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The Hang-Up With HACCP: The Resistance to Translating Science Into Food Safety Law

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I. INTRODUCTION

This article begins with a simple, unanswered question: "What is the hang-up with HACCP?" HACCP, short for Hazard Analysis and Critical Control Point, is widely recognized as the best food safety system available; however, four decades since HACCP's development, large segments of the food industry shun it.[1]

Why has the food industry taken so long to embrace HACCP? Facile answers come quickly: It is too difficult, or too expensive, or too confusing. Closer review, however, reveals that these easy answers only skim the surface of complex causes. The answer reaches back to the oldest common law—to a hole in the U.S. tort liability system—and forward to a regulatory state attempting to address rapid changes in both science and business (e.g., emerging food pathogens and centralization of the food industry).

The last three decades have brought increasing scientific understanding of the causes of foodborne illness, along with heightened public health awareness.[2] Widely-publicized foodborne disease outbreaks have raised the public's concern for food safety.[3] For example, recent large disease outbreaks of *Salmonella* serotype *Enteritidis* from eggs and poultry, *Escherichia coli* O157:H7 from hamburger and apple cider, and *Listeria monocytogenes* from hot dogs and lunchmeat have demonstrated the population's vulnerability to foodborne illness.[4]

In light of this heightened concern and awareness, HACCP—the preventative solution recommended by experts[5]—would seem a likely candidate for widespread acceptance. Nevertheless, millions become ill every year, and thousands die, from food pro-

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[1] *See, e.g.*, Margie Russell, *HACCP: What's the Hang-Up? (Hazard Analysis Critical Control Point System),* CHILTON'S FOOD ENG'G, Dec. 1, 1995, *available at* 481995 WL 12141218 ("The Hazard Analysis Critical Control Point System has been around since 1959. Even though this scientific-based system can prevent food safety hazards, its implementation has been slow.")

[2] *See, e.g., About the National Conference on Emerging Foodborne Pathogens: Implications and Controls,* 3 EMERGING INFECTIOUS DISEASES 415 (1997) ("Infectious diseases transmitted by food have become a major public health concern in recent years."); Stephen R. Crutchfield & Tanya Roberts, *Food Safety Efforts Accelerate in the 1990's*, 23 FOODREVIEW 44 (2000) (awareness of the health risks from foodborne disease has increased over the past ten years).

[3] *See, e.g.,* Crutchfield & Roberts, *supra* note 2, at 44.

[4] *Id.*

[5] *See, e.g.,* FOOD AND DRUG ADMIN., FOOD CODE 2001, RECOMMENDATIONS OF THE UNITED STATES PUBLIC HEALTH SERVICE, FOOD AND DRUG ADMINISTRATION 424 (2001) [hereinafter FDA 2001 FOOD CODE] ("FDA is recommending the implementation of HACCP in food establishments because it is a system of preventive controls that is the most effective and efficient way to ensure that food products are safe."); NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCIENCE, AN EVALUATION OF THE ROLE OF MICROBIOLOGICAL CRITERIA FOR FOODS AND FOOD INGREDIENTS 329 (1985) [hereinafter NAS REPORT, THE ROLE OF MICROBIOLOGICAL CRITERIA].

duced under the current U.S. food safety system,[6] although the tools exist to eliminate much of this danger. Thus, HACCP's slow acceptance presents a paradox.

Section II of this article provides the history of HACCP's slow acceptance along with an overview of HACCP's advantages and the nature of foodborne illness. Section III examines the typical reasons offered for HACCP's slow adoption; a close look reveals that one cannot fully understand the food industry's ambivalence toward HACCP without understanding the role of economics and tort law in the U.S. food safety system. Section IV reviews current regulatory controls on food safety, and discusses the difficulties that regulatory agencies face translating science into food safety law. Finally, Section V discusses proposals for making the food safety system more effective and more efficient with a combination of old tools and a few innovations. By fathoming this seeming paradox of HACCP's slow acceptance, a course for improving the food safety system can be marked.

II. NEED FOR A SCIENCE-BASED AND PREVENTATIVE FOOD SAFETY SYSTEM

The acronym "HACCP" means Hazard Analysis and Critical Control Point. Application of HACCP creates a prevention-based food safety system. In this system, the inherent risks in ingredients, process, and the final food are analyzed; the steps necessary to control the identified risks are established; and those controls are monitored. Thus, HACCP provides process control to prevent food safety problems before they happen.

The Seven HACCP Principles[7]

(1) *Hazard and risk assessment*.
(2) *Determine the critical control points* (CCPs) to control the identified hazards.
(3) Establish *critical limits* for the preventative measures.
(4) Establish procedures to *monitor the CCPs*.
(5) Establish *corrective actions* to be taken when monitoring shows that a critical limit has been exceeded (or when other deviation occurs in CCP monitoring).
(6) Establish *effective recordkeeping systems* to document that the HACCP system is working correctly.
(7) Establish procedures for *verification* that the HACCP system is working correctly.

A. *HACCP's History*

HACCP was developed in the late 1950s[8] and pioneered in the early 1960s by the Pillsbury Company, with participation of the National Aeronautics and Space Adminis-

[6] *See* Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999). *See also* CDC, *Preliminary FoodNet Data on the Incidence of Foodborne Illness—Selected Sites, United States, 2001,* 51 MORBIDITY & MORTALITY WKLY. REP. (MMWR), Apr. 19, 2002, at 325-29, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5115a3.htm (last visited Nov. 12, 2003).

[7] The seven principles are variously described, but the International Commission on Microbiological Specifications for Food (ICMSF), the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), and the U.S. Food and Drug Administration (FDA) define HACCP as consisting of these seven principles. FDA 2001 FOOD CODE, *supra* note 5, at 421-57.

[8] *See, e.g.,* Russell, *supra* note 1.

tration (NASA), the Natick Laboratories of the U.S. Army, and the U.S. Air Force Space Laboratory Project Group.[9] NASA's concern for safe food is clear; typical foodborne illness symptoms (e.g., nausea, diarrhea, vomiting) could be catastrophic in space. Unfortunately, conventional end-product testing was—and still is—incapable of providing the desired 100% assurance against contamination by bacteria, viruses, toxins, and chemical and physical hazards. HACCP was essential to creating space program food that approached—as near as possible—full assurance against contamination.[10]

HACCP was first described in detail to a large audience at the Conference for Food Protection in 1971.[11] It was then applied with great success to low-acid canned foods in 1974.[12] In the decades since its development, HACCP has become widely recognized as the best approach for improving food safety.[13]

One of HACCP's strongest recommendations came in 1985 from the National Academy of Sciences, which recommended that "government agencies responsible for control of microbiological hazards in foods should promulgate appropriate regulations that would require industry to utilize the HACCP system in their food protection programs."[14] In addition, HACCP has been endorsed by the U.S. National Advisory Committee on the Microbiological Criteria for Foods,[15] the International Commission on Microbiological Specifications for Foods,[16] the U.S. Food and Drug Administration (FDA),[17] the Conference on Food Protection, and the Codex Alimentarius Commission of the United Nations.[18]

B. *The Advantages of HACCP*

Although the traditional inspection works well at accomplishing what it was designed to achieve—cleaner food produced under more sanitary conditions—, it is inadequate in preventing many foodborne illnesses.[19] Whereas traditional food safety assurance programs rely on general sanitation inspections and end-product testing, HACCP identifies the risks and then applies preventative control measures.[20]

HACCP's preventative nature may be its most significant design achievement. Reliance on classical end-product testing and inspections is relatively resource-intensive and inefficient because it is reactive rather than preventative.[21] "It's much easier to keep

[9] *See* FDA 2001 FOOD CODE, *supra* note 5, at 423.

[10] *Id.*

[11] *See* Douglas L. Archer, *The Need for Flexibility in HACCP*, 44(5) FOOD TECH. 174 (1990).

[12] *See id. See also* A.V. Riswadkar, *An Introduction to HACCP: The Hazard Analysis & Critical Control Point System for Food Processors,* PROFESSIONAL SAFETY, June 2000, at 33-36.

[13] *See, e.g.,* INST. OF MED., NAT'L RESEARCH COUNCIL, NAT'L ACAD. OF SCIENCE, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 29-30 (1998) ("It is widely accepted by the scientific community that use of HACCP systems in food production, processing, distribution, and preparation is the best known approach to enhancing the safety of foods.").

[14] NAS REPORT, THE ROLE OF MICROBIOLOGICAL CRITERIA, *supra* note 5, at 329.

[15] NAT'L ADVISORY COMM. ON THE MICROBIOLOGICAL CRITERIA FOR FOODS, U.S. DEP'T OF AGRICULTURE, HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (1990).

[16] INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOOD, MICROORGANISMS IN FOODS 2, SAMPLING FOR MICROBIOLOGICAL ANALYSIS: PRINCIPLES AND SPECIFIC APPLICATIONS (Univ. of Toronto Press 2d ed. 1986).

[17] FDA 2001 FOOD CODE, *supra* note 5, at 424.

[18] *See* Michael R. Taylor, *Preparing America's Safety System for the Twenty-First Century—Who Is Responsible for What When It Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy?*, 52 FOOD & DRUG L.J. 13-14 (1997).

[19] *See* Riswadkar, *supra* note 12, at 33-36.

[20] *See id.*; JAMES M. JAY, MODERN FOOD MICROBIOLOGY 408 (5th ed. 1996).

[21] FDA 2001 FOOD CODE, *supra* note 5, at 424 ("Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventative compared to the HACCP approach for ensuring food safety.").

all the needles out of the barn than to find the needle in the haystack," one food safety educator noted. "An ounce of prevention is worth several million pounds of recalled product."[22] Recent outbreaks provide dramatic examples of the economics of failed prevention. For example, $12.5 million worth of apple juice was recalled following contamination of the product with *E. coli*, and the firm—Odwalla, Inc.—paid a $1.5 million federal fine.[23]

Three additional benefits of HACCP are worth noting briefly. HACCP creates a complete system to ensure safety, including plans for corrective actions, recordkeeping systems, and verification steps to ensure that potential risks are controlled. HACCP also clearly recognizes that the responsibility for ensuring safe food rests on the food industry. "A HACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies."[24] Clearly, the food industry is in the best position to proactively ensure safe food. Third, HACCP allows the traditional inspection methods to be more productive. Traditional inspections and end-product testing can achieve clean food produced under sanitary conditions, but they produce only a snapshot of time, rather than a continuous method. HACCP's recordkeeping improves the ability of food managers and regulators to ensure that food workers consistently implement traditional sanitary practices.

HACCP's preventative system of process control can and does prevent hazards that traditional reactive methods could not. For example, after a number of botulism food poisonings, FDA promulgated federal low-acid canning regulations in 1974.[25] Although not called HACCP, these regulations essentially mandated HACCP for low-acid canning and nearly eliminated the incidence of botulism associated with canned food.[26]

To sum up the primary benefits of HACCP, it is a science-based, preventative, and risk control system. HACCP prevents foodborne illness by applying science to identify the risks in a method of food handling or processing. It controls those risks through preventative controls. Finally, HACCP is a complete system that includes corrective actions, recordkeeping, and verification, all of which increase the effectiveness and efficiency of both HACCP and conventional sanitation methods.

This article predominantly addresses the first three aspects of HACCP—science-based, preventative, and risk control—because these three components are foundational for all other aspects of HACCP. Unless science is applied to identify the known risks, all other aspects of a HACCP system will fail. Likewise, if risks are identified, but no controls implemented, then subsequent steps, such as recordkeeping, cannot ensure food safety.

C. *The Nature and Cost of Foodborne Illness*

To fully appreciate the benefits of HACCP, it is necessary to understand the burden of foodborne illness. In excess of 200 known diseases are transmitted through food.[27] These diseases include infections, intoxications, and chronic *sequelae*.[28] The foodborne

[22] Charles E. Morris, *HACCP Under the Microscope,* FOOD ENG'G, Oct. 2000, at 74 (quoting Dr. Timothy Freier, Director of Educational Services for the Siliker Laboratory Group).

[23] *See* Jean C. Buzby et al., *Product Liability and Microbial Foodborne Illness* /AER-799, at 3-4 (Economic Research Service/USDA 2001).

[24] FDA 2001 FOOD CODE, *supra* note 5, at 424.

[25] 21 C.F.R. § 113 (2000).

[26] *See* Archer, *supra* note 11, at 174; Riswadkar, *supra* note 12, at 33-36.

[27] *See* Mead et al., *supra* note 6, at 607 (citing F.L. BRIAN, DISEASES TRANSMITTED BY FOOD (Centers for Disease Control 1982)).

[28] A *sequela* is an aftereffect of disease or injury, or a secondary result of a disease.

infectious agents include bacteria, viruses, and parasites. The intoxications (commonly called poisonings) occur with exposure to bacterial toxins, heavy metals, insecticides, and other chemical contaminants. Disease symptoms range from mild gastrointestinal distress to life-threatening neurological, hepatic, and renal syndromes, to death.[29]

Over the past ten years, science has begun to reveal the grim potential of foodborne pathogens to cause chronic *sequelae*—secondary complications that may develop months, or even years, after the first unpleasant bout of symptoms.[30] Growing evidence exists of a multitude of chronic illnesses resulting from an attack of foodborne disease, such as "arthropathies, renal disease, cardiac and neurological disorders, and nutritional and other malabsorbtive disorders (incapacitating diarrhea)."[31] *Sequelae* include the immediate aftereffects of foodborne disease, toxins with long delay in onset, antigenic and autoimmune effects, and intracellular sequestration. It is estimated that chronic *sequelae* may occur in two to three percent of foodborne illness cases.[32]

The burden of foodborne illness is estimated to be as high as 300 million cases per year,[33] with patient-related costs in the billions of dollars per year.[34] Each year in the United States, a foodborne disease causes an estimated 76 million illnesses,[35] 320,000 hospitalizations, and 5,000 deaths.[36] One of every 100 hospitalizations, and one of every 500 deaths in the United States, is the result of contaminated food. [37]

This lack of certainty in the identification of foodborne illness is a principal reason why the range of estimates of the costs of foodborne illness is wide. One estimate places the cost for direct, patient-related costs of foodborne illness at $164 billion per year.[38] Other estimates attempt to calculate the costs for a limited number of foodborne pathogens (typically five to seven major pathogens), and in these, the estimated annual cost of medical treatment and lost productivity varies from $5.6 billion to $37.1 billion.[39]

Many people casually reference the available aggregate estimates as the total cost of foodborne illness; however, these estimates—by design—are only partial estimates of the burden of foodborne illness. For example, the U.S. Department of Agriculture's (USDA's) Economic Research Service (ERS) estimated the medical costs and losses in productivity of five major foodborne pathogens between $5.6 billion and $9.4 billion.[40]

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[29] *See* James A. Lindsay, *Chronic Sequelae of Foodborne Disease*, 3(4) EMERGING INFECTIOUS DISEASES 1 (1997), *available at* http://www.cdc.gov/ncidod/eid/vol3no4/lindsay.htm (last visited Nov. 10, 2003).

[30] *Id.*

[31] *Id.*

[32] *Id. See also* U.S. GENERAL ACCOUNTING OFFICE (GAO), FOOD SAFETY, INFORMATION ON FOODBORNE ILLNESSES, GAO/RCED-96-96, at 8 (May 1996).

[33] *See* Chryssa V. Deliganis, *Death by Apple Juice: The Problem of Foodborne Illness, the Regulatory Response, and Further Suggestions for Reform*, 53 FOOD & DRUG L.J. 681, 695 (1998) (citing E.J. Mundell, *Food-Borne Illness on the Rise*, REUTERS, Dec. 2, 1997, with the statements of Michael Osterholm, Epidemiologist, Minnesota Dep't of Health, at American Medical Ass'n press conference on public health (Dec. 2, 1997)).

[34] *See* Sanford A. Miller, *The Saga of Chicken Little and Rambo*, 51 J. ASS'N OF FOOD & DRUG OFFICIALS 196 (1987); Jean C. Buzby & Tanya Roberts, *Economic Costs and Trade Impacts of Microbial Foodborne Illness,* 50(1/2) WORLD HEALTH STAT. Q. 57 (1997).

[35] "Illness" as used here means that the disease is serious enough to require medical treatment.

[36] CDC, FOODNET SURVEILLANCE REPORT FOR 1999 (FINAL REPORT) 6, 19 (Nov. 2000) (citing P. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999)).

[37] *See* Buzby et al., s*upra* note 23, at 3.

[38] Miller, *supra* note 34, at 196.

[39] JACK GUZEWICH & MARIANNE P. ROSS, FOOD AND DRUG ADMINISTRATION, EVALUATION OF RISKS RELATED TO MICROBIOLOGICAL CONTAMINATION OF READY-TO-EAT FOOD BY FOOD PREPARATION WORKERS AND THE EFFECTIVENESS OF INTERVENTIONS TO MINIMIZE THOSE RISKS 3 (citing J.C. Buzby & T. Roberts, *Economic Costs and Trade Impacts of Microbial Foodborne Illness,* 50(1/2) WORLD HEALTH STAT. Q. 57 (1997)). *See also* GAO, FOOD SAFETY, INFORMATION ON FOODBORNE ILLNESSES, GAO/RCED-96-96, at 9 (May 1996).

[40] GAO, FOOD SAFETY, INFORMATION ON FOODBORNE ILLNESSES, *supra* note 39, at 9.

This ERS estimate, however, does not include Hepatitis A virus and other significant pathogens. In addition, the ERS estimate and other available estimates do not include difficult-to-quantify costs, such as the public health expenditures on foodborne illness. Further, these aggregate estimates of cost do not include the loss of food (i.e., recall and destruction), lost production, lost sales, or pain and suffering. The aggregate estimates also do not encompass foodborne illness that is too mild to require medical treatment, and they do not include the amount that consumers are willing to pay to avoid mild diarrhea and nausea. Finally, none of the aggregate estimates includes the costs of the chronic *sequelae* of foodborne illness. Estimates of health consequences of chronic *sequelae* indicate that the economic costs may be higher than those of the acute diseases.[41] In this light, even the highest estimate—$164 billion per year for direct medical costs—may be far below the total burden of foodborne illness.

The significant burden of foodborne illness highlights the importance of an effective and efficient food safety system, and the potential gains from the application of HACCP. Safe food is a goal shared by all: consumers, obviously, benefit by having fewer illnesses; society benefits from lower healthcare costs and lost productivity; and food businesses profit from lower liability, fewer production losses (such as recalls), and improved marketability of their product.

The next section discusses the reasons the food industry has not fully embraced HACCP. After providing an overview of the surface explanations, the factors underlying this resistance are analyzed. This analysis includes discussion of the influence of the tort system and market forces on the food safety system. Because cost is the predominant explanation for resistance to HACCP, law and economics is the primary focus of this analysis.

III. INDUSTRY HANG-UPS WITH HACCP

Recognition of HACCP as the best food safety system available has increased not only with scientists, but also among experts in the food industry.[42] Nevertheless, the food industries often have resisted HACCP requirements.[43] The regulations requiring HACCP for meat, seafood, and juice came only after the public outrage generated by large foodborne disease outbreaks outweighed industry resistance.[44] After the first *E. coli* illness outbreak from apple cider, eleven years passed before the juice HACCP regulations were implemented.[45] After a multistate outbreak from apple juice left seventy sickened and one dead, six years passed before the juice HACCP regulations would be required for small cider processors.[46] Moreover, cider and juice processors who sell entirely at retail are still exempt from HACCP.[47]

A. *Surface Explanations for Resistance to HACCP*

"Too difficult, too expensive, and too confusing" is the common refrain offered to explain resistance to HACCP. Commentators have offered other explanations why HACCP has failed to reach its potential, suggesting one or more of the following:[48]

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[41] *See* Lindsay, *supra* note 29, at 2.

[42] *See, e.g.,* Morris, *supra* note 22, at 74.

[43] *See, e.g.,* Russell, *supra* note 1.

[44] *See, e.g.,* ERIC SCHLOSSER, FAST FOOD NATION 197 (1st perennial ed. 2002) ("[T]he nation's leading agribusiness firms have resolutely opposed any further regulation of their food safety practices.")

[45] *See infra* Figure 2, *Escherichia coli* O157:H7 Chronology.

[46] *Id.*

[47] 21 C.F.R. § 120.1(b)(2).

[48] *See* Morris, *supra* note 22, at 74.

- too time consuming;
- too complicated;
- weak prerequisite programs (such as basic sanitation);
- lack of upper-management commitment;[49]
- production trumps HACCP;[50]
- inclusion of nonfood safety issues dilutes the program;[51]
- failure to use science in the planning;
- copied from generic models;
- inadequate employee training;
- inadequate or inefficient documentation;
- failure to follow through on corrective actions;
- fear of legal repercussions for documenting knowledge of risk in products;[52]
- fear of regulators using record keeping to punish the industry;[53] or
- more basic scientific research needed into the causes of foodborne illness.

Analysis of so many different issues poses a task as daunting as cleaning the Augean stables; fortunately, the list sorts out into three basic categories: 1) fear of repercussions, 2) a call for more science, and 3) cost.

1. *Fear of Repercussions From HACCP Records*

Fear of repercussion from adoption of HACCP takes two general forms: fear that government regulators will use HACCP records against the industry, and fear that HACCP records will be damaging if released during the discovery phase of a lawsuit.[54] Undoubtedly, HACCP audits provide more accurate information about the safety of food—or lack of safety—than conventional inspections because HACCP reports whether safety risks were controlled, rather than focusing on general sanitation. In addition, HACCP inspections and HACCP verification audits provide a moving picture of a firm's food safety, versus the single snapshot of sanitation documented during a conventional inspection. Thus, HACCP's virtue at documenting safety success also is feared because it can document safety failures.

Although a few firms may choose a risk management strategy of concealing their safety failures, this article assumes that food businesses prefer prevention to concealment. Generally, businesses will choose rational alternatives, and preventing injury is the most rational way to reduce liability; a business faced with a choice between obscuring food safety failures and implementing an efficient system to prevent food safety risks and subsequent injuries, generally will choose prevention. Because HACCP can identify unsafe food before sale, HACCP's corrective actions can prevent unsafe food from reaching consumers. Therefore, with all other factors equal, fear of repercussions from HACCP recordkeeping cannot rationally account for businesses failing to adopt HACCP.

Moreover, the food industry's fear of liability from HACCP does little to explain why regulators would be slow to adopt HACCP. After all, the food industry may worry that

[49] *Id.*

[50] *Id.* ("[P]roduct is released despite critical control point (CCP) violations.")

[51] *Id.*

[52] *See* Richard S. Silverman, *The Liability of HACCP Risk Assessment, in* FOOD PROTECTION REPORT, 2A (1997).

[53] *See, e.g.*, John Cady, *FDA Reform: The Need for a Sound Science-Based Approach*, 51 FOOD & DRUG L.J. 407 (1996) ("HACCP requires a mindset change from distrustful enforcement to scientific cooperation.").

[54] *See, e.g.*, Silverman, *supra* note 52.

their HACCP records will be turned against them,[55] but regulators lack a corresponding concern and gain nothing from a system that obscures food safety failures. In addition, the food industry's fear of liability from HACCP provides thin reasoning for a government policy choice. Prudent policy prevents injuries, rather than allowing tortfeasors to remain in comfortable anonymity. Therefore, fear of liability—without more—cannot explain the slowness of HACCP adoption.

2. *The Call for More Research*

A call for more scientific research is compelling because the need is irrefutable. A disconcerting eighty percent of foodborne illness occurs from unknown agents.[56] In addition, our knowledge of chronic *sequelae* appears to be just the tip of the iceberg.[57] Undoubtedly, more science to fill the knowledge gaps about foodborne illness would be beneficial.[58]

Because businesses would not be expected to invest in uncertain safety measures, this knowledge gap offers a potential explanation for resistance to HACCP's adoption.[59] Nonetheless, the need for more science cannot explain the resistance to applying preventative measures to currently-known risks. For example, most illnesses from unknown agents are believed to be caused by viruses that are easily transmitted to food. Estimates from the Centers for Disease Control and Prevention (CDC) indicate that a significant portion of foodborne disease may be attributed to poor food-handler hygiene, combined with bare-hand contact of food (such as feces-to-food transmission).[60] Microbiological research to identify these unknown pathogens would be worthwhile, but epidemiology informs us that simply stopping fecal-to-food transmission can reduce the burden of foodborne illness.[61] Thus, much foodborne illness is preventable with current interventions. Disease prevention need not wait until microbiology catches up with epidemiology.[62] Therefore, the need for more science fails to explain the resistance to application of HACCP to prevent currently-understood disease transmission.

Neither the public nor the food industry want pathogens in food, but both find themselves saddled with a food safety system that permits millions of cases of preventable illnesses every year. Blaming inadequate science is a convenient explanation for this paradoxical failure in the food safety system, but the reasons are more complex.

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[55] *See, e.g.*, Cady, *supra* note 53.

[56] CDC, FOODNET SURVEILLANCE REPORT FOR 1999, *supra* note 36, at 6.

[57] *See* Lindsay, *supra* note 29, at 2.

[58] *See, e.g.*, GROCERY MANUFACTURERS OF AMERICA, FOOD SAFETY 1 (Sept. 24, 2001), *available at* http://www.gmabrands.com/news/docs/WhitePaper.cfm?DocID=290 (last visited Nov. 26, 2003) ("The FDA's and USDA's current authority to regulate food products is ample. There should be more emphasis on research and establishing science-based standards ….They must also be able to identify and fight the true causes of foodborne illnesses with the right scientific weapons. These weapons can only be discovered through laboratory research and practical testing.") *See also* Deliganis, *supra* note 33, at 727 ("Foodborne illness is a problem not because of widespread fraud or abuse in the food processing industry, but rather for numerous other reasons, some of which are not completely understood.").

[59] *See, e.g.*, *id.*; Cady, *supra* note 53.

[60] GUZEWICH & ROSS, *supra* note 39, at 3.

[61] Epidemiology is a field of medical science that deals with the incidence, distribution, and cause of disease in a population. By quantifying the occurrence of illness and statistically relating the occurrence to characteristics of the people and their environment (e.g., meal patterns), epidemiology can pinpoint disease causation.

[62] The author suspects that both the food industry and government regulators are less likely to rely on scientific determinations based on epidemiology rather than determinations based on microbiology. Underutilization of epidemiology may be due to a cultural skepticism of statistics. *See generally* DARRELL HUFF, HOW TO LIE WITH STATISTICS (paperback reissue 1994).

B. *Law and Economics Analysis of HACCP Adoption*

The remaining explanations as to why HACCP has failed to reach its potential are cost-related. "Too costly" is the direct explanation, but other reasons relate to cost as well. "Too time consuming," for example, is equivalent to being too costly. Other explanations involve the level of management motivation to implement HACCP. In a business setting, lack of motivation is an economic factor; after all, it is the essence of the U.S. market system that if an endeavor is profitable, businesses will be motivated.

HACCP lends itself to description as costly and confusing. Based as it is on science, HACCP begins with a certain level of complexity, then layers unique terminology and a level of detail that can be confusing to the uninitiated. HACCP's space program connection makes it easy to conjure up images of laboratory settings with gowned workers in sterile fields producing food under conditions too complicated and expensive for ordinary application. Pragmatic managers running real-world businesses view skeptically the image of the "ivory tower" scientists touting the seemingly magical benefits of HACCP.

In reality, the complexity of HACCP correlates with the nature of the risk and complexity of the food processing method. Nonetheless, complexity is not a deterrent to HACCP implementation when it is perceived as profitable. For example, aseptic packaging of juice boxes requires laboratory-like controls and sterile fields, but that packing industry willingly applies sophisticated HACCP controls to avoid juice boxes that otherwise would explode from the growth of spoilage organisms.

The food industry willingly adopts complicated controls when managers perceive a direct benefit. Conversely, when HACCP controls are perceived as too costly, the economic benefits of HACCP are viewed as lower than the business costs of implementation. HACCP is neither magic nor monster; HACCP simply is a science-based, systematic approach to preventative food safety. A commitment to HACCP does entail an economic investment, however, and segments of the food industry do find HACCP investment unprofitable.

Therein lies a contradiction; the consensus of experts is that HACCP is the most effective and efficient[63] food safety system available, but segments of the food industry shun HACCP as too costly. "Too costly" in a business sense denotes a relative versus an absolute quantitative value, and only that a particular investment is *perceived* as costing more than its benefit. For example, Jack-in-the-Box implemented HACCP without a significant increase in cost;[64] for all aspects of their food system, the entire cost worked out to less than a fourth of a cent per burger.[65] While consumers may perceive this as an insignificant cost, even a penny a pound may be too costly from a business perspective if there is no return on that investment. Clearly, the food industry is committed to food safety. After all, safe food generally makes good business sense. Certainly,

[63] Efficient in the sense of being the most cost-effective control system. HACCP is preventative, whereas traditional controls are relatively resource-intensive and inefficient because they are reactive. *See* subsection I. B., *supra*. In addition, food processing and packaging firms can reduce their cost of raw material inspections and qualitative testing, and redundant food safety testing may be eliminated. *See* Michael A. Mazzocco, *HACCP as a Business Management Tool*, 78 AM. J. AGRIC. ECON. 770, 771 (1996).

[64] Jesse D. Lyon, *Coordinated Food Systems and Accountability Mechanisms for Food Safety: A Law and Economics Approach*, 53 FOOD & DRUG L.J. 729, 750 (1998) (quoting Jean Buzby & Tanya Roberts, *Microbial Foodborne Illness: The Costs of Being Sick and the Benefits of New Prevention Policy*, CHOICES 14, 15 (First Quarter 1996).

[65] SCHLOSSER, *supra* note 44, at 210 (noting that the cost of the firm's complete HACCP system raised the cost of the chain's ground beef by about one penny per pound).

the majority of those in the food industry would agree that "safe food is our business" and that "no one stays in business making people sick."[66] Therefore, the paradox of an industry committed to safety, but also not wanting to spend the money for safety improvements because it is perceived as unprofitable, exists.

Law and economics provide two likely explanations for this contradiction: 1) an inefficient market due to imperfect information in the hands of consumers; and 2) externalities that distort the perceived cost of an activity. The next subsections will examine how imperfect information impacts market efficiency and tort liability concerning food safety. Also examined is how externalities distort the food industry's perceived costs of certain activities, resulting in industry opposition to some scientific risk controls—a *sine qua non* of HACCP.

1. *Imperfect Market Controls and Tort Liability*

When perfect information is provided to, and understood by, the consumer before purchase, there is market efficiency and little need for tort litigation or regulation.[67] In that instance, for example, the market is efficient for the sale of apples and oranges in the sense that consumers can choose oranges over apples without being concerned about receiving apples instead. In addition, the market efficiently determines how much consumers are willing to pay to satisfy their relative preferences for oranges and apples.

When imperfect information is available before purchase, but complete information is available after purchase, tort law provides an important remedy. Tort law provides a method of compensation for damages, but also recognizes and protects certain interests and provides a "'prophylactic' factor of preventing future harm."[68] Thus, foodborne illness-based lawsuits provide important economic feedback to firms as to whether they should invest more in food safety.[69]

It is well documented that the market provides incomplete information on a product's risk of inducing foodborne illness;[70] consumer information on unsafe food is incomplete both before and after purchase. Unlike food spoilage organisms, foodborne pathogens often are invisible, odorless, and tasteless. Consumers cannot examine their food and determine that it is free from pathogens. Further, the vast majority of foodborne illness is never traced back to its cause. This market inefficiency creates an underproduction of food safety that a fully functional and competitive market would produce.[71]

For the market system to work, consumers would need inexpensive access to complete information on the safety of their food either before or after purchase. Unfortunately, even the limited available information generally is very costly to obtain,[72] as foodborne pathogen determination requires expensive investigation and laboratory testing. Even if an ill consumer did somehow complete such investigation and laboratory testing, he or she

[66] *See, e.g.*, Russell, *supra* note 1, at 4 ("And safe products are everyone's business.").

[67] *See, e.g.,* JOHN M. ANTLE, CHOICE AND EFFICIENCY IN FOOD SAFETY POLICY 44-45, 54-55 (AEI Press 1995) ("If perfect information was available and consumers knowledgeable, then market controls are efficient. Post-hoc remedies are also efficient if perfect information is available after purchase.").

[68] W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 255 (5th ed. 1984).

[69] Buzby et al., *supra* note 23, at 27.

[70] *See generally id*. at 11; Taylor, *supra* note 18, at 13-14 ("Market mechanisms work reasonably well to satisfy consumer demands for economy, convenience, and choice in the food supply, but they cannot fully satisfy the very high consumer expectations for food safety.").

[71] *See* Buzby et al., *supra* note 23, at 11 ("High transaction costs and information costs dissuade food-poisoning victims from filing lawsuits … limit feedback to firms to produce safer food … the result is a level of food safety that is less than the socially optimal level provided by a perfectly competitive market.").

[72] *See generally id*.; Taylor, *supra* note 18, at 13-14.

would have no way to communicate the information among the large number of people needed to conduct the epidemiology for a foodborne illness investigation.[73]

Moreover, information on foodborne illness generally is not available at any cost. Rarely is the cause of a foodborne illness traced back to the causative food. More than eighty percent of foodborne illness may be unreported; and, even when reported causation is difficult to prove.[74]

Linkage of a foodborne illness to a causative agent (such as a particular microorganism) may be established by statistics or, alternatively, by biochemical typing (often called DNA fingerprinting). Direct linkage by DNA fingerprinting, however, occurs in only a miniscule fraction of all outbreaks. The alternative epidemiological correlation requires a relatively large number of ill persons to provide sufficient data to make the statistical link. Thus, there is better information on pathogens when they cause large outbreaks, such as more than 500 sickened by *E. coli* tainted hamburger in 1993.[75] A disease outbreak with only a dozen, or even fifty, ill individuals may not be recognized unless some other epidemiological link has been established.[76]

The delayed onset of certain types of foodborne illness compounds the difficulty of correlation by any means. Hepatitis A has an incubation period[77] of fifteen to fifty days with a mean incubation period of thirty days.[78] With such a long period between consuming a food and the onset of symptoms, poor recall by the patient as well as recall error and bias make investigation problematic.[79]

Because there are steep obstacles to surmount in proving causation, the vast majority of foodborne illnesses do not result in lawsuits.[80] Post-hoc remedies through tort liability thus provide incomplete feedback to the food industry to uniformly effect a change in food safety.[81] Consequently, society bears nearly all of the cost of foodborne illness.[82]

This lack of market information on the safety of food before and after purchase not only deprives consumers of market options, but it deprives the food industry of an important incentive to improve. That is, the market is inefficient at rewarding firms for implementing improved safety systems. In certain situations, the lack of complete information on foodborne illness provides an economic incentive to firms *not* to implement HACCP because the costs of the risks are externalized, and the expense of preventative measures is saved.

2. *Industry Resistance to Safety Controls Correlated to Externalities*

Economic theory indicates that firms will invest fewer resources in safety measures against risks for which they are less likely to pay for consequential injuries.[83] Con-

[73] Dion Casey, *Agency Capture: The USDA's Struggle to Pass Food Safety Regulations*, 7 KAN. J.L. & PUB. POL'Y 142, 144 (1998).

[74] CDC, FOODNET SURVEILLANCE REPORT FOR 1999, *supra* note 36, at 6.

[75] CDC, *Update: Multistate Outbreak of Escherichia coli O157:H7 Infections from Hamburgers—Western United States, 1992-1993*, 42(14) MORBIDITY & MORTALITY WKLY. REP. (MMWR), Apr. 16, 1993, at 258 [hereinafter CDC, *Multistate Outbreak—Western U.S.*].

[76] *Id*. (noting that foodborne illness outbreaks of 14 ill in Idaho, 34 ill in California, and 58 ill in Nevada may not have been recognized if the epidemiological link to 477 illnesses in Washington had not been established).

[77] The incubation period is the time between ingestion of the infecting pathogen and the first appearance of symptoms of the consequent disease.

[78] GUZEWICH & ROSS, *supra* note 39, at 5-6.

[79] *Id*. at 6 (citing A.R. Walburton et al., *Hepatitis A Outbreak Involving Bread*, 106 EPIDEMIOL. INFECT. 199-202 (1991)).

[80] *See* Buzby et al., *supra* note 23, at 24.

[81] *See generally id.*; Richard Merrill & Jeffrey Francer, *Organizing Federal Food Safety Regulation,* 31 SETON HALL L. REV. 61, 64 (2000).

[82] In addition, many small businesses, particularly retail establishments, are judgment proof because they lack sufficient insurance or assets to remedy the injuries.

[83] *See* Buzby et al., *supra* note 23, at 1.

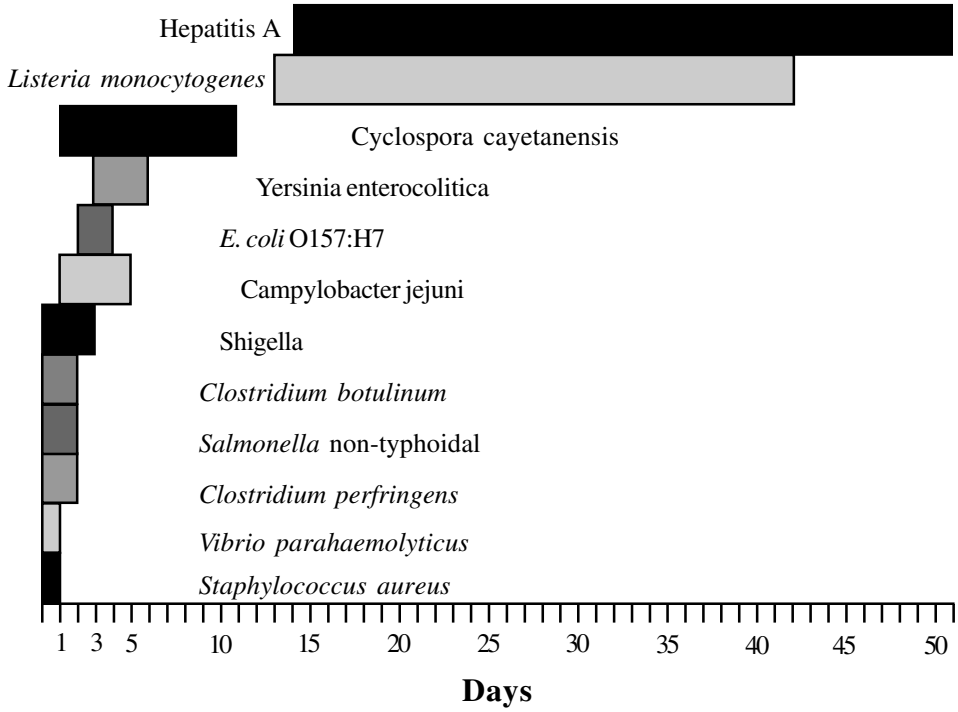
versely, firms will invest more resources in safety controls on risks for which they *are* likely to pay for consequential injuries. This observation does not imply that firms consciously disregard risk or lack social concern for consumer safety. Rather, externalities, by definition, are a distortion, which necessarily creates a corresponding distortion in the perception of risk.

Vomitoxin dramatically illustrates how consumer information about causation of a foodborne disease can create a powerful incentive for food firms to eliminate that risk, and, conversely, how the lack of this consumer information creates a marketplace disincentive to ensuring that food is safe from pathogens. *Staphylococcus aureus* produces vomitoxin, which causes vomiting and diarrhea within two to four hours of ingestion.[84] The food industry widely accepts and implements regulatory controls to prevent this pathogen (e.g., proper cold holding of potentially hazardous foods below 45° Fahrenheit).

On the other hand, two food pathogens with longer incubation periods, Hepatitis A virus and *Listeria monocytogenes*, make it unlikely that ill consumers will be able to pinpoint what food caused their illness. A person who vomits up their meal two hours after eating at a restaurant (e.g., from vomitoxin) is far more likely to implicate the restaurant as the cause of his or her illness than a patron who becomes ill with flu-like symptoms six weeks after eating the food (e.g., *Listeria monocytogenes* or Hepatitis A) (s*ee* Figure 1).

FIGURE 1

Usual Incubation or Latency Periods[85] for Select Foodborne Illnesses[86]



[84] CENTER FOR FOOD SAFETY & APPLIED NUTRITION, FOOD AND DRUG ADMIN., FOODBORNE PATHOGENIC MICROORGANISMS AND NATURAL TOXINS (BAD BUG BOOK), *at* http://www.cfsan.fda.gov/~mow/chap3.html (last visited Nov. 10, 2003); INT'L ASS'N OF MILK, FOOD AND ENVIRONMENTAL SANITARIAN, PROCEDURES TO INVESTIGATE FOODBORNE ILLNESS 102 (5th ed. 1999).

[85] Incubation period is the time between ingestion of the infecting pathogen and the first appearance of symptoms of the consequent disease. Latency period is the time between exposure to a toxin or other harmful agent and the first manifestation of reaction.

[86] *See* CDC, *Surveillance for Foodborne Disease Outbreaks—United States, 1990-1992,* 45 MORBIDITY & MORTALITY WKLY. REP. (MMWR), Oct. 25, 1996, at 56; Economic Research Serv., USDA, Consumer Food Safety Behavior: Restaurants the Chief Target of Foodborne Illness Lawsuits, *available at* http://www.ers.usda.gov/briefing/consumerfoodsafety/feature.htm (last visited Nov. 10, 2003).

In addition to providing little useful information to consumers, these long-onset foodborne pathogens result in imperfect feedback to the food industry. Complaints, lawsuits, and other repercussions associated with foodborne illness have been largely absent with these pathogens, except for large outbreaks (e.g., fifty or more illnesses from a single event, which allows statistical correlation to the specific cause). It is to be expected, then, that the food industry would be more resistant to the expense of implementing risk controls for Hepatitis A and *Listeria monocytogenes*, with their long incubation periods, than for *Staphylococcus aureus* or *Clostridium perfringens*, with their short latency or incubation periods. This is the pattern observed; although not quantified, the food industry's resistance to controlling the risk of a pathogen is related to the delay time from ingestion to onset of illness.[87] This correlation more specifically relates to the likelihood of a business paying for the consequential injuries from a foodborne pathogen risk.

Tens of millions of foodborne illnesses occur every year due to the failure to control these pathogens,[88] at the cost of billions of dollars a year.[89] Because the vector of Hepatitis A and *Listeria monocytogenes* rarely is proven, society subsidizes the food industry's practices by paying the cost of those foodborne illnesses. Thus, the food industry has a perverse economic incentive to continue risky food handling practices relative to Hepatitis A and *Listeria monocytogenes*. Firms with risky food handling save the expense of prevention; and could find themselves at a competitive advantage over those firms that implement preventative practices. Moreover, firms that bear the cost of preventing food contamination cannot be rewarded by the marketplace for their preventive food safety measures because there is incomplete information in the market.

In another example, the retail food industry has been relatively willing to adopt risk controls for *Staphylococcus aureus* with its rapid onset of illness after eating a contaminated food, yet resistant to controls for *Listeria monocytogenes*, which can take days or weeks to incubate before the appearance of symptoms. This observation verifies economic theory, which instructs that firms will invest less in reducing risks if they are unlikely to pay for the consequences of those risks.[90]

No lack of altruism is needed to explain the food industry resistance to preventing the risks of listeriosis. The value of prevention (and the cost of the risk) is colored by many factors, including complaints, lawsuits, bad publicity, loss of business, etc. Among competing messages, it should hardly be surprising that business owners place these messages in a hierarchy, or that they place the market's economic communication at the top of this hierarchy. Simply put, the market's economic voice speaks louder than science.

The market is expected to reflect the desires of consumers—that is, consumers will choose for themselves and pay for the desired level of food safety. This expectation works generally, but fails when the market fails to communicate the safety and risk of a

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[87] *See* Figure 1.

[88] The CDC estimates that each year foodborne illness causes 76 million illnesses, 320,000 hospitalizations, and 5,000 deaths in the United States. *See* CDC, FOODNET SURVEILLANCE REPORT FOR 1999, *supra* note 36, at 6, 19 (citing P. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999)).

[89] GUZEWICH & ROSS, *supra* note 39, at 3 (citing C.B. Dalton et al., *The Cost of Food-Borne Outbreak of Hepatitis A in Denver, Colo.*, 156 ARCH. INTERN. MED. 1013 (1996) (this study estimated the total societal cost of a particular outbreak of Hepatitis A at $809,706)); Jean C. Buzby & Tanya Roberts, *Economic Costs and Trade Impacts of Microbial Foodborne Illness,* 50(1/2) WORLD HEALTH STAT. Q. 57 (1997) (estimates of the annual cost of medical treatment and lost productivity from five major foodborne pathogens range from $6.6 billion to $37.1 billion).

[90] *See* Buzby et al., *supra* note 23, at 1.

food to consumers. Unfortunately, information on the safety or risk of food is largely unavailable to consumers before or after purchase.[91] This market inefficiency undercompensates firms for food safety measures and rewards firms that take certain food safety risks. In short, the market's inefficiency creates a perverse disincentive to implement HACCP in certain circumstances.[92]

For this reason, an important and powerful improvement in the food safety system would be a better feedback loop to the food business—one that makes up for the market's failure to communicate food safety and risk. Options for building such a feedback loop are discussed in Section V *infra*.

IV. GOVERNMENT'S DIFFICULTY IN TRANSLATING SCIENCE INTO CONTROLS

The preceding analysis of the hang-up in HACCP adoption reveals a paradox: experts on food safety and leaders in the food industry agree that HACCP is the best method for ensuring food safety, yet this is contradicted by industry resistance to HACCP. Although HACCP produces safer food, and does so more efficiently than traditional systems, the market is inefficient at rewarding those who improve food safety. Conversely, the market perversely rewards firms that cut back on some food safety measures, because firms that cut these preventative costs may externalize the burden of those food safety risks to the public.

This market inefficiency is the classic situation where state controls are necessary to discourage firms from externalizing a burden on the public. When market controls are inefficient and ineffective at producing the level of safety desired by consumers, the common approach has been to require firms to meet regulatory requirements for design or process standards. Government regulators may face their own challenges, which make it difficult to translate scientific knowledge into regulatory controls.

This section examines the interplay between market forces, traditional regulatory controls, and the difficulty of bureaucrats achieving the level of food safety desired by consumers. Additionally, agency capture, government resource limitations, and the weakness inherent in reliance on bureaucratic middlemen to represent the public's interest are explored for their implications in food safety regulation.

Individual tort lawsuits provide an important element in industry acceptance of regulatory normative standards for those diseases most likely to result in lawsuits (e.g., *Staphylococcus aureus* and *Clostridium* spp). Regulatory controls for these pathogens have been in place for years (e.g., time and temperature controls). In the case of delayed-onset foodborne illness pathogens (e.g., *Listeria monocytogenes*), which correspondingly have a much lower chance of being traced back to the causative food, there is strong opposition from the food industry to such regulatory controls, even in the face of incontrovertible science of the risk.

While the consequences of imperfect risk feedback to the food industry provides an explanation for the food industry's lack of enthusiasm for scientific risk control systems, there remains an enigma concerning government's slow embrace of HACCP for certain

[91] Consumers cannot determine the safety before purchase because food pathogens are generally invisible, usually odorless, and tasteless. After an illness strikes, consumers rarely can identify the food that caused the illness. *See* Section II for a more thorough discussion of foodborne illness investigation and the difficulties in establishing causation.

[92] Other factors may contribute to industry resistance to HACCP; however, without scientific risk controls for pathogens, there can be no HACCP. Step one of HACCP begins with the identification of the risk, and the next six steps involve controlling identified risks. This article focuses on the implementation of science-based risk controls because this step is foundational for all other aspects of HACCP.

aspects of the food production system. Imperfect communication of risk information is a probable culprit behind the food industry's failure to adopt risk controls, but imperfect information cannot so easily explain regulatory agency failures to require risk controls in a timely manner. After all, the food industry is in the business of selling food, and is expected to attend to the market to survive. Government food safety agencies, on the other hand, are in the business of regulating food safety and presumably have the scientific expertise to recognize the known risks identified in food and the benefits of adopting preventative risk controls.

So, what is the regulatory hang-up with HACCP? Typically, only when foodborne illness fatalities occur does the government implement new risk control requirements and, even then, only after the outbreaks and deaths are prominent in the media. For example, it was eleven years after the first outbreak of *E. coli* poisoning from apple cider—and six years after a well-publicized, multistate outbreak from apple juice left seventy sickened and one dead—before juice HACCP regulations were implemented.[93]

The hazards of *Escherichia coli* O157:H7 illustrate regulator slowness to change food safety rules even in the face of clear scientific reasons for change. *E. coli* serotype O157:H7 produces large quantities of shiga-like toxins.[94] The toxins characteristically cause bloody diarrhea because they break through the intestinal walls to the bloodstream, where they damage or even liquefy the kidneys, lungs, pancreas, heart, and the brain.[95]

The USDA knew about the risk of *E. coli* O157:H7 in meat for over a decade before taking action.[96] *E. coli* was widely recognized as a foodborne pathogen by 1971,[97] and in 1987, the National Academy of Sciences (NAS) warned that the USDA's failure to adopt HACCP would result in illness and death—a report that was generally ignored.[98] The NAS' prediction proved accurate in 1993, when over 500 illnesses and four deaths were reported in the Jack-in-the-Box outbreak, which occurred because people ate *E. coli* O157:H7-contaminated hamburger that was undercooked.[99]

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[93] *See* Figure 2, *Escherichia coli* O157:H7 Chronology.

[94] JAY, MODERN FOOD MICROBIOLOGY 527-34 (5th ed. 1996).

[95] Casey, *supra* note 73, at 142.

[96] *See* Figure 2, *Escherichia coli* O157:H7 Chronology.

[97] JAY, *supra* note 94, at 527.

[98] Casey, *supra* note 73, at 147-49 ("[A]ccording to Carol Foreman, an Assistant Secretary of Agriculture under President Carter, USDA and FSIS officials generally ignored the NAS report. Agency officials also failed to pay heed to a 1987 report that urged the FSIS to change to a science-based inspection system and predicted that more food-poisoning illnesses and deaths would occur if the agency failed to do so.")

[99] CDC, *Multistate Outbreak—Western U.S.*, *supra* note 75, at 258; CDC, *Outbreak of Escherichia coli O157:H7 Infection—Georgia and Tennessee, 1992-1993*, 45(12) MORBIDITY & MORTALITY WKLY. REP. (MMWR), Mar. 29, 1996, at 249.

FIGURE 2	
***Escherichia coli* O157:H7 Chronology**[100]	
1700s	The bacterium recognized as a cause of infant diarrhea.[101]
1947	First foodborne outbreak of *E. coli* (undifferentiated) reported. [102]
1971	*E. coli* established as a foodborne pathogen when contaminated cheese caused nearly 400 illnesses in 14 states.[103]
1972	O157:H7-serrotype *E. coli* first isolated and named.[104]
1982	*E. coli* O157:H7 first identified as a foodborne pathogen.[105] Oregon: 24 people struck with bloody diarrhea and severe abdominal pains after eating hamburgers. [106] Michigan: 21 people sickened after eating hamburgers. [107]
1985	Associated with hemolytic uremic syndrome.[108] Ontario: 73 people sickened after eating contaminated meat. [109]
1985	National Academy of Sciences recommends government adopt HACCP.[110]
1986	Washington: 3 people killed by *E. coli* O157:H7. [111]
1987	Utah: 3 people killed by *E. coli* O157:H7. [112] National Academy of Sciences predicts more illness and death if USDA fails to adopt HACCP.
1990	Outbreak from drinking water.[113]
1991	Outbreak from apple cider.[114]
1993	Multistate outbreak from fast food hamburgers; over 500 illnesses, 4 deaths.[115]
1995	Outbreak from fresh produce.[116]
1995	USDA proposed pathogen reduction rule (meat HACCP).[117]
1997	Hudson beef contaminated with *E. coli* results in the recall of 35 million pounds of ground beef, the largest recall of food in nation's history.[118]
1998	Meat HACCP regulations implemented for large processors.[119]

[100] *See* CDC, *E. coli* O157:H7 (chronology) (1997), *at* http://phil.cdc.gov/phil/detail.asp?id=107 (last visited Feb. 13, 2002).

[101] JAY, *supra* note 94, at 527.

[102] *Id*.

[103] *Id*.

[104] *Id*.

[105] CDC, *Multistate Outbreak—Western U.S.*, *supra* note 75, at 258.

[106] Casey, *supra* note 73, at 147.

[107] *Id*.

[108] CDC, *E. coli* O157:H7 (chronology), *supra* note 100.

[109] *Id*.

[110] U.S. GENERAL ACCOUNTING OFFICE (GAO), FOOD SAFETY: RISK-BASED INSPECTION AND MICROBIAL MONITORING NEEDED FOR MEAT AND POULTRY, GAO-94-110, at 4 (1994) [hereinafter GAO REPORT, FOOD SAFETY: RISK-BASED INSPECTION].

[111] CDC, *E. coli* O157:H7 (chronology), *supra* note 100.

[112] *Id*.

[113] *Id*.

[114] *Id*.

[115] CDC, *Multistate Outbreak—Western U.S.*, *supra* note 75, at 258; Casey, *supra* note 73, at 148.

[116] CDC, *E. coli* O157:H7 (chronology), *supra* note 100.

[117] 60 Fed. Reg. 6774 (1995).

[118] SCHLOSSER, *supra* note 44, at 194 (citing Steve Kay, *Hudson Recall Was Larger Than Reported,* CATTLE BUYERS WKLY., Sept. 29, 1997).

[119] Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 61 Fed. Reg. 38,806 (1996) (codified as 9 C.F.R. pts. 304, 308, 310, 320, 327, 381, 416, and 417).

1996	Multistate outbreak from unpasteurized apple juice; 70 sickened, 1 death.[120]
2002	Begin juice HACCP regulation implementation for large processors.[121]
2004	Final juice HACCP regulation implementation for small processors.[122]

A number of well-publicized recalls, such as the *E. coli*-contaminated Hudson beef recall of thirty-five million pounds of ground beef—the largest recall of food in the nation's history—drew the public's attention.[123] Subsequently, a firestorm of criticism lashed USDA and the meat industries.[124] Janis Sowerby of Saranac, Michigan, testified before a 1993 congressional subcommittee hearing on food safety, describing her three-year-old son's death from hemolytic uremic syndrome nine days after eating food contaminated with *E. coli* O157:H7: "I never knew my child could die from eating a sloppy joe. God have mercy on this inadequate meat inspection system."[125]

It was only after public outrage and loss of consumer confidence that USDA finally acted to reduce *E. coli* O157:H7 contamination of meat products and proposed regulations to require meat HACCP[126]—as the NAS had recommended a decade earlier.[127] Even then, the regulations were watered down before promulgation.[128] Moreover, the meatpacking industry fought, and avoided, an effort to grant the government authority to order the recall of tainted food. "Today the U.S. government can demand the nationwide recall of defective softball bats, sneakers, stuffed animals, and foam-rubber toy cows. But it cannot order a meatpacking company to remove contaminated, potentially lethal ground beef from fast food kitchens and supermarket shelves."[129] A number of writers argued that USDA retreated from its food safety mission in the face of industry pressure.[130] Certainly, it would have been better for consumers if USDA had acted sooner. It is estimated that roughly half a million Americans have been made ill by *E. coli* O157:H7 since 1993.[131]

Moreover, agency retrenchment in the face of emerging risks hurts not only the public, but also the food industry. The system deprives businesses of an important mechanism for preventative change. The food industry deserves a regulatory system that proactively

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[120] CDC, *E. coli* O157:H7 (chronology), *supra* note 100. *See also* U.S. Health and Human Services News Release, FDA Publishes Final Rule to Increase Safety of Fruit and Vegetable Juices (Jan. 18, 2001).

[121] Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule, 66 Fed. Reg. 6137 (2001) (codified as 21 C.F.R. pt. 120).

[122] *Id*.

[123] SCHLOSSER, *supra* note 44, at 194 (citing Steve Kay, *Hudson Recall Was Larger Than Reported,* CATTLE BUYERS WKLY., Sept. 29, 1997).

[124] *See, e.g.*, Casey, *supra* note 73, at 142, 148.

[125] Janis Sowerby, *The Human Face of Foodborne Disease*, in FOOD PROTECTION REPORT 2A (Dec. 1993).

[126] 60 Fed. Reg. 6774 (1995).

[127] GAO REPORT, FOOD SAFETY: RISK-BASED INSPECTION, *supra* note 110, at 4.

[128] SCHLOSSER, *supra* note 44, at 215 (e.g., unlike government inspections reports, the records compiled by firms are unavailable to the public, firms are not required to test for known lethal pathogens (e.g., *E. coli* O157:H7), and meat containing pathogens could still be sold to the public) (citing OFFICE OF INSPECTOR GENERAL, USDA, FOOD SAFETY AND INSPECTION SERVICE: IMPLEMENTATION OF THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM, Report No. 24001-3-AT (June 2000.)

[129] SCHLOSSER, *supra* note 44, at 197.

[130] *E.g.,* James A. Albert, *A History of Attempts by the Department of Agriculture to Reduce Federal Inspection of Poultry Processing Plants—A Return to the Jungle,* 51 LA. L. REV. 1183 (1991); THE CENTER FOR PUBLIC INTEGRITY, SAFETY LAST, THE POLITICS OF E. COLI AND OTHER FOOD-BORNE KILLERS (1998); SCHLOSSER, *supra* note 44, at 197; Casey, *supra* note 73, at 141.

[131] SCHLOSSER, *supra* note 44, at 199 (citing Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999) (noting 73,480 illnesses, 2,168 hospitalizations, and 61 deaths—multiplied by 8)).

addresses emerging risks, such as *E. coli* O157:H7, before tens of thousands are sickened, and public outrage vents on the food industry. Commentators have noted the commonality of interest between business and stringent product safety standards.[132] In addition to providing for important societal concerns, high safety standards also create long-term benefits in innovation and creating competitive advantage of industries and nations.[133] In particular, effective safety controls are important for strong food markets because trust in food safety is required to make those markets possible.[134]

A. *Agency Capture*

One potential explanation for slow regulatory implementation of risk controls for known hazards is "agency capture." In the boldest case of agency capture, regulations subsidize private interests at the expense of the public good.[135] Agency capture has been described as the occasion when a regulated firm wins "the hearts and minds of the regulators."[136] Capture in this instance, however, is not an all-or-nothing phenomenon, but a matter of degrees. In the subtlest sense, capture exists any time an agency moves too far toward accommodating a single interest while moving away from its statutory mission.[137] Such capture may provide a measure of public good, but regulators' care is balanced more for the industry's benefit than for the public's.[138] Subtle capture may express itself through simple failure of regulating bodies to question whether traditional industry practices need to change.[139]

A number of authors have cataloged various forces that lead to agency capture, and some have concluded that it is easy for food industries to capture their respective regulatory agencies.[140] There often is an imbalance in representation during government rulemaking or decisionmaking. Regulated firms often have a significant and direct stake in the outcome and have the resources to hire lawyers, experts, and lobbyists. In 2001, for example, the fast food industry exceeded $110 billion in sales.[141] Regulatory agency resources are limited, however, and members of the public individually have little at stake.

Traditional regulatory inspections serve the public by ensuring a level of sanitation and wholesomeness in food, but they also provide a quality-assurance service to the

[132] MICHAEL E. PORTER, THE COMPETITIVE ADVANTAGE OF NATIONS 648-49 (1990).

[133] *Id*.

[134] *See, e.g.,* Taylor, *supra* note 18, at 13-14 ("The importance of proper food safety regulation to protect public health and maintain public confidence in the food supply is widely accepted."). *See generally* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE 63 (1992) (A strong government state helps create strong markets. Historically, advanced capitalism did not appear until central states acquired considerable authority to enforce contract law, impose antitrust law, and build an infrastructure to support communication and travel.).

[135] Casey, *supra* note 73, at 142 (quoting John Sheppard Wiley, Jr., *A Capture Theory of Antitrust Federalism*, 99 HARV. L. REV. 713, 722 (1986)).

[136] AYRES & BRAITHWAITE, *supra* note 134, at 63.

[137] Matthew D. Zinn, *Policing Environmental Regulatory Enforcement: Cooperation, Capture, and Citizen Suits,* 21 STAN. ENVTL. L.J. 81, 107 (2002).

[138] *See* AYRES & BRAITHWAITE, *supra* note134, at 63.

[139] *See, e.g.,* Mark Seidenfeld, *Bending the Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 462 (1999).

[140] *See, e.g.,* Casey, *supra* note 73, at 142, 143 (1) Limits on an agency's resources can create reliance on the regulated industries; 2) a regulated firm has much more at stake than each individual member of the public; 3) the transaction costs of organizing taxpayers are much higher than for small groups, such as industry trade associations; 4) industry lobbyists know the "ins and outs" of an agency's structure and operations (and have an edge over public interest groups); 5) a "revolving door," where regulated firms hire former agency employees; and 6) regulated industries lobby not only the regulators, but also the political masters of the agency).

[141] SCHLOSSER, *supra* note 44, at 3 (citing the National Restaurant Ass'n).

food industry at little expense to the firms because taxpayers subsidize the cost of inspections. In theory at least, the food industry has an economic incentive to lobby for traditional inspections and a disincentive to support regulatory HACCP, which would result in regulatory audits of the industry's own quality assurance work.[142] Thus, the failure of regulators to promulgate requirements for preventative risk control systems, like HACCP, and continued utilization of quality-assurance inspections, could be due in some part to agency capture.

While agency capture arguably accounts for some measure of regulatory agency inaction in the face of emerging risks,[143] cause and effect are difficult to establish. Other explanations also are plausible, such as budgetary constraints and bureaucratic limitations. Inadequate funding of the regulatory agencies charged with meeting the noble-minded goals of health safety laws is so common that the phenomenon has been characterized as a tradition.[144] The need for adequate human resources creates special challenges; food safety agencies must be able to attract and retain scientific expertise to make policy decisions and regulatory judgments. If agencies are not thus prepared, their decisionmaking will become risk-averse and slow, and their decisions may be wrong.

Moreover, agency retrenchment, retreat, and slowness to act also fit patterns explained by human social and hierarchal behavior. People, including regulators, will cooperate with firms simply because an agreeable work life is preferable to one filled with conflict.[145] In addition, internal agency behavioral forces affect agency staff perspectives. For example, a regulator who proposes more stringent food safety rules is likely to face resistance from other regulatory insiders for a variety of reasons. These reasons can range from simple (e.g., changes could mean more work) to complex (e.g., social and hierarchal structures in the agency can create and distort incentives).[146] Moreover, although internal agency forces may be propelled with the best intentions, they nevertheless insulate agency staff from both public and industry viewpoints.[147] Simply put, the dilemma is that the bureaucratic perspective does not represent the citizens' perspective.[148]

B. *The Dilemma of Relying on the Perspective of Bureaucratic Middlemen*

Professor Sax characterized the bureaucratic perspective as one where the forces of bureaucracy work towards "suboptimizing."[149] Bureaucrats with the power to decide—after agency constraints, pressures, and influences are taken into account—produce decisions that seem best for the agency, but may be less than the best for citizens and the regulated industry.[150] The agency insider views an assortment of priorities and agendas, including the agency's own priorities and constraints (e.g., budget, conflict-

[142] HACCP emphasizes industry's role in continuous quality, problem solving, and prevention, rather than relying on periodic government regulatory inspections to identify and solve problems by ordering specific corrective measures.

[143] *See, e.g.*, Casey, *supra* note 73, at 141.

[144] ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION 182 (2d ed. 1996) (citing JOE SAX, DEFENDING THE ENVIRONMENT 60-61 (1970)).

[145] *See, e.g.*, AYRES & BRAITHWAITE, *supra* note 134, at 80 ("Most of us regularly conciliate in circumstances where we could achieve a better result by fighting; we do this because fighting is nasty and unpleasant …little wonder they [regulators] seek to minimize their exposure to conflict even when it is in the public interest.")

[146] Barry Boyer & Errol Meidinger, *Privatizing Regulatory Enforcement*, 34 BUFF. L. REV. 833, 880 (1985).

[147] *See* Albert, *supra* note 130, at 1183-92.

[148] JOSEPH L. SAX, DEFENDING THE ENVIRONMENT 53 (1970).

[149] *Id.*

[150] *Id.*

ing stakeholders, internal and external constituencies, etc.), and the agency must mediate between those multiple interests.[151] The required balancing act may produce the right answers for the agency, but fail to produce optimum solutions for citizens and the regulated industry.

In light of the dilemma of the industry insider, regulatory agencies should not be expected to take a proactive lead in implementing scientific risk controls. Bureaucracy rewards attendance to the agency's priorities—not innovation—so it should not be a surprise when food safety bureaucrats act rationally and rise to internal concerns, rather than push for change.

This dilemma of the insider's perspective presents a special type of challenge. Unlike the case of agency capture, traditional protective measures will have little curative effect here because the agency has not gone astray. The agency is acting rationally and according to what it believes is the balanced course. Honorable, intelligent, and high-minded public officials are as likely to be caught up in suboptimizing behavior as in venal ones,[152] and reliance on bureaucratic middlemen to produce innovation is a function of the dilemma. The "administrative process tends to produce not the voice of the people, but the voice of the bureaucrat—the administrative perspective posing as the public interest."[153]

A strong criticism of the U.S. food safety regulatory system is that it acts in fits and stops and reacts to crises—depending on fits of public outrage to propel improvements.[154] The modern U.S. system of national food law began with enactments in Theodore Roosevelt's administration when public outrage vented on the meat industry after publication of Upton Sinclair's *The Jungle*. Nearly a century later, coffins should not be the impetus for improving food safety.

V. PROPOSALS FOR A MORE EFFICIENT FOOD SAFETY SYSTEM

While a surface inquiry into the resistance to HACCP yields many quick answers, closer examination reveals deeper, structural reasons for the slow adaptation and evolution of the food safety system. This section examines measures to address the imbalances in the food safety system, which were identified in preceding sections. The first imbalance is imperfect market information on food safety, which underrewards firms for improving food safety. The second imbalance is that the bureaucratic perspective—whether due to agency capture, resource restraints, or the dilemma of the insider's perspective—results in the suboptimization of the food safety system, particularly in areas of changing or emerging food safety risks. Because these imbalances underproduce the safety desired by the public and create perverse incentives for firms not to implement preventative food safety systems, correction of these imbalances may be necessary to increase the acceptance and use of HACCP.

A. *Correcting Imperfect Information Availability in the Market*

Market controls have proven inadequate to provide the level of safety that consumers desire largely because information on the safety of food generally is unavailable either before or after purchase. For closely related reasons, tort law has been deficient in providing proper feedback to industry because information on causation by specific

[151] *Id*.
[152] *Id*.
[153] *Id.* at 56.
[154] *See, e.g.,* Casey, *supra* note 73, at 148.

tortfeasors is lacking in foodborne illness cases, even though general causation of foodborne disease is known and preventable (e.g., transmission of Hepatitis A through bare-hand contact of food).

Increasing vertical integration may provide a measure of self-regulation for food safety because it eliminates some of the market's informational failure—that is, the exclusive relationship of vertically-oriented production improves information exchange on food safety.[155] While this information exchange may remove some of the relative obscurity of actors, it does little to remove the relative anonymity of foodborne illness causation to the consumer. As long as a consumer cannot pinpoint the cause of his or her illness, there remains a market disincentive for firms to implement food safety improvements.

Another pertinent change in the marketplace is that U.S. food production is becoming increasingly concentrated.[156] Consolidation of the food industry (both vertical and horizontal integration) means fewer food companies provide food to increasingly more people, so more individuals may be sickened by any single outbreak.[157] The greater the numbers made ill by a single event, the greater the likelihood that epidemiology may link the causative agent with the illness. Take, for instance, the highly-publicized illnesses of over 500 people and the deaths of four caused by Jack-in-the-Box hamburgers in 1993.[158] The outbreak resulted in a new degree of market accountability; and, subsequently, Jack in the Box implemented HACCP for all aspects of its food operations, from suppliers to restaurant servers.[159] Nevertheless, depending on large-scale outbreaks of illness to ensure market accountability hardly provides an acceptable method of providing market information.

Alternatively, it could be recognized that the market is inefficient at rewarding preventative food safety measures and compensate accordingly. The classic solution to this type of market inefficiency is to regulate the industry so that firms cannot profit from the creation of undesirable externalities (i.e., creating foodborne illness, for which society pays the cost). Historically, this approach has been remedial—laws mandating safety measures with penalty provisions for noncompliance. In the remedial approach, a firm's economic benefits from failing to implement safety measures should be eliminated through monetary penalties equal to or exceeding the economic benefit from failing to implement the required risk controls. This approach has proven inadequate, however, because regulatory agencies have been slow to expand regulatory requirements in response to new and emerging food safety risks.

Alternatively, rewards may be given to firms for voluntary implementation of improved safety measures. Examples of incentives include public recognition and awards, such as the Wyoming Department of Agriculture's Blue Ribbon Award (recognizes voluntary implementation of HACCP) and Michigan's Genesee County Health Department sanitation excellence award (recognizes superior food safety performance).[160] Some jurisdictions also have redesigned their fee schedules to provide financial incentives to firms that implement HACCP, achieve better sanitation performance, or whose staff successfully completes food safety education.[161] Incentive programs appear sporadically, however, and generally are too modest in design to broadly affect the food safety system.

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[155] Lyon, *supra* note 64, at 750.

[156] *Id.* at 753.

[157] NAS, ENSURING SAFE FOOD, *supra* note 13, at 3.

[158] Casey, *supra* note 73, at 148.

[159] Lyon, *supra* note 64, at 750.

[160] Robert Pestronk, Ward Lindsay, Neal Fortin, Brendon Kearney & Robert Eadie, *Protecting Our Vulnerable Food Supply*, 30(Supp.) J.L. MED. & ETHICS 101 (Fall 2002).

[161] *See e.g., id.*

The ultimate goal of any food safety system must be inducing a general attitude of food safety, responsibility, and knowledge in the regulated industry. Government resources cannot be expected to provide the level of oversight that would be necessary otherwise. Therefore, communication outreach by regulators to the food industry provides an opportunity to educate about foodborne pathogens and the benefits of science-based, preventative risk control systems, such as HACCP. Most food business owners possess commitment to the community value of providing safe and wholesome food.[162] Therefore, educational outreach on food safety science can provide improvement in food safety (until some limit of economic rationality is reached). In addition, community outreach and public education programs provide regulators the opportunity to explain the measures consumers can take to protect themselves from unsafe food handling, thus creating more informed consumers, who in turn are more likely to reward those businesses that have taken preventative food safety measures.

Because tort liability provides an important feedback loop on food safety and risk, some observers have called for more research and focus on foodborne-illness litigation to improve the economic signals to firms to invest in food safety.[163] Tort liability undercompensates for foodborne illness because it is difficult to prove causation—scientific advances in pathogen detection hold the best chance, therefore, of reducing the relative anonymity of illness causation. DNA fingerprinting of pathogens, recently heralded as "the single most significant scientific achievement in food safety over the last five years,"[164] is one such recent advance in detection. DNA fingerprinting matches a pathogen from one patient directly to a specific food source, thus identifying a previously impossible to detect source of illness. DNA fingerprinting is a significant achievement in piercing pathogen source anonymity and holds the potential to revolutionize post-hoc remedies through tort litigation.

Most of the approaches for improving, or compensating for, an inefficient food safety market call for additional research (e.g., increased incentives to firms that implement improved risk controls, communication outreach on food safety, and advancements in eliminating pathogen anonymity). Preeminently, however, food safety policymakers may apply an understanding of the market's inefficiency due to food pathogen and tortfeasor anonymity to create a fresh perspective. This fresh approach may lead to implementation of reward programs, new community outreach, or reassessment of priorities. In the latter, for example, foodborne illness investigation is often a low functional priority within regulatory programs for a variety of reasons, not the least of which is a perception that foodborne illness investigation and surveillance provides less return in food safety that traditional inspections.[165] Examination of the repercussions from food pathogen anonymity reveals that important improvements in food safety may come from improved foodborne illness investigation and surveillance.

B. *Increasing Citizen Involvement—A Citizens' Food Protection Act*

The second structural imbalance in the U.S. food safety system is the slow response of regulatory programs to new and emerging food safety risks. Protective measures

[162] *See generally* AYRES & BRAITHWAITE, *supra* note 134, at 31.

[163] Buzby et al., *supra* note 23, at 27.

[164] Raymond Formanek, Jr., *An Interview With Joseph A. Levitt: Food for Thought,* FDA CONSUMER, Sept.-Oct. 2001, at 13.

[165] *See, e.g.,* MICHIGAN DEP'T OF AGRICULTURE, APPROPRIATIONS REPORTING REQUIREMENT: LOCAL HEALTH DEPARTMENT CONFORMANCE WITH FOOD SERVICE SANITATION REGULATORY PROGRAM MINIMUM REQUIREMENTS, MARCH 1998 THROUGH SEPTEMBER 2001, at 18 (Nov. 2001) (23% of Michigan's food service regulatory programs failed to implement minimum foodborne illness investigation and surveillance systems) *available at* http://www.michigan.gov/documents/MDA_LHD_MPR_Conformance_2001_15768_7.pdf (last visited Nov. 10, 2003).

against agency capture are available—many at the federal agency level—involving a measure of review or oversight in agency decisionmaking. Review may be provided internally to the organization (e.g., economists, scientists) while oversight by Congress occurs through the scrutiny of reporting requirements. These controls, which are designed to protect against capture, cannot protect, however, against inadequate resources or prevent bureaucratic suboptimizing, where the only expression might simply be failing to question whether traditional industry practices need to change.

Access to the courts can provide the best solution to the risk of agency capture, inadequate government resources, and the dilemma of the insider perspective. "As forums for public deliberation, courts can identify and promote the acceptance of public values. Courts can also ensure that the decisions of other agencies of the government reflect republican deliberation rather than an equilibrium of private interest."[166] For example, as early as the 1880s, scientists recommended that infants be fed heat-treated milk to prevent disease.[167] Pasteurization equipment became reliable, accepted, and widespread by the 1940s, and in 1947, Michigan passed the first state statute requiring milk pasteurization.[168] By the 1960s, pasteurization was the norm across the United States.[169] Nevertheless, FDA did not prohibit the interstate shipment of raw milk—despite the recommendations of its own staff, the CDC, and other authorities—until 1987, and only then after being ordered to do so by the federal courts as the result of two lawsuits by Public Citizen.[170]

Citizen action fosters innovation—two other FDA regulations may never have been promulgated without citizen action (i.e., a requirement for a warning about Reye syndrome on nonprescription aspirin and tampon labeling regulations concerning toxic-shock syndrome).[171]

At present, citizen suits on food safety are the exception and cannot provide balance to the food safety system. For that reason, the author proposes a model Citizens' Food Protection Act (*see* Appendix).[172] While the concept is not new, the application to food safety is novel. The purpose is six-fold: 1) establish the right of the public to clean, safe, and wholesome food that is honestly presented as an enforceable private right; 2) create judicial review of administrative agency action; 3) create standing for private citizens who lack "injury in fact" from an illness; 4) set the stage for common law development; 5) promote implementation preventative food safety measures; and 6) conserve government resources.[173]

Access to the courts is an effective way for individual citizens to participate directly in the decisions affecting food safety. The principle that disputes are best resolved

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[166] Daniel A. Farber & Phillip P. Frickey, *In the Shadow of the Legislature: The Common Law in the Age of the New Public Law,* 89 MICH. L. REV. 875, 879 (1991).

[167] CARL W. HALL & G. MALCOLM TROUT, MILK PASTEURIZATION 2-4 (1968).

[168] *Id*. at 9-11.

[169] *Id*. at 11.

[170] Public Citizen v. Heckler, 602 F. Supp. 611, 612, 614 (1985); Public Citizen v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986).

[171] Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2155 (2000) (citing successful judicial challenges to FDA's failure to act on petitions filed by Public Citizen that had requested rulemaking to require warnings of Reye's syndrome, Public Citizen Health Research Group v. Food & Drug Admin., 740 F.2d 21, 34-35 (D.C. Cir. 1984); toxic shock syndrome, Public Citizen Health Research Group v. Food & Drug Admin., 724 F. Supp. 1013, 1019-22 (D.D.C. 1989); and a ban on interstate sale of raw milk, Public Citizen v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986)).

[172] The model draws heavily from the Michigan Environmental Protection Act originally drafted by Joseph Sax and enacted as 1970 Mich. Pub. Acts 127.

[173] *Cf.* SAX, *supra* note 148, at 248.

between those who have a direct stake in the outcome is a foundational element of the U.S. legal system. Ultimately, citizens, not their bureaucratic surrogates, are the public interest. The access provided by creation of a citizen suit provision in the food safety laws could breathe new life into food safety policy decisionmaking. Bureaucratic middlemen may be slow to identify and protect new and emerging risks in food safety, but citizens, given the tools to do the job, are capable of fighting their own battles.[174] The model law would set the stage for the development of common law on food safety, resulting in responses to new and emerging risks in food safety that are more rapid.

In addition, citizen suits can spare government resources and taxpayer expense by authorizing private regulatory action—citizen suits are considered a crucial element of enforcement in environmental laws.[175] Virtually all federal environmental laws contain citizen suit provisions.[176]

This proposal is not new, rather, it is a revitalization of the right of citizen action.[177] The public not only has an interest in a safe and wholesome food supply, but also has an interest in ensuring the preventative aspects of the food safety law are followed. Citizens want unsafe food practices to cease and should not have to wait until illness or death strike to take action. Citizen suits can allow persons who lack "injury in fact" from a foodborne illness to sue instead from "injury in law" based on serious violations of the food law that undermine the prevention of illness.

Legal redress through citizen suit not only can provide an important source of feedback to the food industry on food safety, but also can provide a means to level the competitive playing field. Industry insiders often know more about the actions of their competitors than the government regulators. Through citizen suits, firms can insist that a rogue competitor play by the rules. Moreover, the fact that firms that take short cuts on safety may face legal repercussions empowers those who wish to act safely.

Ultimately the feedback from citizen suits would strengthen the food industry. There is a commonality of interest between the food industry and the consumer desire for stringent food safety standards. The short-term cost of meeting tough food safety standards will result in long-term benefits—providing for consumer and societal concerns and achieving improved long-term competitive advantage.[178]

The courts are ideally suited to complementing the roles of science, government, and industry in achieving the most efficient balance of safety controls. Joseph Sax's comments concerning environmental law also are apropos to food law:

> [A]n essential format for reasserting participation in governmental process is in the courtroom—not because judges are thought wiser or because the processes of litigation are particularly rapid, but because the court preeminently is a forum where the individual citizen or community group can obtain a hearing on equal terms with the highly organized and experienced interests that have learned so skillfully to manipulate legislative and administrative institutions. The court is attractive too because, free of the constraints which familiarity and close dealing tend to breed, it can bring fresh insights to problem….[179]

[174] SAX, *supra* note 148, at 56.

[175] Phillip M. Bender, *Slowing the Net Loss of Wetlands: Citizen Suit Enforcement of Clean Water Act S 404 Permit Violations*, 27 ENVTL. L. 245, 263 (1997).

[176] *E.g.*, the Clean Water Act, 42 U.S.C. § 7604 (1994), Federal Water Pollution Control Act, 33 U.S.C. 1365 (1994); and Endangered Species Act, 16 U.S.C. § 1540(g) (1994). The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is one exception.

[177] Before the industrialization and centralization of food production, traditional tort law offered this right, because producers and consumers generally knew each other (so causation was not as problematic as today) and scientific and technological change was less rapid.

[178] *See generally* PORTER, *supra* note 132.

[179] SAX, *supra* note 148, at xviii.

Fostering a greater role for citizen involvement in food safety policy presents the best hope for addressing the structural imbalance in the U.S. food safety system that finds regulatory programs slow to respond to new and emerging food safety risks. Citizen suits provide a democratic tool that at once protects against agency capture, limited government resources, and the dilemma of the insider perspective.

VI. CONCLUSIONS

This article began with the simple, unanswered question, "What is the hang-up with HACCP?" While there is widespread recognition that HACCP is the most effective food safety system available, adoption has been slow. Many superficial reasons have been offered, however structural deficiencies in U.S. food safety regulatory system create perverse incentives to maintain inefficient regulatory standards, rather than to adopt preventative food safety controls, such as HACCP. These same structural deficiencies also create undesirable delay in improving the food safety regulations to keep pace with public expectations, for advances in science and technology, and for emerging risks.

Awareness is growing that the U.S. food safety system has not kept pace with these changes. This awareness includes an understanding that the societal burden of foodborne illness is greater than previously appreciated. There is a sense that the current regulatory system serves neither the public nor the industry as well as it could. A strong food safety regulatory system is a necessity to protect the public health, to maintain public confidence in the food supply, and to maintain a strong food industry.

Traditionally, public interest in safe food has been achieved through a combination of industry, government, and private action. This combination remains the most viable and productive mix, however, the balance must ensure that government and industry keep pace with the changes in science and in public expectation. Unfortunately, both the market and tort law currently do not achieve the level of food safety desired by the public. The market is inefficient because information on the safety of food generally is unavailable before or after purchase. Tort law is inefficient because current investigation tools rarely can pinpoint the cause of a foodborne illness to a specific food. With an inefficient market for food safety and an inefficient remedy through tort litigation, the U.S. system creates a perverse economic incentive for food businesses to take risks with food safety. Simply put, market forces trump science.

Incentives for firms that implement preventative risk control, communication outreach on food safety, and advancements in eliminating pathogen source anonymity may correct his imbalance in the marketplace. Moreover, food safety policymakers must apply an understanding of the market's inefficiency due to food pathogen and tortfeasor anonymity in their implementation of reward programs, community outreach, and assessment of agency priorities.

Without efficient market forces and lawsuits under tort law, which provide an important element in industry acceptance of regulatory standards, food safety regulatory agencies fail to consistently require science-based risk controls. Too often, only deaths and public outrage propel government agencies into action. It must be recognized, however, that the regulatory bureaucracy does *not* represent the public's perspective because bureaucratic insiders rationally represent the bureaucracy's interests.

Prevention of foodborne illness and the public's interest in safe food is best served through regulatory controls combined with private causes of action. Because traditional foodborne illness tort litigation provides incomplete economic feedback to firms, and has led to an underproduction of food safety, a solution to reinject citizen action

into food safety needs to be found. The courts uniquely provide the forum for public access into the food safety standards decisionmaking process and counterbalance the dilemmas of agency capture and bureaucratic perspective in the enforcement of food safety standards. To further this end, the addition of a citizen suit provision to food safety law would be beneficial because the courts are a proper means for citizens to participate in decisionmaking that affects their lives.

Legal redress through the courts provides an important source of feedback to the food industry and regulators on the public's perception of food safety, and a means to level the competitive playing field. There is a commonality of interest between the food industry and consumers' desire for stringent food safety standards. The short-term cost of meeting tough food safety standards will result in the long-term benefits of providing for consumer and societal concerns and achieving improved competitive advantage. The courts are ideally suited to complementing the roles of science, government, and industry in achieving the most efficient balance of safety controls.

Involving citizens as empowered third players in food safety decisions will encourage more cooperative efforts by regulators, the regulated, and citizens. The current food safety regulatory system—propelled in fits and stops, reacting to crises and coffins—would no longer so depend on fits of public outrage to drive improvements. A food safety system working with less conflict between the various interest groups would be best for all interests.

APPENDIX

MODEL LAW: THE CITIZENS' FOOD PROTECTION ACT

The following model law illustrates an option for achieving a safer food that is at once democratic, efficient, and simple to draft into law. This option breathes the life into government decision-making by providing means for the ordinary citizen to have a voice in the process. The model Citizens' Food Protection Act draws heavily from the Michigan Environmental Protection Act.[180] While the concept is not new, the application to food safety is novel. The purpose is six-fold:

1. Establish the right of the public to clean, safe, and wholesome food that is honestly presented as an enforceable private right;
2. Create judicial review of administrative agency action;
3. Create standing for private citizens who lack "injury in fact" from an illness;
4. Set the stage for common law development;
5. Promote implementation of preventative food safety measures; and
6. Conserve government resources and spare taxpayer expense.

CITIZENS' FOOD PROTECTION ACT

Actions for declaratory and equitable relief for the protection of food safety; parties; standards; judicial action.

Sec. 1. (1) The attorney general or any person may maintain an action in the circuit court having jurisdiction where the alleged violation occurred or is likely to occur for declaratory and equitable relief against any person for the protection of clean, safe, or wholesome food, or food that is honestly presented.

(2) In granting relief provided by subsection (1), if there is a standard for clean, safe, or wholesome food, or honestly presented food, fixed by rule or otherwise, by the state or an instrumentality, agency, or political subdivision of the state, the court may:

(a) Determine the validity, applicability, and reasonableness of the standard.

(b) If a court finds a standard deficient, direct the adoption of a standard approved and specified by the court.

Payment of costs or judgment; posting surety bond or cash; amount.

Sec. 2. If the court has reasonable grounds to doubt the solvency of the plaintiff or the plaintiff's ability to pay any cost or judgment that might be rendered against him or her in an action brought under this part, the court may order the plaintiff to post a surety bond or cash in an amount of not more than $200.00.

Rebuttal evidence; affirmative defense; burden of proof; referee; costs.

Sec. 3. (1) When the plaintiff in the action has made a prima facie showing that the conduct of the defendant has impaired, spoiled, or adulterated the cleanliness, safety, or wholesomeness of a food or the honest presentment of food; or is likely to impair, spoil, or adulterate the cleanliness, safety, or wholesomeness of a food, or the honest presentment of food, the defendant may rebut the prima facie showing by the submission of evidence to the contrary. The defendant may also show, by way of an affirmative defense, that there is no feasible and prudent alternative to defendant's conduct and that

[180] Originally drafted by Professor Joseph L. Sax and enacted as 1970 Mich. Pub. Acts 127, which was amended and recodified as 1994 Mich. Pub. Acts 451, being MICH. COMP. LAWS §§ 324.1701 to 324.1706 (2001).

his or her conduct is consistent with the promotion of the public health, safety, and welfare in light of the state's paramount concern for the protection of the safety of its food. Except as to the affirmative defense, the principles of burden of proof and weight of the evidence generally applicable in civil actions in the circuit courts apply to actions brought under this part.

(2) The court may appoint a master or referee, who shall be a disinterested person and technically qualified, to take testimony and make a record and a report of his or her findings to the court in the action.

(3) Costs and fees may be apportioned to the parties if the interests of justice require.

Granting of relief; administrative, licensing, or other proceedings; adjudication; judicial review.

Sec. 4. (1) The court may grant temporary and permanent equitable relief or may impose conditions on the defendant that are required to protect the cleanliness, safety, or wholesomeness of food, or the honest presentment of food.

(2) If administrative, licensing, or other proceedings are required or available to determine the legality of the defendant's conduct, the court may direct the parties to seek relief in such proceedings. Proceedings described in this subsection shall be conducted in accordance with and subject to the Administrative Procedures act of 1969, Act No. 306 of the Public Acts of 1969, being sections 24.201 to 24.328 of the Michigan Compiled Laws. If the court directs parties to seek relief as provided in this section, the court may grant temporary equitable relief if necessary for the protection of the cleanliness, safety, or wholesomeness of food, or the honest presentment of food. In addition, the court retains jurisdiction of the action pending completion of the action to determine whether adequate protection from adulteration or impairment of the cleanliness, safety, or wholesomeness of food, or the mislabeling or impairment of the honest presentment of food is afforded.

(3) On completion of proceedings described in this section, the court shall adjudicate the impact of the defendant's conduct towards the cleanliness, safety, or wholesomeness of food, or the honest presentment of food in accordance with this part. In adjudicating an action, the court may order that additional evidence be taken to the extent necessary to protect the rights recognized in this part.

(4) If judicial review of an administrative, licensing, or other proceeding is available, notwithstanding the contrary provisions of Act No. 306 of the Public Acts of 1969 pertaining to judicial review, the court originally taking jurisdiction shall maintain jurisdiction for purposes of judicial review.

Administrative, licensing, or other proceedings; intervenors; determinations; doctrines applicable.

Sec. 5. (1) If administrative, licensing, or other proceedings and judicial review of such proceedings are available by law, the agency or the court may permit the attorney general or any other person to intervene as a party on the filing of a pleading asserting that the proceeding or action for judicial review involves conduct that has, or is likely to have, the effect of adulterating or impairing the cleanliness, safety, or wholesomeness of food, or mislabeling or impairing of honest presentment of food.

(2) In administrative, licensing, or other proceedings, and in any judicial review of such a proceeding, the alleged adulteration or impairment of the cleanliness, safety, or wholesomeness of food, or mislabeling or impairment of honest presentment of food shall be determined, and conduct shall not be authorized or approved that has or is likely to have such an effect if there is a feasible and prudent alternative consistent with the reasonable requirements of the public health, safety, and welfare.

(3) The doctrines of collateral estoppel and res judicata may be applied by the court to prevent multiplicity of suits.

Supplemental nature; other causes of action not affected; liberal construction.

Sec. 6. This act shall be supplemental to existing administrative and regulatory procedures provided by law. This act shall not affect any other cause of action that is available and shall be liberally construed to effect its purpose.