices for making sure [that] ‘food and non-food contact surfaces were cleanable, properly designed, constructed, and used.’”<sup>403</sup> But, more than this, the investigation revealed that PCA had, on numerous occasions, *knowingly and intentionally* sold peanuts and peanut products *after private laboratory tests had confirmed that they were contaminated with Salmonella*.

State inspectors reported that they “flagged the problems” and required follow-up but “there is no evidence that Peanut Corporation of America was ever closed by the state or otherwise penalized” and although PCA insisted that “there were regular visits and inspections of the Blakely facility by federal and state regulators in 2008,”<sup>404</sup> the “FDA...never inspected the plant, instead delegating that duty under a contract to the Georgia Department of Agriculture.”<sup>405</sup> State inspectors visited the plan in October 2008 while contaminated products were being produced but “they did not test either the factory or the peanut products for Salmonella.”<sup>406</sup> Oscar Garrison, Georgia’s Assistant Agricultural Commissioner for Consumer Protection, explained that the state does “pull product samples from time to time” but “can only run 4,500 samples [each] year.”<sup>407</sup> The state must inspect 16,000 food-processing and food-sales stores annually; its ability to conduct pathogen testing and analysis is thus severely limited.

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<sup>401</sup> Roni Caryn Rabin, *Peanut Plant Had History of Health Lapses*, The New York Times, 26 January 2009 [available online: [http://www.nytimes.com/2009/01/27/health/27peanuts.html?\\_r=1](http://www.nytimes.com/2009/01/27/health/27peanuts.html?_r=1)].

<sup>402</sup> *Ibid.*

<sup>403</sup> *Ibid.*

<sup>404</sup> *PCA Salmonella Outbreak Could Lead to Food Safety Reform*, NewsInferno.com, 24 February 2009 [available online: <http://www.newsinferno.com/archives/4811>].

<sup>405</sup> Lyndsey Layton, *Peanut Processor Knowingly Sold Tainted Products: It Found Salmonella 12 Times*, The Washington Post, 28 January 2009 [available online: [http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s\\_pos=](http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s_pos=)].

<sup>406</sup> *Ibid.*

<sup>407</sup> *Ibid.*

Although state officials did not test the Blakely plant for Salmonella, private laboratories hired by PCA did. But because companies are not required to disclose internal tests to federal or state regulators, however, no one outside the company knew about the problem until the 2008-2009 outbreak was traced back to Blakely plant. When *Salmonella* was discovered by public health officials in Minnesota during their investigation of a nursing home kitchen in the aftermath of a food-poisoning case, Parnell insisted that “we suspect the Salmonella could have been introduced by cross-contamination after the tub was opened...we do not believe the Salmonella came from our facility...we send hourly [peanut butter] samples to an independent lab to test for Salmonella during production....and we have never found any Salmonella at all.”<sup>408</sup> This was a deliberate lie, demonstrated by the fact that this email (dated 12 January 2009) was sent several *months* after an exchange between Parnell and Lightsey that discussed positive tests result for *Salmonella* at the Blakely plant.<sup>409</sup> After their investigation of the outbreak, officials at the FDA and the CDC reported that PCA “found Salmonella in internal tests a dozen times in 2007 and 2008 but sold the products anyway, sometimes after getting a negative finding from a different laboratory” and sometimes before the re-tests were complete.<sup>410</sup> Rather than destroy the contaminated products as required by federal law, PCA distributed them in bulk quantities to institutions (including schools, food pantries, and government agencies<sup>411</sup>), food service industries, and private label food companies.

At a hearing into the outbreak before the U.S. House Subcommittee on Oversight and Investigations, “emails revealed that...Parnell repeatedly told employees to ship tainted products;” furthermore, emails between Parnell and PCA employees consistently emphasize issues of profitability while displaying a complete disregard for public health.<sup>412</sup> An official at one of the private labs used by PCA to test for *Salmonella* “reported that PCA’s plant manager in

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<sup>408</sup> Stewart Parnell, et. .al., *Email to Samuel Lightsey, et. al.*, 12 January 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/pcaemailtolightsey.1.12.2009.pdf](http://energycommerce.house.gov/Press_111/20090211/pcaemailtolightsey.1.12.2009.pdf)].

<sup>409</sup> *Ibid.* In addition, numerous other emails between Parnell and other PCA employees dated June 2008 and August 2008 discussed positive *Salmonella* test results.

<sup>410</sup> Lyndsey Layton, *Peanut Processor Knowingly Sold Tainted Products: It Found Salmonella 12 Times*, *The Washington Post*, 28 January 2009 [available online: [http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s\\_pos=](http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s_pos=)].

<sup>411</sup> The Federal Emergency Management Agency was forced to recall emergency rations; moreover, the United States military chose to destroy contaminated products on bases in the United States and abroad.

<sup>412</sup> *PCA Salmonella Outbreak Could Lead to Food Safety Reform*, *NewsInferno.com*, 24 February 2009 [available online: <http://www.newsinferno.com/archives/4811>].

Georgia, Sam Lightsey, admitted to shipping products before receiving lab results...the official stated: ‘when I called Mr. Lightsey in early October 2008 to give him the serology reports...that confirmed Salmonella, he paused and said ‘Uh Oh,’ or something to that effect, and then told me he had released the product for shipping...when I asked if he could get it back, he said it was on a truck headed to Utah.’”<sup>413</sup> As Representative Henry A. Waxman, Chairman of the House Committee on Energy and Commerce, said in his opening statement *The Salmonella Outbreak: the Continued Failure to Protect the Food Supply*, “the documents obtained by the Subcommittee...show a company that was more concerned with its bottom line than the safety of its customers...even after FDA began investigating in January [2009] and forced<sup>414</sup> the company to recall some products, PCA’s first concern was financial.”<sup>415</sup> Georgia Agriculture Commissioner Tommy Irvin elaborated, PCA “tried to hid [the contamination] so they could sell [their peanut butter]...now they’ve caused a mammoth problem that could destroy their company—and it could destroy the peanut industry.”<sup>416</sup>

### *The Problem with Private Certification*

Although neither the FDA nor state officials mandated that PCA perform pathogen tests at its production and processing facilities, several of PCA’s bulk buyers required PCA to allow private laboratories to provide pathogen testing services. As the House investigation revealed, “PCA’s large customers, such as Kellogg’s, engaged contractors to conduct audits of the Blakely plant” in order to ensure that their products were produced and processed according to high safety and quality standards and that risks of physical, chemical, and, especially, microbial

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<sup>413</sup> Henry A. Waxman, *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/hawopen.pdf](http://energycommerce.house.gov/Press_111/20090211/hawopen.pdf)].

<sup>414</sup> A poor choice of words since the FDA cannot legally *force* a company to recall a food product, even one known to be a danger to public health. See forthcoming analysis of the problems with voluntary recalls for more information.

<sup>415</sup> Henry A. Waxman, *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/hawopen.pdf](http://energycommerce.house.gov/Press_111/20090211/hawopen.pdf)].

<sup>416</sup> *Peanut Plant Problem Forces Fresh Recall: U.S. Army the Latest to Pull Items in Ever-Growing List Reaching Back to 2007*, MSNBC.com, 29 January 2009 [available online: <http://www.msnbc.msn.com/id/28899634/>].

contamination were minimized.<sup>417</sup> But the peanut crisis of 2008-2009 highlighted a series of problems with private inspection and certification systems, undermining many of the theoretical advantages of bottom-up, market-driven food safety governance mechanisms.

PCA contracted with J. Leek Associates, Inc. (JLA-USA), the U.S. division of JLA-Global. JLA is “a marketer and producer of confidence regarding safety and performance of food and beverage *ingredients* and products...[it provides] its client with knowledge and with reliable, cost-efficient system and information to assure that their product safety and performance needs are met.”<sup>418</sup> Operating in U.S. and international markets and thus aware of a variety of food safety regulatory regimes and protocols, JLA offers its customers “analysis and certification” as well as “private consultation in highly technical areas” designed to address the “unique [safety and quality] challenges of the food industry.”<sup>419</sup> JLA scientists test raw materials, finished products, and environmental swabs for pesticide residues, heavy metals, microbial contamination, and extraneous matter, as well as for sensory quality; quality variance, risks, and disposition; and fats and oils composition/quality.<sup>420</sup> Moreover, although laboratory analysis is the company’s primary service, JLA offers product and process development support including “design, implementation, and auditing of QA/QC and HACCP programs” as well as “food safety and sanitation” systems.<sup>421</sup> JLA laboratories are “certified by various government agencies [including the USDA] and private organization” and have “received many yearly awards for accuracy and precision in various analyses.”<sup>422</sup> It “uses a strict program of statistical process control” including “detailed documentation of methods, analyst certifications, and quality assurance practices,” “regular internal audits of all sites,” and “yearly audits by both

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<sup>417</sup> Bart Stupak, *The Salmonella Outbreak: A Collective Failure to Protect the Public*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/stupakopen.pdf](http://energycommerce.house.gov/Press_111/20090211/stupakopen.pdf)].

<sup>418</sup> *About Us*, J. Leek Associates, Inc., accessed 6 January 2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)] (emphasis added).

<sup>419</sup> *Ibid.*

<sup>420</sup> *Analytical Services*, Leek Associates, Inc., accessed 6 January 2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)].

<sup>421</sup> *Technical Services*, J. Leek Associates, Inc., accessed 6 January 2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)].

<sup>422</sup> *Internal Quality Assurance*, J. Leek Associates, Inc., accessed 6 January 2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)].

official organizations and clients” to ensure that its results and recommendations are reliable, rapid, and repeatable.<sup>423</sup>

In the course of its investigation of the peanut butter outbreak, the U.S. House of Representatives heard testimony from JLA employees regarding its work for PCA. In a written statement to the House Subcommittee on Oversight and Investigations, JLA President Darlene Cowart revealed that “from January 1, 2007 through September of 2008 [JLA] tested approximately 1000 samples of product for PCA...of these in 2007 six (6) samples were confirmed positive for Salmonella...in 2008 we issued a total of four (4) confirmed Salmonella positive [certificates of analysis].”<sup>424</sup> At the committee’s request, Cowart clarified JLA’s laboratory testing procedures for *Salmonella*. She told the committee “first we pull a representative sample from the customer’s containers to get a 375 gram composite sample...we put that composite sample with other substances into a sterile bag and incubate the mixture...we move some of the mixture into test tubes for other procedures and we put the remaining mixture into what is called a VIDAS machine...the machine’s computer automatically gives the result—either positive or negative for Salmonella.”<sup>425</sup> She went on to explain “if the test is negative then we issue a negative certificate of analysis (COA) which is sent to the customer.”<sup>426</sup> “If the result is positive,” however, JLA “calls [it] a presumptive positive which must be confirmed because, at this point, several organisms can look like Salmonella but are not.”<sup>427</sup> Cowart went on to say that “since the tests necessary to confirm the presumptive positive can take five (5) days, we notify the customer of the presumptive positive by email and telephone call...if, after the confirmation process, we find that Salmonella is ruled out, we prepare a negative COA for immediate release to the customer...if we do confirm the presumptive positive to be Salmonella, then we prepare and issue a positive COA and again notify the customer via telephone call and

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<sup>423</sup> *Ibid.*

<sup>424</sup> Darlene M. Cowart, *Testimony Before the Sub-Committee on Oversight and Investigation of the United States House of Representatives Energy and Commerce Committee*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_cowart.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_cowart.pdf)].

<sup>425</sup> *Ibid.*

<sup>426</sup> *Ibid.*

<sup>427</sup> *Ibid.*

email.”<sup>428</sup> Cowart concluded by reporting that “following a confirmed Salmonella positive issued to PCA in late August 2008, PCA discontinued sending product samples to JLA.”<sup>429</sup>

During the House hearing, another JLA official confirmed that “the firm’s contract was terminated after its test found Salmonella at the PCA Georgia facility on several occasions.”<sup>430</sup> But internal documents and conversations between PCA and JLA personnel indicate that PCA first tried to “shop around” for a private laboratory that was less likely to issue a positive result for *Salmonella*. PCA began by sending samples to a competing laboratory so that it could compare results with JLA. Michelle Pronto, manager of JLA’s microbiology laboratory, testified (in writing) that “during a phone conversation in August 2008, Sammy Lightsey (PCA) informed me that the Albany, Georgia JLA lab was reporting higher aerobic plate count (APC) results and higher coliform results than another lab e had apparently used...he told me that he had pulled duplicate samples simultaneously and sent one set of samples to JLA and the other to another lab, and that our results were always higher for APC and coliform.”<sup>431</sup> Ponto went on to testify that Lightsey “confirmed that because of high coliform results, [PCA had decided] to send samples to a different lab.”<sup>432</sup>

Duplicate samples were sent to Deibel Laboratories, an outside testing service that is USDA-certified to test for *Salmonella* and is “on the approved list for almost all of North America’s leading food producers” for microbial testing.<sup>433</sup> Deibel also offers consultant services, helping clients “get out of problematic situations arising from pathogenic or spoilage issues at the food processing level” by providing risk assessments and plant audits.<sup>434</sup> Moreover, Deibel helps its customers implement HACCP and GAPs risk reduction systems; Deibel works “with companies to improve their manufacturing systems for the production of safe and

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<sup>428</sup> *Ibid.*

<sup>429</sup> *Ibid.*

<sup>430</sup> *PCA Salmonella Outbreak Could Lead to Food Safety Reform*, [NewsInferno.com](http://www.newsinferno.com), 24 February 2009 [available online: <http://www.newsinferno.com/archives/4811>].

<sup>431</sup> Michelle Pronto, *Response to Questions*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/prontolettertowaxmanandstupak.2.10.2009.pdf](http://energycommerce.house.gov/Press_111/20090211/prontolettertowaxmanandstupak.2.10.2009.pdf)].

<sup>432</sup> *Ibid.*

<sup>433</sup> *Food Microbiology*, Deibel Laboratories, 2005 [available online: [http://www.deibellabs.com/services\\_FoodMicroBiology.html](http://www.deibellabs.com/services_FoodMicroBiology.html)].

<sup>434</sup> *Risk Management*, Deibel Laboratories, 2005 [available online: <http://www.deibellabs.com/MicroRiskManagement.html>].

wholesome foods” while facilitating GAP Analysis audits that “allow the firm to have another pair of eyes on the written document systems as well as an onsite inspection of the manufacturing practices...the goal of this type of an audit is to identify opportunities for improvements.”<sup>435</sup> Although Deibel did not “provide day-to-day testing services for PCA as [it does] for many of [its] clients...during 2007 and 2008, PCA’s Plainview, Texas and Blakely, Georgia facilities sporadically submitted samples containing peanuts to Deibel Labs to test.”<sup>436</sup>

On June 23, 2008, both JLA and Deibel tested PCA lot 8168 for *Salmonella* contamination. JLA reported a confirmed positive for *Salmonella* while Deibel reported a negative *Salmonella* result. The lot was released. On August 11, 2008 samples pulled from PCA lot 8224 tested positive for *Salmonella* at the JLA lab. PCA noted, however, that the “numbers [were] abnormally low to be accompanied by a positive *Salmonella* [result].”<sup>437</sup> PCA asked that JLA retest the sample and determine if the original sample was contaminated during laboratory operations. It also sent its retained samples to Deibel Laboratories for a full analysis. This lot produced “147 case of Creamy Stabilized for Perry’s Ice Cream,” “138 cases of Cream Stabilized for Stock,” and “218 cases of Creamy Stabilized for Lofthouse.”<sup>438</sup> The Perry’s Ice Cream and Stock Butter was placed on hold in inventory. One-hundred eighty two cases of the Lofthouse butter were shipped and delivered before retest results were received. On August 21, 2008 Lightsey reported to Parnell that “the results [from] Deibel show the product to be clean and in spec for micro analysis.”<sup>439</sup> Parnell ordered that the lot be “turned loose.”<sup>440</sup> Shortly thereafter, PCA plant manager Lightsey told JLA that it would no longer receive samples from PCA.

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<sup>435</sup> *GAPs Analysis*, Deibel Laboratories, 2005 [available online: <http://www.deibellabs.com/MicroGapAnalysis.html>].

<sup>436</sup> Charles T. Deibel, *Statement*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_deibel.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_deibel.pdf)].

<sup>437</sup> Stewart Parnell and Samuel Lightsey, *Email Correspondence 8/21/2008*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/parnellemailtolightsey.8.21.2008.pdf](http://energycommerce.house.gov/Press_111/20090211/parnellemailtolightsey.8.21.2008.pdf)].

<sup>438</sup> *Ibid.*

<sup>439</sup> *Ibid.*

<sup>440</sup> *Ibid.*

This case demonstrates a number of weaknesses that characterize private, bottom-up, third-party inspection and certification systems of risk reduction and economic governance. First, as Chapter 7 explained, third-party certifiers, like JLA and Deibel, are profit-seeking ventures. To survive in a competitive market, they must balance two, often conflicting, objectives. On the one hand, they must provide accurate and reliable analyses designed to reduce risks of physical, chemical, or microbial contamination and to help customers implement more efficient and effective food safety systems. But, on the other hand, they must satisfy the demands of their customers, that is to say, the demands of the companies sending samples for analysis. If the customer's priority is food safety, these two goals can be simultaneously achieved. If the customer's priority is profit maximization, however, a third-party certifier might be tempted to sacrifice the former in favor of the latter. And, as Chapter 5 suggests and the 2008-2009 Peanut Scandal reveals, in the absence of accountability mechanisms designed to ensure that an external authority "watches the watchers," there is nothing to prevent food producers and third party certifiers from pursuing a "race to the bottom" that nullifies the effectiveness of the bottom-up regulatory regime. Although neither JLA nor Deibel could account for the discrepancies in their test results,<sup>441</sup> this case clearly indicates that a food producing firm focused more on profit maximization than on food safety will seek pathogen tests that are most *favorable*, if not most accurate or reliable, in order to turn product into revenue. This undermines public *trust* in third-party certification systems and reinforces the need for top-down, public, mandatory, and enforceable regulatory structures and accountability mechanisms.

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<sup>441</sup> JLA president Cowart did mention in her testimony before Congress that "JLA [does] not take the samples from the product nor does [it] have knowledge of the sampling procedure used by PCA for the samples [it receives]...the information provided on the Request for Analysis is the only information about the sample that JLA receives." Thus it is possible that PCA is responsible for the discrepancies; neither JLA nor Deibel had any way of knowing if the lot numbers on the samples they received were accurate or if sampling procedures were correctly implemented at the PCA plant in Blakely, GA. This represents another risk associated with private, third-party testing procedures. Moreover, Michael Rogers, a senior FDA investigator, observed that it is possible for Salmonella to "hide" in small pockets of large batches of peanut butter; thus different samples one batch could yield both positive and negative test results. For this reason, the product should have been discarded after it first tested positive; it should not have been re-tested or released. (Darlene M. Cowart, *Testimony Before the Sub-Committee on Oversight and Investigation of the United States House of Representatives Energy and Commerce Committee*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_cowart.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_cowart.pdf)])

Moreover, although JLA and Deibel test results<sup>442</sup> “revealed a consistent pattern of Salmonella contamination,” neither PCA’s customers nor federal or state officials could require that PCA release those internal test results.<sup>443</sup> Thus no one knew about the history of positive Salmonella results or about PCA’s *tendency to re-test lots that had been confirmed positive for Salmonella and operate based on the more favorable result until the post-crisis investigation began*. By that time, the damage had been done. Customers who thought that they were reducing the risks of foodborne contamination by requiring private inspections and certification discovered that their efforts had been undermined by a corporation willing to engage in guile and opportunism in order to enhance their profit margins. And, in the end, PCA had to recall more than two years of product, most of which had already been consumed, before filing for bankruptcy and shutting its doors.

#### *The Problem with Recalls, Ingredients, and Traceability*

The first confirmed case of *Salmonella* associated with the 2008-2009 outbreak was found in a dog that had eaten contaminated biscuits. Soon thereafter, in early January 2009, Minnesota public health officials found *Salmonella* in an open tub of King Nut peanut butter produced by PCA at its Blakely, GA plant. Although PCA initially reported that “investigating agencies [including] the Food and Drug Administration and the Centers for Disease Control and Prevention [did not] believe there [was] Salmonella in any [PCA] product...and [did not] state that they believe[d] [PCA was] the source of the Salmonella found in the partially-used tub,” the

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<sup>442</sup> On September 29, 2008 Lightsey reported to Parnell that Deibel test results came back positive for Salmonella on Lot 8265 of peanut granules (meal had been produced in the same lot). Several cases of this lot had been shipped *before* test results were received; Lightsey stated that customers needed to be called and told to hold the product until it could be cleared. This may or may not have been done. Parnell’s response was “the time lapse, besides the cost is costing us huge \$\$\$\$ and causing obviously a huge lapse in time from the time we pick up peanuts until we can invoice.” He goes on to say that PCA needs to “protect itself” and that the pathogen tests “absolutely give us no protection, just an indication at best...” It is unclear what needs to be “protected”—the company’s reputation, its liability, or its bottom-line. (Stewart Parnell and Samuel Lightsey, *Email 10/6/2008*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/parnellemailtolightseyvoth.10.6.2008.pdf](http://energycommerce.house.gov/Press_111/20090211/parnellemailtolightseyvoth.10.6.2008.pdf)].

<sup>443</sup> Bart Stupak, *The Salmonella Outbreak: A Collective Failure to Protect the Public*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/stupakopen.pdf](http://energycommerce.house.gov/Press_111/20090211/stupakopen.pdf)].

FDA quickly traced the rapidly expanding outbreak back to peanut products produced at the Blakely, GA plant.<sup>444</sup> The FDA pressured PCA to recall products associated with the outbreak, thus beginning the largest food recall in U.S. history. By mid-2009, almost 4,000 products had been recalled due to *Salmonella* contamination at the Blakely, GA plant.<sup>445</sup>

On January 13, 2008 PCA announced “a voluntary recall of peanut butter produced in its Blakely, GA processing plant on or after July 1, 2008 because of possible *Salmonella* contamination.”<sup>446</sup> Three days later it issued “an expanded recall of peanut butter produced on or after August 8, 2008 in its Blakely, GA processing plant as well as the voluntary recall of peanut paste produced in the same plant on or after September 26, 2008, because of possible *Salmonella* contamination.”<sup>447</sup> Finally, on January 28, 2009, “PCA voluntarily recall[ed] all peanuts and peanut products processed in its Blakely, GA plant since January 1, 2007...the expanded recall include[d] all dry- and oil-roasted peanuts, granulated peanuts, peanut meal, peanut butter, and peanut paste.”<sup>448</sup> As Appendix A indicates, at least 200 food producing and processing firms received dry- or oil-roasted peanuts, granulated peanuts, peanut meal, peanut butter, and/or peanut paste from PCA’s Blakely plant. Moreover, those 200 firms represent a wide variety of producers and processors; thus contaminated peanut butter was included in products from low-cost snack crackers to organic ready-to-eat granola bars to TV dinners and from diet aids to guilty pleasures to children’s snacks. Shoppers at discount stores, mainstream supermarkets, and specialty grocers were exposed to products that contained contaminated or potentially contaminated peanuts. The crisis thus affected numerous food demographics and a wide range of American (and Canadian) consumers.

This outbreak was particularly complicated and widespread because the contamination was traced back to an *ingredient* rather than a finished product. The FDA classified the 2008-2009 peanut butter crisis as “an ingredient-driven outbreak; that is, potentially contaminated ingredients affected many different products that were distributed through various channels and

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<sup>444</sup> Stewart Parnell, et. .al., *Email to Samuel Lightsey, et. al.*, 12 January 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/pcaemailtolightsey.1.12.2009.pdf](http://energycommerce.house.gov/Press_111/20090211/pcaemailtolightsey.1.12.2009.pdf)].

<sup>445</sup> See Appendix A for a complete list of the 3,918 products recalled by the FDA.

<sup>446</sup> *Timeline of Events in Peanut-Salmonella Outbreak*, Associated Press, 9 February 2009 [available online: [http://www2.wjbf.com/jbf/news/consumer/article/timeline\\_of\\_events\\_in\\_peanut-Salmonella\\_outbreak/10795/](http://www2.wjbf.com/jbf/news/consumer/article/timeline_of_events_in_peanut-Salmonella_outbreak/10795/)].

<sup>447</sup> *Ibid.*

<sup>448</sup> *Ibid.*

consumed in various settings.”<sup>449</sup> Unlike the 2007 outbreak of *Salmonella* associated with commercial peanut butter, the 2008-2009 outbreak affected many firms, many products, many consumers, and, for that reason, highlighted many problems with the U.S. food safety regulatory regime.

In March 2007 “public health officials in multiple states, with the assistance of the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) [investigated] a large multistate outbreak of *Salmonella* serotype Tennessee infections...an epidemiologic study comparing foods that ill and well persons said they ate showed that consumption of Peter Pan™ peanut butter and Great Value™ peanut butter were both statistically associated with illness...product testing confirmed the presence of the outbreak strain of *Salmonella* Tennessee in opened jars of peanut butter obtained from ill persons.”<sup>450</sup> In response, the FDA advised “consumers not to eat any Peter Pan...[or]...Great Value peanut butter with a product code beginning with 2111.” Both peanut butters were produced in a single facility in Georgia owned by ConAgra foods; peanut butters produced at other plants or by other manufacturers were not affected. As of May 22, 2007, 628 persons in 47 states had been infected with the outbreak strain of *Salmonella* Tennessee. Onset dates ranged from August 1, 2006 to April 23, 2007. Approximately 20% of those affected were hospitalized but no deaths were associated with the outbreak.

The FDA isolated *Salmonella* Tennessee “from 13 unopened jars of Peter Pan and Great Value peanut butter with production dates ranging from August 2006 to January 2007 and from two plant environmental samples.”<sup>451</sup> Once the source of the outbreak was confirmed, ConAgra voluntarily recalled the products and destroyed existing product in their possession. They also halted production at their Georgia plant, pending further investigation of its operations, including heating temperatures, to determine the cause of the contamination. The outbreak and recall were

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<sup>449</sup> U.S. Food & Drug Administration, *Major Project Recalls: Peanut Products Recalls: FDA’s Investigation*, U.S. Department of Health and Human Services, 18 June 2008 [available online: <http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/FDA%E2%80%99sInvestigation/default.htm>].

<sup>450</sup> *Salmonellosis: Outbreak Investigation, February 2007*, Centers for Disease Control and Prevention: Division of Bacterial and Mycotic Diseases, 7 March 2007 [available online: [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis\\_2007/outbreak\\_notice.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2007/outbreak_notice.htm)].

<sup>451</sup> Centers for Disease Control and Prevention, *Multistate Outbreak of Salmonella Serotype Tennessee Infections Associated With Peanut Butter—United States, 2006-2007*, Morbidity and Mortality Weekly Report, Volume 52, Number 21, 1 June 2007 [available online: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5621a1.htm>].

featured prominently in the national media. Peter Pan and Great Value peanut butters were removed from store shelves and the CDC observed that “new case reports decreased substantially after the February 14 recall;” new cases were investigated to determine if those consumers were still eating peanut butter from the contaminated lots.<sup>452</sup> In April 2007, the cause of the outbreak was identified.<sup>453</sup> Moisture from a leaky roof and a faulty sprinkler system “allowed the growth of low levels of dormant Salmonella that were likely present from raw peanuts or peanut dust.”<sup>454</sup> ConAgra upgraded its facility and resumed production, returning peanut butter to store shelves in August 2007.

The 2007 peanut butter outbreak was quickly contained and efficiently managed using a system of voluntary recalls and media saturation; it was traced to two brand-name peanut butters with a specific and easily identifiable lot number, distributors and consumers were able to discard the potential dangerous products with relative ease. The 2008-2009 outbreak was far more complicated. First, outbreak was initially associated only with King Nut peanut butter, a bulk product sold by PCA to institutions such as schools, hospitals, and extended care facilities. It took time for regulators to realize the extent of the contamination and the breadth of the affected population. And although PCA eventually recalled the products produced in the Blakely, GA plant since January 1, 2007, no one—not consumers or producers or regulators or distributors—knew with any degree of certainty which products were implicated. As Stephen F. Sundlof, director of the CFSAN, reported in late January 2009, “we don’t have a good idea of how much of [the contaminated] product is still out there.”<sup>455</sup> As Sundlof testified before Congress, “PCA sold peanut butter in bulk containers ranging in size from five to 1,700 pounds and peanut paste in sizes ranging from 35-pound containers to tanker trucks...in addition, peanut meal, granulated peanuts, and oil and dry roasted peanuts were sold by PCA in bulk containers of various sizes and, in some instances, in retail-sized containers...through its investigation, FDA determined that PCA distributed potentially contaminated products to more than 300 consignee

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<sup>452</sup> *Ibid.*

<sup>453</sup> Miranda Hitti, *Peanut Butter Salmonella Source Found*, WebMD Health News, 6 April 2007 [available online: <http://www.webmd.com/food-recipes/news/20070406/peanut-butter-Salmonella-source-found>].

<sup>454</sup> Julie Jargon and Jane Zhang, *Peanut-Butter Probe Focuses on Georgia Plant*, WSJ.com, 15 January 2009 [available online: <http://online.wsj.com/article/SB123194586477481479.html>].

<sup>455</sup> Gardiner Harris, *Peanut Product Recall Grows in Salmonella Scare*, NYTimes.com, 28 January 2009 [available online: <http://www.nytimes.com/2009/01/29/us/29peanut.html>].

firms, many of whom then further distributed products for consumption as peanut butter or for use as ingredients in hundreds of different products.”<sup>456</sup> “Many companies that received peanuts and peanut products manufactured by PCA’s Blakely facility...in turn, conducted voluntary recalls,” continued Sundlof, but this “exponentially [increased] the scope of the recall.”<sup>457</sup> The FDA worked with purchasers to identify affected products and facilitate their removal from the market and contacted thousands of firms throughout the entire distribution chain that may have purchased or further distributed PCA products; for this reason, the list of recalled products expanded to include nearly 4000 products. The FDA urged retailers to stop selling recalled products, encouraged directors of institutions and food service establishments to make sure that they were not serving recalled products, and called upon consumers to check the FDA website to determine which products had been recalled and to dispose of all recalled products in a safe manner.

But for consumers, the outbreak was both frustrating and confusing. As Peter Hurley, whose 3-year-old son Jacob was poisoned<sup>458</sup> with *Salmonella* as a consequence of the 2008-2009 outbreak, testified before Congress “we did not know how Jacob got the poisoning and because of that we did not know how to protect the rest of our family...all we knew was [that] Jacob had Salmonella poisoning and that five or six people had [already] died in a new outbreak linked to peanut butter...but, at the time, only KING NUT PEANUT BUTTER was listed as a source, which we knew we did not have.”<sup>459</sup> The Hurley family contacted Jacob’s school to ask if it served King Nut peanut butter and to find out if other children were sick; the school did not and none were. Hurley went on to say, “as Jacob’s diarrhea continued, my wife was given the OK from the pediatrician’s office for Jacob to eat his favorite comfort food, AUSTIN TOASTY CRACKERS WITH PEANUT BUTTER...the very food that we later found was the cause of his

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<sup>456</sup> Stephen F. Sundlof, *Statement*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_sundlof.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_sundlof.pdf)].

<sup>457</sup> *Ibid.*

<sup>458</sup> Jacob Hurley survived his experience with *Salmonella*.

<sup>459</sup> Peter K. Hurley, *Salmonella poisoning of Jacob M. Hurley due to his eating contaminated peanut butter crackers from a Peanut Corporation of America processed product*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_hurley.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_hurley.pdf)].

poisoning.”<sup>460</sup> Neither the consumer nor his doctor knew that the crackers were contaminated with the same strain of *Salmonella* found in King Nut peanut Butter until an Oregon state epidemiologist visited the Hurley home, confiscated the peanut butter crackers, and tested them for *Salmonella*.

Hundreds of Americans experienced similar frustrations; the recall list changed too quickly and encapsulated too many products to be effective. Unlike the 2007 recall, consumers could not reference a brand name with a specific lot number to identify contaminated products. And unlike the 2007 outbreak, the 2008-2009 crisis continued for months; many of the affected products had a long shelf life and thus consumers continued to eat contaminated foods well past the peak of the epidemic. In the absence of a top-down traceability regime, customers were left with one option: scour food labels and avoid anything that contained a peanut by-product; this was both ineffective and inefficient. As regulators, food firms, and consumers discovered, a food safety regulatory regime that is *reactive* rather than *proactive* cannot respond quickly, efficiently, or effectively to a widespread outbreak of a foodborne illness. For this reason, the pressure for legislative reform grew in the aftermath of the crisis.

### Consequences: Food Safety and Its Governance After Peanut Butter

The 2008-2009 peanut butter crisis was emblematic of the weaknesses that permeate the U.S. food safety regulatory regime. As details of the scandal emerged, the media, the public, and government representatives initiated demands for a complete transformation of U.S. food safety and its regulation. Although much of the post-crisis criticism focused on the Peanut Corporation of America, critics also emphasized the need for a new, top-down, public food safety regulatory mandate. As Eller explained, blame for the 2008-2009 peanut butter crisis “needs to be placed on both the FDA and the Peanut Corporation of America plant in Georgia...both parties are the culprits in this ‘sticky’ situation.”<sup>461</sup> Eller, like many others in the aftermath of the outbreak, emphasized the need for public *accountability* in the U.S. food safety regulatory regime and

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<sup>460</sup> *Ibid.*

<sup>461</sup> Brian Eller, *Blame is Shared in Peanut Butter Crisis*, The Daily Collegian Online, 5 February 2009 [available online: [http://www.collegian.psu.edu/archive/2009/02/05/blame\\_is\\_shared\\_in\\_peanut\\_butt.aspx](http://www.collegian.psu.edu/archive/2009/02/05/blame_is_shared_in_peanut_butt.aspx)].

called for more stringent standards, both for food producers and for food regulators. For when guile and opportunism undermine bottom-up, market-based regulatory regimes or privatized accountability mechanisms, the need for *top-down*, “*command and control*” regulation imbued with *public* accountability mechanisms becomes apparent.

When Congress held investigatory hearings into the peanut butter crisis, it invited victims’ family members to testify. Each ended his testimony with a plea for Congress to reform the U.S. food safety regulatory regime. For example, Jeffrey Almer, son of victim Shirley Almer and representative of Safe Tables Our Priority (S.T.O.P.), explained that his mother’s death “and the deaths of seven others could have been so easily prevented if it were not for the greed and avarice of the Peanut Corporation of America [which was] more concerned with squeezing every dollar possible at the expense of sanitary conditions and sound food manufacturing processes.”<sup>462</sup> Almer insisted that “every company should have a moral and ethical compass when producing the nation’s food supply.”<sup>463</sup> But “*in this absence*, [the United States needs] a *cohesive proactive regulatory system to serve as [a] safety net*.”<sup>464</sup> Almer proposed the following changes to the U.S. food safety regulatory regime: (1) the institution of “a food safety system that is prevention based with companies being mandated to have validated process controls;” (2) the “development and enforcement of mandated performance standards with companies facing stiff penalties for non-compliance;” (3) “increased inspection by the federal government with less reliance on states policing the same companies that they wish to promote;” (4) “increased lab capacity in order to diagnose foodborne illness cases faster” and adequate staffing “of the PulseNet system so that it can...become a more active system;” (5) “mandatory recall authority for the government regulatory agencies;” (6) “traceability of ingredients and products;” and (7) cooperation between “the government and industry” designed to “correct a multitude of problems.”<sup>465</sup>

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<sup>462</sup> Jeffrey Almer, *Testimony: Salmonella Contamination*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_almer.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_almer.pdf)].

<sup>463</sup> *Ibid.*

<sup>464</sup> *Ibid.* (emphasis mine)

<sup>465</sup> *Ibid.*

Lou Tousignant, son of victim Clifford Tousignant, echoed Almer writing, “companies like PCA who make our food should have rules that they live by...Companies should be inspected more than once every five years...Companies should not be allowed to shop around for lab results...Companies like King Nut should not be allowed to slap a label on a product they received from a factory that they do nothing about, never visited, nor ever inspected...the FDA should also have the right to recall contaminated food themselves [rather than] wait for the companies to do so.”<sup>466</sup> And Peter Hurley, a police officer, suggested that Congress approach food safety monitoring and control using criminal law enforcement methodologies. Hurley explained “we need to have a faster 9-1-1 oriented medical response to food contamination;” we need “state epidemiologists...who will come to your house on a weekend night to collect evidence just like a police officer would do in a rape case...[and] the cop on the beat approach as well...you need FDA inspectors out there with the authority to stop production immediately when there is a problem...[and] the FDA needs the ability to criminally prosecute quickly and effectively when needed.”<sup>467</sup>

Many calls for regulatory reform came from regulators themselves. During the House hearings, CFSAN Director Sundlof explained that “the facts of this outbreak...highlight the need to enhance the FDA’s statutory authority to protect consumers from foodborne outbreaks...at this time we want to [emphasize] the...need for new or enhanced authority in several areas: (1) authority for FDA to issue preventative controls for high-risk foods; (2) authority for enhanced access to food records during routine inspections to ensure that inspectors have access to all information that bears on product safety; and (3) authority for FDA to require food facilities to renew their registrations every two years, and allow FDA to modify the registration categories.”<sup>468</sup> “In addition,” Sundlof noted “that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from

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<sup>466</sup> Lou Tousignant, *Testimony*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_tousignant.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_tousignant.pdf)].

<sup>467</sup> Peter K. Hurley, *Salmonella poisoning of Jacob M. Hurley due to his eating contaminated peanut butter crackers from a Peanut Corporation of America processed product*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_hurley.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_hurley.pdf)].

<sup>468</sup> Stephen F. Sundlof, *Statement*, United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, 11 February 2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_sundlof.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_sundlof.pdf)].

commerce.”<sup>469</sup> Similarly, Deibel, president of a private, third-party regulatory institution, urged Congress “to look at the entire [food safety] model used today” in its attempt to “prevent an incident like [the peanut butter crisis] from occurring again.” Deibel explained that “our nation’s current food safety system relies heavily on inspections conducted by the FDA and the state agencies with which it contracts...this is a reactive response, rather than the comprehensive, systemic approach needed to safeguard our food.” Deibel went on to say that “the FDA should focus on quality-control systems that minimize the potential for contamination to occur in the first place and develop mitigating strategies that correct a potential issue before it impacts food safety.” Deibel reminded legislators that “small and medium sized companies, in particular, could greatly benefit from guidance documents from the FDA” but emphasized that “the FDA’s job is...not to provide guidance, and so they do not do so...as a result, opportunities to improve food production practices are missed.” “Testing,” said Deibel, “like inspection, is only one piece of an overall food safety policy...it is the last chance to catch a problem...the larger piece is on the front end...by taking a preventative, systematic approach, we can implement reforms that will go a long way towards ensuring that all consumers have access to a safe and wholesome food supply.” However, as the experience of the USDA in the aftermath of the Jack-in-the-Box crisis indicates, a systematic attempt to reform the U.S. food safety regulatory regime could not originate from *within* food safety agencies themselves. Meaningful reform would require, first and foremost, a transformation of the antiquated statutory mandate governing U.S. food safety and its regulation.

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<sup>469</sup>*Ibid.*

## CHAPTER 9

### FOOD SAFETY, REGULATION, AND ACCOUNTABILITY

#### A NEW FRAMEWORK FOR THE 21<sup>ST</sup> CENTURY

For more than 100 years, efforts to enhance the regulatory powers of the FDA and the USDA with regard to food safety have almost always failed. Although consumers may wish to hold the USDA and the FDA accountable for what appears to be an increasingly more dangerous food system, the USDA and the FDA do not have the authority to force food producers to comply with more stringent food safety standards. Outbreaks of foodborne illnesses may have prompted consumers to define the “public interest” in terms of food safety but the statutory authority of U.S. food safety regulatory agencies has not kept pace. The question is: why not? Why has the federal government remained until now unresponsive to public demands for more stringent food safety requirements?

The answer requires that we consider a less technocratic and more political perspective on regulation and accountability. For the problem is not one of technical capacity or feasibility; it is not that we *cannot* create a food production system that reduces the risks of physical, chemical, and microbial contamination and it is certainly not the case that the industrialization of food production has rendered food fundamentally and unequivocally unsafe. The problem is that we simply have not done it; we have not incorporated advances in food science, microbiology, industrial design, and information systems into the U.S. food safety regulatory regime in ways that would make it appropriate and effective given 21<sup>st</sup> century methods of production, processing, preparation, and distribution. We have not created a regulatory system with the capacity to adapt and change to new risk, hazards, dangers, and threats and so we have guaranteed that the “public interest” will be underrepresented when compared to the “special interests” that use their power and influence to perpetuate an obsolete food safety accountability framework and regulatory regime.

For the past century the application of industrial logics to food production has concentrated power in the food industry in the hands of a few large agribusinesses, corporations

that are among the most politically powerful in the United States. And these agribusinesses have, at every level and in every venue, fought against attempts (legislative or executive) to update the 1906 food safety regulatory regime. The inadequacies of the U.S. food safety regime, therefore, are not a consequence of regulatory negligence or a lack of oversight; they are a product of a process in which the government has turned food safety responsibilities over to consumers because producers have systematically opposed any attempt to do otherwise.

It would be unfair to imply that food corporations are not concerned with food safety. In fact, the willingness of many food producers to turn to private, bottom-up, third-party mechanisms designed to reduce the risks of contamination would indicate just the opposite. In the case of peanut butter, for example, many of PCA's customers, including Kraft, relied upon private pathogen testing as a measure of food safety. And yet many food producers have vehemently opposed attempts by government regulators to implement similar systems, structures, and standards. The question is why? Is it because, as the peanut butter crisis indicates, private regulatory regimes are more easily thwarted by guile and opportunism? Who is accountable to whom, for example, when private certification agencies must market their services to the very corporations they are supposed to regulate? How do private inspectors enforce high standards and remain in business?

Regulatory regimes are best understood, not as mere collections of technical standards and mechanisms, but as expression of political values and cultural attachments. They can reflect and reinforce existing power relationships or transform and reconstitute the ways by and through which power is distributed, legitimated, and exercised. At a time when political values, cultural attachments, and power relationships appear to be shifting relative to the problem of food safety, it is important to ask: what are the statutory mandates of U.S. food safety regulatory agencies and how are they lacking but also what values, conceptions of the "public interest," and knowledge systems should frame discussions, not of what food safety accountability and regulation are and why, but what they should be and how. Crises drive new ideas about regulation and accountability, the public interest and efficiency standards; in the face of major food safety proposals that are being debated and the ways in which they would revolutionize notions of accountability and regulation, cultural, political, and economic questions are as vitally important as their scientific counterparts.

Recent food safety crises and scandals indicate that the U.S. food safety regulatory regime is an antiquated relic of the early 20<sup>th</sup> century when understandings of food “safety” were limited to food “purity.” Although revolutionary, the 1906 Pure Food and Drugs Act and the 1906 Federal Meat Inspection Act were the product of compromise and negotiation between progressive advocates, who lobbied for the creation of a national food safety regime in the name of the “public good”, and food producing and processing firms, who supported purity-based government regulation in the name of competitive advantage and profitability. The 1906 act thus created a limited framework that, over time, became fragmented, ineffective, and inefficient system of food safety governance. As Erik Olson, head of food safety at the PEW Research Center, commented, the FDA and the USDA “simply do not have the tools to really protect our food supply.”<sup>470</sup> And while producers and processors are increasingly “taking matters into their own hands” by joining voluntary food safety systems, “part of the solution lies in Washington.”<sup>471</sup>

Mike Taylor, Senior Advisor to the FDA Commissioner, revealed in 2010 that federal food regulators “are hamstrung [and], as a result, [they] often find [themselves] in a reactive mode.”<sup>472</sup> As previous chapters demonstrate, the regulatory powers of the FDA and the USDA are, ultimately, insufficient. For example, neither the USDA nor the FDA has the power to issue mandatory recalls or to require the implementation of product traceability mechanisms. Neither can conduct pathogen testing. With limited exceptions, neither can require that producers and processors implement process-based food safety systems, such as HACCP, GAPs, or GMPs.<sup>473</sup> Neither has effective or efficient inspections powers; the FDA can inspect processing facilities only with notice and under a host of limitations and conditions whereas the USDA’s inspection powers have become increasingly limited, particularly under the Regan and both Bush administrations. Ultimately, that the FDA and USDA have, for the most part, fulfilled their food safety statutory mandates is of little comfort; the mandate itself must be reconsidered

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<sup>470</sup> CBSNews, *CBS Reports: Where America Stands: Food Safety*, CBS, 9 January 2010 [available online: <http://www.cbsnews.com/video/watch/?id=6076741n>].

<sup>471</sup> *Ibid.*

<sup>472</sup> *Ibid.*

<sup>473</sup> The FDA can and does recommend that producers follow GAP and GMP guidelines. To encourage producers to do so the FDA publishes a set of GMPs. Moreover, the FDA has been given the authority to require the implementation of HACCP plans for several food commodities and has been given a greater degree of food safety authority with respect to niche food products such as infant formula.

in the context of a top-down regulatory regime enhanced by public accountability mechanisms designed to promote physical, chemical, and microbiological food *safety* rather than food *purity*.

To do so, lawmakers and regulators would benefit from an analysis of the food safety regulatory regimes enacted by other advanced industrial economies. For regulation, as Brown understands, is enhanced by *learning*. Brown writes, regulatory regimes can be enhanced by the development of processes and structures that allow for the “exploration differences, creation of new knowledge, dissemination of ideas and results, and retention of useful learning.”<sup>474</sup> For this reason, although regulatory regimes tend to change slowly and infrequently, *policy analysis* remains an essential part of the policy process; regulatory regimes must be assessed, adapted, and transformed so that they may effectively and efficiently reduce the risks of market failures and enhance the public good. In recent years, food safety regulators have learned from failures of the U.S. food safety regulatory regime. In an effort to learn from the Jack-in-the-Box crisis, for example, the USDA attempted to institute pathogen reduction supplemented by HACCP controls. Similarly, in an endeavor to learn from foodborne illness outbreaks associated with fresh produce, the FDA instituted the GAPs Initiative. The peanut crisis demonstrated that attempts to reform of the U.S. food safety regulatory regime must be revolutionary and, for that reason, attached to a new statutory mandate. In its aftermath, therefore, food regulators and national legislators are challenged to learn, not only from the outbreak and its consequences, but from the successes of the public, top-down, command and control food safety regulatory regimes enacted in other advanced industrial economies.

Many Western economies established food safety regimes around the turn of the 20<sup>th</sup> century that were similar to the 1906 framework in the United States. However, they have since updated, modernized, or reformed their food safety standards to address concerns about microbiological contamination and to incorporate process-based safety provisions. Great Britain, for example, where only 2% of the population contracts a foodborne illness annually, introduced mandatory pathogen testing in the 1970s and constructed a regulatory regime grounded in public accountability mechanisms including inspection, mandatory recalls, and civil liability. France (see below) similarly adopted an administrative food safety system based on scientific risk

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<sup>474</sup> L. David Brown, *Multiparty Social Action and Mutual Accountability*, in Alnoor Ebrahim and Edward Weisband (eds), *Global Accountabilities: Participation, Pluralism, and Public Ethics*, Cambridge, U.K.: Cambridge University Press (2007), pp. 106.

assessment, pathogen reduction, and public inspections and traceability decades before similar proposals made headway in the U.S. Congress.

To understand why the United States and Western Europe adopted radically different regulatory approaches to food safety, one would have to compare their cultural values, economic systems, political structures, and social dynamics. European food safety regimes view food safety as a public, collective good, provided to consumers on a non-rivalrous and non-excludable basis. Although many scholars argue that so-called “command and control” food safety systems are less efficient and effective than product-based or voluntary mechanisms, it is significant to note that the success of the European model demonstrates that top-down, public regulatory regimes and accountability frameworks can reduce the risks of market failure associated with food safety, particularly the risks of microbial contamination and foodborne illness. Moreover, the European example reveals that food safety can enhance corporate efficiency, competitiveness, and profitability. A new regulatory approach for the 21<sup>st</sup> century, therefore, can promote public health and welfare while simultaneously advancing the economic self-interest of agrifood firms if public officials are willing to *learn* from the experiences of its European counterparts.

#### *A Comparative Perspective: French Food Safety: Top-Down Governance and Public Accountability*

The French Consumer Code, which governs food safety, is based on the Law of August 1<sup>st</sup>, 1905, a law that created an administrative body to fight fraud and established the government’s scope of action in the area of food safety.<sup>475</sup> During the 20<sup>th</sup> century, however, “French food policy has constantly evolved, showing an ever stronger will to better take food safety aspects into consideration...the major steps in this policy are linked with scientific breakthroughs, new production techniques, the experience of industry professionals, and

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<sup>475</sup> FrenchFoodSafety, *Food Safety System*, Ministry of Agriculture and Fishing, 2005 [available online: [http://www.securitesanitairedesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide\\_anglais.pdf?nocache=1242666640.88](http://www.securitesanitairedesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide_anglais.pdf?nocache=1242666640.88)].

decisions made within the framework of [the] European Union.”<sup>476</sup> But it was “various crises that marked the final decade of the 20<sup>th</sup> century” that “led the French government to step up its efforts in the area of food safety...thus the law of July 1, 1998 [provided] an improved monitoring of health risks and stricter control of the safety of products destined for human consumption.”<sup>477</sup>

Today the French food safety regulatory regime is grounded in five food safety governing principles: (1) food industry firms (producers, processors, and distributors) hold primary responsibility [for food safety]; (2) regulations must be constantly adapted to keep pace with scientific advances and new techniques in the health field; (3) a system for certifying and inspecting industry firms falls under the responsibility of the government authorities, which have the power to penalize non-compliant firms when necessary; (4) the French Alert Network and the European Union’s Rapid Alert Network are responsible for health monitoring and mobilization in the event of potential or proven dangers; [and] (5) government authorities are qualified to manage risks, in particular in emergency situations.” Thus the French regime emphasizes binding standards, public research, and government-run inspections; it is a pro-active approach to food safety as a public good.

The French food safety regime “governs every aspect of a product’s life cycle, from its compliance with safety regulations, its composition and labeling, up to the way in which it travels through the distribution channel.” Moreover, the Rural Code “constitutes the regulatory environment for food production firms and stipulates the contents of healthy/sanitary inspections, and the quality of food products.” In July 1999, the French government formalized the “farm-to-fork” approach with its Agricultural Orientation Law which stipulates that “food safety begins in the field or on the ranch and is built up step-by-step throughout the entire processing chain, all the way up to the consumer’s plate.”<sup>478</sup> This reinforced the importance of traceability throughout the food system. Finally, the Law of July 1<sup>st</sup>, 1998 improved health monitoring and food safety

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<sup>476</sup>*Ibid.*

<sup>477</sup>*Ibid.*

<sup>478</sup>*Ibid.*

inspection by creating the French Food Safety Agency (AFSSA), a public institution in charge of “assessing food-related health and nutrition risks.”<sup>479</sup>

According to French directives of the 1990’s, French food producers and processors are bound by “the principle of ‘proven safety’ as stipulated in the Consumer Code.”<sup>480</sup> This means that agrifood firms must “ensure the safety of their products [by] identifying the critical points of their activity,” implementing HACCP-based safety systems, and conducting inspections based on HACCP guidelines and methods. Failure to do so “may lead to severe administrative penalties ranging from seizure of manufactured food products up to closure of the company.”<sup>481</sup> However, although food industry firms hold primary responsibility for food safety, they receive a great deal of government support. Under the French food safety regime, regulations must keep pace with publicly funded and conducted scientific research.<sup>482</sup> Moreover, government agencies are responsible for inspections at production facilities,<sup>483</sup> product inspections,<sup>484</sup> and investigations following outbreaks of foodborne illnesses, as well as outbreak monitoring, mobilization, and control.<sup>485</sup> Although food producers and processors must implement traceability systems, the government conducts mandatory product recalls as necessary. Nearly 8000 French public officials work to safeguard the food supply; most are involved in inspections and certifications in production, processing, and distribution centers.

To implement these regulatory controls, three ministries—the Ministry of Agriculture and Fisheries in conjunction with its General Directorate for Food (DGAL), the Ministry of Health in conjunction with its General Directorate of Health (DGS), and the Ministry of Consumer Affairs in conjunction with its General Directorate for Fraud Repression

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<sup>479</sup>*Ibid.*

<sup>480</sup>*Ibid.*

<sup>481</sup>*Ibid.*

<sup>482</sup> Primarily conducted by the French Food Safety Agency, which is a governmental organization created to assess the nutritional and health risks of food products. Its 12 laboratories provide research and scientific/technical support for food safety authorities. The French Food Safety Agency focuses special attention on “high risk” foods as well as specific pathogens (such as *Listeria*, *E. coli*, and *Salmonella*).

<sup>483</sup> Every food firm is inspected before and after it opens. It is then inspected on a regular schedule according to the risks associated with its activity and its hygiene/sanitation/safety record.

<sup>484</sup> Including their composition, their microbiological characteristics, and their temperature throughout production, transport, storage, and distribution.

<sup>485</sup> Unlike the USDA, which can only inspect slaughterhouses, French food safety authorities have the power to inspect farms and ranches. This provides an extra layer of protection since food safety hazards can be identified before animals are brought to a central processing facility.

(DGCCRF)—exercise regulation power with respect to food safety. The General Directorate for Fraud Repression focuses “on the safety, fairness, and quality of all consumer goods (in terms of composition, additives, authorized processing, labeling, [and] sales practices,” including food. Thus it is the DGCCRF that governs food safety relative to food *purity* and *adulteration*. For example, in 2004 DGCCRF performed “2615 labeling inspections for raw materials, mixed products, additives, etc.”<sup>486</sup> It is significant to note, however, that although the U.S. system limits public regulatory authority to issues of purity and adulteration, the DGCCRF is only one, very limited, actor within the French food safety regulatory regime. Within the French system, it is the Ministry of Agriculture and Fisheries’ General Directorate for Food is the “pilot Ministry in matters regarding food safety.”<sup>487</sup> It handles “health and safety risks within the agriculture and food industries” and is responsible for determining and implementing policies for food safety and quality. It controls investigations, conducts continuous inspections in slaughterhouses, and establishes standards for agrifood firms along the farm-to-fork chain. In 2004 it “carried out 200,000 document inspections in animal health and protection, 4,000 specific inspections in slaughterhouses, and 5,000 [inspections] in meat cutting rooms.”<sup>488</sup> Finally, the General Directorate of Health conducts investigations into outbreaks of foodborne diseases.

Within the French system, “coordination and collaboration between the various administrative organizations present locally within each *département*” promotes the efficient and effective governance of food safety and quality.<sup>489</sup> Thus there is a “short chain of command between the central administration—the decision maker—and the *départements*, which carry out the orders.”<sup>490</sup> Although fragmented, the agencies and *départements* work together according to clear divisions of authority and labor to promote food safety. Moreover, the French food safety system is regularly subjected to external audits organized by the European Commission. Not only does this monitor compliance with European regulations, it ensures that the public, top-

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<sup>486</sup> FrenchFoodSafety, *Food Safety System*, Ministry of Agriculture and Fishing, 2005 [available online: [http://www.securitesanitairesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide\\_anglais.pdf?nocache=1242666640.88](http://www.securitesanitairesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide_anglais.pdf?nocache=1242666640.88)].

<sup>487</sup> *Ibid.*

<sup>488</sup> *Ibid.*

<sup>489</sup> *Ibid.*

<sup>490</sup> FrenchFoodSafety *Ibid.*

down institutions that comprise the French food safety regulatory regime remain accountable, not only to the French people, but to an external governance mechanism.

The French system, based upon public, top-down governance and accountability mechanisms, effectively promotes food safety and, in particular, reduces the risks of foodborne disease. Not only is “food safety the main preoccupation of the French food industry,” producers and processors do not limit their conception of food safety to food *purity*<sup>491</sup>. Instead, 85% said that microbial contamination was their primary concern. Of those questioned, 77% cited physical contamination as a common risk and 62% reported concerns about chemical contamination. Although respondents insisted that some risks were outside of their control, they recognized that many risks could be managed within the companies themselves: more than 70% said that staff and machinery could be responsible for contamination and acknowledged that these were risks over which food producers and processors exerted control.

The proof, however, is in the results. Each year France reports approximately 750,000 cases of foodborne illness (1,210 per 100,000 inhabitants) and approximately 400 deaths associated with foodborne pathogens (0.9 per 100,000 inhabitants). *Salmonella* ranks as France’s leading reported foodborne cause of illness and death, accounting for 8000 illnesses and 300 deaths per year. *Campylobacter*, *Listeria*, *Hepatitis A*, and parasites including toxoplasma account for many of the remaining sicknesses and deaths. By comparison, the United States reports approximately 76 million cases of foodborne illness (26,000 cases for every 100,000 inhabitants) and 5000 deaths associated with foodborne pathogens (1.7 per 100,000 inhabitants) each year. As a CBS News report that ran on January 9, 2010 indicated, 25% of Americans contract foodborne illnesses each year. In France, where a top-down, public regulatory regime promotes accountability at every step of the farm-to-fork chain, the rate of foodborne infection is only 1%.<sup>492</sup> If the United States is going to reform its food safety regulatory regime, therefore, it should consider using the public policy process to mimic the success of the French system.

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<sup>491</sup> Chris Jones, *French Food Firms Preoccupied by Safety* FoodQualityNews.com, 15 April 2008 [available online: <http://www.foodqualitynews.com/Public-Concerns/French-food-firms-preoccupied-by-safety/>].

<sup>492</sup> Doug Powell, *Food Safety News, Like Other News is Repetitive, Superficial, Dubious*, BarfBlog: Musings About Food Safety and Things that Make You Barf, 12 January 2010 [available online: <http://barfblog.foodsafety.ksu.edu/2010/01/articles/food-safety-communication/food-safety-news-like-other-news-is-repetitive-superficial-dubious/>].

### The Public Policy Process and the U.S. Food Safety Regulatory Regime

The U.S. food safety regulatory regime, past, present, and proposed, demonstrates the dynamics of a public policy process in which agents, institutions, and interests compete for influence and power relative to their values, preferences, and attachments. The 1906 framework illustrates the policy preferences of early 20<sup>th</sup> century progressives; the fact that the 1906 framework has not been updated despite its increasingly antiquated mandate and accountability framework demonstrates preferences associated with neo-liberalism, government restraint, and corporate dominance in the latter part of the 20<sup>th</sup> century. Current regulatory proposals indicate a change in values and preferences, both in terms of a “public good” but also relative to corporate self-interest. The establishment of the 1906 regulatory interface, its operations for the past 100 years, and the challenges it now faces can be best understood as the product of political interactions between competing interests.

Public policy is often defined as an intentional course of government action designed to respond to a public concern or problem. But public policy encompasses more than what governments choose to do; it includes what they *choose not to do* as well. Some argue that policy shapes politics. Others contend that politics shape policy. Both are correct. As an institutional output framed by political activity, elite preferences, group dynamics, and competing notions of social gain and public interest, economic values, and cultural attachments, public policies tend to emerge as compromises between competing interests and values. In this sense, policy is more than an *output*; it is a *process*, as Dunn wrote, of agenda setting, policy formulation, policy adoption, policy implementation, policy assessment, policy adaptation, policy succession, and policy termination.

Most definitions of “policy,” the “policy process,” and “policy regimes” center upon the notion of the “public.” Policy addresses *public* concerns, serves the *public* interest, is a product of *public* will, and is an output of *public* participatory practices. But what public? Whose concerns, whose interests, whose will, and whose participation dominate policy formulation, implementation, and assessment? A “public” is generally understood to be a community or a group that shares a common interest. But, as Stone writes, the United States is at once a single

public (a national community) and many fragmented publics. As Stone goes on to emphasize, there are winners and losers in the policy process; policies do not serve, represent, advantage, or constrain all members of the national polity equally and in the same way. Of particular concern with respect to food safety policy is the influence of “special interests,” including food producing and processing firms. Although one may argue that public policy should be developed, implemented, and evaluated in ways that advance the *public interest* rather than *special interests*, this is not always the case. How the *public interest* is conceptualized and how the interests of many competing *publics* are incorporated (nor not incorporated) into the policy process are key issues relative to the question of policy formulation and, in this case, re-formulation.

While the policy process is often defined in terms of public support, contradicting goals and values, agent motivations, and issue framing, it is also a function of technical, political, and economic feasibility. Here science advisors play an important, if often informal, role. In the case of food safety, advances microbiology, chemistry, toxicology, and industrial design have allowed food scientists to conceptualize food safety beyond notions of purity, adulteration, and cleanliness and to challenge the effectiveness of product-based (or performance) standards in comparison to process-based system. However, technical progress has not guided food safety policy formulation, implementation, and assessment; regulators and legislators have not *learned* from food scientists in ways that would enhance the efficiency and effectiveness of the U.S. food safety regulatory regime. The degree to which scientific knowledge is incorporated into the policy process—and the degree to which regulators allow political considerations to corrupt the integrity of or undermine the legitimacy of technical analysis—illustrate a political dynamic, particularly with respect to the current food safety legislative proposals.

A public policy regime is a network of social/cultural, political, and legal agents, actors, institutions, and mechanisms that advocate, formulate, establish, implement, and evaluate government responses to issues of public concern. Thus a public policy regime is characterized by a broad range of general features: culture, ideology, mass media, interest groups, policy advisors, political parties, public opinion, local/state/national government institutions (including executive, legislative, and judicial bodies), laws, regulations, and judicial opinions. But, more than this, *The Art of the Game* emphasizes that a public policy regime includes a wide range of political/cultural values, attachments, and tensions: power, authority, legitimacy, representation,

and responsiveness as they mediate the tensions among needs and rights, pluralism and elitism, public and private, equality and justice, and efficiency and effectiveness. A public policy regime thus includes courses of action and inaction, formal and informal players, and intentional and unintentional consequences.

Domhoff argues that the policy process begins in corporate boardrooms. And the political influence of large, powerful corporations is strikingly evident in an analysis of the U.S. food safety regulatory regime. For more than a hundred years, large food producing and processing firms have fought to limit the scope of the U.S. food safety policy regime to notions of food *purity*. Just as food producing and processing firms dominated the policy process at the turn of the 20<sup>th</sup> century, agrifood firms, which are now larger and more powerful, continue to shape the regulatory environment in which they are required to operate in ways advantageous to their economic self-interest. In doing so, they have prevented the development and implementation of top-down accountability standards oriented to proactive physical, chemical, and microbiological food safety, thereby limiting the effectiveness of the public regulatory apparatus.

As Domhoff writes, industries sometimes turn to national government to regulate inter-industry competition, to protect against liability, to avoid state regulatory proposals, or to shift corporate responsibility onto government agencies. In 1906, established food producers and processors crafted the 1906 Pure Food and Drug Act in ways that enhanced their competitive advantage relative to smaller agrifood firms. Similarly, meat processors advocated the passage of the 1906 Federal Meat Inspection Act in order to prevent the implementation of more severe food safety proposals, including ones that called for the nationalization of the slaughterhouse industry. Since 1906, however, food producers and processors have largely opposed attempts to enhance the power and authority of public food safety regulators. Now, when agrifood firms want to use regulation as a competitive weapon, they turn to third-party certifiers and private regimes designed to appeal to consumer preferences but to avoid public oversight. But as the peanut butter scandal of 2008-2009 demonstrates, market-based third-party accountability frameworks are susceptible to the very market failures that justify food safety regulations in the first place. Thus, a new policy framework designed for the 21<sup>st</sup> century must go beyond private,

third-party, voluntary efforts to promote food safety. But what top-down, public mechanisms reduce the risks of market failure associated with food safety efficiently and effectively?

Beginning in January 2009, in the midst of the peanut butter scandal, the 111<sup>th</sup> Congress considered ten separate bills designed to reform the U.S. food safety regulatory regime. Eight of those proposals would act as “stop-gap” measures designed to address specific weaknesses in the U.S. food safety regulatory regime but fail to address the broader need for revision. Two proposals, however, represent revolutionary attempts to radically transform the U.S. food safety regulatory regime into a top-down, public system of governance and accountability comparable to the French model. The question thus becomes: what are the strengths and weaknesses of these policy proposals? To what extent are they able to reduce the risks of market failure associated with food safety?

*Eight Short-Sighted Proposals Before the 111<sup>th</sup> Congress:*

In the aftermath of the 2008-2009 peanut crisis, Congressional representatives made food safety reform a legislative priority. Representative Rosa DeLauro (D-CT), chairwoman of the House Appropriations subcommittee with jurisdiction over the FDA, announced, “I want to make this the year that we fix the nation’s food safety system.”<sup>493</sup> DeLauro “called for the Justice Department to conduct a criminal investigation” of the outbreak; she also sponsored the 2009 Food Safety Modernization Act, a law that would radically transform the U.S. food safety regulatory regime (see Chapter 9).<sup>494</sup> Focusing on the need for *accountability* in food safety, Representative Diana DeGette (D-CO) “likened food manufacturers to truant children who ‘can’t be relied on to report their own problems and correct them in a timely fashion.”<sup>495</sup> DeGette continued “we’re going to have to make them do it.”<sup>496</sup>

In 2009, therefore, Congress considered ten bills designed to enhance the regulatory authority of the FDA and/or to completely transform the U.S. food safety regulatory regime. At

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<sup>493</sup> Gardiner Harris, *Peanut Product Recall Grows in Salmonella Scare*, NYTimes.com, 28 January 2009 [available online: <http://www.nytimes.com/2009/01/29/us/29peanut.html>].

<sup>494</sup> *Ibid.*

<sup>495</sup> *Ibid.*

<sup>496</sup> *Ibid.*

their best, the provisions of these bills would transform the U.S. regulatory regime from one focused on adulteration and consumer education to one equipped to prevent foodborne illnesses and to promote food *safety* rather than food *purity*. They would empower government agencies to hold food producers accountable to a conception of the “public interest” that emphasizes food safety as a collective good. And they would reform the currently fragmented food safety regime, with its divided authority among a myriad of federal and state agencies, into a more consolidated framework.<sup>497</sup> At their worst, however, they would perpetuate a weak, fragmented, ineffective, inefficient, and reactive regulatory regime dedicated to antiquated notions of food *purity* at the expense of a more comprehensive approach to food *safety*.

The Food and Drug Administration Globalization Act of 2009 (H.R. 759) would amend the FD&CA to “set forth provisions governing food safety, including requirements for each food facility: (1) a hazard analysis of facilities that manufacture, process, pack, transport, or hold food for consumption in the United States; (2) identification and implementation of preventative controls; and (3) a written food safety plan.”<sup>498</sup> In addition, it would require “the Secretary of Health and Human to: (1) issue science-based performance standards to significantly minimize, prevent, or eliminate the occurrence of such hazards; (2) establish science-based minimum standards for the safe production and harvesting of fruits and vegetables as necessary; (3) establish a risk-based inspection schedule; and (4) establish a program to expedite the movement of certified food through the importation process.”<sup>499</sup> Moreover, it would “provide for: (1) an accreditation system for food facilities; and (2) certification of laboratories to conduct sampling and testing of food” as well as to “establish an active surveillance system for food” in coordination with the Centers for Disease Control and Prevention.<sup>500</sup> It was introduced on January 28, 2009, referred to the House Committee on Energy and Commerce.

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<sup>497</sup> One scholar commented that the federal government’s attempts to enact more stringent food safety requirements come a time when state governments are becoming more lenient. But both major pieces of legislation shift responsibility and authority from the states to the federal government; the Food Safety Modernization Act of 2009 even includes a provision stating that the existence of interstate commerce for all food commodities is assumed in order to give the federal government authority over all food produced in the United States (in particular, over “local producers” that have until now been exempt from FDA and USDA oversight and regulation).

<sup>498</sup> Congressional Research Service, *Summary: Food and Drug Administration Globalization Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-759&tab=summary>].

<sup>499</sup> *Ibid.*

<sup>500</sup> *Ibid.*

The Tracing and Recalling Agricultural Contamination Everywhere (TRACE) Act of 2009 (H.R. 814) would amend “the Federal Meat Inspection Act to direct the Secretary of Agriculture to establish a traceability system for all stages of manufacturing, processing, packaging, and distribution of food.”<sup>501</sup> The TRACE Act would enable the Department of Agriculture “to trace: (1) each animal to any location at which the animal was held at any time before slaughter; and (2) each carcass or part of a carcass and food product forward from slaughter through processing and distribution to the ultimate consumer.”<sup>502</sup> It “directs the Secretary to establish a traceability system for all stages of production, processing, and distribution of meat and meat food products produced through the slaughter of animals” and “authorizes the Secretary to: (1) prohibit or restrict entry to a slaughtering establishment of an animal not so identified; and (2) require a person or entity to maintain records.”<sup>503</sup> Moreover, it would amend “the Poultry Products Inspection Act and the Egg Products Inspection Act to establish similar provisions for poultry and poultry products and for eggs and egg products.”<sup>504</sup> The bill was introduced on February 3, 2009 and referred to House Subcommittee on Livestock, Dairy and Poultry.

The Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2009 (H.R. 815) would amend the “Federal Meat Inspection Act and the Poultry Products Inspection Act to require a person (other than a household consumer) who has reason to believe that a meat or poultry article handled by such a person is adulterated or misbranded to notify the Secretary of Agriculture of the identity and location of this article.”<sup>505</sup> Upon confirming that the product is misbranded or adulterated, it requires that the Secretary “(1) provide all appropriate persons an opportunity to cease distribution of the article, make appropriate notifications, and recall the article; and (2) require an immediate cessation of distribution if voluntary action is not taken.”<sup>506</sup> It also authorizes the Secretary to: “(1) refuse to provide, or to withdraw, inspections of an

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<sup>501</sup> Congressional Research Service, *Summary: TRACE Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-814&tab=summary>].

<sup>502</sup> *Ibid.*

<sup>503</sup> *Ibid.*

<sup>504</sup> *Ibid.*

<sup>505</sup> Congressional Research Service, *Summary: Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-815&tab=summary>].

<sup>506</sup> *Ibid.*

establishment for willful or repeated violations of the respective Act; (2) to deny or suspend inspection in the public interest to protect the health or welfare of consumers to ensure the effective performance of an official duty under the respect Act; and (3) assess civil penalties for violations.”<sup>507</sup> Finally, the Act would amend the FD&CA to include the same provisions, powers, and conditions. It was introduced on February 3, 2009 and referred to the House Committee on Energy and Commerce.

The Keeping America’s Food Safe Act of 2009 (H.R. 999) would amend the FD&CA “to require: (1) certification of any food safety laboratory or a sampling service that is analyzing, testing, or collecting samples of imported food; and (2) [require] such laboratories or services to submit to the Secretary of Health and Human Services the results of all tests conducted on behalf of an importer.”<sup>508</sup> The Act includes whistle-blower protection, sets forth penalties for falsification, enables the FDA to conduct mandatory recalls of contaminated products, and requires that the Secretary “establish a certification program to ensure that imported food meets the food safety standards applied to food production in the United States” and set forth certification criteria for foreign countries.<sup>509</sup> Moreover, it would require that the Secretary develop and maintain websites and develop school curricula on food safety. It was introduced on February 11, 2009 and referred to the House Committee on Energy and Commerce.

The Safe Food Enforcement, Assessment, Standards, and Targeting (Safe FEAST) Act of 2009 (H.R. 1332) would amend the FD&CA to “expand the authority of the Secretary of Health and Human Services to regulate food, including by authorizing the Secretary to: (1) suspend the registration of a food facility; and (2) order a cessation of distribution, or a recall, of food.”<sup>510</sup> It mandates that each food facility “evaluate hazards and implement preventative controls” and directs the Secretary to allocate inspection resources “based on the risk profile of food facilities or food.”<sup>511</sup> It requires the Secretary to: “(1) recognize bodies that accredit food testing laboratories; (2) identify preventative programs and practices to promote the safety and security

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<sup>507</sup> *Ibid.*

<sup>508</sup> Congressional Research Service, *Summary: Keeping America’s Food Safe Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-999&tab=summary>].

<sup>509</sup> *Ibid.*

<sup>510</sup> Congressional Research Service, *Summary: Safe FEAST Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-1332&tab=summary>].

<sup>511</sup> *Ibid.*

of food; and (3) improve the capacity of the Secretary to track and trace raw agriculture commodities” as well as to “enhance foodborne illness surveillance systems” with the assistance of the Centers for Disease Control and Prevention.<sup>512</sup> Finally, it provides for: “(1) foreign supplier verification activities; (2) a voluntary qualified importer program; and (3) the inspection of foreign facilities registered to import food.”<sup>513</sup> It was introduced on March 5, 2009 and referred to the House Committee on Energy and Commerce.

The Imported Seafood Enhancement Act of 2009 (S. 92) would require “the Secretary of Health and Human Services to: (1) issue an order refusing admission into the United States of all imports of seafood or seafood products originating from a country or exporter which the Secretary determines [does] not meet food safety requirements under the Federal Food, Drug, and Cosmetic Act or which are not likely to meet food safety requirements of any other federal law; and (2) notify all U.S. ports of entry of such refusal within five days.”<sup>514</sup> It was introduced on January 6, 2009 and referred to the Senate Committee on Health, Education, Labor and Pensions.

The Food Safety and Tracking Improvement Act of 2009 (S. 425) would amend the FD&CA to “require the Secretary of Health and Human Services to establish a traceability system for all stages of manufacturing, processing, packaging, and distribution of food through which the Secretary can retrieve the history, use, and location of each article of food shipped in interstate commerce.”<sup>515</sup> It also would amend “the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act” to require a person (other than a household consumer) who has reason to believe that any meat, poultry, egg, or egg product handled by such person is adulterated or misbranded to notify the Secretary of Agriculture of the identity and location of the article” and the FD&CA to require the same disclosure.<sup>516</sup> Upon finding that the article is adulterated or misbranded, the Act would require the Secretary “to: (1) provide all appropriate persons an opportunity cease distribution of the article, make appropriate

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<sup>512</sup>*Ibid.*

<sup>513</sup>*Ibid.*

<sup>514</sup> Congressional Research Service, *Summary: Imported Seafood Enhancement Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-92&tab=summary>].

<sup>515</sup> Congressional Research Service, *Summary: Food Safety and Tracking Improvement Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-425&tab=summary>].

<sup>516</sup>*Ibid.*

notifications, and recall the article; and (2) require an immediate cessation of distribution if voluntary action is not taken.”<sup>517</sup> It authorizes the Secretary to: “(1) refuse to provide, or to withdraw, inspections of an establishment for willful or repeated violations of the respective Act; (2) deny or suspend inspection in the public interest to protect the health and welfare of consumers or to ensure the effective performance of an official duty under the respective act; and (3) assess civil penalties for violation.”<sup>518</sup> It was introduced on February 12, 2009 and referred to the Senate Committee on Agriculture, Nutrition, and Forestry.

The Ending Agricultural Threats: Safeguarding America’s Food For Everyone (EAT SAFE) Act of 2009 (S. 429) would require the Secretary of Agriculture “to: (1) establish food safety and agroterrorism training programs for appropriate federal employees and border patrol agents; (2) hire additional Food Safety and Inspection Service personnel; (3) provide notification of smuggled food products to the public and to the Department of Health and Human Services and (4) provide the public with notification of recalled food products.”<sup>519</sup> It would amend the Federal Meat Inspection Act and the Poultry Products Inspection Act “to establish civil penalties for failure to present imported meat and poultry products for inspection” and would amend the FD&CA to “require federal certification of food safety labs.”<sup>520</sup> Finally, it would amend “the Agricultural Research, Extension, and Education Reform Act of 1998 to direct the Secretary...to establish a foodborne illness education and outreach program.”<sup>521</sup> It was introduced on February 12, 2009 and referred to the Senate Committee on Agriculture, Nutrition, and Forestry.

These proposals represent limited, short-sighted attempts to reform the U.S. food safety regulatory regime. Although several include provisions that would mandate the use of process-based food safety systems and many would authorize federal authorities to conduct mandatory recalls of contaminated products, these policies fail to give the U.S. food safety regulatory regime a 21<sup>st</sup> century mandate. Some remain focused on food *purity* and *adulteration* rather than food *safety*; several return to the notion of “consumer education” but ignore broader food safety needs; none reform the divided system of food safety regulation that characterizes the current

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<sup>517</sup> *Ibid.*

<sup>518</sup> *Ibid.*

<sup>519</sup> Congressional Research Service, *Summary: EAT SAFE Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-429&tab=summary>].

<sup>520</sup> *Ibid.*

<sup>521</sup> *Ibid.*

regime; many emphasize food *imports* and food biosecurity at the expense of food safety; and although many include provisions designed to address problems made visible by recent food safety crises, most remain tied to the early 20<sup>th</sup> century notions of food safety, ignoring the many limitations faced by the FDA and the USDA 100 years later.

The Food and Drug Administration Globalization Act of 2009, for example, would require process controls for food producers, make the adherence to GAPs mandatory for fresh produce producers and processors, and require accreditation for private laboratories. However, it ignores the fact that the FDA lacks the research capacities of the USDA, does not allow for increased funding for inspections and accreditation, and does not resolve the risks of private laboratory pathogen testing revealed by the peanut butter crisis; laboratories may be accredited by the federal government, but their information is controlled by food producers and processors that may seek profitability through guile and opportunism. Similarly, the Safe FEAST Act of 2009 would require hazard prevention at the producer/processor level, permit mandatory recalls, implement a traceability system, and promote import certification, but fails to implement a top-down, public oversight program. Although it would empower federal authorities to allocate inspection resources based on the risk profile of the producer, processor, or food product, it does not allocate additional inspection resources nor does it allow inspectors to use pathogen testing to assess the producer or processor's safety regime. Moreover, although the Act would require that the government *recognize bodies that accredit* food testing laboratories, it does not empower regulatory authorities to *accredit those laboratories* directly. Rather than introduce greater accountability into the system of pathogen testing, this provision would open the door to guile, opportunism, and market failure *at another intermediary step* in the process. It would not *necessarily* enhance food safety.

Several of the proposals remain limited to the food safety regulatory authority of the USDA. For example, the TRACE Act of 2009 would institute a farm-to-fork traceability system, its scope is limited to meat, poultry, and eggs. It would enhance the authority of the USDA, but does nothing for the FDA, the regulatory authority that is responsible for 80% of the U.S. food supply. The Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act would give both the USDA and the FDA mandatory recall power, but maintains the early 20<sup>th</sup> century emphasis on *misbranded* and *adulterated* products; it would not allow regulatory authorities to

recall products that are *unsafe*, merely *impure*. The Food Safety and Tracking Improvement Act of 2009 include similar recall powers but again limit their use to foods that are found to be *adulterated* or *misbranded*.

The Keeping America's Food Safe Act of 2009 would require that private laboratories be certified by the federal government *and* mandate that they release lab test results to federal authorities *but only* for *imported* foods. Although the safety of food imports is a concern and currently only 1% of imported foods are inspected by the FDA, the vast majority of foodborne illnesses are traced back to *domestically* produced foods and food products. This emphasis on imported foods is echoed in the Imported Seafood Enhancement Act of 2009, which would require that imported seafood *meet the safety standards established by the FD&CA*. Although this proposal purportedly responds to widespread concerns about the safety of imported seafood (including shrimp), its use of the current U.S. food safety regulatory regime as a benchmark renders it ineffective. Because the U.S. food safety regulatory regime reduces the risk of food *adulteration* and does not emphasize food *safety*, this law would do virtually nothing to enhance the *safety* of imported seafood.

Finally, several of the proposals go to great lengths to give federal regulators powers they already have under the existing food safety regulatory regime. For example, the EAT SAFE Act of 2009 would allow the USDA to provide food safety and agroterrorism training to federal employees. Yet the USDA already trains federal personnel in food safety and biosecurity. Moreover, the Act would require that regulators notify the public of food recalls; both the FDA and the USDA already do this to the best of their abilities. Finally, like the Keeping America's Food Safe Act of 2009, the EAT SAFE Act of 2009 would emphasize *consumer education* rather than *processor controls*, *imports* rather than *domestically produced foods*, and the *certification of private laboratories* rather than *public pathogen testing*.

These regulatory proposals give the existing U.S. food safety regulatory regime a face life, a new veneer to camouflage an outdated and ineffective system. They give the *appearance* of enhanced food safety but without the kinds of top-down, public governance and accountability mechanisms necessary to produce *safe* food rather than *pure* food at all points along the farm-to-fork chain. Two additional proposals before the 111<sup>th</sup> Congress, however, combine a broader understanding of food safety with a public commitment to governance and accountability. The

Food Safety Modernization Act of 2009 and the Food Safety Enhancement Act of 2009 thus represent transformative change for the U.S. food safety regulatory regime, change that has the capacity to effectively and efficiently reduce the risks of market failures associated with physical, chemical, and microbiological food contamination.

*Closer to Real Reform: The Food Safety Modernization and Food Safety Enhancement Acts of 2009*

The Food Safety Modernization Act of 2009 Act argues that “federal food safety standard setting, inspection, enforcement, and research efforts should be based on the best available science and public health considerations and food safety resources should be systemically deployed in ways that most effectively prevent food-borne illnesses.”<sup>522</sup> Moreover, it recognizes that “there is no official with full-time responsibility and budget authority for food safety at the [FDA] and food safety competes unsuccessfully with the drug and medical device program<sup>523</sup> for senior agency management attention and resources.”<sup>524</sup> Thus the Food Safety Modernization Act would “assign all the authorities and responsibilities of the Secretary of Health and Human Services related to food safety to the Administrator of Food Safety [and would] transfer to Administration all functions of specified federal agencies that relate to the administration or enforcement of food safety laws.”<sup>525</sup>

The Food Safety Modernization Act of 2009 (H.R. 875) would create a Food Safety Agency within the Department of Health and Human Services. The Agency would: “(1) administer a national food safety program; and (2) ensure that persons who produce, process, or distribute food prevent or minimize food safety hazards.”<sup>526</sup> While it would consolidate the food safety functions of the FDA, the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration, it would not, however, create a single food safety agency

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<sup>522</sup> H.R. 875, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/billtext.xpd?bill=h111-875>].

<sup>523</sup> And now, given that the FDA is charged with regulating tobacco, food safety must compete with yet another high priority, resource intensive regulatory commitment.

<sup>524</sup> H.R. 875, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/billtext.xpd?bill=h111-875>].

<sup>525</sup> Congressional Research Service, *Summary: Food Safety Modernization Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-875&tab=summary>].

<sup>526</sup> *Ibid.*

responsible for the entirety of the U.S. food supply; the USDA would maintain its control over meat and poultry. The Act does nothing to enhance the regulatory authority of the USDA. This stands as a key weakness of the proposed legislation since most food safety scholars, practitioners, and critics *as well as the United States Government Accountability Office* advocate for the creation of a single, centralized, independent government regulatory agency for food safety.

The Act does, however, emphasize the need for public accountability within the food safety system. It thus provides for: (1) facility registration; (2) federal inspections of all producing/processing facilities, including farms and vineyards; (3) federal oversight of producer/processor preventative process control plans; (4) mandatory recalls of contaminated products; (5) federal access to grower/producer/processor records and mandatory disclosure of pathogen test results; (6) suspended registration for violators; (7) a farm-to-fork traceability system; (8) laboratory accreditation; (9) a national health registry designed to better track outbreaks of foodborne illnesses; and (10) criminal and civil penalties for violators. Moreover, it mandates that agrifood firms adopt preventative process controls and requires that the Agency enforce performance standards for food safety, establish an inspection program, strengthen foodborne illness surveillance systems, require that imported foods meet U.S. standards, and establish a traceability system for food.<sup>527</sup> Specifically focused on microbiological food safety hazards, the Act empowers the Administrator to “maintain a DNA matching system and epidemiological system for foodborne illness identification, outbreaks, and containment” and requires that the FSA “establish guidelines for a sampling system” for all foods produced or sold within the United States. Finally, it stipulates that imports must meet U.S. standards and must be certified either by an accredited foreign government or an accredited third-party certifying agency.

The Food Safety Modernization Act of 2009 updates the meaning of *adulterated* to include any food or food product that bears or contains “a contaminant that causes illness or death among sensitive populations.” This definition, however, remains vague. What are *sensitive populations*? The Act specifically references the elderly, the immuno-suppressed, and

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<sup>527</sup>*Ibid.*

children,<sup>528</sup> but are foods adulterated only if they cause illness or death among these groups? Rather than updating the 20<sup>th</sup> century mandate focused on food *purity*, therefore, the Food Safety Modernization Act makes the legal prohibition against adulterated foods more complex, convoluted, and ineffective.

The Food Safety Enhancement Act of 2009 (H.R. 2749) would similarly institute a U.S. food safety regulatory regime based upon facility registration, public inspections, process-based safety systems, traceability, mandatory recalls, and criminal penalties for violators. But it would also *legally transform* food *purity* to food *safety*, enhancing the power of federal regulatory authorities under existing laws *as well as* the new statute. The Act amends the FD&CA to “deem a food misbranded if it was manufactured, processed, packed, or held in a facility that is not registered” and “requires annual registration of food facilities” while authorizing the Secretary of Health and Human Services to “suspend the registration of any food facility for [violations]...that could result in serious adverse health consequences of death to humans or animals.” While this language is reminiscent of the 20<sup>th</sup> century commitment to food *purity*, Sections 102 and 103 of the Act “deems a food to be adulterated [or misbranded] if it has been [1] manufactured, processed, packed, transported, or held under conditions that do not meet the requirements for hazard analysis and risk-based preventative controls,” (2) “manufactured, processed, packed, transported, or held under conditions that do not meet performance standards,” or (3) grown, harvested, processed, packed, sorted, transported, or held under conditions that do not meet safety standards for raw agricultural commodities.”<sup>529</sup> Thus the Food Safety Enhancement Act of 2009 legally transforms food *purity* into an outcome of science-based food safety grounded in *process* controls *as well as* *product* standards. In addition, the Act “requires the owner, operator, or agent of a food facility to: (1) conduct a hazard analysis; (2) identify and implement effective preventative controls; (3) monitor preventative controls; (4) institute corrective actions as necessary; (5) conduct verification activities; and (6) maintain records of monitoring, corrective action, and verification” and requires that each food facility “implement a food safety plan before introducing any shipment of food into interstate

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<sup>528</sup> The Act does *not* identify pregnant women as a sensitive population even though several foodborne pathogens, such as *Listeria monocytogenes*, present particular health hazards for pregnant women and their fetuses.

<sup>529</sup> Congressional Research Service, *Summary: Food Safety Enhancement Act of 2009*, Govtrack.us, 2009 [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-2749&tab=summary>].

commerce.”<sup>530</sup> To ensure compliance, the Act gives the FDA the authority to inspect all food production and processing facilities operating in the United States (see below).

The Act also requires that the FDA establish: (1) “science-based performance standards applicable to foods or food classes to minimize to an acceptable level, prevent, or eliminate the occurrence of the most significant foodborne contaminants and the most significant resulting hazards,” (2) “science-based standards for conducting a hazard analysis, documenting hazards, identifying and implementing preventive controls, and documenting the implementation of the preventive controls,” and (3) “scientific and risk-based food safety standards for the growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities.”<sup>531</sup> It authorizes the FDA to “conduct research to assist in the implementation of this Act, including studies to: (1) improve sanitation and food safety practices in the production, harvesting, and processing of food products; and (2) develop improved techniques for monitoring food and inspecting food products.”<sup>532</sup> And the Act promotes food *biosecurity* as well as food *safety*. It “requires the owner, operator, or agent of a food facility to implement a food defense plan that includes: (1) an identification of conditions and practices that may permit a hazard to be intentionally introduced; and (2) a description of preventive measures implemented” and “authorizes the Secretary to establish by regulation or guidance preventive measures for specific product types to prevent intentional contamination throughout the supply chain” that must be implemented by producers and processors. It thus transforms the U.S. food safety regulatory regime into a *proactive* system of process and product controls designed to “prevent unintentional contamination throughout the supply chain” and to facilitate cooperation and coordination between producers/processors and regulators.<sup>533</sup>

In response to the peanut crisis of 2008-2009, in which PCA was could not be compelled to turn over its product tests to regulatory authorities until the federal investigation began, the Act authorizes the Secretary to “require the submission of finished product test results documenting the presence of contaminants in food posing a risk of severe adverse health consequences or death for certain high-risk food facilities after completion of pilot projects and a

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<sup>530</sup>*Ibid.*

<sup>531</sup>*Ibid.*

<sup>532</sup>*Ibid.*

<sup>533</sup>*Ibid.*

feasibility study.”<sup>534</sup> It also “directs each person who manufactures, processes, packs, transports, distributes, receives, or holds an article of food in the United States or for import into the United States to permit an officer or employee of the Secretary to have access to and copy all records bearing on whether that food may be adulterated, misbranded, or otherwise in violation of [federal law]; it gives federal regulators access to farm records for any farm that produces a commodity associated with an outbreak of a foodborne illness.”<sup>535</sup> In addition, it expands the FDA’s inspection authority. It stipulates that every food production or processing facility submit to FDA inspections every six to twelve months (for high risks producers, processors, or products) or three years (for low risk producers, processors, and products) and requires that all producers/processors submit to pathogen testing by *federally accredited laboratories that are audited to ensure accountability*.

The Act includes reactive provisions as well. For example, it requires that the FDA establish a tracing system for food so that each food can be traced from growers to producers to manufacturers to processors to packers to transporters to distributors to consumers. It also mandates that producers and processors “notify the Secretary of adulterated or misbranded food that presents a reasonable probability that the use or consumption of, or exposure to...will cause a threat of serious adverse health consequences or death to humans or animals” so that the Secretary can request an immediate cessation of distribution of the food, to seize contaminated products, or to issue a mandatory recall. It authorizes the FDA to improve foodborne illness surveillance systems with the cooperation of the Centers for Disease Control and Prevention. It implements a national public education program on food safety, designates funding for food safety research, and seeks to promote greater public awareness of food safety from farm to fork. Finally, the Act includes criminal and civil penalties for those who violate food safety standards and regulations. It requires that the FDA fine food facilities that commit a violation of the FD&CA (as amended) and thus require additional inspections or prompt a food recall and “extends the sentence for prohibited acts related to adulterated or misbranded food from imprisonment for not more than one year to imprisonment for not more than ten years.”<sup>536</sup>

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<sup>534</sup>*Ibid.*

<sup>535</sup>*Ibid.*

<sup>536</sup>*Ibid.*

The proposed legislation is thus designed to give the FDA a far broader food safety statutory mandate and to empower it to enact standards, procedures, and oversight mechanisms directly relevant to the question of accountability. It focuses on public, top-down governance mechanisms and shifts regulatory focus away from private voluntary, market-based arrangements. For example, it transforms the GAPs Initiative into a mandatory system of fresh produce safety and extends requirements for process controls to all food producers/processors. It is not, however, a “one size fits all” command-and-control regime; each producer/processor is required to develop, implement, assess, and revise its own HACCP plan. Although the Act permits the FDA to issue guidance documents to assist producers and processors in this task, agrifood firms remain free to tailor their food safety systems to their individual needs and operations. The Food Safety Enhancement Act of 2009 thus promotes a radical revision of the U.S. food safety regulatory regime. But it has one significant weakness: it applies only to the regulatory authority of the FDA; it does nothing to revise or enhance the regulatory authority of the USDA and perpetuates, therefore, the divided authority of the U.S. food safety system.<sup>537</sup>

Thus although the Food Safety Modernization Act of 2009 and the Food Safety Enhancement Act of 2009 would transform the U.S. food safety regulatory regime into a system more analogous to the French model, none of the regulatory proposals that emerged in the aftermath of the peanut butter scandal create a single, public, top-down, centralized, science-based, process-focused approach to physical, chemical, and microbiological food safety. While not ideal, this compromise is not necessarily a detriment to efficient, effective, proactive food safety regulation. As Shames reported, the GAO is looking “to get food safety off of the high risk list.”<sup>538</sup> To achieve this goal, the GAO recommended the institution of “some kind of food safety council [designed to bring] many of the principals together.”<sup>539</sup> President Obama did so when he established the Food Safety Working Group,<sup>540</sup> a body that has already issued some

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<sup>537</sup> This may be because meat and poultry producers and processors have successfully fought every attempt at national food safety regulation since the early 1900’s (even the 1906 Federal Meat Inspection Act was weakened by the meat industry). In fact, the meat and poultry industry has opposed the Food Safety Enhancement Act of 2009, a proposal that doesn’t affect their operations (see below).

<sup>538</sup> Lisa Shames, interview by Courtney I. P. Thomas, 27 January 2010.

<sup>539</sup> *Ibid.*

<sup>540</sup> The Food Safety Working Group is designed to make sure that all federal agencies with food safety authority work synergistically, allocate resources efficiently, and react to crises effectively. To advance their efforts, President Obama’s newest budget allocates an additional \$1.5 billion to the FDA to reorganize the way it monitors

food safety guidance.<sup>541</sup> But “ultimately what [the GAO would] like to look at beyond that is a governmentwide food safety plan so the various agencies can discuss their food safety goals, make sure they are complimentary, discuss their strategies and make sure they are reinforcing, and ultimately make for a more coordinated federal response.”<sup>542</sup>

And yet the GAO is not a staunch advocate of a single food safety agency. Shames explains that, in the past, the “GAO had recommended a single food agency.”<sup>543</sup> After it made this recommendation, however, “the U.S. government established the Department of Homeland Security.”<sup>544</sup> This experience “gave [the GAO] a better understanding of what happens when the government merges institutions.”<sup>545</sup> Since 2003, DHS has been unable to develop “a comprehensive plan to address the transformation, integration, management, and mission” challenges associated with the consolidation of government agencies.<sup>546</sup> Thus, the GAO is looking to study “what ought to be the federal organization for food safety, whether it be a single agency which actually combines USDA and FDA or another proposal [that would allow] all those agencies [with food safety mandates within the Department of Health and Human Services], such as FDA or the CDC, [to] consolidate all of their food safety responsibilities so that there would be a single food safety agency under HHS.”<sup>547</sup> The latter is the solution given legislative form in the Food Safety Modernization Act of 2009. As Shames concluded, “every single strategy is going to have its strengths and its limitations... every public organization faces

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the production of food, step up inspections, expand its laboratory capacities, and improve its ability to trace the source of an outbreak of a foodborne illness. Some have called the budget overly optimistic because it depends on \$250 million in user fees included in the Food Safety Enhancement Act of 2009 that has passed the House but not the Senate.

<sup>541</sup> In January 2010, President Obama also nominated Elisabeth Hagen to the position of chief food safety official at the USDA, a position that had been vacant for more than a year, and Michael Taylor to the position of “Food Safety Czar” at the FDA. Both were contentious appointments: Hagen is a physician and infectious disease specialist with little food safety experience to speak of while Taylor has been criticized for his stance on and prior administrative experience regarding Genetically Modified Foods and Bovine Growth Hormones.

<sup>542</sup> Lisa Shames, interview by Courtney I. P. Thomas, 27 January 2010.

<sup>543</sup> *Ibid.*

<sup>544</sup> *Ibid.*

<sup>545</sup> *Ibid.*

<sup>546</sup> United States Government Accountability Office, *High-Risk Series: An Update*, Report to Congress, January 2009, pp. 49 [available online: <http://www.gao.gov/new.items/d09271.pdf>].

<sup>547</sup> Lisa Shames, interview by Courtney I. P. Thomas, 27 January 2010.

a lot of pressures...it has to come up with an approach that is within budget and [it has to] be aware of what a strategy can and can't do and come up with mitigating strategies."<sup>548</sup>

In this context, it is important to note that many of the current proposals would reform the most egregious problems with the current system; traceability, the power of mandatory recall, and federal oversight of third-party inspectors/certifiers/laboratories would reduce the risks of market failures associated with food safety, though not as much as would processor controls, mandatory pathogen testing, and direct federal oversight and inspection of all growing, production, and processing activities. Despite the fact that the peanut butter crisis disrupted food safety policy equilibrium leading to the introduction of ten regulatory proposals, however, none gained headway with the 111<sup>th</sup> Congress in 2009. The reasons indicate that the U.S. food safety regulatory regime may be entering a phase of *restored equilibrium*; although the time for transformative change has come, the moment may very well pass if advocates for reform continue to lose momentum relative to the policy process.

### *Restored Equilibrium: Lost Momentum and the Current Status of Food Safety Reform*

On March 31, 2009 the last reported illness associated with the 2008-2009 outbreak of *Salmonella* linked to peanut butter produced by the Peanut Corporation of America plant in Blakely, GA was recorded by the Centers for Disease Control and Prevention. The outbreak was “expected to continue at a low level for [several more months] since consumers, unaware that they [had] recalled products in their home [were expected to] continue to consume these products, many of which [had] a long shelf life.”<sup>549</sup> After several federal investigations, a House hearing, the largest food-product recall in U.S. history, 714 illnesses, and nine deaths, the peanut butter scandal was relegated to the pages of history. And as public attention shifted away from food safety crises, demands for revolutionary reform of the U.S. food safety regulatory regime lost momentum. Although both houses of Congress are currently considering transformative

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<sup>548</sup> *Ibid.*

<sup>549</sup> Centers for Disease Control and Prevention, *Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008-2009*, Department of Health and Human Services, 29 April 2009 [available online: <http://www.cdc.gov/Salmonella/typhimurium/update.html>].

proposals with regard to food safety, the policy process has stalled; equilibrium, it would appear, has been restored.

In June 2009 federal authorities investigated a national outbreak of *E. coli* 0157:H7 linked to raw refrigerated cookie dough produced and sold by the Nestle Corporation, one of the world's largest agrifood firms and a self-proclaimed proponent of food safety. Nestle issued a voluntary recall of its Toll House™ cookie dough products including refrigerated cookie bar dough, cookie dough tubs, cookie dough tubes, limited edition cookie dough items, seasonal cookie dough, and Ultimates cookie bar dough. Approximately 300,000 cases of chocolate chip, gingerbread, sugar, and peanut butter cookie dough we recalled. In the aftermath of the outbreak, Sarah Klein, attorney in the food safety group at the Center for Science in the Public Interest called the news “disheartening” but went on to say, “unfortunately, I don’t think people who have been working in food safety...can be surprised at this point and sadly, I don’t think the American people are surprised either.”<sup>550</sup> But the outbreak, which caused no deaths and was well managed by federal authorities working in cooperation with Nestle, did not reinvigorate calls for regulatory reform.

In October 2009, Plum Organics, a food producer in Emeryville, CA, recalled its apple and carrot portable pouch baby food because of concerns over botulism contamination. The company released that the product “did not meet the FDA guidelines for proper acidity level.”<sup>551</sup> The company explained that “due to a mixing error during production, one batch of this product was improperly blended...as a result, it did not meet [the company’s] standard for quality.”<sup>552</sup> The mistake was discovered during routine product tests and Plum Organic took “the [immediate] step of recalling all Apple and Carrot Portable Pouches with [a May 21, 2010 best buy date] to eliminate any questions in the minds of consumers about the safety of our products.”<sup>553</sup> Although the product in question was organic (and thus assumed by many

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<sup>550</sup> Associated Press, *Nestle Recalls Cookie Dough Products for E. coli: 66 Reports of Illnesses Across 28 States since March; 28 People Hospitalized*, MSNBC.com, 19 June 2009 [available online: [http://www.msnbc.msn.com/id/31444614/ns/health-infectious\\_diseases/](http://www.msnbc.msn.com/id/31444614/ns/health-infectious_diseases/)].

<sup>551</sup> Kate Sobel, *Plum Organics Voluntarily Recalls Select Batch of Apple and Carrot Portable Pouches Due to Potential Health Risk*, Plum Organics, 19 October 2009 [available online: <http://www.fda.gov/Safety/Recalls/ucm187323.htm>].

<sup>552</sup> *Ibid.*

<sup>553</sup> *Ibid.*

consumers to be safer than conventionally produced alternatives) and designed for infant consumption, no illnesses were reported and the episode, the recall was conducted efficiently and effectively by the food producer and demonstrated Plum Organics' commitment to food safety, and thus received very little media attention.

In November 2009, an outbreak of *E. coli* 0157:H7 linked to ground beef produced by Fairbank Farms of Ashville, NY renewed concerns about ingredient contamination. Fairbank farms<sup>554</sup> recalled 546,000 pounds of fresh ground beef after 28 illnesses and two deaths were reported to the CDC were traced its products. In its recall notice, the U.S. Department of Agriculture noted that “the possibly tainted meat had been sold in numerous ways, from meatloaf and meatball mix to hamburger patties.”<sup>555</sup> Some of the ground beef was sold at Trader Joe's, Price Chopper, Lancaster, Wild Harvest, Shaw's, BJ's, Ford Brothers, and Giant stores; those products were marked with a specific label to facilitate traceability and recall. The rest of the ground beef, however, was “packaged in wholesale-sized containers under the Fairbank Farms name [and] was distributed to stores in Maryland, Massachusetts, North Carolina, New Jersey, New York, Pennsylvania, and Virginia [with a wide variety of packaging] and sell-by dates.” Shortly after the recall, Senator Kirsten Gillibrand (NY), who “wants federally mandated *E. coli* inspections of all ground beef,” commented that this outbreak was “a stark reminder that food is still going straight to our kitchens and grocery stores without being properly tested to ensure its safety...its spreading diseases and costing too many lives.” “It's time,” Gillibrand said, “to address the gaps in the inspection process.”

Yet despite the fact that these and other outbreaks of foodborne illnesses indicate that the U.S. food safety regulatory regime is antiquated, inefficient, and ineffective, reform measures were not a priority for the 111<sup>th</sup> Congress. Kingdon writes that problems, policies, and politics put issues on the national public policy agenda. In the case of food safety, a series of crises signaled the emergence of problems with the U.S. food safety regulatory regime. At the same time, a gradual accumulation of knowledge and perspectives among food safety specialists in

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<sup>554</sup> In 2007 Fairbank Farms recalled 884 pounds of ground beef because of possible *E. coli* contamination. In 2008 it recalled 22,481 pounds of ground beef that may have contained pieces of plastic, indicating that although microbiological food safety dominates the public discourse, physical food safety is a continuing concern.

<sup>555</sup> Ben Dobbin, *CDC: Tainted Ground Beef May Be Linked to Two Deaths*, Associated Press, 2 November 2009 [available online: <http://www.newsvine.com/news/2009/11/02/3451904-cdc-tainted-ground-beef-may-be-linked-to-2-deaths>].

both the private and public spheres generated demands for policy reform. Finally, “swings of national mood, vagaries of public opinion, election results, changes of administration, and turnover in Congress” all signaled that food safety was an issue whose “time had come.”<sup>556</sup> A wide array of powerful political figures appeared dedicated to food safety regulatory reform: newly-elected President Obama, Congressional leaders, administrative directors, civil servants, food scientists, consumer interest groups, the media, and public opinion cited food safety regulatory reform as a top priority. But although ten food safety proposals, some more radical than others, were introduced to the House of Representatives and the Senate, each designed to enhance the power of the regulatory regime, all but one remained tabled in committee and none progressed through the entirety of the policy process; the Food Safety Enhancement Act of 2009 passed the House of Representatives but was not considered by the Senate during the 2009 session. Why and what does this mean for the future of U.S. food safety regulation?

With economic power comes political influence and today many argue that agribusinesses dominate the U.S. policy process, particularly on issues of food safety and food regulation, in ways that advance their corporate interests at the expense of the “general welfare.” For many years agribusinesses opposed updates to the 1906 food safety regulatory framework. Agribusiness opposition cannot explain the current state of restored equilibrium, however, because many food producers and processors have expressed tacit support for food safety reform measures. This may be because the transaction costs attached to the current proposals threaten the existence of small “local” food producers<sup>557</sup> and thus could potentially eliminate market competitors; large agribusinesses afford to implement the process-controls, testing, inspection, and traceability requirements<sup>558</sup> that both major pieces of reform legislation include whereas many small producers cannot. This would be consistent with the large, conventional agrifood firm approach to food safety legislation established in 1906. It is also possible that

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<sup>556</sup> John W. Kingdon, *Agendas, Alternatives, and Public Policies*, Glenview, IL: Scott, Foresman, and Company (1984), pp. 18

<sup>557</sup> Several of the food safety proposals have been said to threaten the existence of so-called “local” producers because they hold all producers and products—local and conventional—to the same process and product standards. The Food Safety Modernization Act goes further by legally presuming that all foods and food products produced in the United States are part of interstate commerce and thus subject to the terms of the law. Local producers and their supporters have opposed attempts to regulate local food production while advocating for more stringent food safety controls for “conventional” producers.

<sup>558</sup> In fact, many producers implemented similar controls before the peanut butter scandal of 2008-2009 with others following suit after the outbreak.

agribusinesses are looking to shift responsibility for outbreaks of foodborne illnesses onto government regulatory agencies in an attempt to protect their brands and avoid civil liability. Alternatively, firms may hope that more stringent safety requirements will make them more competitive in international markets. Or perhaps agribusinesses have finally learned that food safety is good for business. In any case, the absence of an organized effort to prevent the passage of public reform measures represents a change in the food safety regulatory dynamic that has existed for the past 100 years.

The only food producing/processing sector that has voiced strong opposition to proposed reforms is the beef industry represented by the National Cattlemen's Beef Association. In June 2009 it released a statement urging Congress to reconsider provisions in the Food Safety Enhancement Act of 2009, which is ironic considering that the Act changes the regulatory authority of the FDA rather than the USDA. The Association, however, opposed attempts to authorize the FDA to conduct on-farm inspections saying that this would undermine the USDA's regulatory authority in ensuring the safety of meat and poultry products. The extension of regulatory power, however, was not designed to give the FDA authority of meat or poultry; it was designed to ensure that growers were adhering to what would become mandatory GAPs guidelines and to allow the FDA to implement a tracing program for *all food products*, including meat and poultry. But it was not a *food safety* provision. Moreover, the USDA *doesn't* have the authority to do farm inspections or to implement traceability for meat or poultry from farm-to-fork; its inspection power is limited to the slaughterhouse and any traceability information it obtains comes from the producers themselves in the absence of federal oversight. The release stated that the "FDA does not have the money, employees, or expertise to properly oversee the livestock and poultry."<sup>559</sup> This is true. But the Act didn't give the FDA that power or responsibility.

Thus restored equilibrium cannot be attributed to corporate opposition. The explanation lies instead in the willingness of citizens and legislators to become distracted from regulatory reform by political and economic crises and debates such as: the transfer of power to a new Democratic administration and Congress, military conflict in Iraq and Afghanistan, economic recession and the bailout proposals, climate change, and, of course, health care reform. It is

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<sup>559</sup> *Cattlemen's Capitol Concerns*, National Cattlemen's Beef Association, 11 June 2009.

perhaps the latter that most thoroughly dominated policy discourse throughout 2009, pushing food safety reform from the forefront of public concern to the recesses of political debate. Moreover, although President Obama's support for food safety reform, stemming, in part, from his daughter's affinity for peanut butter sandwiches, may have helped move propels through Congress at the beginning of his tenure as President, a year of anti-Obama fervor and the emergence of the so-called "Tea Party" movement raises the possibility that Presidential support may now be a hindrance to regulatory reform. Although food safety reform featured prominently on the Congressional agenda in the early months of 2009, therefore, it quickly faded into the background as government officials shifted their attention to competing problems and priorities. By the end of 2009, therefore, the American people, the Obama administration, and the 111<sup>th</sup> Congress had become distracted from issues of food safety and the potential for reform was greatly diminished. And food producing and processing firms were thus free to operate as they had for a century—protected from public, top-down food *safety* regulation.

### *The Continuing Need for a 21<sup>st</sup> Century Approach to Food Safety and Its Regulation*

U.S. food safety regulation is a story about the power of special interests to subvert the "public" interest. It is a story about U.S. food culture, of the willingness of American consumers to assume, first, that the food they eat *is safe* and, moreover, that government agencies *have the power to ensure that safety*. But, more than this, it is a story about the relationship between people and their government. As recent debates about health care reform demonstrate, Americans remain profoundly opposed to "big government." Even in the aftermath of an economic crisis promoted and perpetuated by the absence of government regulation over corporate interests, they eschew public attempts to regulate economic activity as "socialist" and/or "un-American." Whereas the French, by comparison, have implemented a *dirigiste* economy that couples open markets with strong public regulation, Americans distrust government intrusions into the economic lives of individual citizens. Often believing that the individual, the private sphere, or the market can promote the public good more effectively and efficiently than any government entity, Americans largely oppose attempts to aggrandize the power of the national government.

Thus the Progressive spirit of the early 20<sup>th</sup> century has been replaced by neo-liberal devotion to unencumbered markets, small government, and individual freedom. As Croley writes, “not since the 1960s have either Republicans or Democrats run on a platform that defends big government, much less advocate[d] for increased reliance on regulatory government as a solution to social problems.”<sup>560</sup> Skepticism toward regulatory government is, Croley explains, a self-fulfilling prophesy. Regulatory failures are expected while regulatory successes go unnoticed. Ultimately, “the refrain that regulatory government is doomed to fail becomes internalized after repetition...citizens and commentators come to expect less, and therefore demand less, from regulatory government.”<sup>561</sup> Attempts to reform the U.S. food safety regulatory regime, therefore, become framed by widespread opposition to government activism. Each year more than 76 million Americans are the victims of the American tendency to demonize government regulation, however necessary or desirable.

Ten food safety regulatory proposals remain before Congress awaiting action in committees and subcommittees. The Food Safety Enhancement Act has passed the House and awaits action in the Senate; it remains the most transformative proposal before Congress and its passage would revolutionize food safety regulation in the United States. But although consumer interest groups and advocates are pushing for action on reform proposals during this session of Congress, they require a catalyst—something to once again disrupt equilibrium and set the policy process back in motion.

To produce revolutionary change, food safety advocates, food producing and processing firms, and government officials must come together to support reform; thus a policy proposal must simultaneously enhance food safety *as well as* advance the corporate interests of food producers. The Food Safety Enhancement Act of 2009 has that potential. In the past, however, reform has emerged only in the aftermath of a food safety crisis. In 1906 it was a crisis in the meat processing industry. In the 1950’s it involved the chemical contamination of cranberries. In the 1990’s it centered upon microbial contamination, both of meat products and of fresh produce. The tragic truth remains, therefore, that nothing is likely to be done to reform the U.S. food safety regulatory regime under the 111<sup>th</sup> Congress unless there is a large, widespread,

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<sup>560</sup> Steven P. Croley, Regulation and Public Interests: The Possibility of GOOD Regulatory Government, Princeton, NJ: Princeton University Press (2008), pp. 1.

<sup>561</sup> *Ibid*, pp. 2.

preventable, and *catastrophic* failure of the current safety system stemming from corporate negligence, opportunism, or malfeasance. To produce the inertia necessary for change, the outbreak cannot be contained, well-managed, or the consequence of mere happenstance; instead many Americans must be sickened and hospitalized and some must die as a consequence of a physical, chemical, or microbiological contamination that could have been prevented if regulatory reform measures were in place. Media surveillance, sanction, and sensation must capture public attention and transform public opinion, leading food producing and processing firms to fear the impacts on consumer confidence, brand image, liability, and, ultimately, “bottom-line” profit margins enough support widespread reform.<sup>562</sup> Then, and only then, is Congress likely to find the political will transform the U.S. food regulatory regime *away* from 20<sup>th</sup> century notions of food *purity* toward 21<sup>st</sup> century conceptualizations of science-based food *safety*.

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<sup>562</sup> On February 24, 2010, the New York Times broke a story that could potentially drive Congress to act on the regulatory proposals currently before it for consideration. According to the article, federal agents have discovered that purchasing managers for Frito-Lay, Safeway, Kraft, and B&G Foods have accepted bribes to allow tomato products with high levels of mold or other defects to be sold to consumers. Prosecutors, who have focused their attention on Frederick Scott Salyer, the owner of SK Foods, say that “for years, SK Foods shipped its customers millions of pounds of bulk tomato paste and puree that fell short of basic quality standards—with falsified documentation to mask the problems...often that meant mold counts so high the sale should have been prohibited under federal law; at other times it involved breaching specifications in the sales contracts, such as acidity levels or the age of the product.” [William Neuman, *Bribes Let Tomato Vendor Sell Tainted Food*, *New York Times*, 24 February 2010 [available online: <http://www.nytimes.com/2010/02/25/business/25tomatoes.html>]. As with peanut butter from PCA, the tainted tomato shipments reached more than 55 companies; “in some cases, companies detected problems and sent the products back—but in many cases, according to prosecutors, they did not, and the tainted ingredients wound up in food sold to consumers.” [*Ibid*]. In 2007, for example, Salyer “allegedly ordered subordinates to ship 3.4 million pounds of moldy tomato paste to Kraft... accompanied by documentation falsely claiming that it met federal mold limits.” [*Ibid*]. A Kraft spokeswoman reported that Kraft “was a victim of SK Foods’ fraud” but confessed that Kraft “relied on [mold] tests [conducted] by suppliers.” [*Ibid*]. As Randy W. Worobo, an associate professor of food microbiology at Cornell University, wrote, “there’s been a lot of hype about inferior-quality products being made in China and then sold to the U.S. consumer; this is exactly the same thing but it’s based in the U.S.” [*Ibid*]. Here again, guile and opportunism represent market failures relative to food safety that justify top-down, command-and-control regulatory oversight. It is possible that this scandal, like the peanut butter scandal of 2008-2009 will direct Congressional attention back to the issue of food safety and its regulation, prompting action by Congress to revise the mandate of the FDA and USDA. However, since no illnesses or deaths were attributed to the sale of substandard products to major food producing firms, it is equally possible that this crisis, like so many others, will go unnoticed by consumers and lawmakers alike. Here the media play an important role in agenda setting; if this crisis gets a lot of attention in the national press, Congressional action on food safety proposals is more likely than if it is ignored by those who tell American consumers and voters what they should care about, when, and why.

## WORKS CITED

- (2005) *Food Microbiology*. Deibel Laboratories. [available online: [http://www.deibellabs.com/services\\_FoodMicroBiology.html](http://www.deibellabs.com/services_FoodMicroBiology.html)].
- (2005) *GAPs Analysis*. Deibel Laboratories. [available online: <http://www.deibellabs.com/MicroGapAnalysis.html>].
- (2005) *Risk Management*. Deibel Laboratories. [available online: <http://www.deibellabs.com/MicroRiskManagement.html>].
- (2009) *Cattlemen's Capitol Concerns*. National Cattlemen's Beef Association, 6/11/2009.
- (2009) *H.R. 875*. Govtrack.us [available online: <http://www.govtrack.us/congress/billtext.xpd?bill=h111-875>].
- (2009) *PCA Salmonella Outbreak Could Lead to Food Safety Reform*. NewsInferno.com. 2/24/2009 [available online: <http://www.newsinferno.com/archives/4811>].
- (2009) *Peanut Plant Problem Forces Fresh Recall: U.S. Army the Latest to Pull Items in Ever-Growing List Reaching Back to 2007*. MSNBC.com. 1/29/2009 [available online: <http://www.msnbc.msn.com/id/28899634/>].
- (2009) *Timeline of Events in Peanut-Salmonella Outbreak*. Associated Press. 2/9/2009 [available online: [http://www2.wjbf.com/jbf/news/consumer/article/timeline\\_of\\_events\\_in\\_peanut-Salmonella\\_outbreak/10795/](http://www2.wjbf.com/jbf/news/consumer/article/timeline_of_events_in_peanut-Salmonella_outbreak/10795/)].
- (2009) *Upsetting – The Salmonella Peanut Butter Plant is a Repeat Offender*. FoodeducateBlog. 1/26/2009 [available online: <http://www.fooducate.com/blog/2009/01/26/upsetting-the-Salmonella-peanut-butter-plant-is-a-repeat-offender/>].
- (2009) *Welcome*. OUKosher.org. [available online: <http://www.oukosher.org/>].
- (2010) *2010 Budget Blueprint: Agency by Agency*. Washington Post. 2/2/2010 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2010/02/01/AR2010020103209.html>].
- About Us*. J. Leek Associates, Inc. Accessed 1/6/2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)]

Allen, Arthur. (2009) *The Unusual Suspects*. Washington Post: Health and Science. 12/8/2009 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2009/12/04/AR2009120403633.html>].

Almer, Jeffrey. (2009) *Testimony: Salmonella Contamination*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_almer.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_almer.pdf)].

*Analytical Services*. Leek Associates, Inc. Accessed 1/6/2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)].

Antle, John M. (1995) Choice and Efficiency in Food Safety Policy. Washington, DC: The American Enterprise Institute Press.

*American Federation of Government Employees, AFL-CIO, et al. Appellants v. Daniel R. Glickman, Secretary of the U.S. Department of Agriculture, et. al., Appellees*. (2000) U.S. Court of Appeals for the District of Columbia Circuit.

*American Public Health Association, et. al. v. Earl Butz, Secretary of Department of Agriculture, et. al.* (1974) United States Court of Appeals, District of Columbia Circuit [available online: <http://cases.justia.com/us-court-of-appeals/F2/511/331/399042/>].

Associated Press. (2009) *Nestle Recalls Cookie Dough Products for E. coli: 66 Reports of Illnesses Across 28 States since March; 28 People Hospitalized*. MSNBC.com, 6/19/2009 [available online: [http://www.msnbc.msn.com/id/31444614/ns/health-infectious\\_diseases/](http://www.msnbc.msn.com/id/31444614/ns/health-infectious_diseases/)].

Becker, Gary S. (1983) *A Theory of Competition Among Pressure Groups for Political Influence*. The Quarterly Journal of Economics. Volume XCVIII, Number 3.

Belasco, Warren. (2006) Meals to Come: A History of the Future of Food. Berkeley, CA: University of California Press.

Bratsch, Tony. (2004) *Common Sense for Fresh Produce Growers*. Virginia Vegetable, Small Fruit, and Specialty Crops. [available online: <http://pubs.ext.vt.edu/2906/2906-1359/2906-1359.html>].

- Brewer, M. S. and C. J. Prestat. (2002) *Consumer Attitudes Toward Food Safety Issues*. Journal of Food Safety. Volume 22.
- Brown, L. David. (2007) *Multiparty Social Action and Mutual Accountability*. In Alnoor Ebrahim and Edward Weisband (eds). Global Accountabilities: Participation, Pluralism, and Public Ethics. Cambridge, UK: Cambridge University Press.
- Burris, John E. *A Cranberry Affair of 1959*. Wisconsin Wetherby Cranberry Library Digital Collections. [available online: <http://content.wisconsinhistory.org/cdm4/document.php?CISOROOT=/cran&CISOPTR=1887&REC=8&CISOSHOW=1880>].
- Cassell, Gail. *FDA Science and Mission at Risk: Report of the FDA Science Board's Subcommittee on Science and Technology*. U.S. Food and Drug Administration. 2/25/2008 [available online: [http://energycommerce.house.gov/Press\\_110/022508.ScienceBoardReport.EstimatedResources.pdf](http://energycommerce.house.gov/Press_110/022508.ScienceBoardReport.EstimatedResources.pdf)].
- Cassidy, John. (2009) How Markets Fail: The Logic of Economic Collapse. New York, NY: Farrar, Straus, and Giroux.
- CBSNews. (2009) *CBS Reports: Where America Stands: Food Safety*. CBS. 1/9/2010 [available online: <http://www.cbsnews.com/video/watch/?id=6076741n>].
- Centers for Disease Control and Prevention. (2009) *Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008-2009*. Department of Health and Human Services, 4/29/2009 [available online: <http://www.cdc.gov/Salmonella/typhimurium/update.html>].
- Centers for Disease Control and Prevention. (2007) *Multistate Outbreak of Salmonella Serotype Tennessee Infections Associated With Peanut Butter—United States, 2006-2007*. Morbidity and Mortality Weekly Report. Volume 52, Number 21 [available online: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5621a1.htm>].
- Centers for Disease Control and Prevention. (2007) *Salmonellosis: Outbreak Investigation, February 2007*. Division of Bacterial and Mycotic Diseases. 3/7/2007 [available online: [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis\\_2007/outbreak\\_notice.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2007/outbreak_notice.htm)].

Center for Food Safety and Applied Nutrition. (1998) *Good Agricultural Practices: A Self-Audit for Growers and Handlers*. United States Department of Health and Human Services. [available online: <http://ucce.ucdavis.edu/files/filelibrary/5453/4362.pdf>].

Center for Food Safety and Applied Nutrition. (2004) *Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption*. United States Department of Health and Human Services. [Available Online: <http://www.cfsan.fda.gov/~dms/prodpla2.html>].

Center for Food Safety and Applied Nutrition. (2008) *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables*. United States Department of Health and Human Services. [available online: <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm#ch1>].

Coase, Ronald H.(1990). *The Firm, the Market, and the Law*. Chicago, IL: University of Chicago Press.

Congressional Research Service. (2009) *Summary: EAT SAFE Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-429&tab=summary>].

Congressional Research Service. (2009) *Summary: Food and Drug Administration Globalization Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-759&tab=summary>].

Congressional Research Service (2009) *Summary: Food Safety and Tracking Improvement Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-425&tab=summary>].

Congressional Research Service. (2009) *Summary: Food Safety Modernization Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-875&tab=summary>].

Congressional Research Service. (2009) *Summary: Food Safety Enhancement Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-2749&tab=summary>].

- Congressional Research Service. (2009) *Summary: Imported Seafood Enhancement Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=s111-92&tab=summary>].
- Congressional Research Service. (2009) *Summary: Keeping America's Food Safe Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-999&tab=summary>].
- Congressional Research Service. (2009) *Summary: Safe and Fair Enforcement and Recall for Meat, Poultry, and Food Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-815&tab=summary>].
- Congressional Research Service. (2009) *Summary: Safe FEAST Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-1332&tab=summary>].
- Congressional Research Service. (2009) *Summary: TRACE Act of 2009*. Govtrack.us [available online: <http://www.govtrack.us/congress/bill.xpd?bill=h111-814&tab=summary>].
- Coppin, Clayton A. and Jack High. (1999) The Politics of Purity: Harvey Washington Wiley and the Origins of Federal Food Policy. Ann Arbor, MI: The University of Michigan Press.
- Cowart, Darlene M. (2009) *Testimony*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_cowart.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_cowart.pdf)].
- Croley, Steven P. (2008) Regulation and Public Interests: the Possibility of GOOD Regulatory Government. Princeton, NJ: Princeton University Press.
- Curtis, Patricia A. (2005) Guide to Food Laws and Regulations. Ames, IA: Blackwell Publishing.
- Deibel, Charles T. (2009) *Statement*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_deibel.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_deibel.pdf)].
- Dobbin, Ben Dobbin. (2009) *CDC: Tainted Ground Beef May Be Linked to Two Deaths*. Associated Press, 11/2/2009 [available online: <http://www.newsvine.com/news/2009/11/02/3451904-cdc-tainted-ground-beef-may-be-linked-to-2-deaths>].

- Doering, Christopher. (2009) *USDA Chief cites problems in food safety system*. Reuters. 3/31/2009 [available online: <http://www.reuters.com/article/healthNews/idUSTRE52U7K920090331>].
- Ebrahim, Alnoor and Edward Weisband (eds.). (2007) Global Accountabilities: Participation, Pluralism, and Public Ethics. Cambridge: Cambridge University Press.
- Eller, Brian. (2009) *Blame is Shared in Peanut Butter Crisis*. The Daily Collegian Online. 2/5/2009 [available online: [http://www.collegian.psu.edu/archive/2009/02/05/blame\\_is\\_shared\\_in\\_peanut\\_butt.aspx](http://www.collegian.psu.edu/archive/2009/02/05/blame_is_shared_in_peanut_butt.aspx)]
- Ettlinger, Steve. (2007) Twinkie, Deconstructed: My Journey to Discover How the Ingredients Found in Processed Foods are Grown, Mined (Yes, Mined), and Manipulated into What America Eats. London: Hudson Street Press.
- Federal Meat Inspection Act*. United States Department of Agriculture. [available online: <http://www.fsis.usda.gov/Regulations/FMIA/index.asp>].
- Food & Drug Administration. (2008) *Major Project Recalls: Peanut Products Recalls: FDA's Investigation*. U.S. Department of Health and Human Services. 6/18/2008 [available online: <http://www.fda.gov/Safety/Recalls/MajorProductRecalls/Peanut/FDA%E2%80%99sInvestigation/default.htm>].
- Food, Inc.* (2009) *Directed by Robert Kenner*.
- Food Safety and Inspection Service. (2009) *About FSIS*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/index.asp](http://www.fsis.usda.gov/About_FSIS/index.asp)].
- Food Safety and Inspection Service. (2009) *About FSIS: The National Advisory Committee on Microbiological Criteria for Foods*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/NACMCF/index.asp](http://www.fsis.usda.gov/About_FSIS/NACMCF/index.asp)].
- Food Safety and Inspection Service. (2009) *About FSIS: Office of Consumer Affairs and Public Education*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/OPACE/index.asp](http://www.fsis.usda.gov/About_FSIS/OPACE/index.asp)].

- Food Safety and Inspection Service. (2009) *About FSIS: Office of Data Integration and Food Protection*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/ODIFP/index.asp](http://www.fsis.usda.gov/About_FSIS/ODIFP/index.asp)].
- Food Safety and Inspection Service. (2009) *About FSIS: Office of Field Operations*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/OFO/index.asp](http://www.fsis.usda.gov/About_FSIS/OFO/index.asp)].
- Food Safety and Inspection Service. (2009) *About FSIS: Office of Outreach, Employee Education, and Training*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/OOEET/index.asp](http://www.fsis.usda.gov/About_FSIS/OOEET/index.asp)].
- Food Safety and Inspection Service. (2009) *About FSIS: Office of Public Health Service*. United States Department of Agriculture. [available online: [http://www.fsis.usda.gov/About\\_FSIS/OPHS/index.asp](http://www.fsis.usda.gov/About_FSIS/OPHS/index.asp)].
- Food Safety Online. (2009) *Home* [available online: <http://www.foodsafetyonline.org/>].
- Fortin, Neal D. (2009) Food Regulation: Law, Science, Policy, and Practice. New York, NY: Wiley.
- Freidbert, Susanne. (2004) French Beans and Food Scares: Culture and Commerce in an Anxious Age. Oxford (UK): Oxford University Press.
- FrenchFoodSafety. (2005) *Food Safety System*, Ministry of Agriculture and Fishing [available online: [http://www.securitesanitairesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide\\_anglais.pdf?nocache=1242666640.88](http://www.securitesanitairesaliments.agriculture.gouv.fr/sections/guide-sa-curita/ta-chargez-guide-dans/sections/guide-sa-curita/ta-chargez-guide-dans/food-safety-system/downloadFile/file/Guide_anglais.pdf?nocache=1242666640.88)].
- Frieden, Jeffery. (2007) Global Capitalism: Its Rise and Fall in the 20<sup>th</sup> Century. New York, NY: W. W. Norton & Co.
- Government Accountability Office. (2003) *Food-Processing Security: Voluntary Efforts are Underway, But Federal Agencies Cannot Fully Assess their Implementation*. [Available Online: <http://www.gao.gov/new.items/d03342.pdf>]
- Grant, R. W. and R. O. Keohane. (2004) *Accountabilty and Abuses of Power in World Politics*. Internationals Law and Justice Working Paper. Institute for International Law and Justice, New York University School of Law.

- Growing a Nation: The History of American Agriculture: 1840*. [available online: <http://www.agclassroom.org/gan/timeline/1840.htm>].
- Harris, Gardiner. (2009) *Peanut Product Recall Grows in Salmonella Scare*. NYTimes.com. 1/28/2009 [available online: <http://www.nytimes.com/2009/01/29/us/29peanut.html>].
- Harvey, David. (2005) *A Brief History of Neo-Liberalism*. Oxford: Oxford University Press.
- Hatanaka, Maki, Carmen Bain, and Lawrence Busch. (2005) *Third Part Certification in the Global Agrifood System*. *Food Policy*. Volume 30.
- Havinga, Tetty. (2006) *Private Regulation of Food Safety By Supermarkets*. *Law and Policy*. Volume 28, Number 4.
- Henson, Spencer and Julie Caswell. (1999) *Food Safety Regulation: An Overview of Contemporary Issues*. *Food Policy*. Volume 24.
- Henson, Spencer and Michael Heasman. (1999) *Food Safety, Regulation and the Firm: Understanding the Compliance Process*. *Food Policy*. Volume 23.
- Henson, Spencer and Thomas Reardon. (2005) *Private Agri-Food Standards: Implications for Food Policy and the Agri-Food System*. *Food Policy*. Volume 30.
- Hicks, David. (2009) *Peanut Butter Recall is Being Handled Responsibly*. *Communicating Through Crisis*. 1/15/2009 [available online: <http://crisisexperts.blogspot.com/2009/01/peanut-butter-recall-is-being-handled.html>].
- Hilts, Philip J. (2003) *Protecting America's Health: the FDA, Business, and One Hundred Years of Regulation*. New York, NY: Alfred A. Knoph.
- Hitti, Miranda. (2007) *Peanut Butter Salmonella Source Found*. WebMD Health News. 4/6/2007 [available online: <http://www.webmd.com/food-recipes/news/20070406/peanut-butter-Salmonella-source-found>].
- Howard, L. R. and A. R. Gonzales. (2001) *Food Safety and Produce Operations: What is the Future?* *HortSci*. Volume 36.
- Hurley, Peter K. (2009) *Salmonella poisoning of Jacob M. Hurley due to his eating contaminated peanut butter crackers from a Peanut Corporation of America processed product*. United States House of Representatives Committee on Energy and Commerce,

- Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_hurley.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_hurley.pdf)].
- Hutt, Peter Barton and Richard A. Merrill. (1991) Food and Drug Law: Cases and Materials, 2<sup>nd</sup> Edition. New York, NY: The Foundation Press.
- Internal Quality Assurance*. J. Leek Associates, Inc. Accessed 1/6/2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html](http://jlaglobal.com/usa/pages/01_about_us.html)].
- Jargon, Julie and Jane Zhang. (2009) *Peanut-Butter Probe Focuses on Georgia Plant*. WSJ.com. 1/15/2009 [available online: <http://online.wsj.com/article/SB123194586477481479.html>].
- Jones, Chris. (2008) *French Food Firms Preoccupied by Safety*. FoodQualityNews.com. 4/15/2008 [available online: <http://www.foodqualitynews.com/Public-Concerns/French-food-firms-preoccupied-by-safety>].
- Kalt, Joseph P. and Mark A. Zupan. (1984) *Capture and Ideology in the Economic Theory of Politics*. The American Economic Review. Volume 74, Number 3.
- Kingdon, John W. (1984) Agendas, Alternatives, and Public Policies. Glenview, IL: Scott, Foresman, and Company.
- Kolko, Gabriel. (1963) The Triumph of Conservatism. New York, NY: Macmillan.
- Kruse, Timothy Messer. (2003/2009) *Pure Food and Drug Movement*. Dictionary of American History. The Gale Group Inc. *Encyclopedia.com*. [available online: <http://www.encyclopedia.com/doc/1G2-3401803469.html>].
- Lamb, Ruth de Forest. (1936) American Chamber of Horrors. New York, NY: Farrar & Rinehart.
- Lautenberg, et. al. (2006) *Letter of December 12, 2006*. Reproduced: *Fresh Produce and Food Safety: An Introduction to GAPs*. Robert Williams.
- Layton, Lyndsey. (2009) *Peanut Processor Knowingly Sold Tainted Products: It Found Salmonella 12 Times*. The Washington Post. 1/28/2009 [available online: [http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s\\_pos=](http://www.washingtonpost.com/wp-dyn/content/article/2009/01/27/AR2009012702992.html?sid=ST2009012703730&s_pos=)].

- Lindblom, Charles E. (2001) The Market System: What It Is, How It Works, and What To Make of It. New Haven, CT: Yale University Press.
- Lindblom, Charles E. (1979) *Still Muddling, Not Yet Through*. Public Administration Review. Volume 39, Number 6.
- Loader, Rupert and Jill E. Hobbs. (1999) *Strategic Responses to Food Safety Legislation*. Food Policy. Volume 24.
- Madia, Matthew. (2009) *USDA Budget Leaves Food Safety Agency Wanting*. OMB Watch. 10/14/2009 [available online: <http://www.ombwatch.org/node/10472>].
- Manheim, et. al. (2006) Empirical Political Analysis: Research Methods in Political Science, 6<sup>th</sup> Edition. New York, NY: Pearson.
- Martinez, Marian Garcia and Niger Poole. (2004) *The Development of Private Fresh Produce Safety Standards: Implications for Developing Mediterranean Exporting Countries*. Food Policy. Volume 29.
- Maxwell, Simon and Rachel Slater. (2004) *Food Policy: Old and New*. In Simon Maxwell and Rachel Slater (eds). Food Policy: Old and New. London: Blackwell Publishing.
- Mead, Paul S. et. al. (1999) *Food-Related Illness and Death in the United States*. Centers for Disease Control and Prevention [available online: <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>].
- “Meat Inspection.” Texas A & M Meat Science. [available online: <http://meat.tamu.edu/meatinsp.html>].
- Miller, John M. (2008) *Private Food Standards Gain Favor: Wal-Mart, McDonald’s Adopt European Safety Guidelines*. Wall Street Journal (Eastern Edition). 3/11/2008.
- Morrone, Michele. (2008) Poisons on Our Plates: the Real Food Safety Problem in the United States. Westport, CT: Praeger.
- Nestle, Marion. (2003) Food Politics: How the Food Industry Influences Nutrition and Health. Berkeley, CA: University of California Press.

- Nestle, Marion. (2003) Safe Food: Bacteria, Biotechnology, and Bioterrorism. Berkeley: University of California Press.
- Neuman, William. (2010) *Bribes Let Tomato Vendor Sell Tainted Food*. New York Times. 2/23/2010 [available online: <http://www.nytimes.com/2010/02/25/business/25tomatoes.html>].
- ODA Commodity Inspection Division. (2009) *GAP/GHP Certification*. Oregon Department of Agriculture. [available online: [http://www.oregon.gov/ODA/CID/ghp\\_gap.shtml](http://www.oregon.gov/ODA/CID/ghp_gap.shtml)].
- O'Donnell, Edward T. (2009) *The Great Cranberry Scare of 1959: 46 Years Ago*. Hibernian Chronicle. 11/25/2009-12/1/2009 [available online: <http://www.irishecho.com/newspaper/story.cfm?id=17486>].
- Osborne, Dennis, et. al. (2006) *Gaining Producer Buy-In for Food Safety and Security in the United States*. HortTechnology. Volume 26, Number 4.
- Parnell, Stewart and Samuel Lightsey. (2008) *Email Correspondence 8/21/2008*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, [available online: [http://energycommerce.house.gov/Press\\_111/20090211/parnellemailtolightsey.8.21.2008.pdf](http://energycommerce.house.gov/Press_111/20090211/parnellemailtolightsey.8.21.2008.pdf)].
- Parnell, Stewart. (2008) *Email to Samuel Lightsey*. 10/6/2008 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/parnellemailtolightseyvoth.10.6.2008.pdf](http://energycommerce.house.gov/Press_111/20090211/parnellemailtolightseyvoth.10.6.2008.pdf)].
- Parnell, Stewart, et. al. (2009) *Email to Samuel Lightsey, et. al.* 1/12/2009 [available online: [http://energycommerce.house.gov/Press\\_111/20090211/pcaemailtolightsey.1.12.2009.pdf](http://energycommerce.house.gov/Press_111/20090211/pcaemailtolightsey.1.12.2009.pdf)].
- Pawlick, Tomas F. (2006) The End of Food: How the Food Industry is Destroying Our Food Supply—and What You Can Do About It. Fort Lee, NJ: Barricade.
- Petersen, Ken. *USDA 3<sup>rd</sup> Party Audit Verification Program*. USDA Agricultural Marketing Service, Fresh Produce Branch: Good Agricultural Practices and Good Manufacturing Practices. [available online: [http://www.gaps.cornell.edu/Eventscalendar/USDA\\_3rd\\_Party\\_Audit\\_Verification\\_Programs.pdf](http://www.gaps.cornell.edu/Eventscalendar/USDA_3rd_Party_Audit_Verification_Programs.pdf)].

- Pivarnik, L. F., et. al. (2005) *New England Consumers' Willingness to Pay for Fresh Fruits and Vegetables Grown on GAP-Certified Farms*. Food Production Trends. Volume 25, Number 4.
- Porterfield, Elaine and Adam Berliant. (1995) *Jack in the Box Ignored Safety Rules*. The News Tribune. 6/16/1995. [available online: [http://www.marlerclark.com/case\\_news/detail/jack-in-the-box-ignored-safety-rules](http://www.marlerclark.com/case_news/detail/jack-in-the-box-ignored-safety-rules)].
- Powell, Doug. (2010) *Food Safety News, Like Other News is Repetitive, Superficial, Dubious*. BarfBlog: Musings About Food Safety and Things that Make You Barf. 1/12/2010 [available online: <http://barfblog.foodsafety.ksu.edu/2010/01/articles/food-safety-communication/food-safety-news-like-other-news-is-repetitive-superficial-dubious/>].
- Pronto, Michelle. (2009) *Response to Questions*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/prontolettertowaxmanandstupak.2.10.2009.pdf](http://energycommerce.house.gov/Press_111/20090211/prontolettertowaxmanandstupak.2.10.2009.pdf)].
- Rabin, Roni Caryn. (2009) *Peanut Plant Had History of Health Lapses*. The New York Times. 1/26/2009 [available online: [http://www.nytimes.com/2009/01/27/health/27peanuts.html?\\_r=1](http://www.nytimes.com/2009/01/27/health/27peanuts.html?_r=1)].
- Randall, Ed. (2009) Food, Risk, and Politics: Scare, Scandal, and Crisis: Insights into the Risk Politics of Food Safety. Manchester (UK): Manchester University Press.
- Rangarajan, Anusuya, et. al. *Food Safety Begins on the Farm, a Grower's Guide: Good Agricultural Practices for Fresh Fruits and Vegetables*. GAPsNET. Cornell University Department of Food Science. [available online: <http://www.gaps.cornell.edu/Educationalmaterials/Samples/FSBFEngLOW.pdf>].
- Rastogi, Nina Shen. (2010) *Kosher and Halal Meat is No Safer or Better for the Environment than Other Meat*. Washington Post. 2/2/2010 [available online: <http://www.washingtonpost.com/wp-dyn/content/article/2010/02/01/AR2010020103209.html>].
- Rhode Island Food Safety Education. (2009) *Glossary*. University of Rhode Island [available online: <http://www.uri.edu/ce/ceec/food/factsheets/glossary.html>].

- Roberts, Cynthia A. "Food Safety." Food and Culture Encyclopedia. [available online: <http://www.answers.com/topic/food-safety>].
- Robinson, Scott E. (2008) *Punctuated Equilibrium*. Encyclopedia of Public Administration and Public Policy, 2<sup>nd</sup> edition. 4/15/2008 [available online: <http://www.informaworld.com/smpp/content~db=all~content=a792053393>].
- Romeo, Peter. (2008) *Regulators, Consumer Advocates Lament Gaps in U.S. Food Saety Inspections as Imports Increase*. Nation's Restaurant News. Volume 42, Number 6. 2/11/2008.
- Sabatier, Paul A. (1991) *Towards Better Theories of Public Policy*. PS: Political Science and Politics. Volume 24, Number 2.
- Salatin, Joel. (2007). Everything I Want To Do Is Illegal: War Stories From the Local Food Front. Swoope, VA: Polyface.
- Seabright, Paul. (2005) The Company of Strangers: A Natural History of Economic Life. Princeton, NJ: Princeton University Press.
- Schmit, Julie. (2007) *Report: FDA so underfunded, consumers are put at risk*. USA TODAY. 12/2/2007 [available online: [http://www.usatoday.com/news/washington/2007-12-02-fda\\_N.htm](http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm)].
- Schmit, Julie. (2007) *U.S. Food Imports Outrun FDA Resources*. USA TODAY. 3/18/2007 [available online: [http://www.usatoday.com/money/industries/food/2007-03-18-food-safety-usat\\_N.htm](http://www.usatoday.com/money/industries/food/2007-03-18-food-safety-usat_N.htm)].
- Schlosser, Eric. (2002) Fast Food Nation: The Dark Side of the All-American Meal. New York, NY: Harper Perennial.
- Shames, Lisa. (2010) Interview by Courtney I. P. Thomas. 1/27/2010
- Simonne, Amy. (2009) *Principles and practices of Food Safety for Vegetable Production in Florida*. University of Florida: IFAS Extension. [available online: <http://edis.ifas.ufl.edu/cv288>].
- Simontacchi, Carol. (2007) The Crazy Makers: How the Food Industry is Destroying Our Brains and Harming Our Children. New York, NY: Jeremy P. Tarcher/Penguin.

- Sobel, Kate. (2009) *Plum Organics Voluntarily Recalls Select Batch of Apple and Carrot Portable Pouches Due to Potential Health Risk*. Plum Organics, 10/19/2009 [available online: <http://www.fda.gov/Safety/Recalls/ucm187323.htm>].
- Solomon, Ethan B, et. al. (2002) *Transmission of Escherichia coli 0157:H7 from Contaminated Manure and Irrigation Water to Lettuce Plant Tissue and Its Subsequent internalization*. Applied Environmental Microbiology. Volume 68, Number 1.
- Starbird, S. Andrew. (2000) *Designing Food Safety Regulations: the Effect of Inspection Policy and Penalties for Noncompliance on Food Processor Behavior*. Journal of Agricultural and Resource Economics. Volume 25, Number 2.
- Steingarten, Jeffrey. (1997) The Man Who Ate Everything: And Other Gastronomic Feats, Disputes, and Pleasurable Pursuits. New York, NY: Vintage Books.
- Stearns, Dennis. (2009) *BPI Ground Beef Salmonella Recall: Will the Meat Industry Sue, and Who Will the USDA Stand Up For?* Food Poison Journal: Surveillance & Analysis on Food Poison News & Outbreaks. 8/6/2009. [available online: <http://www.foodpoisonjournal.com/2009/08/articles/food-poisoning-watch/bpi-ground-beef-Salmonella-recall-will-the-meat-industry-sue-and-who-will-the-usda-stand-up-for/>].
- Stigler, George J. (1971) "The Theory of Economic Regulation." *Bell Journal of Economics and Management*. Issue 2.
- Stovicek, Robert. (2009) *Testimony Before Congress*. House Subcommittee on Horticulture and Organic Agriculture. 5/14/2009. [available online: <http://agriculture.house.gov/testimony/111/h051409/Stovicek.doc>].
- Stupak, Bart. (2009) *The Salmonella Outbreak: A Collective Failure to Protect the Public*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/stupakopen.pdf](http://energycommerce.house.gov/Press_111/20090211/stupakopen.pdf)].
- Sundlof, Stephen F. (2009) *Statement*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_sundlof.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_sundlof.pdf)].
- Theodoulou, Stela Z. and Chris Kofinis. (2004) The Art of the Game: Understanding American Public Policy Making. Belmont, CA: Thompson-Wadsworth.

- Technical Services*. J. Leek Associates, Inc. Accessed 1/6/2010 [available online: [http://jlaglobal.com/usa/pages/01\\_about\\_us.html/](http://jlaglobal.com/usa/pages/01_about_us.html/)].
- “These Cranberries.” (1959) *The New Republic*. 11/30/1959.
- Tousignant, Lou. (2009) *Testimony*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_tousignant.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_tousignant.pdf)].
- United States Department of Agriculture and United States Food and Drug Administration. (2007) *CARVER + Shock Description*. 7/18/2007 [available online: <http://www.fsis.usda.gov/PDF/CARVER.pdf>].
- United States Environmental Protection Agency. (2009) *Agriculture: Demographics*. 9/10/2009 [available online: <http://www.epa.gov/oecaagct/ag101/demographics.html>].
- United States Government Accountability Office. (2009) *High-Risk Series: An Update*. Report to Congress [available online: <http://www.gao.gov/new.items/d09271.pdf>].
- Unnevehr, Laurian J. and Helen H. Jensen. (1998) *The Economic Implications of Using HACCP as a Food Safety Regulatory Standard (Working Paper, Center for Agricultural and Rural Development, Iowa State University, Ames, IA)*. 12/15/1998.
- Vogel, David (ed.). (2004) *Dynamics of Regulatory Change: How Globalization Affects National Regulatory Policies*. Berkeley, CA: University of California Press.
- Wagstaff, D. J. (1986) *Public Health and Food Safety: A Historical Association*. *Public Health Reports*. Volume 10: Number 6 (November-December).
- Waxman, Henry A. (2009) *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply*. United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations [available online: [http://energycommerce.house.gov/Press\\_111/20090211/hawopen.pdf](http://energycommerce.house.gov/Press_111/20090211/hawopen.pdf)].
- Wilson, Bee. (2008) *Swindled: The Dark History of Food Fraud, From Poisoned Candy to Counterfeit Coffee*. Princeton, NJ: Princeton University Press.
- Wolf, Jr., Charles. (1993) *Markets or Governments: Choosing between Imperfect Alternatives*, 2<sup>nd</sup> Edition. Cambridge, MA: The MIT Press.

Wolf, Jr. Charles. (1979) *A Theory of Nonmarket Failure: Framework for Implementation Analysis*. Journal of Law and Economics. Volume 22, Number 1.

Young, James Harvey. (1989) Pure Food: Securing the Federal Food and Drugs Act of 1906. Princeton, NJ: Princeton University Press.

Zhang, Jane. (2006) *Politics & Economics: Food Safety Concerns Extend Beyond California: Regulators Still Struggle to Discover the Cause of Spinach E. coli Outbreak*. The Wall Street Journal (Eastern Edition). 9/18/2006.

## Appendix A

*This list includes human and pet food subject to recall in the United States since January 2009 related to peanut products distributed by Peanut Corporation of America.*

*The information is current as of October 28, 2009.*

### Brownie Product Recalls

- Allann Bros Coffee
- Annie B's (Wholesale Dessert Products)
- Avanza Supermarket
- Boston Cookies
- Econofoods (excluding Wisconsin stores in Sturgeon Bay, Clintonville, Marquette, Holton and Iron Mountain)
- Erin Baker's
- Family Fresh Market
- Family Thrift Center
- Food Bonanza
- Frankly Natural Bakers
- Pick'n Save (Ohio stores in Van Wert and Ironton only)
- Prairie Market
- SunMart Foods
- Sweet Life
- Sweet Sisters
- TF Processors
- The Father's Table
- Tri-O-Plex
- Wholesale Food Outlet

### Cake and Pie Product Recalls

- Allann Bros Coffee
- Annie B's (QVC Products)
- Annie B's (Wholesale Dessert Products)
- Avanza Supermarket
- Awrey Bakeries
- Baker's
- Bindi North America
- Casino Chef
- Charlie's
- Chef Pierre
- City Market

- Cuisine Innovations
- Dillons
- Econofoods (excluding Wisconsin stores in Sturgeon Bay, Clintonville, Marquette, Holton and Iron Mountain)
- Family Fresh Market
- Family Thrift Center
- Follow Your Heart
- Food 4 Less
- Food Bonanza
- Foods Co.
- Fred Meyer
- Fry's
- Gerbes
- Hilander
- Jay C
- Junior's
- Just Desserts
- King Soopers
- Kmart Bakery
- Kroger
- Owen's
- Pay Less
- Pick'n Save (Ohio stores in Van Wert and Ironton only)
- Prairie Market
- Presentations
- QFC
- Ralphs
- Rich Products Corporation
- Scott's
- Smith's
- SunMart Foods
- Sweet Life
- Sweet Sisters
- Wegmans
- Wholesale Food Outlet
- Candy Product Recalls
- 20/20 Lifestyles
- 4-H Fundraising
- Allann Bros Coffee
- American Almond

- Amy's Decadent Chocolates
- Bartons Confectioners
- Bear Poop
- Bear Scat
- Best Choice
- Best Choice (AWG)
- Blains Farm & Fleet
- Blanton's
- Botticelli
- Brach's
- Brown & Haley
- Buffalo Chips
- Cable Car
- Camp Masters
- Candy Place
- Casey's
- Casey's General Store
- Cherry Hill Supremes
- Cherrydale Farms
- Chicken Coop Poop
- Chopanpea
- Choxie
- Coblenz Chocolate Company
- Country Life Natural Foods
- Cow Patties
- Cow Pies
- Crew Rations
- Dazzling Delicacies
- Deer Droppings
- Diabeteze
- Diabetic Emporium
- Diabetone gluco
- Dillon's
- Dino Eggs
- Dr. Smoothie
- Dutch Valley
- EARTH FARE
- Eagle Premium
- Eagle Premium (Amcon)
- Eillien's Candies Inc.

- Euphoria
- Every Day's A Party
- Fannie May
- Farley's
- Felix & Oscar
- Fish Eggs
- Food Club
- Food Lion
- Fortune Fundraising
- Fresh Pick's Meat & Produce
- Fresh&Easy
- Fritzie Fresh
- Funway
- GFS
- GKI
- Gayle's Chocolates
- Germack
- Giambri
- Gold Emblem
- Goo Goo
- Gurley's
- Haddington Farms
- Hadley's Fruit Orchards
- Hallmark
- Harry and David
- Harvest Fresh Market
- Hawk's Lair Inc.
- Heart and Soul Candies
- Heavenly Candy's
- Here's Howe
- Hiller's
- Holiday Stationstores, Inc.
- Hy-Vee
- HyVee
- JL Manufacturing
- Jelly Belly
- Johnny Pomodoro's
- Karma
- Kerry Ingredients & Flavours
- Kilwin's

- Kings
- Koeze Company
- Koppers
- Koppers Chocolate
- L & L Food Centers
- Landies
- Landmark
- Laura Lynn (Ingles)
- Lehi Valley Trading Company
- Lizard Eggs
- Madelaine
- Marich
- Marketplace
- Maxfield
- Meijer
- Mills Fleet Farm
- Monster Eggs
- Moose Droppings
- Mr. Chocolate
- NATURALLY PREFERRED
- Nassau Candy
- Nature's Candy
- Natures World Delights
- Nut Bar Candy Shoppe
- Oakridge Family Food Centers
- Old Fashion Candy Company
- Olsen's Piggly Wiggly
- Omaha Steaks
- Osprey Poop
- Palmer Candy
- Palmer Peg
- Palmer Selects
- Pear's Gourmet
- Pecan Deluxe Candy Company
- Penhurst Candy Co.
- Plum Markets
- Prairie Dog Pebbles
- Premier Packing Company
- Primrose
- Private Labeled or Family Choice

- Rain Creek Baking Company
- Rain Creek Baking Corporation
- Rite Aid
- Rodhe's IGA Marketplace
- S & S Candies
- SPARTAN
- SRF
- SUNRIDGE
- Sathers
- Sconza
- Sconza Candy
- Sentry Food
- Shurfine
- Shurfine - Western Family
- Shurfine-Western Family
- Shurfresh
- Silver Lake
- Simply Enjoy
- Sinbad
- SinbadSweets.com
- Something Better Natural Foods
- South Bend Chocolate Company
- Southern Home
- Southern Homes
- Spartan
- Spartan Stores
- Star Kay White Inc.
- Stuckey's
- Sunbird Snacks
- Sunny Select
- Superior
- Sweet Factory
- Taufelen Candy Co.
- The Candy Lady
- The Foreign Candy Co.
- The Kidz Kompany
- The Peanut Shop
- Theo
- Torn Ranch
- Tree of Life

- Ultimate Confections
- Ultimate Nut & Candy Co.
- Valu Time
- Wal-Mart
- Wal-Mart Label
- Walgreens
- Wegmans Swiss Recipe
- Werner
- Wilson Candies
- WinCo Foods bins
- Zachary
- ✚ Cereal Product Recalls
  - Bear Naked
  - Erin Baker's
  - Michaelene's
  - Michaelene's Gourmet Granola
  - Nature's Path
  - Naughty but Nice
- ✚ Cookie Product Recalls
  - ABC
  - AFC
  - Allann Bros Coffee
  - Annabella
  - Apple Mountain
  - Archer Farms
  - Arico
  - Arizona Gold
  - Auntie Ono (Hawaii)
  - Avanza Supermarket
  - Baba Joon's Chocolate Chewies
  - Baker Jo's
  - Baker Jo's Peanut Butter
  - Baker's
  - BakerSource
  - Bear's
  - Best Brands Corp.
  - Best Maid
  - Block & Barrel
  - Blue Heron Bakery
  - Blue Ribbon

- Boston Cookies
- Breadfarm
- CAMDEN CREEK
- Camden Creek
- Christie Cookie
- City Market
- Classic Bake `n' Serve
- Classic Breaks
- Cookie Machine
- Cougar Mountain
- Cub Foods
- Delphina's Bakery
- Devonshire
- Dillons
- Dough-to-Go
- Dough-to-Go (California)
- Econofoods (Excluding Wisconsin stores in Sturgeon Bay, Clintonville, Marquette, Holton and Iron Mountain)
- Erin Baker's
- Evening Rise
- Family Fresh Market
- Family Thrift Center
- Famous Amos
- Food 4 Less
- Food Bonanza
- Food Lion Bake Shop
- Foods Co.
- Frankly Natural Bakers
- Fred Meyer
- Fry's
- Gerbes
- Gigi's
- Glutenfreeda's
- Gourmet Cookie Dough
- Gourmet Cookie Dough JT Ent
- Grandessa
- Hilander
- Hy-Vee
- Innisbrook
- Jana's

- Jane Dough's (Washington, Nevada and Arizona)
- Jay C
- Jimmy's Cookies
- Keebler
- King Soopers
- Kroger
- Lisa's Favorites
- Little Lambs
- Lofthouse
- Mrs. GoodCookie
- To Go
- One Smart Cookie
- Ovens of Ashley
- Owen's
- Parco Foods Chuck's Chunky
- Parker
- Pastries Plus
- Pay Less
- Pick'n Save (Ohio stores in Van Wert and Ironton only)
- Prairie Market
- QFC
- QSP
- READI-BAKE
- Ralphs
- Red Apple
- Red Wheel Fundraising
- Sam's Choice
- School Kine Cookies
- Scott's
- Smith's
- SunMart Foods
- Sweet Life
- Sweet Sisters
- Trader Joe's
- Tri-O-Plex
- Uncle Eddies Vegan
- WalMart Bakery
- Wegmans
- Wholesale Food Outlet
- ZAP

#### ✚ Cracker Product Recalls

- Austin Quality Foods
- Cambridge
- Keebler
- Little Debbie
- Meijer
- ShopRite
- Weis Quality
- Donut Product Recalls
- Kmart Bakery
- Mighty-O
- Wegmans
- Dressing and Seasoning Product Recalls
- Kariba Farms
- WOW
- Fruit and Vegetable Product Recalls
- Eating Right
- H-E-Buddy
- Nutty Nanners
- Ready Pac Cool Cuts
- Trader Joe's

#### ✚ Ice Cream Product Recalls

- #216 Schwan's
- Aldi Sundae Shoppe
- America's Choice
- Artic Classic
- Artic Star
- Baldwin
- Belfonte
- Best Choice
- Big Y
- Bindi North America
- Bliss Brothers Dairy
- Blue Bunny
- Blue Bunny Personals
- Bon
- Braum's
- Breyers Tin Roof Sundae
- Breyers Tin Roof Sundae ice cream
- Brigham

- Broughton
- Buck's
- Byrne Dairy
- California Dream
- Carnival
- Central Dairy
- Component
- Country
- Country Classic
- Country Delight
- Creamy Creations
- Cub
- Cub Foods
- Cumberland Farms
- DeConna
- DeLuxe
- Deluxe
- Dolly Madison
- Dynamic Duos
- Econo
- Family Pak
- Fastco
- Fat Boy
- Flav-O-Rich
- Flav-o-rite
- Flavorit           e
- Food City
- Food Club
- Frederick Farms
- Galliker
- Garber's
- Giant
- Giant Eagle
- Grande
- Great Value
- Greens
- Hagan
- Hannaford Denali
- Hershey's
- High's

- Hiland
- Hill Country Fare
- Hood
- House of Flavors
- Hudsonville Creamery and Ice Cream Co.
- Humboldt Creamery
- Hy-Top
- Hy-Vee
- IGA
- Ice Cream
- Ice Girl
- JJ Lawson
- Jewel
- Kay's
- Kemps
- Key Food
- Krasdale
- Lowes
- Luvel
- Market Basket
- Market Pantry
- Meadow Gold Herd
- Megarooms
- Meijer
- Meijer's
- Nestle
- North Star
- Old Fashioned
- Old Recipe
- Our Family
- Pathmark
- Perry's
- Pierre's
- Piggly Wiggly
- Price Chopper
- Pricerite
- Private Selection
- Publix
- Purity
- QC

- Redners
- Rich Products Corporation
- Rich's
- Richfood
- River Valley
- Roundy's
- Ruggles
- Shamrock Farms
- Shop 'n Save
- Shoprite
- Shurfine
- Shurfresh
- Southern Belle
- Southern Home
- Stater Bros
- Stewart's Shops
- Stop & Shop
- Sundae Shoppe
- Super A Nut
- Supreme Indulgence
- Sysco
- Tops
- Trauth
- Turkey Hill Dairy
- Turner
- Uncle Buck's
- United Dairy
- Valu Time
- Velvet
- Velvet Olde Mill
- Wegmans
- Weis
- Weis Quality
- Welsh Farms
- Western Family
- White Rose
- Wilcoxson's
- Winn Dixie
- Wonder Ice Cream
- World Classic Trading Company

- Yarnell's
- ✚ Peanut Product Recalls
  - "Nut Hut" Kiosks
  - AMSTERDAM GOURMET
  - Abercrombie USA Grown
  - Allnuts
  - Always Save
  - American Almond
  - Anna's Pantry
  - Arco Nut & Candy
  - Ass Kickin'
  - Aurora Natural
  - Austinuts
  - Avon Cider Mill
  - B & B Fruit Stand
  - Bad Byron's
  - Baldwin County
  - Banana Moon
  - Barefoot General Store
  - Barnyard Produce
  - Baskets Etc.
  - Battleview Orchard
  - Bayhill Accents, LTD.
  - Bayview Shop
  - Best Choice
  - Blains
  - Blains Farm & Fleet
  - Bloomers Flower Shop
  - Bo'tes Imports
  - Borzynski Farm
  - Braswell Food Company
  - Briarpatch on 34, LLC
  - Brine's Market, LLC
  - Brookside Restaurant
  - Bucciarelli Farm
  - Burke Garden Center
  - Bushnell Farms
  - C&K Market, Inc.
  - Calabash Nautical Gifts
  - Callahan's General Store

- Candies Tolteca Co. Mexican Candies
- Casey's
- Casey's General Store
- Celebrate Maryland
- Celebrate Redlands
- Centrella
- Chop Shop
- Church Street Market
- Clark's Nutrition Natural Foods Market
- Community Co-op
- Confederate Cemetery Board
- Cook's Shoppe
- Corinna's Country House
- Country Aire
- Cumby's Snacks
- DUREY LIBBY
- Davis Lewis Orchards
- Davis Produce
- Dean's Market
- Di's Antiques Old Stuff
- Dick & Jane's Farm
- Dingman's Dairy
- Doin' The Charleston
- Donna's #6 Produce
- Driskell's Foods
- E & S Sales
- EARTH FARE
- Eagle Premium
- Econo Pac
- Eillien's
- Farmer's Market
- Fazenda
- Fillet & Vine
- First Choice
- Fool On The Hill
- Ford Flower
- Franklin's General Store
- Fresh Approach
- From The Heart, LLC
- GA Association of Educators

- GCB Partners DBA All Sauced Up
- Galena Canning
- Gel Spice Co.
- Gelson's Finest
- Georgia Peanuts
- Gimbels Of Main
- Glory Bee Foods
- BloryBee Foods, Inc.
- Gordon County Farm Bureau
- Grand Rapids Popcorn
- Granville Cheese Inc.
- Graul's Market
- Greene County Farm Bureau
- Grillmaster SGT
- Grower's Outlet
- HERSHEY IMPORT COMPANY
- Hadley's Fruit Orchards
- Hahn's Market
- Happy Cow Creamery
- Herman's Nut House
- Hialeah Products, New Urban Farms, Epicure Market, Stiles Market, Gardners Market, Baileys General Store, Hales Grove River Market, The Sandy Butler, Carmines Market, Joannas Marketplace, Crown Wine & Spirits, Florida Snacks, Rosen Plaza Hotel, Rosen Shingle Creek, Grapevine Gourmet, Perricones Marketplace, Kastners, Salamander Market, Oh Nuts, Mazzaro Market, Portofino Market, Portofino Winebank, Artdeco Market, Diamond Café & Market, Surfmed, Sunharvest Snacks, Healthy State of Mind, Fisher Island, Golden Cockatoo, Kosher Marketplace
- Highland
- Hilltop Produce
- Huck's General Store
- Huffman's Market
- In-Room Plus
- Ingleside Plantation
- J & K Gnatt DBA Willis Produce
- Jack In The Beanstalk
- Jackson County Farm Bureau
- Jacob's Market, Inc.
- Jane's Expressions
- Janssen's Market

- Jefferson General Store
- Jekyll Books
- Jensen's Finest Foods
- Kern Valley Produce
- Key Foods Private Label
- Kiefer Co. DBA Souvenir Village
- Kitty Clover
- Kruse Farms Market
- L.H Webb & Son Market, Inc.
- Laxmi
- Lazy Gator
- Lehi Valley Trading Company
- Lewis Jones Food Market
- Lian How
- Lindy's Downtown Market
- Lloyd's Florist
- Locust Grove Smoke House
- Love From Minnesota
- Lunds and Byerly's
- M & M Produce, Inc.
- Maeco Foods
- Main Course
- Mama Mellace's
- Marbella Farmers Market
- Marietta Museum Of History
- Market Mixture, LLC
- Market Pantry
- Markets of Meijer
- Marlow
- Marshall Pottery
- Meijer
- Mills Fleet Farm
- Murphree's Fruit & Vegetables
- My Butcher & More C/O Meat
- Nanny's Country Barn
- Nassau Candy
- Nature's Promise
- New Century Snacks
- North Shore Fruit Basket
- Nugget

- Nuts For You
- Oglethorpe County Farm Bureau
- Olde Home Place Shop
- Osage's
- Otto's Produce Market
- Owl N' Things
- PIC-A-NUT
- Parnell's Pride
- Past Times Inc.
- Peaches Fruit & Produce
- Peanut Corporation of America
- Peanut Corporation of America or Parnell's Pride
- Pearl Country Store
- Peoples Flower Shop
- Persnickety LLC
- Piggly Wiggly
- Plantation Shoppe
- Poplar Grove Plantation
- Premier Packing Company
- Primrose
- Prissy's
- R.J.'s Steakery
- Ramapo Ridge Private Label
- Red Eagle
- Reggie's
- Reid's Orchard
- Robinson Crusoe
- Rombach Farms
- Root Farms
- SNACK SHACK
- SUNRIDGE
- SYSCO Classic
- Safeway's "Nut Hut" Kiosk
- Sea Treasures
- Seasons In The Sun
- Sheridan Fruit Company, Inc.
- Sherm's
- Skinner's
- Slater's Great American
- Smart Nutrition

- Snack Naturally
- Snackerz
- Southern Museum Of Civil War
- Stapleton
- Stein Mart
- Stoller Fisheries/OKOBOJI
- Stony Point Apiaries
- SunRidge Farms
- Sunbird Snacks
- Sunset Orchard
- Supreme Choice
- Susie's Bake Shoppe
- Texas Best III Travel Plaza
- Texas Star Nut & Food Company
- Texas Store
- The Alps
- Thrifty Nut
- Torn & Glasser
- Toucan Market
- Town & Country
- Trax Farms Market
- Tropical Nut and Fruit
- Tropical Nuts
- Valued Naturals
- Vella Farms
- WEST BANK GOURMET
- WOODSTOCK FARMS
- Walker County Farm Bureau
- Walt's Market
- Ward's SuperMarket
- Wellington Farm Market
- Werner
- Whaley's Market, Inc.
- Whole Foods Market
- William Harris Homestead
- WinCo Foods
- Ya'lls Texas Store
- Yoke's
- Your Gifted Basket, Inc
- Stapleton

✚ Peanut Butter Product Recalls

- "Nut Hut" Kiosks
- Allann Bros Coffee
- American Almond
- Andronico's
- Bear Naked
- Blue Heron Bakery
- Breadfarm
- Bulk Commodity
- Cornucopia
- Fresh Direct
- GRANDE GOURMET
- Glory Bee Foods
- King Nut
- LUCKY
- Lamb's Market
- New Seasons
- POCO PAC
- Parnell's Pride
- Peanut Corporation of America or Parnell's Pride
- SUNRIDGE
- Sherm's
- Town & Country
- Ultimate Nut & Candy Co.
- Unbranded for further distribution
- Vitamin Cottage
- Whole Foods
- WinCo Foods

✚ Peanut Paste Product Recalls

- Peanut Corporation of America or Parnell's Pride

✚ Pet Food Product Recalls

- Aggieville USA, Mountain Grove, MO
- Alaska Canine Cookies
- American Health Kennels, Inc.
- American Nutrition, Inc.
- Breadfarm
- Carolina Prime
- Carolina Prime Pet
- Farm Style
- Grreat Choice

- Happy Tails
- Healthy Hide
- Healthy-hide Deli-wrap
- Hill Country Fare
- Integrity
- Mill Creek
- Morning Melodies
- Morning Song
- Next Gen Pet Products
- Northwest Royal
- Premium
- Royal Wing
- Salix
- Scotts
- Shoppers Valu
- Springfield Prize
- Vita Bone Flavors
- Vita Snacks
- Western Family Biscuits
- Western Trade Group, Inc.
- Yeaster

 Pre-Packaged Meals Product Recalls

- Allann Bros Coffee
- Dinners Ready
- Ethnic Gourmet
- Follow Your Heart
- Fresh Direct
- Gluten Free Café
- Market of Choice
- Meal BREAKS
- Red Cloud Food Service
- Reser's
- Sure-Pak
- The Traditions
- Trader Joe's
- Trader Ming's

 Snack Bar Product Recalls

- 10th Tee
- 11th Tee
- Advantage

- All Natural Mega Protein
- Allann Bros Coffee
- Arbonne
- Archer Farms
- Arico
- Attain
- Avanza Supermarket
- Balance
- Bartons Confectioners
- Beneficial Foods
- Betty Lou's
- Breadfarm
- CAN DO KID
- CLIF BAR
- Can Do Kid
- Cascadian Farm
- Champions
- Cherrydale Farms
- Complete Life
- Day Break
- Delphina's Bakery
- Detour
- Detour Biker
- Detour Core Strength
- Detour Runner
- Dr. Melina
- Dr. Smoothie
- EB Performance
- Econofoods (Excluding Wisconsin stores in Sturgeon Bay, Clintonville, Marquette, Holton and Iron Mountain)
- Endulge
- Evening Rise
- Family Fresh Market
- Family Thrift Center
- Food Bonanza
- Fresh&Easy
- GNC Triflex
- Genisoy
- Glucerna
- Health Valley

- Honest Foods
- Isagenix
- Isagenix IsaLean
- JamFrakas
- Jay Robb
- Jenny's Cuisine
- Jenny's Delites
- Karma
- Kashi TLC
- LUNA
- LÄRABAR
- MLO BIO PROTEIN BARS
- MLO XTREME PROTEIN BARS
- MOJO
- Market Pantry
- Met-Rx
- NUTRILITE
- Naturally Preferred
- Nature's Path
- Nature's Plus
- Naughty but Nice
- Nestle
- NutriPals
- NutriSystem
- Nutty Crunchers
- Odwalla
- Odyssey
- Oh Soo Good
- Oh Yeah!
- Optimum Energy Bars
- Paleybar
- Perfect Weight America
- Pick'n Save (Ohio stores in Van Wert and Ironton only)
- Pit bull
- Potent Life
- Prairie Market
- ProFlex15
- ProFlex20
- Promax
- Promax 70

- Promedis
- Rockin' Roll
- Roman Meal
- SOY PROTEIN BARS
- Shaklee
- Slim-Fast MEAL OPTIONS
- Slim-Fast optima
- Special K Protein
- SunMart Foods
- SunRidge
- Supreme Protein
- TITAN
- TWISTED
- Think Thin
- Trader Joe's
- Tri-O-Plex
- Triple Delicious
- WHA GURU CHEW
- Wholesale Food Outlet
- Wright's
- XS
- Zone
- ZonePerfect
- fücoPROTEIN

✚ Snack and Snack Mix Product Recalls

- A Southern Season Private Label
- ACME
- ALDI
- Acme
- Albertsons
- Anna's Pantry
- Arroyo Seco
- Aunt Patty's
- Aurora Natural
- Austinuts
- Avanza Supermarket
- BRIDGEHAMPTON GORP
- Banana Moon
- Bartons Confectioners
- Bear Naked

- Berry Blossom
- Betty Lou's
- Blains Farm & Fleet
- Bloom
- Blue Heron Bakery
- Break-A-Way Canada Private Label (Includes Gourmet Line)
- Break-A-Way U.S. Private Label
- Bristol Farms
- Bunny Food
- C&K Market, Inc.
- Café W
- Caribou
- Casey's
- Casey's General Store
- Champion
- Chef Inspired
- Cherrydale Farms
- Clark's Nutrition Natural Foods Market
- Country Village Nutrition Shoppe
- Cumby's Snacks
- Cupids Crunch
- Dancing Star
- Davis Lewis Orchards
- Dutch Valley
- EARTH FARE
- EXPRESS SNACKS
- Eagle Premium (Amcon)
- Econofoods (Excluding Wisconsin stores in Sturgeon Bay, Clintonville, Marquette, Holton and Iron Mountain)
- Eillien's
- Erin Baker's
- FOOD LION
- FULL CIRCLE
- Family Fresh Market
- Family Thrift Center
- Farmer's Market
- First Choice
- Food Bonanza
- Food Club
- Frankly Natural Bakers

- Fred Meyer
- Freedom Trail Mixes of Boston Private Label
- Fresh to Market
- Full Circle
- GRATEFUL HARVEST
- Gelson's Finest
- Glory Bee Foods
- Gourmet
- Gramma Anna's
- Grandpa's Oven
- Great Skott Foods
- Greenwise
- HEB
- HERSHEY IMPORT COMPANY
- Hadley's Fruit Orchards
- Happy Healthy Private Label
- Herman's Nut House
- Hialeah Products, New Urban Farms, Epicure Market, Stiles Market, Gardners Market, Baileys General Store, Hales Grove River Market, The Sandy Butler, Carmines Market, Joannas Marketplace, Crown Wine & Spirits, Florida Snacks, Rosen Plaza Hotel, Rosen Shingle Creek, Grapevine Gourmet, Perricones Marketplace, Kastners, Salamander Market, Oh Nuts, Mazzaro Market, Portofino Market, Portofino Winebank, Artdeco Market, Diamond Café & Market, Surfmed, Sunharvest Snacks, Healthy State of Mind, Fisher Island, Golden Cockatoo, Kosher Marketplace
- Hy-Vee
- HyVee
- In-Room Plus
- International
- J.J. Kelly
- Jensen's Finest Foods
- Jensen's Private Collection
- Jewel
- KA-ME
- Kern Valley Produce
- Key Foods Private Label
- Kings
- Koppers Chocolate
- Lehi Valley Trading Company
- Lesserevil

- Lunds and Byerly's
- MT. HOOD MIX8818
- Magical Munchies Private Label
- Mama Mellace's
- Marbella Farmers Market
- Marin
- Market Basket Private Label
- Martha Stewart
- Mega Snax
- Mills Fleet Farm
- Mountain Man
- NATURALLY PREFERRED
- NATURE'S PROMISE
- Nassau Candy
- Nature's Original
- Natures World
- Naughty but Nice
- New Century Snacks
- Nugget
- Ocean Spray
- Olympia Delight
- Orchard Crest Farms
- Our Kitchen
- PIC-A-NUT
- Parnell's Pride
- Pear's Gourmet
- Pick'n Save (Ohio stores in Van Wert and Ironton only)
- Prairie Market
- Premier Packing Company
- Premium Orchard
- Produce Patch
- Publix
- Rachels Private Label
- Ramapo Ridge Private Label
- Reindeer Food
- RiverTrail
- Rock Creek
- Root Farms
- Royal Snacks
- SUN HARVEST

- SUNRIDGE
- SYSCO Classic
- Sconza
- Shaw's
- Shurfine Brand
- Simbree
- Simply Enjoy
- Snack Naturally
- Snack'rs
- Something Better Natural Foods
- Stapleton
- Stone Mountain Line
- SunMart Foods
- SunRidge Farms
- Sunbird Snacks
- Sunbird Snacks Gourmet Line
- Sunridge Farms
- Sunset Orchard
- Superior
- Supreme Choice
- Sweet Life
- The Long Trail Brewing Company
- The Mark
- Torn Ranch
- Town & Country
- Trail's End
- Tree of Life
- Valu Time
- Valu Time
- Valued Naturals
- WOODFIELD FARMS
- WOODSTOCK FARMS
- Werner
- White Birtch Private Label
- Whole Foods
- Wholesale Food Outlet
- Wild West Private Label
- WinCo Foods
- Zachary

 Topping Product Recalls

- Barefoot Contessa
- Best Choice
- Eillien's Candies
- Fred Meyer
- Herman's Nut House
- Kroger
- PIC-A-NUT
- Ralphs
- Simply Enjoy
- Stonewall Kitchen

U.S. Food and Drug Administration

Available online: <http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm>

## **Appendix B**

*Email correspondence between Courtney I. P. Thomas and Virginia Polytechnic Institute & State University Institutional Review Board Regarding Elite Interviews with Public Officials*

On 9/25/09 4:19 PM, "Courtney I. P. Thomas" <[courts@nephandus.com](mailto:courts@nephandus.com)> wrote:

Good afternoon,

I am a doctoral candidate in Planning, Governance, and Globalization. I am working on my dissertation on the politics of food safety and would like to conduct interviews with public officials with Congress, the FDA, the USDA, and the GAO as well as (possibly) representatives for interest groups regarding laws currently before Congress.

My committee and I are a bit confused about the role of the IRB relative to my research. As I understand from the IRB flowchart, I have to have IRB approval if the research involves obtaining information about living individuals. It seems that my research does not meet this criteria as I am not seeking information about individuals but about the legislative process and the history of the US food safety regulatory regime. Am I correct, therefore, that I do not need IRB approval to conduct the aforementioned interviews?

Your guidance would be much appreciated.

Best,  
Courtney I. P. Thomas

\*\*\*\*\*

Courtney I. P. Thomas  
PhD Candidate, Virginia Tech  
Research and Editorial Assistant  
Professor Edward Weisband  
Administrative GTA  
PSCI/IS/GEOG 2064: The Global Economy and World Politics Spring 2009 [copowell@vt.edu](mailto:copowell@vt.edu)  
<<mailto:copowell@vt.edu>>

-----Original Message-----

From: Green, Carmen [<mailto:ctgreen@vt.edu>]  
Sent: Friday, September 25, 2009 4:27 PM

To: Courtney I. P. Thomas  
Subject: Re: research question

Good Afternoon Courtney,

If you are collecting data regarding their opinions, then you will need IRB approval to conduct the interviews.

If you are not collecting their opinions or any information about the individuals, and you are only collecting information about the legislative process and the history of the US safety regulatory regime, then you do not need IRB approval to conduct the interviews.

Have a nice weekend.

Sincerely,  
Carmen

\*\*\*\*\*

Carmen T. Green, M.S.  
IRB Administrator

Virginia Polytechnic Institute and State University Office of Research Compliance 2000 Kraft  
Drive, Suite 2000 (0497) Blacksburg, VA 24060  
Phone: (540) 231-4358  
Fax: (540) 231-0959  
<http://www.irb.vt.edu>

**Interview with Lisa Shames (GAO) began with the following disclaimer: I am not asking for information about you or for your opinions. I am instead collecting information about U.S. regulatory history, the legislative process, and the U.S. food safety regulatory regime.**