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Mandatory Recall Authority:
A Sensible and Minimalist
Approach to Improving Food Safety

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I.

Introduction

A reoccurring and divisive issue in the debate over food safety in the United States is whether the government should have the authority to order companies to recall unsafe food from commerce.² Recent events have renewed interest in the debate: the discovery of the mad cow disease in Washington State, leading to the recall of beef products that may have been exposed to tissues containing the agent that causes bovine spongiform encephalopathy (BSE);³ well-publicized, large-scale recall failures,⁴ the threat of bioterrorism's introducing harmful bacteria and toxins into the food chain;⁵ and, finally, an overall increasing concern about the safety of food in the United States.⁶

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² For example, on December 12, 2002, the United States Department of Agriculture Food Safety and Inspection Service held a public meeting on the topic of "Improving the Recall Process." The meeting included a lively discussion on the implications of mandatory recall authority. Food Safety and Inspection Service (FSIS), Transcript of Proceedings: *Improving the Recall Process*, Wash. D.C. (Dec. 12, 2002).

³ See *USDA Revises State Count on BSE Recall; Says More Than 500 Firms Have Been Notified*, 6 FOOD CHEMICAL NEWS (2004) (describing how consumer groups are using the BSE incidents as another opportunity to call for mandatory recall).

⁴ See, e.g., OFFICE OF THE INSPECTOR GENERAL, UNITED STATES DEPARTMENT OF AGRICULTURE, GREAT PLAINS REGIONAL AUDIT REPORT 24601-2-KC, FOOD SAFETY AND INSPECTION SERVICE OVERSIGHT OF PRODUCTION PROCESS AND RECALL AT CONAGRA PLANT (ESTABLISHMENT 969) (2003) (highly critical of government's role in the recall of beef products in 2002 involving ConAgra).

⁵ See UNITED STATES GENERAL ACCOUNTING OFFICE, BIOTERRORISM: A THREAT TO AGRICULTURE AND THE FOOD SUPPLY (2003) (summary of threat of bioterrorism to United States food supply).

⁶ For a recently published best-selling book criticizing the modern food industry and the overall safety of food, see ERIC SCHLOSSER, FAST FOOD NATION (2002). For other similarly postured books, see MOLLY

Currently, the government does not have the authority to mandate a recall of unsafe food; recalls of unsafe food products are voluntarily conducted by food companies and are monitored by government agencies.⁷ This contrasts with the authority that government has to order a recall for many non-food products.⁸

Defenders of the current voluntary food recall system contend that the government has sufficient enforcement authority and that mandatory recall authority would undermine the cooperative arrangement that exists between government and private industry.⁹ Proponents of mandatory recall authority believe that the voluntary recall system does not meet the challenges and needs of the modern food production industry and that in order to protect public health, the government should be armed with mandatory recall authority such as it has for other non-food products.¹⁰ Defenders of the current voluntary recall system include members and representatives of the food industry;¹¹ supporters of a mandatory recall system include consumer advocacy groups¹² and, interestingly enough, most recently the American Farm Bureau.¹³

IVINS, BUSHWACKED 125 –147 (2003); MARION NESTLE, *SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM* (2003).

⁷ See GENERAL ACCOUNTING OFFICE, GAO/RCED-00-195, *FOOD SAFETY: ACTIONS NEEDED BY USDA AND FDA TO ENSURE THAT COMPANIES PROMPTLY CARRY OUT RECALLS* (2000), at 3.

⁸ See, e.g., Consumer Protection Safety Act (CPSA) 15 U.S.C. § 2064 (1998) (empowering the Consumer Protection Safety Commission to order recalls of consumer products).

⁹ See FSIS Public Meeting, *supra* note 2, at 178-182, 190-201.

¹⁰ See, e.g., Caroline Smith DeWaal, Statement at the FSIS Public Meeting *Improving the Recall Process*, Wash. D.C. (Dec. 12, 2002).

¹¹ Notable food industry representatives supportive of the current voluntary recall system include the National Food Processors Association and the National Meat Association. See *USDA Mandatory Recall? "Why Fix Something That is Not Broken?"* MEAT INDUSTRY INTERNET NEWS SERVICE (Oct. 7, 1997), at www.spcnet.com/mii/1997/971029 (comments by Kelley Johnston, NFPA's Vice President of Government Affairs and Communications, in testimony to the Senate Agriculture Committee); see also National Meat Association, Comments Before the Senate Agriculture Committee, Oct. 8, 1997, available at <http://www.nmaonline.org/files/pr10-8.htm>.

This article examines this debate in four parts. Part one explains the need for an effective recall system to protect consumers from foodborne illnesses. Part two examines the current voluntary food recall system, including its basis, form, and rationale. Part three notes the criticism of the voluntary recall system, fueled by the failure of large-scale recalls, and proposed mandatory recall legislation that was developed in direct response to these recall failures. Part four recommends, in the event that mandatory recall authority is extended to the government, essential components for an effective mandatory food recall system and summarizes its potential benefits.

This article concludes that the granting of mandatory recall authority to government with appropriate safeguards is a sensible, minimalist approach to the protection of public health. It is sensible because mandatory recall authority would improve a recall system that generally works fairly well but has also experienced significant breakdowns leading to severe criticism of the food industry and the government agencies responsible for monitoring the voluntary recall system. These improvements include expediting the removal of unsafe food from commerce, providing essential insurance against the bad-actor food company, strengthening the government's hand against bioterrorism, enhancing consumer confidence in food, aligning incentives for food companies to protect consumers against unsafe food, reducing liability exposure of food companies, and creating a more rational food recall system in the context of

¹² Representative consumer advocates groups supportive of a mandatory food recall system include Safe Tables Our Priority (S.T.O.P.) and the Center for Science in the Public Interest (CSPI). To view these groups' respective Web sites and positions on food recall, see <http://www.safetables.org>; <http://www.cspinet.org/>.

¹³ See AM. FARM BUREAU FED'N, FARM BUREAU POLICIES FOR 2004 (2004), at 39 (adopting the following resolution: “[w]e support granting the Secretary of Agriculture authority to impose mandatory quarantine and recall of meat products based on scientific testing and detection procedures.”).

domestic and international food safety policy. It is a minimalist approach because, with appropriate safeguards in place, mandatory recall authority should not undermine the current cooperative recall culture existing between government and private industry. Food companies would continue to have incentives to voluntarily recall their unsafe food without undue concern of government overreach.

II.

Need for an Effective Food Recall System

While the United States is generally regarded as having the safest food supply in the world,¹⁴ foodborne illness caused by consuming contaminated foods or beverages is a compelling public health problem: the Centers for Disease Control and Prevention estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually.¹⁵ Compounding the problem is the constantly changing nature of foodborne illness.¹⁶ While improvements in food safety, such as pasteurization and proper canning, have all but eliminated some diseases,¹⁷ new foodborne infections have emerged. Today there are more than 250 different foodborne diseases, most of which are infections, caused by a variety of bacteria, viruses, and parasites.¹⁸ The most commonly recognized foodborne infections are those caused by

¹⁴ See ECONOMIC RESEARCH SERVICE, USDA BRIEFING ROOM, GOVERNMENT FOOD SAFETY POLICIES, available at <http://www.ers.usda.gov/Briefing/FoodSafetyPolicy/>.

¹⁵ See Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999), available at <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>.

¹⁶ See CENTERS FOR DISEASE CONTROL, *FOODBORNE ILLNESS*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm.

¹⁷ See *id.*

¹⁸ See *id.* The other type of foodborne diseases is poisonings, caused by harmful toxins or chemicals that have contaminated the food. See *id.*

the bacteria *E. coli* 0157:H7,¹⁹ *Salmonella*,²⁰ *Listeria*,²¹ and *Campylobacter*,²² and by a group called *calicivirus*, also known as the Norwalk viruses.²³

¹⁹ An estimated 73,000 cases of infection and 61 deaths occur in the United States each year from *Escherichia coli* 0157:H7. The organism lives in the intestines of healthy cattle. It was first recognized as a cause of illness in 1982 during an outbreak of severe bloody diarrhea that was traced to contaminated hamburgers. Human illness from *E. coli* 0157:H7 follows consumption of food or water that has been contaminated with cow feces. Most infections occur from eating undercooked ground beef. The illness it causes is often a severe and bloody diarrhea and painful abdominal cramps. It can cause temporary anemia, profuse bleeding, and kidney failure. See *id.* See also CENTERS FOR DISEASE CONTROL, *ESCHERICHIA COLI* 0157:H7, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm#What%20is%20Escherichia%20coli%200157:H7.

²⁰ Each year 40,000 cases of *Salmonella* are reported in the United States. Because many milder cases are not diagnosed or reported, the actual number of infections may be much higher. *Salmonella* is a bacterium that is widespread in the intestines of birds, reptiles, and mammals. It can spread to humans from a variety of different foods of animal origin. It causes salmonellosis, which includes fever, diarrhea, and abdominal cramps. With persons most vulnerable, such as the elderly, infants, and those with impaired immune systems, it can be life-threatening. It is estimated that 600 people die each year with acute *Salmonella*. See Mead, *supra*, note 15. See also CENTERS FOR DISEASE CONTROL, *SALMONELLOSIS*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellaosis_g.htm#What%20is%20salmonellaosis. In November of 2003, the USDA announced that the rate of *Salmonella* in raw meat and poultry dropped by sixty-six percent (66%) over the past six years and by sixteen percent (16%) in 2003 compared with 2002. USDA attributed the drop in reported *Salmonella* to strong, science-based enforcement of food safety rules. See USDA Press Release, Tests Show Salmonella in Meat and Poultry Products Declines 66 Percent, available at <http://www.usda.gov/news/releases/2003/11/0396.htm>.

²¹ An estimated 2,500 persons become seriously ill with *listeriosis* each year, and of this number, 500 persons die. *Listeria monocytogenes* is found in soil and water. Uncooked vegetables, meats, processed foods, and unpasteurized dairy products may contain the bacterium. *Listeria* may be killed by cooking; however, in certain ready-to-eat foods such as hot dogs and deli meats, contamination may occur after cooking but before packaging. *Listeria* primarily affects pregnant women, newborns, and adults with weakened immune systems. *Listeria* causes fever, muscle aches, and sometimes-gastrointestinal symptoms such as nausea or diarrhea. See CENTERS FOR DISEASE CONTROL, *LISTERIA*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm#symptoms. In October of 2003, USDA announced a one-year, twenty-five percent (25%) drop in positive *Listeria monocytogenes* samples and a seventy percent (70%) decline compared with years prior to the implementation of the Hazard Analysis and Critical Control Points (HACCP) system. See FSIS News Release, *Listeria* in FSIS Ready-to-Eat Products Shows Significant Decline, available at <http://www.fsis.usda.gov/OA/news/2003/rtdedata.htm>.

²² *Campylobacter* is estimated to affect over one million people in the United States every year, or 0.5% of the population. Most cases go undiagnosed or unreported. It is estimated that 100 persons with *Campylobacter* infections will die each year. *Campylobacter* is a bacterial pathogen that causes fever, diarrhea, and abdominal cramps. It is the most commonly identified bacterial cause of diarrheal illness in the world. These bacteria live in the intestines of healthy birds, and most raw poultry meat has *Campylobacter* on it. Eating undercooked chicken or other food that has been contaminated with juices dripping from raw chicken is the most frequent source of this infection. See Mead, *supra* note 15. See also CENTERS FOR DISEASE CONTROL, *CAMPYLOBACTER INFECTIONS*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm#What%20is%20campylobacteriosis.

²³ *Norwalk-like virus* is an extremely common form of foodborne illness, though rarely diagnosed. It causes an acute gastrointestinal illness, usually with more vomiting than diarrhea that resolves itself after a

Foodborne illness outbreaks are also becoming increasingly widespread and complicated. The classic outbreak of foodborne illness was confined to a local community, generally caused by a catered meal or a potluck dinner.²⁴ Changes in the way food is prepared and consumed today²⁵ cause foodborne illness outbreaks to affect many persons in many different places, spread out over long periods of time.²⁶

To protect consumers from these foodborne illnesses, unsafe food products must be removed quickly and efficiently from commerce.²⁷ Food safety is, of course, ideally achieved by ensuring that recalls need not occur in the first place;²⁸ however, once unsafe food enters commerce, recalls are a critical tool for protecting the health and lives of consumers.²⁹

III.

Overview of the Current Voluntary Food Recall System

The current voluntary food recall system is marked by a unique food safety regulatory approach that allocates responsibilities to two government agencies that in turn

few days. Unlike many foodborne pathogens that have animal reservoirs, *Norwalk-like viruses* spread primarily from one infected person to another, such as kitchen workers who contaminate a salad or sandwich as they prepare it. *See* Mead, *supra* note 15.

²⁴ *See id.*

²⁵ These changes include first, the increasing consumption of a greater variety of foods, particularly seafood, fresh fruits, and vegetables that are eaten raw; second, the dramatic increase in the variety of foods imported from all over the world; and, third, the increasingly number of people eating more of their meals away from home. *See* Joseph A. Levitt, *FDA's Foods Program*, 56 FOOD DRUG L.J. 255, 255-256 (2001).

²⁶ *See id.*

²⁷ *See* UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE, REPORT OF THE RECALL WORKING GROUP (Aug. 10, 1998), available at <http://www.fsis.usda.gov/OA/programs/recallwg.htm>.

²⁸ *See* FSIS Public Meeting, *supra* note 2, at 10.

²⁹ *See id.*

develop oversight procedures and protocol for voluntary food recalls conducted by private companies.

A. Dual Agency Responsibility for Food Recall

The two government agencies charged with food recall responsibility are the United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA).³⁰ USDA derives its regulatory authority from the Meat Inspection Act³¹ and the Poultry Products Inspection Act,³² giving it responsibility for the regulation of meat, poultry, and certain egg products. USDA administers a food safety and inspection program over these products through its branch agency, the Food Safety and Inspection Service (FSIS).³³ FDA derives its regulatory power from various laws including the Federal Food, Drug, and Cosmetic Act,³⁴ giving it responsibility for the regulation of all other food products, including whole (or shell) eggs, sea food, milk, grain products, fruits and vegetables, and certain canned, frozen, and otherwise packaged foods containing meat, poultry, and eggs that are not regulated by USDA.³⁵

³⁰ GENERAL ACCOUNTING OFFICE, *supra* note 7, at 5.

³¹ 21 U.S.C. § 601(1999).

³² *See id.* at §§ 451-469 (1999).

³³ *See* 7 C.F.R. § 2.53 (2004) (describing various FSIS responsibilities).

³⁴ 21 U.S.C. § 392(a) (1999).

³⁵ The distinctions between food products regulated by USDA and FDA are often confusing. For example, FDA regulates the safety of egg shells, while USDA regulates processed egg products, except for certain processed egg products. *See* 21 U.S.C. §§ 1033(f), 1034(a), 1052(c) (1999); 7 C.F.R. § 55.2 (2004) (definition of “egg product”). *See generally* Michael R. Taylor, *Preparing America’s Food 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, 18-19 (1997) (addressing the fragmented federal food safety system).

This food safety regulatory regime for USDA and FDA prohibits the adulteration and misbranding of food.³⁶ Implementing regulations and policy statements define adulteration and misbranding, and USDA and FDA enforce these provisions when violations are encountered.³⁷ An important tool used by USDA and FDA in the enforcement of these provisions is the recall of food.³⁸

B. Basis for Voluntary Recall: the Implicit Threat

Despite the importance of recall as an enforcement tool, neither USDA nor FDA has statutory authority to mandate a recall.³⁹ Recalls administered by USDA and FDA is strictly voluntary.⁴⁰ What then triggers a voluntary recall? What leverage does the USDA or FDA have to motivate companies to voluntarily recall their food product?⁴¹

³⁶ See 21 U.S.C. §§ 402, 453(g)(3), and 601(m)(3) (1999).

³⁷ The basic legal standard for what constitutes adulterated food is the same under the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act. Generally speaking, the regulatory statutes establish four adulteration provisions: 1) a food is considered adulterated if it contains a harmful substance that may pose a safety risk; 2) a food is adulterated if it contains an added harmful substance that is acquired during production or cannot be reasonably avoided, and it exceeds applicable tolerance levels; 3) a food is adulterated if it contains a substance that has been intentionally added to the food but that has not been approved or otherwise sanctioned for use by a regulatory agency or one of the food safety statutes; and, 4) a food is adulterated if it has been handled under unsanitary conditions, creating a risk of contamination with a substance that may pose a safety threat. See THE FOOD INSTITUTE, HACCP & U.S. FOOD SAFETY GUIDE (2d ed.), at sec. 2, at p. 6.

³⁸ See Dr. Garry L. McKee, Food Safety & Inspection Service OIG Audit Report on ConAgra, Washington, D.C. (Oct. 2, 2003).

³⁹ FSIS plainly states that “[a] food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death.” FOOD SAFETY AND INSPECTION SERVICE, BACKGROUNDER/KEY FACTS, FSIS FOOD RECALLS (2002), available at <http://www.fsis.usda.gov/Oabackground/bkrecalls.htm>. See also CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION, INDUSTRY AFFAIRS STAFF BROCHURE, FDA RECALL POLICIES (June 2002), available at <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

⁴⁰ GENERAL ACCOUNTING OFFICE, *supra* note 7, at 3.

⁴¹ Headlines in the news indicate that it is commonly misperceived that food products are subject to mandatory recall by the government. Examples include “FDA Orders Peanut Butter Recall,” and “FDA Orders 6,500 Cases of Red-Dyed Mints Recalled.” The headlines are, of course, wrong in indicating that the Agency can order these recalls. See CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 39, available at <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

The answer is simple: it is the implicit threat of regulatory action, liability, and adverse publicity.⁴²

The threat of regulatory action involves an array of regulatory enforcement tools available to USDA and FDA in varying degree and scope: warning letters,⁴³ adverse publicity,⁴⁴ injunction,⁴⁵ retention,⁴⁶ seizure,⁴⁷ and criminal prosecution.⁴⁸ These sanctions are not mutually exclusive and may build upon one another.⁴⁹ Given these

⁴² See FSIS Public Meeting, *supra* note 2, at 20-21.

⁴³ A warning letter from the FDA is a written communication to a company asserting that there has been a violation of the FDCA or implementing regulations. The letter will typically request that the company inform the agency about the action the company will take to correct the alleged violation. The warning letter will generally caution the company that enforcement action may be initiated “without further notice.” If a company does not correct the violation, further sanctions may be imposed. In contrast to FDA’s practice, USDA warning letters are sent after the department has decided not to take further regulatory action. In other words, the warning letter closes the file. See THE FOOD INSTITUTE, *supra* note 37, at Sec. 2, p.13.

⁴⁴ Adverse publicity consists of the dissemination of information that the company is not cooperating with enforcement officials. See 21 U.S.C. § 705 (1999).

⁴⁵ If FDA or USDA seeks an injunction, they must go to the U.S. Attorney where the company is located. If the prosecutor agrees to take the case, he or she will file a request for an injunction with the U.S. District Court. See THE FOOD INSTITUTE, *supra* note 37, at sec. 2, p.17.

⁴⁶ USDA retains product when an in-plant inspector places a “tag” on product located at a federally inspected facility that he or she believes to be adulterated or misbranded. Once tagged, a product cannot be removed from the facility without USDA approval. In most instances, a product is either reconditioned or destroyed within a few days. See *id.* at 15.

⁴⁷ In a seizure proceeding, the government initially seeks a court order authorizing the United States Marshall to “seize” the product. A seizure action seeks the destruction of a product, not merely a prohibition against its shipment. Once seized, the product cannot be moved without the court’s permission. The government will also file a complaint requesting that the product be “condemned” and destroyed. See *id.* at 16.

⁴⁸ The Food, Drug, and Cosmetic Act (FDCA), the Poultry Products Inspection Act (PPIA), and the Federal Meat Inspection Act (FMIA) have strong criminal provisions that are essentially strict liability statutes: to obtain a conviction, the government need not establish intent to violate the law. Two types of criminal violations exist: misdemeanors and felonies. Under FDCA, most food violations are misdemeanors; however, FDA can request a felony conviction if the government can prove intent to defraud or mislead or if there has been a prior conviction. Under PPIA and FMIA, any violation involving the distribution or attempted distribution of an adulterated food is a felony. See *id.* at 18.

⁴⁹ See *id.* at 12.

regulatory threats, a recall may be the only practical option for a company experiencing a food safety problem.⁵⁰

Companies also recall food products to minimize and avoid liability.⁵¹ A failure to recall unsafe food significantly increases a company's liability exposure and the risk of class actions and punitive damages.⁵² Companies also risk adverse publicity that could destroy their brand image.⁵³ Consequently, some observers deem the term "voluntary" recall a misnomer since it is compelled by regulatory, legal, and marketing pressures.⁵⁴

C. Regulatory Oversight of Voluntary Recall

USDA and FDA oversee, monitor, and coordinate voluntary recall activities.⁵⁵ USDA procedures for recalls of defective meat are found in an FSIS Directive;⁵⁶ FDA procedures for recalls are published in the Code of Federal Regulations.⁵⁷ These procedures have been developed into recall programs that USDA, through FSIS, and FDA employ for the foods they regulate.⁵⁸ Notwithstanding these recall programs and

⁵⁰ See FSIS Public Meeting, *supra* note 2, at 17-21.

⁵¹ See generally John M. Packman, *Civil and Criminal Liability Associated with Food Recalls*, 53 FOOD & DRUG L.J. 437 (1998).

⁵² See *id.*

⁵³ See FSIS Public Meeting, *supra* note 2, at 181.

⁵⁴ See National Meat Association, *supra* note 11, available at <http://www.nmaonline.org/files/pr10-8.htm>.

⁵⁵ See GENERAL ACCOUNTING OFFICE, *supra* note 7, at 5.

⁵⁶ See UNITED STATES DEPARTMENT OF AGRICULTURE, FSIS INFORMATION CENTER, FSIS DIRECTIVE 8080.1, REV. 3, RECALL OF MEAT AND POULTRY PRODUCTS, available at http://www.fsis.usda.gov/OA.recalls/rec_intr.htm; UNITED STATES DEPARTMENT OF AGRICULTURE, FSIS DIRECTIVE, RECALL OF MEAT AND POULTRY PRODUCTS (Jan. 19, 2000), available at <http://www.fsis.usda.gov/OPPDE/frdad/FSISDirectives/8080.1Rev3.htm>.

⁵⁷ See 21 C.F.R. §§ 7.40-.59 (2003).

⁵⁸ See GENERAL ACCOUNTING OFFICE, *supra* note 7, at 6.

the presence of the implicit threat, the essence of food recall activity is still voluntary: companies are not required by law to recall unsafe food,⁵⁹ and even if companies elect to voluntarily recall unsafe food, they are not required by law or regulation to notify USDA or FDA of their recall.⁶⁰

1. FSIS Voluntary Recall Program

When FSIS learns that adulterated or misbranded meat or poultry may be in commerce,⁶¹ it conducts a preliminary investigation to determine whether a recall of the food product is warranted.⁶² If FSIS determines that a recall is necessary, it convenes a meeting of its Recall Committee that is comprised FSIS scientists, technical experts, field inspection managers, enforcement personnel, and communication specialists.⁶³ The Recall Committee evaluates available information and, based on the health risk of the food product, categorizes the recall into one of three classes: a Class I recall where a strong likelihood exists that a product will cause serious adverse health consequences or death,⁶⁴ a Class II recall where a remote possibility exists of an adverse health

⁵⁹ *See id.*

⁶⁰ *See id.* at 7, 11.

⁶¹ FSIS can learn about the possibility of unsafe meat from several sources: the company that manufactured or distributed the meat, test results received by FSIS as part of its sampling program, FSIS field inspectors and compliance officers, consumer complaints, epidemiological data submitted by state or local public health departments, and government agencies. *See* FSIS, REPORT OF THE RECALL WORKING GROUP, *supra* note 27, available at <http://www.fsis.usda.gov/Oabackground/bkrecalls.htm>.

⁶² The preliminary investigation includes some or all of the following steps: collecting and verifying information about the inspected food; documenting a chronology of events; contacting the manufacturer of the food for more information; discussions with FSIS field inspection and compliance personnel; interviewing a consumer who allegedly became ill or injured from eating the food; collecting and analyzing food samples; and, contacting state and local health departments. *See id.*

⁶³ *See* FSIS DIRECTIVE, *supra* note 56, available at <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev3.htm>.

⁶⁴ An example of a Class I recall would be meat that is contaminated with pathogenic bacteria, such as *Listeria monocytogenes* in a ready-to-eat product or *Escherichia coli* 0157:H7 in raw ground beef. Another

consequence resulting from consuming the meat or poultry product,⁶⁵ or a Class III recall where the consumption of the product will not cause adverse health consequences.⁶⁶ The Recall Committee also recommends the depth and scope of the recall.⁶⁷ FSIS and the recalling company conduct effectiveness checks to determine the adequacy of notice about the recall and the success in removing the product.⁶⁸ FSIS notifies the public of recalls in two ways: a press release⁶⁹ and a recall notification report.⁷⁰ FSIS also posts recall notification reports on its Web site and sends these reports to food safety and public health officials throughout the country.⁷¹

example includes the adding of Class I allergens, such as peanuts or eggs, as an ingredient in processed meat without listing them on the label. *See* FSIS, REPORT OF THE WORKING RECALL GROUP, *supra* note 27, available at <http://www.fsis.usda.gov/OA/programs/recallwg.htm>.

⁶⁵ An example of a Class II recall would be the presence of dry milk as an ingredient in sausage without mention of the dry milk on the label. Another example is the presence of undeclared allergens such as milk or soy products. *See id.* The well-publicized Class II recall announced on December 23, 2003, involving the BSE incident was designated a Class II by the FDA due to an extremely low likelihood that the products contained the infectious agent that causes BSE. The infected tissues including the brain, spinal cord, and distal ileum, were all removed from the carcass on the day of slaughter, meaning that the meat produced were cuts that would not be expected to be infected or have an adverse public health impact. *See* FSIS UPDATE OF RECALL ACTIVITIES (Feb. 9, 2004), available at <http://www.fsis.usda.gov/oa/recalls/prelease/update067-2003.html>.

⁶⁶ An example of Class III recall would be improperly labeled processed meat in which added water is not listed on the label as required by the federal regulations. *See id.*

⁶⁷ *See* OFFICE OF THE INSPECTOR GENERAL, *supra* note 4, at 3.

⁶⁸ *See* GENERAL ACCOUNTING OFFICE, *supra* note 7, at 29.

⁶⁹ In February 2000, USDA began issuing press releases for all three classes of recalls, even if the product is not identifiable to consumers. *See id.* at 16, 28. The press release is issued to media outlets in the area where the product was distributed and to an email list-serv. *See* FSIS BACKGROUNDER, *supra* note 39. The public can request to receive FSIS press releases and other FSIS materials by subscribing to the *FSIS Constituent Update* at www.fsis.usda.gov/oa/update/subscribe.asp. The news release is posted on the FSIS Recall Web site at www.fsis.usda.gov/OA/recalls/rec_intr.htm.

⁷⁰ Recall Notification Reports (RNR) provide the public with detailed information about meat and poultry recalls. RNRs are sent by facsimile and electronic mail to food safety and public health officials throughout the country. *See id.*

⁷¹ The RNR are posted on the FSIS Recall Web site at www.fsis.usda.gov/OA/recalls/rec_intr.htm.

2. FDA Voluntary Recall Program

When FDA learns that a recall needs to be, will be, or has been initiated,⁷² the FDA's district office⁷³ obtains preliminary information about the recall and product and provides this information to FDA's Center for Food Safety and Applied Nutrition (CFSAN)⁷⁴ and FDA's Office of Regulatory Affairs (ORA)⁷⁵ within 24 hours.⁷⁶ The district office may assist the company in developing a recall strategy, although companies are not required to consult with FDA or modify its recall strategy on the basis of FDA's recommendations.⁷⁷ CFSAN prepares a written health hazard evaluation that is used to classify the recall into one of three classes:⁷⁸ a Class I recall for dangerous or defective products that predictably could cause serious health problems or death,⁷⁹ a Class II recall for products that might cause a temporary health problem or pose only a slight threat of a serious nature,⁸⁰ and a Class III recall for situations where eating the food will not cause

⁷² FDA's recall regulations request that a company notify FDA when a company removes or corrects a distributed product. *See* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION INDUSTRY, *supra* note 39, available at <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

⁷³ For a description of the responsibilities of district offices in a food product recall, see Sandra Nowlin Whetstone, *ORA's Role at FDA Headquarters and in the Field for Product Recalls*, 53 FOOD & DRUG L. J. 513 (1998).

⁷⁴ *See id.* (describing CFSAN).

⁷⁵ *See id.* (describing ORA).

⁷⁶ FDA's *Regulatory Procedures Manual* describes procedures for FDA staff to use in handling recalls of FDA regulated food products. *See* GENERAL ACCOUNTING OFFICE, *supra* note 7, at 31.

⁷⁷ *See id.* at 32.

⁷⁸ *See id.* at 32-33.

⁷⁹ Examples of Class I recall are a food found to contain botulinal toxin and food with undeclared allergens. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 39, available at <http://vm.cfsan.fda.gov/~lrd/recall2.html>.

⁸⁰ *See id.*

adverse consequences.⁸¹ FDA monitors the progress of a company's recall through its termination.⁸² FDA encourages the recalling company to issue a press release for Class I and selected Class II recalls.⁸³ When FDA believes that the public needs to be alerted about a serious hazard, FDA will issue its own press release.⁸⁴ FDA also posts an Enforcement Report on its Web site, listing all food recalls by the agency.⁸⁵

3. Market Withdrawal and Stock Recovery

In addition to recalls, other actions may be taken by a food company to remove a product from commerce, including market withdrawal and stock recovery.⁸⁶ Market withdrawal is the removal of a distributed product that involves a minor violation that would not be subject to legal action by the FDA or FSIS, or when the company wishes to remove a product from distribution for other reasons, such as when a product does not meet the company's internal specifications.⁸⁷ Stock recovery is the removal of a product that has not been placed in retail distribution channels but is still under the direct control of the food company.⁸⁸

⁸¹ Examples of Class III recall are a container defect, off-taste color, leaks in a bottle, and a lack of English labeling in a retail food. *See id.*

⁸² *See* GENERAL ACCOUNTING OFFICE, *supra* note 7, at 33.

⁸³ *See id.* at 34.

⁸⁴ *See id.*

⁸⁵ This is found through FDA Enforcement Reports, a weekly publication, available at <http://www.fda.gov/opacom/7alerts.html>.

⁸⁶ *See* NATIONAL FOOD PROCESSORS ASSOCIATION, FACT SHEET ON FOOD AND BEVERAGE PRODUCT RECALL, *available at* <http://www.nfpa-food.org/members/science/recallqa.html>.

⁸⁷ 21 C.F.R. § 7.3(j) (1996) (2003); *see also* FOOD PROCESSORS, *supra* note 86.

⁸⁸ 21 C.F.R. § 7.3(k) (1996) (2003); *see also* FOOD PROCESSORS, *supra* note 86.

D. Policy Rationale for Voluntary Recall

Support for the current voluntary recall system rests on two predicates: first, that it effectively removes unsafe food products from commerce;⁸⁹ and second, that it engenders cooperation between government and industry.⁹⁰ Defenders of the voluntary recall system believe that companies have generally initiated recalls without delays, either on their own initiative or in response to requests to voluntarily do so.⁹¹ USDA officials often comment that there are no instances in which companies delayed or failed to initiate a recall;⁹² however, a United States General Accounting Office (GAO) report questions this claim on the grounds that it is purely anecdotal, since USDA nor FDA systematically measure the full extent of companies' recall activities.⁹³ The same GAO report also noted that the FDA reported at least nine cases where companies delayed or failed to initiate a recall.⁹⁴ In spite of the GAO criticism of USDA's claim, USDA officials continue to make the claim.⁹⁵ This alleged success is credited to the "implicit threat" of government enforcement, adverse publicity, and liability exposure.⁹⁶ Given

⁸⁹ USDA and FDA documented more than 3,700 food recalls from the mid-1980's through 1999. GENERAL ACCOUNTING OFFICE, *supra* note 7, at 33. In the last decade, the number and size of recalls have increased dramatically, particularly Class I recalls. Michael Ollinger & Nicole Ballenger, *Weighing Incentives for Food Safety in Meat and Poultry*, AMBER WAVES, April 2003, available at [http://www.ers.usda.gov/Amberwaves/April 03/Features/WeighingIncentives.htm](http://www.ers.usda.gov/Amberwaves/April%2003/Features/WeighingIncentives.htm).

⁹⁰ See FSIS Public Meeting, *supra* note 2.

⁹¹ See FSIS RECALL WORKING GROUP, *supra* note 27, at 14.

⁹² FRONTLINE, PBS, MEAT RECALLS, available at <http://www.pbs.org/wgbh/pages/frontline/shows/meat/safe/recalls.html>.

⁹³ See OFFICE OF THE INSPECTOR GENERAL *supra*, note 4, at 37.

⁹⁴ See *id.*

⁹⁵ See FSIS Public Meeting, *supra* note 2, at 191.

⁹⁶ See FSIS Public Meeting, *supra* note 2, at 20-21.

this success, mandatory recall authority is viewed unnecessary, since USDA and FDA arguably have more than enough authority and leverage to require the recall of unsafe food products.⁹⁷

Advocates of “voluntary” recalls often prefer the term “cooperative” recall as being more descriptive of the present system in which the recalling company and the government agency work together to evaluate the product and risk and to recover that product.⁹⁸ The concern is that mandatory recalls would destabilize the current cooperative regulatory environment and antagonize a private sector that is motivated to prevent foodborne illnesses.⁹⁹ Instead of a cooperative environment, the mandatory recall system would generate an adversarial system marked by litigation and recrimination.¹⁰⁰

Supporters of voluntary recall also view this “cooperative” recall approach as consistent with the direction in which USDA and FDA are moving on the Hazard Analysis and Critical Points System (HACCP).¹⁰¹ HACCP is heralded as critical to government and industry joint efforts to ensure safe food.¹⁰² The idea behind HACCP is that the government agency monitor and oversee a company’s performance and record keeping.¹⁰³ The logical extension is then made that since the current voluntary recall

⁹⁷ See National Meat Association, *supra* note 11, available at <http://www.nmaonline.org/files/pr10-8.htm>; see also James H. Hodges, *Meat and Poultry Regulatory Update*, 54 FOOD & DRUG L. J. 459, 460 (1999).

⁹⁸ See National Meat Association, *supra* note 11, at <http://www.nmaonline.org/files/pr10-8.htm>.

⁹⁹ See MEAT INDUSTRY INTERNET NEWS SERVICE, *supra* note 11, available at www.spcnet.com/mii/1997/971029

¹⁰⁰ See FSIS Public Meeting, *supra* note 2, at 179-82.

¹⁰¹ See *id.* The GAO report notes that since January 2000, USDA contends that the responsibility for the food recall process rests with food companies due to the requirement that food companies are required to implement HACCP systems. See GENERAL ACCOUNTING OFFICE, *supra* note 7, at 20.

¹⁰² See MICHAEL S. SCHUMANN ET AL., FOOD SAFETY LAW 123-35 (1997).

¹⁰³ See *id.*

system is based on monitoring and oversight by government, it fosters the same spirit of cooperation created by HACCP.¹⁰⁴ This argument frames the overall “cooperative” regulatory philosophy of USDA’s and FDA’s food safety responsibilities, but it leaves unanswered the practical question: does a voluntary or mandatory food recall system best remove unsafe food from commerce?

IV.

Criticism of Voluntary Recall Leading to Efforts to Enact Mandatory Recall Legislation

Record-breaking recalls that have taxed the ability of the USDA and the recalling companies to effectively remove unsafe meat from commerce have provoked stinging criticism of the voluntary recall system from the media, consumer advocacy groups, members of Congress, government officials, and the Office of Inspector General.¹⁰⁵ These recalls were followed by proposed legislation that would have empowered USDA and FDA with mandatory recall authority. All attempts to empower these agencies with mandatory recall authority, however, have failed.

A. Hudson Foods Recall of 1997

In 1997, Hudson Foods, Inc. (Hudson), an Arkansas-based meat processing company, engaged in what became the nation’s largest beef recall.¹⁰⁶ Hudson was the fifth largest producer of chicken products and the twelfth largest producer of turkey

¹⁰⁴ See FSIS Public Meeting, *supra* note 2, at 181-82.

¹⁰⁵ The increase in the number and size of food recalls over the last several years is attributed to regulatory changes, improved testing techniques, and an adeptness at identifying foodborne illness outbreaks. See Ollinger and Ballenger, *supra* note 89, available at <http://www.ers.usda.gov/Amberwaves/April03/Features/WeighingIncentives.htm>.

¹⁰⁶ See Rick Weiss, *USDA Widens Investigation of Arkansas Meat Company*, WASH. POST, Aug. 17, 1997, at A11, available at <http://www.washingtonpost.com/wp-srv/politics/govt/admin/stories/glick081797.htm>.

products in the country and was a supplier of beef products to such major chains as Burger King, Boston Market, and Wal-Mart.¹⁰⁷ USDA learned of a problem from the Colorado Department of Public Health and Environment after it received reports of illness from several Colorado consumers who had eaten Hudson hamburger patties in early July of 1997.¹⁰⁸ The meat was traced to a Nebraska plant owned by Hudson, where quarter-pound hamburger patties were found contaminated with *E. coli* 0157:H7.¹⁰⁹ Eventually, sixteen people became ill as a result of eating meat processed at the Hudson plant.¹¹⁰

Relying on estimates by Hudson officials as to how much beef should be recalled, the recall was limited to only 20,000 pounds, even though the plant produced 400,000 pounds per shift.¹¹¹ Hudson officials¹¹² told investigators that the contaminated lot included 3,400 pounds of meat that had been “reworked” into 20,000 pounds of hamburger the next day. Plant officials neglected to tell USDA investigators, however, that meat continued to be reworked from one day to the next, so that once a contaminated lot of meat got into the system, it would be mixed sequentially into all subsequent lots.

¹⁰⁷ *See id.*

¹⁰⁸ *See* United States Department of Agriculture, Press Release, Glickman Announces Hudson to Act on USDA Recommendation to Close Nebraska Plant, Recall All Hudson Beef Products (Aug. 21, 1997), available at <http://www.usda.gov/news/releases/1997/08/0283>.

¹⁰⁹ *See* United States Department of Agriculture, Press Release, Developments in Hudson Foods E. coli Outbreak (Aug. 20, 1997), available at <http://www.usda.gov/news/releases/1997/08/0284>.

¹¹⁰ *See* Weiss, *supra* note 106, at A11.

¹¹¹ *See id.*

¹¹² Two Hudson officials were indicted on federal charges of misleading USDA officials about the extent of potential contamination in the early stages of the recall. *See* Jeff Taylor & Alison Young, *Recalls Expose the Limits of USDA*, DETROIT FREE PRESS, March 5, 1999, available at <http://www.freep.com/news/health/qlegis5.htm>.

Once this information was disclosed and it was faced with the possibility of having its plant closed down, Hudson began a voluntary recall that eventually included 25 million pounds of potentially contaminated meat.¹¹³ The problem with the expanded recall, however, was that much of the beef being recalled was already sold and presumably consumed.¹¹⁴

1. Response to Hudson Foods Recall

The Hudson Recall was viewed as an example of the breakdown of the voluntary food recall system. Critics noted that USDA's lack of recall authority results in dangerous delays when companies such as Hudson question the extent or basis for a recall and wait before acting.¹¹⁵ Consumer groups advocated that mandatory recall authority be given to the government.¹¹⁶ Members of Congress also promoted mandatory recall. United States Senator Tom Harkin (D-Iowa) stated at the time that "[m]andatory recall authority puts the secretary in a stronger position to ensure that recalls occur on time and that they cover all the contaminated products."¹¹⁷ The USDA also issued a press release stating that "[m]andatory notification will improve food safety because the quicker USDA is notified of potentially contaminated meat and poultry, the quicker

¹¹³ See Weiss, *supra* note 106, at A11.

¹¹⁴ See *Hamburger Recall Rises to 25 million Pounds*, CNN INTERACTIVE, Aug. 21, 1997, available at <http://www.cnn.com/US/9708/21/beef.update/index.html>.

¹¹⁵ See *Consumer Group Pushes Food Safety Law*, CNN INTERACTIVE, Feb. 4, 1998, available at <http://www.cnn.com/HEALTH/9802/04/safe.food/>.

¹¹⁶ See *id.*

¹¹⁷ See Taylor & Young, *supra* note 112, available at <http://www.freep.com/news/health/qlegis5.htm>.

American consumers can be protected.”¹¹⁸ Not everyone shared Senator Harkin’s and the USDA’s views, however. Meat processors opposed mandatory recall, contending that it is not needed since USDA could not cite any cases of companies refusing a recall request and that there were adequate incentives for companies to recall unsafe food products.¹¹⁹

2. Proposed Food Safety Enforcement Enhancement Act of 1997

The Food Safety Enforcement Enhancement Act of 1997 (FSEEA) was introduced in direct response to the Hudson Foods recall.¹²⁰ FSEEA authorized USDA to require mandatory recall of adulterated or misbranded products when companies refused to take voluntary action.¹²¹ Upon a finding by the Secretary of Agriculture that reasonable probability exists that a meat or poultry product could endanger public health if consumed, the Secretary would provide the company with an opportunity to cease distribution and recall the product.¹²² If the company refused to take direct action, the Secretary could then mandate a recall.¹²³

¹¹⁸ See United States Department Of Agriculture, Press Release No. 0297.97, Glickman Unveils Proposed Law to Strengthen Meat, Poultry Recalls (Aug. 29, 1997), available at <http://www.usda.gov/news/releases/1997/08/0297>.

¹¹⁹ See MEAT INDUSTRY INTERNET NEWS SERVICE, *supra* note 11, at www.spcnet.com/mii/1997/971029.

¹²⁰ See Hana Simon, Comment, *Food Safety Enforcement Act of 1997: Putting Public Health Before the Meat Industry’s Bottom Line*, 50 ADMIN. L. REV. 679, 682 (1998); see also CSPI, Press Release, Recipe For Safe Food Campaign Launched to Improve Food Safety Laws (Feb. 24, 1998), available at <http://www.cspinet.org/new/recipepr.htm>.

¹²¹ See United States Department of Agriculture, Press Release, Introduction of the New Food Safety Legislation (Aug. 29, 1997), available at <http://www.usda.gov/news/releases/1997/08/0298>.

¹²² See *id.*

¹²³ See *id.*

At the same time, FDA proposed analogous legislation known as the FDA Food Safety Enforcement Act.¹²⁴ Citing specific instances where companies failed to enforce a voluntary recall,¹²⁵ FDA proposed adding a new section to the FDCA that provided that persons (other than consumers) who had a reasonable basis for believing that a food article in interstate commerce might be adulterated would be required to notify the Secretary of DHHS immediately.¹²⁶ If the agency's request for a voluntary recall were rebuffed, the provision would allow the Secretary to order the recall.¹²⁷

B. ConAgra Recall of 2002

The next large-scale recall plagued with problems involved contaminated meat processed and produced at the ConAgra plant in Greeley, Colorado.¹²⁸ The plant is one of the largest in the nation, employing about 2,500 people.¹²⁹ The plant slaughters about 1.2 million cattle a year and processes, on average, about 350 cattle per hour.¹³⁰

¹²⁴ See FOOD AND DRUG ADMINISTRATION, FDA TALK PAPER, FDA PROPOSES LEGISLATION TO IMPROVE FOOD SAFETY (Aug. 29, 1997) (description of proposed FDA legislation). The FDA version of FSEEA was sponsored by Representative Frank Pallone (D-N.J.). See also CENTER FOR FOOD SCIENCE IN THE PUBLIC INTEREST, GIVE THE FOOD AND DRUG ADMINISTRATION TOUGH NEW AUTHORITY TO ENFORCE FOOD SAFETY LAWS, at <http://www.cspinet.org/reports/hr3070.html>.

¹²⁵ The first case involved Royal Line smoked salmon contaminated with *Listeria*. The salmon, sold in plastic packages, was imported from Denmark. The salmon's United States distributor refused to cooperate in the recall. The second case involved hummus dips and salads produced by Cedar's Mediterranean Foods, Inc. that were potentially contaminated with dangerous bacteria. Although the company claimed to be implementing a voluntary recall, it apparently had not removed all foods subject to recall from the market, and FDA had to repeat recall warnings about the products. See *id.*

¹²⁶ See FDA TALK PAPER, *supra* note 124.

¹²⁷ See *id.*

¹²⁸ See OFFICE OF INSPECTOR GENERAL, *supra* note 4, at 3.

¹²⁹ See *id.* at 1n.2.

¹³⁰ See *id.*

Beginning in mid-June 2002, at least 46 people in 16 states became ill from contaminated meat.¹³¹ ConAgra officials agreed to an initial voluntary recall of 354,200 pounds of ground beef produced in late May of that year.¹³² A subsequent FSIS review of ConAgra records showed that beef product from the Greeley plant had been testing positive for *E. coli* 0157:H7 as early as April 12, 2002, and as late as July 11, 2002. At that time, the Greeley plant produced over 1 million pounds of beef a day.¹³³

On July 18, 2002, because of the FSIS review, ConAgra decided that the recall needed to be expanded to include over 18 million pounds of ground beef and beef trim.¹³⁴ FSIS then issued a Notice of Intended Enforcement to ConAgra that allowed the company three days to respond in writing to demonstrate why an inadequacy determination should not be made against its sanitation standard operating procedure and its HACCP system. Based on ConAgra's response and planned corrective actions, the Notice was held in abeyance, and the plant continued to operate from July through mid-November.¹³⁵ On November 15, 2002, due to repeated zero-tolerance failures, FSIS suspended inspection services, effectively closing the plant. The plant was allowed to resume operations on November 20, 2002, after presenting FSIS with planned corrective actions.¹³⁶ Despite the recall, the majority of the beef was never returned.¹³⁷

¹³¹ *See id.* at 1.

¹³² *See id.*

¹³³ *See id.*

¹³⁴ *See id.* at 2.

¹³⁵ *See id.*

¹³⁶ *See id.*

¹³⁷ *See* CNN INTERACTIVE HAMBURGER RECALL, *supra*, note 114, available at <http://www.cnn.com/US/9708/21/beef.update/index.html>.

2. Response to ConAgra Recall

Although some in the meat industry viewed the ConAgra recall as too broad,¹³⁸ as in the Hudson recall, USDA's actions in the ConAgra recall received widespread publicity and criticism in the press and from Congress.¹³⁹ These critics noted that the recall did not start until the end of June, even though contaminated product was first produced in April, and that the recall had to be expanded because not all potentially contaminated products had been identified until July.¹⁴⁰

At the request of Congress, the Office of Inspector General (OIG) evaluated the effectiveness of USDA's management and oversight of the ConAgra product and on September 30, 2003, issued an audit report.¹⁴¹ The report found that both ConAgra and FSIS were unprepared for the recall because adequate controls and processes were not in place to timely identify the source of the contaminated product or ensure that appropriate enforcement actions would be taken.¹⁴² According to the OIG, FSIS "needs to reassess its management and oversight of the recall process."¹⁴³ The report further noted that FSIS failed to address problems that it was aware of prior to the recall. Before the recall, FSIS issued multiple noncompliance notifications to ConAgra for fecal contamination of

¹³⁸ See Elizabeth Becker, *ConAgra Sets Off Latest Food Poisoning Epidemic*, N.Y. TIMES, July 20, 2002, available at <http://www.organicconsumers.org/Toxic/ConAgra0702.cfm>.

¹³⁹ See *id.* at 2. See e.g., Bill McAllister, *Senators Seek Meat-Recall Probe*, DENV. POST, July 31, 2002, available at <http://www.denverpost.com/Stories/0,1413,36%7E53%7E64269,00.html>; George B. Pyle, *The Dangers of Mystery Meat*, WASH. POST, Aug. 17, 2002, at A17.

¹⁴⁰ See OFFICE OF INSPECTOR GENERAL, *supra* note 4, at 2.

¹⁴¹ See *id.* at i.

¹⁴² See *id.* at ii.

¹⁴³ See *id.*

product but took no decisive enforcement action. Instead, it continually allowed ConAgra to introduce superficial stopgap measures.¹⁴⁴ Stopping short of recommending mandatory recall authority,¹⁴⁵ the report made thirty-one key recommendations for FSIS to implement in its management of future recalls.¹⁴⁶

FSIS deemed the IGO report irrelevant for four reasons.¹⁴⁷ First, FSIS noted that at the time of the report's issuance it had already implemented changes in its recall procedure.¹⁴⁸ Second, FSIS did not view the conditions described in the report as widespread but as isolated to a single plant.¹⁴⁹ Third, FSIS had already eliminated a program that exempted ConAgra and other meat processors from the FSIS's own testing program for *E. coli*.¹⁵⁰ Fourth, federal inspectors now undergo training focused on public health and systematically review plant-generated testing data.¹⁵¹

3. Proposed Safer Meat, Poultry, and Foods Act of 2002

The Safer Meat, Poultry, and Foods Act of 2002 (Safer Act) was introduced in the wake of the ConAgra recall¹⁵² and addressed recall authority for both USDA and FDA and enforcement generally. The Safer Act had three key parts: first, the authority to

¹⁴⁴ *See id.*

¹⁴⁵ *See id.*

¹⁴⁶ *See id.* at 16-94.

¹⁴⁷ *See* McKee, *supra* note 38.

¹⁴⁸ *See id.*

¹⁴⁹ *See id.*

¹⁵⁰ *See id.*

¹⁵¹ *See id.*

¹⁵² *See* Bill McAllister, *supra* note 139, available at <http://www.denverpost.com/Stories/0,1413,36%7E53%7E64269,00.html>.

mandate the recall of meat, poultry, or food products, whether those be FDA-regulated products or USDA-regulated products; second, the requirement that companies notify USDA or FDA if they know their product is adulterated; and, third, authority to levy fines for violations of food safety regulations.¹⁵³ Despite strong support from consumer groups,¹⁵⁴ the Safer Act and the FSEEA met the same fate: they died in committee.¹⁵⁵ The demise of these bills demonstrates a continual resistance to the government's having mandatory food recall authority.¹⁵⁶

C. The Logical Conundrum of Voluntary Recall Support

Despite their apparent persuasive appeal to lawmakers, the arguments in favor of voluntary recall -- that the government already has sufficient enforcement power and that mandatory recall authority will destabilize the cooperative nature of the voluntary recall system¹⁵⁷ -- are difficult to reconcile. If the government's impressive array of enforcement tools compel "voluntary" recalls, then mandatory recalls should not disrupt the tone of the current regulatory environment since both systems share the common goal of compelling the recall of unsafe food products. A more tenable criticism would be that mandatory recall authority would be superfluous, not disruptive. Moreover, if a

¹⁵³ See SAFER Meat, Poultry, and Food Act, available at <http://www.theorator.com/bills108/hr3547.html>.

¹⁵⁴ See Consumers Union, Press Release, Consumer Reports Magazine Backs Harkin Food Safety Bill in Chicken Expose (Feb. 24, 1998), available at <http://www.consumersunion.org/food/0224harkin.htm>; CNN INTERACTIVE, *Consumer Group*, *supra* note 115, available at <http://www.cnn.com/HEALTH/9802/04/safe.food/>; Safe Tables, Press Release, Victims' Organization Calls ConAgra's 'Voluntary' Recall of 18 Million Pounds of E. Coli-Poisoned Meat 'A Sham' (June 19, 2002), available at http://www.safetables.org/Media/Press_Releases/pr_conagra_sham_06_2002.html.

¹⁵⁵ 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, 719 (1998).

¹⁵⁶ See FSIS Public Meeting, *supra* note 2, at 191.

¹⁵⁷ See FSIS Public Meeting, *supra* note 2, at 179-82.

mandatory recall system can be devised that still allows and encourages voluntary recalls by food companies, then the implicit threat that now compels voluntary recalls will continue to compel companies to do so. The difference will be that a mandatory recall system will render the implicit threat a real threat.

It is also difficult to reconcile the disparate treatment by the government in the recall of food and non-food products. The government has mandatory recall authority for numerous non-food products:¹⁵⁸ the Consumer Protection Safety Commission (CPSC) has the authority to order a recall unsafe consumer products;¹⁵⁹ the Environmental Protection Agency (EPA) has the authority to order a recall of dangerous chemicals;¹⁶⁰ the FDA has the authority to order a recall for a number of medical products¹⁶¹ and for one food product – infant formula;¹⁶² the National Highway Traffic System Administration (NHTSA) of the U.S. Department of Transportation has the authority to order a recall of motor vehicle products;¹⁶³ and, the U.S. Coast Guard (USCG) has the authority to order a recall of recreation boats and related equipment.¹⁶⁴ The inconsistency in the recall policy towards food and non-food products raises important policy questions. Are unsafe food products less of a public health concern than dangerous consumer and

¹⁵⁸ Six federal agencies with different jurisdictions have joined together to create a “one stop shop” Web site for U.S. government recalls. See <http://www.recalls.gov/>.

¹⁵⁹ See Consumer Protection Safety Act, 15 U.S.C. § 2064 (1998).

¹⁶⁰ See Toxic Substances Control Act, 15 U.S.C. § 2605 (1998).

¹⁶¹ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360h(b) (1999).

¹⁶² See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 350a(e)(1)(B) (1999).

¹⁶³ See National Traffic and Motor Vehicle Safety Act, 49 U.S.C. § 30118 (b) (1997).

¹⁶⁴ See Federal Boat Safety Act, 46 U.S.C. § 4310 (2003).

other non-food products? Is there a rational public policy explanation as to why food products should be singled out for exemption to mandatory recall authority?

V.

Devising a Sensible Mandatory Food Recall System

Given the reported shortcomings of the current voluntary recall system for food products, it is worth evaluating the merits of a mandatory food recall system. This section recommends the necessary components for an effective mandatory recall system and lists the benefits derived from implementation of these components. This section also examines the potential benefit of delegating food recall responsibility to a single food safety agency, rather than two different government agencies.

A. Necessary Components of Mandatory Recall System

In order to give teeth to the recall enforcement powers of FDA and USDA and at the same time protect against the concern of government overreach,¹⁶⁵ a mandatory recall system needs to have both express powers and safeguards. Below are some of the powers and safeguards that should be considered by policy makers.

1. Express Powers

- **Express Authority to Mandate a Recall** -- The first obvious tool is the express authority to mandate the recall of food products, whether they are FDA or USDA regulated products. If the agency finds that the food product is adulterated or misbranded and that there is a reasonable probability that human consumption of such food presents a

¹⁶⁵ See MEAT INDUSTRY INTERNET NEWS SERVICE, *supra* note 11, at www.spcnet.com/mii/1997/971029.

threat to public health, the agency should be provided the authority to stop the distribution and recall the product.¹⁶⁶

- **Fast-Track Recall** – Consideration should be given to adopting a fast-track-recall program for unsafe food products patterned after the CPSC fast-track program.¹⁶⁷ The CPSC’s award winning fast-track program¹⁶⁸ encourages companies to recall dangerous products quickly and efficiently in a streamlined process.¹⁶⁹ The CPSC program eliminates some of the procedural steps in the traditional consumer goods recall process, including the staff preliminary determination that the product contains a defect that presents a substantial product hazard.¹⁷⁰ A similar streamlined process should work with the food industry.

- **Notification Requirement** – All companies throughout the distribution chain should be required to notify USDA or FDA if they know their food product is adulterated or misbranded.¹⁷¹ Where the objective is to remove the unsafe food product from commerce, it is imperative that companies are legally obligated to notify the authorities when they discover a problem.

¹⁶⁶ The “reasonable probability” standard for triggering the mandatory recall authority was included in both the FSEEA and SAFER Act proposals. *See* FDA TALK PAPER, *supra*, note 124; *see also* SAFER Meat, Poultry, and Food Act, *supra* note 153, available at <http://www.theorator.com/bills108/hr3547.html>.

¹⁶⁷ *See* Section 15(b) of the Consumer Product Safety Act, 15 U.S.C. § 2064(b) (1998).

¹⁶⁸ The CPSC fast-track program was named a 1998 winner of the prestigious innovations in American Government award. *See* U.S. CONSUMER PRODUCT SAFETY COMMISSION, INNOVATIONS IN AMERICAN GOVERNMENT AWARD: FAST-TRACK RECALL PROGRAM, available at <http://www.cpsc.gov/fast.html>.

¹⁶⁹ *See* Mark J. Schoem, Foreword to U.S. Consumer Product Safety Commission Recall Handbook, available at <http://www.cpsc.gov/businfo/8002.html> (May 1999).

¹⁷⁰ *See id.*

¹⁷¹ A notification provision was included in both the FSEEA and SAFER Act proposals. *See id.* The SAFER Act excepted from this notification requirement household consumers. *See id.*

- **Authority to Levy Fines** – In addition to mandatory recall authority, USDA and FDA should be given authority to levy fines for violations of food safety regulations.¹⁷² The amount of fines should be established to be fair to the infringing company but significant enough to deter irresponsible conduct.¹⁷³
- **Comprehensive Mandatory Recall Coverage** -- USDA and FDA should have the authority to order the recall of suspected food from the entire food distribution system.¹⁷⁴ This farm-to-table continuum would include food processors, meat packing plants, restaurants, and grocery stores.
- **Emergency Powers for Acts of Terrorism** -- There should be a provision for immediate notice and recall if an act of terrorism is suspected to have rendered a food product unsafe.¹⁷⁵ In the event of a terrorism threat, certain safeguards enumerated in this article may need to be suspended to protect public health. Acts of terrorism threatening the safety of food is an increasing concern for at least two reasons.¹⁷⁶ First, the

¹⁷² Former Secretary of Agriculture, Dan Glickman, noted the discrepancy between the USDA ability to levy fines for food safety infractions compared to other government powers: “Currently, the USDA can levy fines for abuse of circus elephants, selling a cat without a license and marketing a potato that’s too small, Yet we do not have the ability to fine companies for producing unsafe food. That is unacceptable.” Taylor & Young, *supra*, note 112, *available at* <http://www.freep.com/news/health/qlegis5.htm>.

¹⁷³ Both the FSEEA and SAFER Act proposals authorized the Secretary to impose civil penalties of not more than \$100,000 for each violation against a company that violates provisions of the Act. *See* United States Department of Agriculture, Press Release, *supra* note 121, *available at* <http://www.usda.gov/news/releases/1997/08/0298>.

¹⁷⁴ Both the FSEEA and SAFER Act proposals extend the notification and recall requirements to all companies involved in the distribution chain. *See id.*

¹⁷⁵ Under the administrative detention provision of new Bioterrorism Act, for the first time, FDA will have authority to detain food where it has evidence that the food could cause serious illness or death. *See* The Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act), Pub. L. No. 107-188, § 143, 116 Stat. 594 (2002).

¹⁷⁶ *See* Peter Chalk, *Hitting America’s Soft Underbelly: The Potential Threat of Deliberate Biological Attacks Against the U.S. Agricultural and Food Industry*, RAND, National Defense Research Institute (2004), at 7.

increasing number of entry points in the farm-to-table continuum increase the chances for toxins and bacteria to be introduced into the food chain with relative ease.¹⁷⁷ Second, a lack of security and surveillance render many meat and vegetable processing and packing plants susceptible to deliberate bio-attacks.¹⁷⁸

- **Authority to Require Recall Plans** – FSIS and FDA should be given authority to require food companies to include in their HACCP plan the steps that would be necessary to conduct an effective recall of food product.¹⁷⁹ Ensuring that food companies include plans for a recall in their HACCP plan would help maximize the recovery of contaminated product.¹⁸⁰

2. Safeguards

- **Allowing for Voluntary Recall** – A company should have the option of voluntarily recalling its food product and notifying the public within the time and manner prescribed by the agency.¹⁸¹ Although the Consumer Product Safety Act empowers the CPSC to order product recalls, nearly all recalls administered by CPSC are still voluntary.¹⁸² This is also true with other non-food products – notwithstanding mandatory

¹⁷⁷ *See id.* at 16.

¹⁷⁸ *See id.*

¹⁷⁹ Recommendation No. 12 in the GAO report following the ConAgra recall recommended that FSIS should seek such authorizing legislation. *See* OFFICE OF INSPECTOR GENERAL, *supra* note 4, at 42.

¹⁸⁰ *See id.* at 43.

¹⁸¹ Providing the company the opportunity to voluntarily recall the adulterated or misbranded product was specified in both the FSEEA and SAFER Act proposals. *See id.*

¹⁸² *See* James T. O'Reilly, *Product Recalls & the Third Restatement: Consumers Lose Twice from Defects in Products and in the Restatement Itself*, 33 U. MEM. L. REV. 883, 899 (Summer 2003).

recall authority, companies nearly always engage in voluntary recall of substandard products.¹⁸³

- **Extension of Due Process** -- Due process protection should be afforded to the food companies.¹⁸⁴ A company should be able to request an informal hearing before an independent administrative judge when USDA or FDA issues a recall order. If the company requests the hearing, the agencies should only require that the company stop distributing the suspect food product and notify others to cease its distribution. The food product would not be recalled until the hearing is held. The hearing would need to take place as soon as possible after the issuance of the order.¹⁸⁵ Allowing for an extra couple of days for a hearing in the rare case of a dispute is a small delay compared to the protracted delays experienced in the Hudson Foods and ConAgra recalls.

- **Limiting Liability** – Limiting the liability of food companies who comply with the government’s request for recall by giving them some immunity from civil actions may provide another incentive for compliance. Food companies will already have limited their liability, however, by quickly and efficiently recalling unsafe food

¹⁸³ See *Pesticides: Topical and Chemical Fact Sheets*, United States Environmental Protection Agency, available at http://www.epa.gov/pesticides/factsheets/health_fs.htm (most pesticides registrants voluntarily recall substandard pesticide products); Kevin M. McDonald, *Judicial Review of NHTSA-Ordered Recalls*, 47 Wayne L. Rev. 1301, 1318 (Winter 2001/Spring 2002) (nearly all motor vehicle recalls are voluntary).

¹⁸⁴ Critics of mandatory recall authority have expressed concern that this authority would “present the opportunity for potential administrative abuse,” Hodges, *supra* note 96. Testimony to the Senate Committee from the National Food Processors Association articulated concern that “[g]iving the Secretary of Agriculture the administrative power to mandate the recall of meat and poultry products, without judicial review, is an unwarranted expansion of government power.” See MEAT INDUSTRY INTERNET NEWS SERVICE, *supra* note 11, at www.spcnet.com/mii/1997/971029.

¹⁸⁵ Both the FSEEA and SAFER Act proposals provided an informal hearing as to why the food product should not be recalled no later than two (2) business days after the issuance of the recall order. See United States Department Of Agriculture, Press Release, *supra* note 121, available at <http://www.usda.gov/news/releases/1997/08/0298>.

products.¹⁸⁶ Also, it may be difficult justify giving food companies favorable treatment over non-food companies that timely and effectively recall unsafe products.

B. Benefits of Mandatory Recall Authority

Implementation of these powers and safeguards will benefit consumers and food companies. These benefits range from increasing the effectiveness of food recalls to creating a more rational food recall system in the context of both domestic and international policy.

- **Decreases Delay in Recalling Unsafe Food --** Mandatory notification and mandatory recall authority should speed up the recall process.¹⁸⁷ The sooner USDA and FDA are notified of potentially contaminated food products, the quicker these agencies can protect American consumers.¹⁸⁸ Also, the implicit threat that compels recalls under the voluntary recall system becomes a real and direct threat under a mandatory recall system. In other words, mandatory recall gives the government additional leverage to engage companies in a quick and effective recall of unsafe food products.¹⁸⁹ This

¹⁸⁶ See Packman, *supra* note 51 at 438-39.

¹⁸⁷ See United States Department of Agriculture, Press Release No. 0297.97, *supra* note 118, at [available at http://www.usda.gov/news/releases/1997/08/0297](http://www.usda.gov/news/releases/1997/08/0297).

¹⁸⁸ See FOOD SAFETY AND INSPECTION SERVICE, BACKGROUNDER, THE SAFETY OF AMERICAN MEAT AND POULTRY (1997), *available at* <http://www.usda.gov/news/releases/1997/10/0346>.

¹⁸⁹ Former Secretary of Agriculture, Dan Glickman, stated:

We don't have time for a protracted debate over how much product should be recalled. We don't have time for a snail's pace procedure to stop a plant's production until they clean up their act. One the experts make the determination that these steps are necessary, we need to move quickly. Every minute we wait is another minute a person could become ill or worse. That's something that weighs very heavily on our minds every time we deal with an outbreak.

Secretary Dan Glickman, Address at the USDA Headquarters, Aug. 29, 1997, *available at* <http://www.usda.gov/news/releases/1997/08/0298>.

leverage would avert the problem where a Hudson Foods or a ConAgra might agree to voluntarily recall their unsafe food product, but minimize the size of the initial recall. A type of CPSC fast-track recall program would further accelerate recalls of unsafe food.

- **Provides Insurance Policy Against the “Bad Apple” Company** – If for no other reason, mandatory recall authority is justified in its role as insurance against the occasional non-cooperative company.¹⁹⁰ Voluntary recalls may work for the most part; however, there is always the possibility of a Hudson Foods or a ConAgra – a “bad apple” company -- that refuses or is unable to cooperate fully in the recall of its unsafe food product. Mandatory recall authority is needed to equip the government with the requisite authority to force the non-compliant company to act without delay.

- **Protects Against Terrorist Acts** – Given the concern of bioterrorism threats to the safety of food in the United States,¹⁹¹ it is sensible that the government agencies charged with the safety of the nation’s food supply – USDA and FDA – should have the authority to mandate the immediate recall of unsafe food.¹⁹²

- **Preserves Voluntary Recalls** – As already noted in this article, it is likely that most companies will opt for voluntary recall, as do most companies who fall under the jurisdiction of the CPSC and other government agencies with authority to order a

¹⁹⁰ See United States Department of Agriculture, Press Release, *supra* note 121, available at <http://www.usda.gov/news/releases/1997/08/0298>. See also FOOD SAFETY AND INSPECTION SERVICE, *supra* note 188, available at <http://www.usda.gov/news/releases/1997/10/0346>.

¹⁹¹ See generally UNITED STATES GENERAL ACCOUNTING OFFICE, BIOTERRORISM, *supra* note 5.

¹⁹² See Caroline Smith DeWaal, Statement at the National Food Policy Conference, *Protecting the Public Under the New Bioterrorism Act*, (May 9, 2003) (stating that although the new Bioterrorism Act grants new authorities to protect the American food supply, mandatory food recall authority is essential to dealing with potential terrorist threats against the food supply).

recall of non-food products.¹⁹³ If this is the case, mandatory recall will occur only in those rare instances where a company wants to contend with FDA or USDA or delay or refuse to meet a voluntary recall request. This probable outcome means that the cooperative enforcement environment between government and private industry will continue.

- **Enhances Consumer Confidence in Food** – An important function of an effective recall is to maintain consumer confidence in the United States food supply. Consumers are generally surprised to discover that the government does not have the authority to mandate the recall of unsafe food.¹⁹⁴ Large-scale recalls that are mishandled by companies and government damage consumer confidence in the food supply.¹⁹⁵ It is reasonable to believe that consumers will feel more assured in the safety of the United States food supply if government has the authority to mandate recall when a serious foodborne illness problem occurs.

- **Aligns Incentives to Protect Consumers from Unsafe Food** – The decision by a food company to engage in a purely voluntary recall is made when the

¹⁹³ See Cassie Orban, Student Note, *The Product Recall Process: Mechanics and Shortcomings*, 12 LOY. CONSUMER L. REV. 311, 320-21 (2000).

¹⁹⁴ Former Secretary of Agriculture, Dan Glickman stated:

I'll tell you right now that I agree wholeheartedly with the consumer groups who feel that one of the biggest loopholes out there is the fact that I do not have the authority to order a recall. I would doubt that most Americans are even aware of this. I think that most folks would be shocked to know that industry – and not federal food safety experts – ultimately make the decision as to whether or not food is recalled when the public's safety is compromised.

United States Department of Agriculture, Press Release, *Developments in Hudson Foods E Coli Outbreak* (Aug. 21, 1997), available at <http://www.usda.gov/news/releases/1997/08/0284>.

¹⁹⁵ See, e.g., Alan Hall, *Recalls of Contaminated Food and New Foodborne Infections Have Shaken Faith in the Food Supply*, SCI. AM., Nov. 3, 1997.

expected costs of the recall are less than the costs of the implicit threat of liability, negative publicity, or regulatory action.¹⁹⁶ This “costs” analysis does not involve, however, full consideration of the social costs – the harm to public health.¹⁹⁷ Giving the government the authority to mandate recalls will more fully allow government agencies to account for social costs and cause food companies to internalize these social costs when making safety decisions that effect the probability of recall.¹⁹⁸

- **Increases Scope and Depth of Recall** – The development of traceability systems is enabling food companies to track product distribution and target recall activities.¹⁹⁹ By giving the government mandatory recall coverage, the chances of removing unsafe food with the advent of new traceability systems from all levels of the food chain are increased considerably.

- **Reduces Liability Exposure of Food Companies** – Foodborne illnesses expose food companies to liability exposure under state product liability laws.²⁰⁰ Several law and consulting firms now specialize in foodborne illness lawsuits.²⁰¹ Speeding up the recall process leads to less contaminated food consumed by consumers, which in turn

¹⁹⁶ See Michael R. Thompsen & Andrew M. McKenzie, *Market Incentives for Safe Foods: An Examination of Shareholder Losses From Meat and Poultry Recalls*, 82(3) AMER. J. AGR. ECON. 526, 536 (Aug. 2001).

¹⁹⁷ See *id.*

¹⁹⁸ See *id.*

¹⁹⁹ ECONOMIC RESEARCH SERVICE, USDA BRIEFING ROOM, TRACEABILITY IN THE U.S. FOOD SUPPLY: MARKET INCENTIVES TO ESTABLISH TRACEABILITY, available at <http://www.ers.usda.gov/Briefing/Traceability/marketincentives.htm>.

²⁰⁰ See generally, JEAN C. BUZBY ET AL., UNITED STATES DEPARTMENT OF AGRICULTURE, REPORT NO. 799, PRODUCT LIABILITY AND MICROBIAL FOODBORNE ILLNESS (April 2001).

²⁰¹ See *id.* at 27.

leads to a reduction of liability exposure for companies.²⁰² When faced with the prospects of an unsafe food product, companies have a conflict of interest: they want to remove contaminated product from commerce while at the same time not taint their brand image.²⁰³ This dilemma may cause a company to engage in a recall, but one that is smaller and slower than is necessary to protect public health, such as the ConAgra recall. Mandatory recall authority helps remove the pressure of this conflict: the food company will be more compelled to act quickly and efficiently, thus lessening its liability exposure.²⁰⁴

- **Standardizes Government’s Recall Policies** – Mandatory food recall authority standardizes the government’s recall policies and practices, creating a more rational domestic public health network. For example, it makes little sense to give the government the authority to order the recall of 125,000 detachable plugs on power adapters, as it did in 2003, where there were reported twelve plugs breaking open but no injuries²⁰⁵ and not the authority to order the recall of hamburger contaminated with deadly *E. coli 0157:H7* bacteria.

- **Creates Food Recall Policy Consistent with International Trading Partners** – Countries globally are intensifying their efforts to improve food safety in response to increasing food safety problems and consumer expectations.²⁰⁶ Mandatory

²⁰² See Packman, *supra*, note 51, at 438-39.

²⁰³ See Thompsen, *supra*, note 196, at 536.

²⁰⁴ See O’Reilly, *supra*, note 182, at 901-02.

²⁰⁵ See U.S. CONSUMER PROTECTION SAFETY COMMISSION, 2003 ANNUAL PERFORMANCE REPORT (Feb. 2004), at 25.

²⁰⁶ WORLD HEALTH ORGANIZATION, FACT SHEET ON FOOD SAFETY AND FOODBORNE ILLNESS, NO. 237 (January 2002), available at <http://www.who.int/inf-fs/en/fact237.html>.

recall is an enforcement tool used by the major trading partners to the United States to ensure the removal of unsafe food products.²⁰⁷ Although this fact alone is not a compelling reason for mandatory food recall authority, it does suggest that the prevailing global view in an ever-increasing global food economy is that mandatory authority is imperative.

- **Positions USDA and FSIS as Public Health Agencies – FDA and FSIS** within USDA are viewed as public health agencies.²⁰⁸ The credibility of FDA and FSIS in fulfilling this role depends on how well they protect public health.²⁰⁹ Having the ultimate authority to cause the removal of unsafe food in a timely and effective manner promotes the credibility of these agencies.²¹⁰

²⁰⁷ See FSIS, BACKGROUNDER *supra* note 188, available at <http://www.usda.gov/news/releases/1997/10/0346>.

²⁰⁸ Due to the responsibilities of the USDA to market meat, the claim has been made that USDA is not by its nature a public health agency. This observation is generally made in support of a single, separate regulatory food safety agency. See Aparna Surendran, *Meat Inspection Suffers Because Industry, Government at Odds*, PHILADELPHIA INQUIRER, June 4, 2003, available at <http://www.centredaily.com/mld/centredaily/news/6010859.htm> (remarks by Carol Tucker Foreman, Head of the Consumer Federation of America).

²⁰⁹ As stated by a USDA official, “recalls are a critical tool for us to carry out our public health mission.” FSIS Public Meeting, *supra* note 2, at 10.

²¹⁰ At the time of the GAO report of 2000, which criticized the recall process of USDA and FDA, the GAO reported USDA’s position that it needed mandatory recall authority to improve food safety and has supported proposed legislation. GENERAL ACCOUNTING OFFICE, *supra* note 18, at 20. Dr. Catherine Woteki, former Undersecretary for Food Safety, stated that the USDA “believe that in order to truly protect the public health, USDA needs the authority to mandate a recall when voluntary efforts fail.” Catherine Woteki, Address, Washington D.C. (Oct. 5, 1998), available at http://www.fsis.usda.gov/OA/speeches/1998/cw_recall.htm.

C. Single Agency to Administer Recalls

A recent GAO report criticizes the fragmented government agency approach to food safety.²¹¹ The report notes that food safety in the United States is governed by a complex system of thirty food safety laws, twelve federal agencies to administer these laws, and fifty interagency agreements to govern the combined food safety responsibilities of these twelve agencies.²¹² The report concludes that a single independent food safety agency is needed to improve the effectiveness and efficiency of the current food safety system.²¹³

The report specifically criticizes the current dual agency responsibility over food recalls.²¹⁴ The report finds that having both the FSIS and FDA involved in the recall of unsafe food is confusing and nonsensical in many cases.²¹⁵ The report notes that with the recent BSE-infected animal case found in Washington state, FSIS conducted a recall of meat distributed in markets in six states; however, had the meat been used, for example, in canned soups containing less than two percent meat, FDA, not FSIS, would have worked with the companies to recall these foods.²¹⁶

²¹¹ See GENERAL ACCOUNTING OFFICE, GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP (March 30, 2004).

²¹² *Id.* at 2.

²¹³ *Id.* at 17-20.

²¹⁴ *Id.* at 13-15.

²¹⁵ *Id.* at 15.

²¹⁶ *Id.*

VI.

Conclusion

As stated by a USDA official in the aforementioned December 12, 2002 public meeting, “the time certainly is right to examine our recall process.”²¹⁷ Both sides in the debate over whether the government should have the authority for the recall of unsafe food products share a common goal: unsafe food products should be removed from commerce effectively and quickly. Both sides are far apart, however, in determining the appropriate role of government in the recall process. Proponents of the current voluntary food recall system are quick to point to the past successes of recalling unsafe food from commerce, and express concern about government intrusion and overreach. Proponents of a mandatory food recall system are quick to point to the past highly publicized failures of large-scale voluntary recalls and the disparate treatment of food products from non-food products subject to mandatory recall authority.

Lost in the debate is how a mandatory recall system with the proper components and safeguards can be a sensible and minimalist approach to improving the current recall system that for the most part works fairly well. Voluntary recalls would continue to be the norm, as government and the food industry would continue to work together to ensure that unsafe food is removed effectively and quickly from commerce. The change would be the additional leverage given to government to compel a recall. With a heightened sense of concern for food safety in an era of terrorist threats and the changing nature of food production and distribution, giving the government additional leverage to compel the recall of unsafe food products makes sense for the protection of consumers and for the well-being of the food industry.

²¹⁷ FSIS Public Meeting, *supra* note 2, at 5.

