MANDATORY RECALL AUTHORITY: A SENSIBLE AND MINIMALIST APPROACH TO IMPROVING FOOD SAFETY

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I. INTRODUCTION

A recurring 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. Recent events have renewed interest in the debate: the discovery of 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); well-publicized, large-scale recall failures; the threat of bioterrorists introducing harmful bacteria and toxins into the food chain; and, finally, an overall increasing concern about the safety of food in the United States. Currently, the government does not have the authority to mandate a recall of unsafe food; recalls of unsafe food products are conducted voluntarily by food companies and are monitored by multiple government agencies. This contrasts with the authority that the government has to order a recall for many nonfood products.

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. 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, to protect public health, the government should be armed with mandatory recall authority such as it has for other nonfood products. Defenders of the current voluntary recall system include members and representatives of the food industry; supporters of a mandatory recall system include consumer advocacy groups and, interestingly enough, most recently the American Farm Bureau.

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 the 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 also has 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 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 overreaching.
II. NEED FOR AN EFFECTIVE FOOD RECALL SYSTEM

While the United States generally is regarded as having one of the safest food supplies in the world, foodborne illness caused by consuming contaminated foods or beverages is a compelling public health problem: the Centers for Disease Control and Prevention (CDC) estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually. Compounding the problem is the constantly changing nature of foodborne illness. While improvements in food safety, such as pasteurization and proper canning, have all but eliminated some diseases, 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. The most commonly recognized foodborne infections are those caused by the bacteria *E. coli* O157:H7, *Salmonella*, *Listeria*, and *Campylobacter*, and by a group called calicivirus, also known as the Norwalk-like viruses.

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

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

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

A. Dual Agency Responsibility for Food Recalls

The two government agencies charged with food recall responsibility are the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA). USDA derives its regulatory authority from the Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), 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). FDA derives its regulatory power from various laws, including the Federal Food, Drug, and Cosmetic Act (FDCA), which gives the agency responsibility for the regulation of all other food products including whole (or shell) eggs; seafood; 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.

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

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; recalls administered by these two agencies are strictly voluntary. What, then, triggers a voluntary recall? What leverage does USDA or FDA have to motivate companies to voluntarily recall their food product? The answer is simple: it is the implicit threat of regulatory action, liability, and/or adverse publicity.

The threat of regulatory action involves an array of regulatory enforcement tools available to USDA and FDA in varying
degree and scope: warning letters, adverse publicity, injunction, retention, seizure, and criminal prosecution. These sanctions are not mutually exclusive and may build upon one another. These enforcement tools generally are not effective, however, in removing tainted food products fast enough, because they often require court intervention. Notwithstanding their cumbersome nature, these regulatory threats may make a recall the only practical option for a company experiencing a food safety problem.

Companies also recall food products to minimize and avoid liability. A failure to recall unsafe food significantly increases a company’s liability exposure and the risk of class actions and punitive damages. Companies also risk adverse publicity that could destroy their brand image. Consequently, some observers deem the term “voluntary recall” a misnomer, because usually regulatory, legal, and/or marketing pressures compel it.

C. Regulatory Oversight of Voluntary Recall

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

1. FSIS Voluntary Recall Program

When FSIS learns that adulterated or misbranded meat or poultry may be in commerce, it conducts a preliminary investigation to determine whether a recall of the food product is warranted. If FSIS determines that a recall is necessary, it convenes a meeting of its Recall Committee, which is comprised of FSIS scientists, technical experts, field inspection managers, enforcement personnel, and communication specialists. The Recall Committee evaluates the 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 the product will cause serious adverse health consequences or death, a Class II recall where a remote possibility exists of an adverse health consequence resulting from consuming the meat or poultry product, or a Class III recall where the consumption of the product will not cause adverse health consequences. The Recall Committee also recommends the depth and scope of the recall. FSIS and the recalling company conduct effectiveness checks to determine the adequacy of notice about the recall and the success in removing the product. FSIS notifies the public of recalls in two ways: a press release and a recall notification report. FSIS also posts recall notification reports on its website and sends these reports to food safety and public health officials throughout the country.

2. FDA Voluntary Recall Program

When FDA learns that a recall needs to be, will be, or has been initiated, FDA’s district office obtains preliminary information about the recall and product and provides this information to FDA’s Center for Food Safety and Applied Nutrition (CFSAN) and FDA’s Office of Regulatory Affairs (ORA) within twenty-four hours. The district office may assist the company in developing a recall strategy, although companies are not required to consult with FDA or modify their recall strategy on the basis of FDA’s recommendations. CFSAN prepares a written health hazard evaluation, which is used to classify the recall into one of three classes: a Class I recall for dangerous or defective products that predictably could cause serious health problems or death; a Class II recall for products that might cause a temporary health problem or pose only a slight threat of a serious nature; and a Class III recall for situations where eating the food will not cause adverse consequences. FDA monitors the progress of a company’s recall through its termination. FDA encourages the recalling company to issue a press release for Class I and selected Class II recalls. When FDA believes that the public needs to be alerted about a serious hazard, FDA will issue its own press release. FDA also posts an Enforcement Report on its website, listing all food recalls by the agency.

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. Market withdrawal is the removal of a distributed product that involves a minor violation that would not be subject to legal action by 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. Stock recovery is the removal of a product that has not been placed in retail distribution channels but still is under the direct control of the food company.

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; and second, that it engenders cooperation between government and industry. Defenders of the voluntary recall system believe that companies generally have initiated recalls without delays, either on their own initiative or in response to requests to do so voluntarily. USDA officials often comment that there are no instances in which companies delayed or failed to initiate a recall; however, a U.S. General Accounting Office (GAO) report questions this claim on the grounds that it is purely anecdotal; neither USDA nor FDA systematically measures the full extent of companies’ recall activities. The same GAO report also noted that FDA reported at least nine cases where companies delayed or failed to initiate a recall. In spite of the GAO criticism of USDA’s claim, USDA officials continue to make that claim, and credit this alleged success to the “implicit threat” of government enforcement, adverse publicity, and liability exposure. Given this presumed success, mandatory recall authority is viewed as unnecessary because USDA and FDA arguably have more than enough authority and leverage to require the recall of unsafe food products.

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 the product. 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. Instead of a cooperative environment, it is argued that the mandatory recall system would generate an adversarial system marked by litigation and recrimination.

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). HACCP is heralded as critical to government and industry joint efforts to ensure safe food. The idea behind HACCP is that the government agency monitors and oversees a company’s performance and recordkeeping. The logical extension is then made that because the current voluntary recall system is based on monitoring and oversight by government, it fosters the same spirit of cooperation created by HACCP. 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 USDA and 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 (OIG). For example, a voluntary recall of hot dogs and other ready-to-eat meat products initiated on December 22, 1998, by Sara Lee Corporation placed USDA under fire for its inability to mandate a recall, in addition to its failure to issue a timely press release. These Sara Lee meat products had caused a nationwide outbreak of listeriosis, resulting in twenty-one deaths and at least 100 illnesses in twenty-two states. USDA relied on an announcement issued by the Sara Lee plant that did not mention the full scope of the recall or the dire nature of the illness. USDA did not issue a press release until one month after the government had first confirmed that eating the contaminated meat could be fatal.

Two other examples--the Hudson Foods recall of 1997 and the ConAgra recall of 2002--were followed directly by proposed legislation to empower USDA and FDA with mandatory recall authority. Both legislative attempts failed. Examining these two recalls and the subsequent failed legislative proposals illustrates the level of criticism toward the voluntary recall system.
A. Hudson Foods Recall of 1997

In 1997, Hudson Foods, Inc., an Arkansas-based meat processing company, engaged in what became the nation’s largest beef recall. USDA learned of a problem from the Colorado Department of Public Health and Environment; the state agency had received reports of illness from several Colorado consumers who had eaten Hudson hamburger patties in early July 1997. The meat was traced to a Nebraska plant owned by Hudson, where quarter-pound hamburger patties were found to be contaminated with E. coli 0157:H7. Eventually, sixteen people became ill as a result of eating meat processed at the Hudson plant.

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. Hudson officials 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. Once this information was disclosed, and the company 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.

1. Response to Hudson Foods Recall

The Hudson Foods 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. Consumer groups advocated that mandatory recall authority be given to the government. Members of Congress also promoted mandatory recall. U.S. Senator Tom Harkin (D-IA) 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.” 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 American consumers can be protected.”

Not everyone shared Senator Harkin’s and USDA’s views, however; meat processors opposed mandatory recall, contending that it was not needed because 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.


The Food Safety Enforcement Enhancement Act of 1997 (FSEEA) was introduced in direct response to the Hudson Foods recall. FSEEA authorized USDA to require mandatory recalls of adulterated or misbranded products when companies refused to take voluntary action. Upon a finding by the Secretary of Agriculture that a 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. If the company refused to take direct action, the Secretary could then mandate a recall.

At the same time, FDA proposed analogous legislation, known as the FDA Food Safety Enforcement Act. Citing specific instances where companies failed to enforce a voluntary recall, 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 the U.S. Department of Health and Human Services (DHHS) immediately. If the agency’s request for a voluntary recall were rebuffed, the provision would allow the Secretary to order the recall.

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. The plant is one of the largest in the nation, employing about 2,500 people. The plant slaughters about 1.2 million cattle a year and processes, on average, about 350 cattle per hour.

Beginning in mid-June 2002, at least forty-six people in sixteen states became ill from contaminated meat. ConAgra officials agreed to an initial voluntary recall of 354,200 pounds of ground beef produced in late May of that year. A subsequent FSIS review of ConAgra records showed that beef products 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 one million pounds of beef a day.

On July 18, 2002, because of FSIS’ review, ConAgra decided that the recall needed to be expanded to include over eighteen million pounds of ground beef and beef trim. 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. 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. Despite the recall, the majority of the beef was never returned.

1. Response to ConAgra Recall

Although some in the meat industry viewed the ConAgra recall as too broad, as in the Hudson recall, USDA’s actions in the ConAgra recall received widespread publicity and criticism in the press and from Congress. 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 of the potentially-contaminated products had been identified until July.

At the request of Congress, the OIG evaluated the effectiveness of USDA’s management and oversight of the ConAgra product and on September 30, 2003, issued an audit report. The report found that both ConAgra and FSIS were unprepared for the recall because adequate controls and processes were not in place to identify in a timely manner the source of the contaminated product or to ensure that appropriate enforcement actions would be taken. According to the OIG, FSIS “needs to reassess its management and oversight of the recall process.” 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 product but took no decisive enforcement action. Instead, it continually allowed ConAgra to introduce superficial stopgap measures. Stopping short of recommending mandatory recall authority, the report made thirty-one key recommendations for FSIS to implement in its management of future recalls.

FSIS deemed the OIG report irrelevant for four reasons: first, FSIS noted that at the time of the report’s issuance it already had implemented changes in its recall procedure; second, FSIS viewed the conditions described in the report as isolated to a single plant rather than widespread; third, FSIS already had eliminated a program that exempted ConAgra and other meat processors from FSIS’ own testing program for E. coli; and fourth, federal inspectors now undergo training focused on public health and they systematically review plant-generated testing data.


The Safer Meat, Poultry, and Foods Act of 2002 (Safer Act) was introduced in the wake of the ConAgra recall and addressed recall authority for both USDA and FDA, and enforcement generally. The Safer Act had three key parts: first, the authority to 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, the authority to levy fines for violations of food safety regulations. Despite strong support from consumer groups, the Safer Act and the FSEEA met the same fate: they died in committee. The demise of these bills demonstrates a continual resistance to giving the government mandatory food recall authority.
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 system—are difficult to reconcile. If the government’s impressive array of enforcement tools compels “voluntary” recalls, then mandatory recalls should not disrupt the current regulatory environment because 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 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 also is difficult to reconcile the disparate treatment by the government in the recall of food and nonfood products. The government has mandatory recall authority for numerous nonfood products: the Consumer Product Safety Commission (CPSC) has the authority to order a recall of an unsafe consumer product; the Environmental Protection Agency (EPA) has the authority to order a recall of a dangerous chemical; FDA has the authority to order a recall for a number of medical products and for one food product—infant formula; the National Highway Traffic System Administration (NHTSA) of the U.S. Department of Transportation has the authority to order a recall of a motor vehicle product; and the U.S. Coast Guard (USCG) has the authority to order a recall of recreation boats and related equipment. The inconsistency in the recall policy toward food and nonfood products raises important policy questions. Are unsafe food products less of a public health concern than dangerous consumer and other nonfood 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 a Mandatory Recall System

To give teeth to the recall enforcement powers of FDA and USDA, and at the same time protects against government overreaching, 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 threat to public health, the agency should be provided the authority to stop distribution and recall the product.

• **Fast-Track Recall**—Consideration should be given to adopting a fast-track recall program for unsafe food products patterned after CPSC’s fast-track program. CPSC’s award-winning fast-track program encourages companies to recall dangerous products quickly and efficiently in a streamlined process. 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. 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. Where the objective is to remove the unsafe food product from commerce, it is imperative that companies are obligated legally to notify the authorities when a problem is discovered.
• Authority to Levy Fines--In addition to mandatory recall authority, USDA and FDA should be given the authority to levy fines for violations of food safety regulations. 176 The amount of the fines should be fair to the infringing company, but significant enough to deter irresponsible conduct. 177

• Comprehensive Mandatory Recall Coverage--USDA and FDA should have the authority to order the recall of suspected food from the entire food distribution system. 178 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. 179 In the event of a terrorism threat, certain safeguards enumerated in this article may need to be suspended to protect public health. Terrorist acts involving the safety of food are an increasing concern for at least two reasons: 180 first, increasing numbers 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; 181 and second, a lack of security and surveillance renders many meat and vegetable processing and packing plants susceptible to deliberate bio-attacks. 182

• Authority to Require Recall Plans--FSIS and FDA should be given the authority to require food companies to include in their HACCP plan the steps that would be necessary to conduct an effective recall of a food product. 183 Ensuring that food companies include plans for a recall in their HACCP plan would help maximize the recovery of a contaminated product. 184

• Required Announcement--Government agencies and food companies should be required to announce a recall to the public that not only is timely but also that conveys information sufficient to warn consumers about the risks involved with the product in question. 185 Such a requirement would help prevent situations like the Sara Lee recall, in which there was a lack of timely and adequate warning to consumers. 186

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. 187 Although the CPSA empowers CPSC to order product recalls, nearly all recalls administered by CPSC still are voluntary. 188 This also is true with other nonfood products--notwithstanding mandatory recall authority, companies nearly always engage in voluntary recalls of substandard products. 189

• Extension of Due Process--Due process protection should be afforded to food companies. 190 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 require only 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. 191 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 a recall by giving them some immunity from civil actions may provide another incentive for compliance. Food companies already will have limited their liability, however, by quickly and efficiently recalling unsafe food products. 192 Also, it may be difficult to justify giving food companies favorable treatment over nonfood companies that timely and effectively recall unsafe products.

*580 B. Benefits of Mandatory Recall Authority

Implementation of these powers and safeguards will benefit consumers and food companies. The 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. 193 The sooner USDA and FDA are notified of potentially-contaminated food products, the quicker these
agencies can protect American consumers.\textsuperscript{194} 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 quick and effective recalls of unsafe food products.\textsuperscript{195} This leverage would avert the situation where a company might voluntarily agree to recall their unsafe food product, but minimize the size of the initial recall. A CPSC type of fast-track recall program would further accelerate recalls of unsafe food products.

- \textbf{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 noncooperative company.\textsuperscript{196} Voluntary recalls may work for the most part; however, there always is the possibility of 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 noncompliant company to act without delay.

- \textbf{Protects Against Terrorist Acts}--Given the concern over the possibility of bioterrorism threats to the safety of food in the United States,\textsuperscript{197} 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.\textsuperscript{198}

- \textbf{Preserves Voluntary Recalls}--As noted earlier in this article, it is likely that most companies will opt for voluntary recall, as do most companies who fall under the jurisdiction of CPSC and other government agencies with the authority to order \textsuperscript{581} recalls of nonfood products.\textsuperscript{199} If this is the case, mandatory recall will occur only in those rare instances where a company wants to contend with FDA or USDA, to 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.

- \textbf{Enhances Consumer Confidence in Food}--An important function of an effective recall is to maintain consumer confidence in the U.S. food supply. Consumers generally are surprised to discover that the government does not have the authority to mandate the recall of an unsafe food.\textsuperscript{200} Large-scale recalls that are mishandled by companies and government damage consumer confidence in the food supply.\textsuperscript{201} It is reasonable to believe that consumers will feel more assured in the safety of the U.S. food supply if the government has the authority to mandate a recall when a serious foodborne illness problem occurs.

- \textbf{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 expected costs of the recall are less than the costs of the implicit threat of liability, negative publicity, and/or regulatory action.\textsuperscript{202} This “costs” analysis, however, does not involve full consideration of the social costs--the harm to public health.\textsuperscript{203} Giving the government the authority to mandate recalls will more fully allow government agencies to account for social costs and will cause food companies to internalize these social costs when making safety decisions that affect the probability of recall.\textsuperscript{204}

- \textbf{Increases the Scope and Depth of a Recall}--The development of traceability systems is enabling food companies to track product distribution and to target recall activities.\textsuperscript{205} 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.

- \textbf{Reduces Liability Exposure of Food Companies}--Foodborne illnesses expose food companies to liability exposure under state product liability laws.\textsuperscript{206} Several law and consulting firms now specialize in foodborne illness lawsuits.\textsuperscript{207} Speeding \textsuperscript{582} up the recall process leads to less contaminated food consumed by consumers, which in turn leads to a reduction of liability exposure for companies.\textsuperscript{208} When faced with the prospect of an unsafe food product, companies have a conflict of interest: they want to remove the contaminated product from commerce, but they fear that too much adverse publicity generated by a recall may taint their brand image.\textsuperscript{209} 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.\textsuperscript{210}

- \textbf{Standardizes the 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 that the government has the authority to order the recall of 125,000 detachable plugs on power adapters (as it did in 2003, where
twelve plugs were reported as breaking open, but no injuries attributed to the breakage were reported\textsuperscript{211}, but does not have the authority to order the recall of hamburger contaminated with deadly \textit{E. coli 0157:H7} bacteria.

\textbullet \textit{Creates a Food Recall Policy Consistent With International Trading Partners}--Globally, countries are intensifying their efforts to improve food safety in response to increasing food safety problems and consumer expectations.\textsuperscript{212} Mandatory recall is an enforcement tool used by the United States’ major trading partners to ensure the removal of unsafe food products.\textsuperscript{213} 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.

\textbullet \textit{Positions FDA and USDA (FSIS) as Public Health Agencies}--FDA and FSIS within USDA are viewed as public health agencies.\textsuperscript{214} The credibility of FDA and FSIS in fulfilling this role depends on how well they protect public health.\textsuperscript{215} Having the ultimate authority to cause the removal of unsafe food in a timely and effective manner promotes the credibility of both of these agencies.\textsuperscript{216}

\textit{*583 C. Single Agency to Administer Recalls}

A recent GAO report criticizes the fragmented government agency approach to food safety.\textsuperscript{217} 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.\textsuperscript{218} The report concludes that a single independent food safety agency is needed to improve the effectiveness and efficiency of the current food safety system.\textsuperscript{219}

The report specifically criticizes the current dual agency responsibility over food recalls.\textsuperscript{220} The report finds that having both FSIS and FDA involved in the recall of unsafe food is confusing and nonsensical in many cases.\textsuperscript{221} 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.\textsuperscript{222}

\textbf{VI. CONCLUSION}

As stated by a USDA official at a December 12, 2002 public meeting, “[T]he time certainly is right to examine our recall process.”\textsuperscript{223} Both sides in the debate over whether the government should have the authority to recall 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 the 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 overreaching. Proponents of a mandatory food recall system are quick to point to highly-publicized failures of large-scale voluntary recalls in the past, and to the disparate treatment of food products and nonfood products that are 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, which 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 the 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.

Footnotes

\textsuperscript{a1} Mr. Roberts is a Research Associate Professor of Law and Director of the National Agricultural Law Center, University of Arkansas School of Law, Fayetteville, Ark.
For example, on Dec. 12, 2002, the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) 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. FSIS, Transcript of Proceedings: Improving the Recall Process, Wash., D.C. (Dec. 12, 2002) [hereinafter FSIS Public Meeting].

See USDA Revises State Count on BSE Recall; Says More Than 500 Firms Have Been Notified, 6 FOOD CHEM. NEWS, Jan. 7, 2004, at 6 (describing how consumer groups are using the BSE incidents as another opportunity to call for mandatory recall).


For a recently published best-selling book criticizing the modern food industry and the overall safety of food, see E. SCHLOSSER, FAST FOOD NATION (2002). For other similarly-postured books, see M. IVINS, BUSHWACKED 125-47 (2003); M. NESTLE, SAFE FOOD: BACTERIA, BIOTECHNOLOGY, AND BIOTERRORISM (2003).


See FSIS Public Meeting, supra note 1, at 178-82, 190-201.

See, e.g., FSIS Public Meeting, supra note 1 (statement of Caroline Smith DeWaal, Center for Science in the Public Interest (CSPI)).


Representative consumer advocates groups supportive of a mandatory food recall system include Safe Tables Our Priority (S.T.O.P.) and CSPI. To view these groups’ respective websites and positions on food recall, see http://www safetables.org and http://www.cspinet.org/ (last visited Dec. 14, 2004).

See AMERICAN FARM BUREAU FEDERATION, FARM BUREAU POLICIES FOR 2004, at 39 (2004) (adopting the following resolution: “We support granting the Secretary of Agriculture authority to impose mandatory quarantine and recall of meat products based on scientific testing and detection procedures.”).


16 See id.

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

18 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 the 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 CDC, *Escherichia coli* 0157:H7, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm#What%20is%20Escherichia%20coli%200157%3aH7 (last visited Dec. 9, 2004).

19 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 et al., supra note 14. See also CDC, *Salmonellosis*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_g.htm (last visited Dec. 9, 2004).

20 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. *Cooking may kill listeria*; 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 CDC, *Listeriosis*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/listeriosis_g.htm#symptoms (last visited Dec. 9, 2004).

21 *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 et al., supra note 14. See also CDC, *Campylobacter Infections*, at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/campylobacter_g.htm#What%20is%20campylobacteriosis (last visited Dec. 9, 2004).

22 *Norwalk-like virus* is an extremely common form of foodborne illness, although rarely diagnosed. It causes an acute gastrointestinal illness, usually with more vomiting than diarrhea, which resolves itself after a 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 et al., supra note 14.
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 increasing 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, 255-56 (2001).

See id.

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See FSIS Public Meeting, *supra* note 1, at 10.

See id.

GAO, *FOOD SAFETY, supra* note 6, at 5.


The distinctions between food products regulated by USDA and FDA often are 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); 7 C.F.R. § 55.2 (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).

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

The basic legal standard for what constitutes adulterated food is the same under the FDCA, the FMIA, and the PPIA. 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* sec. 2, at 6 (2d ed. 2000).


GAO, FOOD SAFETY, supra note 6, at 3.

News headlines indicate that it is commonly misperceived that food products are subject to mandatory recall by the government (e.g., “FDA Orders Peanut Butter Recall,” and “FDA Orders 6,500 Cases of Red-Dyed Mints Recalled”). Such headlines inaccurately suggest that the agency can order these recalls. See CFSAN, Industry Affairs Staff Brochure, supra note 38.

See FSIS Public Meeting, supra note 1, at 20-21.

A warning letter from FDA is a written communication to a company asserting that there has been a violation of the FDCA or its implementing regulations. The letter typically will request that the company inform the agency about the action the company will take to correct the alleged violation. The warning letter generally will 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 36, sec. 2, at 13.

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

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 36, sec. 2, at 17.

USDA retains a product when an in-plant inspector places a “tag” on a product located at a federally-inspected facility that he or she believes to be adulterated or misbranded. Once tagged, the 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.

In a seizure proceeding, the government initially seeks a court order authorizing the U.S. 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 also will file a complaint requesting that the product be “condemned” and destroyed. See id. at 16.

The FDCA, the PPIA, and the FMIA have strong criminal provisions that essentially are 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 the 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 the PPIA and the FMIA, any violation involving the distribution or attempted distribution of an adulterated food is a felony. See id. at 18.

See id. at 12.


See FSIS Public Meeting, supra note 1, at 17-21.

See *id.*

See FSIS Public Meeting, *supra* note 1, at 181.


See GAO, *FOOD SAFETY, supra* note 6, at 5.


See GAO, *FOOD SAFETY, supra* note 6, at 6.

See *id.*

See *id.* at 7, 11.

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 26.

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.*


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 example is the inclusion 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 RECALL WORKING GROUP, *supra* note 26.

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 Dec. 23, 2003 (the BSE incident) was designated Class II by FSIS 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 consisted of cuts that would not be expected to be infected or to 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.htm (last visited Feb. 16, 2005).
An example of a Class III recall would be improperly labeled processed meat in which added water is not listed on the label as required by federal regulations. See id.

See OIG, FSIS & CONAGRA, supra note 3, at 3.

See GAO, FOOD SAFETY, supra note 6, at 29.

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 Fact Sheet, Food Recalls, supra note 38. The public can request to receive FSIS press releases and other FSIS materials by subscribing to the FSIS Constituent Update, available at www.fsis.usda.gov/oa/update/subscribe.asp (last visited Jan. 9, 2005). The news release is posted on the FSIS Recall website at www.fsis.usda.gov/Fsis_Recalls/index.asp (last visited Jan. 9, 2005).

Recall Notification Reports (RNRs) 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 FSIS Fact Sheet, Food Recalls, supra note 38.

The RNRs are posted on the FSIS Recall website at http://www.fsis.usda.gov/Fsis_Recalls/index.asp (last visited Dec. 9, 2004).

FDA’s recall regulations request that a company notify FDA when a company removes or corrects a distributed product. See CFSAN, Industry Affairs Staff Brochure, supra note 38.

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

See id. (describing CFSAN).

See id. (describing ORA).

FDA’s Regulatory Procedures Manual describes procedures for FDA staff to use in handling recalls of FDA-regulated food products. See GAO, FOOD SAFETY, supra note 6, at 31.

See id. at 32.

See id. at 32-33.

Examples of Class I recalls are foods found to contain botulinal toxin and foods with undeclared allergens. CFSAN, Industry Affairs Staff Brochure, supra note 38.

See id.

Examples of a 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.

See GAO, FOOD SAFETY, supra note 6, at 33.
See id. at 34.

See id.

This is found through FDA Enforcement Report, a weekly publication, available at http://www.fda.gov/opacom/alerts.html (last visited Jan. 9, 2005).

See NFPA, Fact Sheet on Food and Beverage Product Recall (on file with author).

21 C.F.R. § 7.3(j); see also NFPA Fact Sheet, supra note 86.

21 C.F.R. § 7.3(k); see also NFPA Fact Sheet, supra note 86.

USDA and FDA documented more than 3,700 food recalls from the mid-1980s through 1999. GAO, FOOD SAFETY, supra note 6, 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, Apr. 2003, available at http://www.ers.usda.gov/AmberWaves/April03/Features/WeighingIncentives.htm (last visited Feb. 16, 2005).

See FSIS Public Meeting, supra note 1.

See FSIS, REPORT OF THE RECALL WORKING GROUP, supra note 26, at 14.


See GAO, FOOD SAFETY, supra note 6, at 37.

See id.

See FSIS Public Meeting, supra note 1, at 191.

See id. at 20-21.


See MEAT INDUS. INTERNET NEWS SERV., supra note 10.

See FSIS Public Meeting, supra note 1, at 179-82.
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 GAO, FOOD SAFETY, supra note 6, at 20.


See id.

See id.

See FSIS Public Meeting, supra note 1, at 181-82.

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 & Ballenger, supra note 89.

See Peter Perl, Poisoned Package, WASH. POST MAG., Jan. 16, 2000, at 8.


See Perl, supra note 106, at 8.

See id.


See id.


See Weiss, supra note 110, at A11.

See id.

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, Mar. 5, 1999, available at http://www.freep.com/news/health/qlegis5.htm (last visited Jan. 9, 2005).

See Weiss, supra note 110, at A11.

See CNN INTERACTIVE, Hamburger Recall Rises to 25 Million Pounds (Aug. 21, 1997), at


120 See id.

121 See Taylor & Young, supra note 116.


123 See MEAT INDUS. INTERNET NEWS SERV., supra note 10.


126 See id.

127 See id.

128 See id.


130 See FDA Talk Paper, supra note 128.

131 See id.

132 See OIG, FSIS & CONAGRA, supra note 3, at 3.

133 See id. at 1 n.2.

134 See id.
See id. at 1.

See id.

See id.

See id. at 2.

See id.

See id.

See id. at 1.

See id.

See id. at ii.

See id.

See id.

See id. at 16-94.

See McKee, supra note 37.

See id.

See id.

See id. at 1.
See id.

See McAllister, supra note 143.


See Deliganis, supra note 49, at 719.

See FSIS Public Meeting, supra note 1, at 191.

See id. at 179-82.

Six federal agencies with different jurisdictions have joined together to create a “one-stop shop” website for U.S. government recalls. See http://www.recalls.gov (last visited Feb. 16, 2005).


See 21 U.S.C. § 360h(b) (FDCA § 518).

See 21 U.S.C. § 350a(e)(1)(B) (FDCA § 412 (e)(1)(B)).


See MEAT INDUS. INTERNET NEWS SERV., supra note 10.

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 128; see also SAFER Meat, Poultry, and Food Act, supra note 157.

See 15 U.S.C. § 2064(b) (CPSA § 15(b)).


See id.

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.

Former Secretary of Agriculture, Dan Glickman, noted the discrepancy between USDA’s 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 116.

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 USDA Press Release, Glickman Proposed Law, supra note 122.

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

Under the administrative detention provision of the new Bioterrorism Act, for the first time, FDA will have the 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, Pub. L. No. 107-188, § 143, 116 Stat. 594 (2002). See also id. §§ 414, 704 (codified at 21 U.S.C. §§ 350c and 374(a), respectively, setting forth recordkeeping requirements).


See id. at 16.

See id.

Recommendation No. 12 in the GAO report issued following the ConAgra recall suggested that FSIS should seek such authorizing legislation. See OIG, FSIS & CONAGRA, supra note 3, at 42.

See id. at 43.

See generally notes 106-09 and accompanying text.

See id.

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.


Critics of mandatory recall authority have expressed concern that this authority would “present the opportunity for potential administrative abuse,” Hodges, supra note 97. Testimony to the Senate Committee from NFPA 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 INDUS. INTERNET NEWS SERV., supra note 10.

Both the FSEEA and SAFER Act proposals provided an opportunity for an informal hearing as to why the food product should not be recalled no later than two business days after the issuance of the recall order. See USDA Press Release, Glickman Proposed Law, supra note 122.

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

*See USDA Press Release, Glickman Proposed Law, supra note 122.*


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. Once 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.


*See USDA Press Release, Glickman Proposed Law, supra note 122. See also FSIS Backgrounder, supra note 194.*

*See generally GAO, BIOTERRORISM THREAT, supra note 4.*

*See Caroline Smith DeWaal, Protecting the Public Under the New Bioterrorism Act, Statement at the National Food Policy Conference, Wash D.C. (May 9, 2003), available at http://www.cspinet.org/foodsafety/new_bioact.html (last visited Feb. 16, 2005) (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).*


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.


See id.

See id.

See id.


See id. at 27.


See Thomsen & McKenzie, supra note 202, at 536.

See O’Reilly, supra note 188, at 901-02.


See FSIS Backgrounder, supra note 194.

Due to USDA’s responsibilities to market meat, the claim has been made that USDA is not by its nature a public health agency. This observation generally is made in support of a single, separate regulatory food safety agency. See Aparna Surendran, Meat Inspection Suffers Because Industry, Government at Odds, PHIL. INQUIRER, June 4, 2003, available at http://www.centredaily.com/mld/centredaily/news/6010859.htm (last visited Feb. 16, 2005) (remarks by Carol Tucker Foreman, Head of the Consumer Federation of America). See generally 59 FOOD & DRUG L.J. 383-458 (2004) (special issue devoted to multi-author discussion re: establishing single food regulatory agency).

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 1, at 10.
At the time of the GAO report of 2000, which criticized the recall process of USDA and FDA, the GAO noted USDA’s position that it needed mandatory recall authority to improve food safety and supported proposed legislation. GAO, FOOD SAFETY, supra note 6, at 20. Dr. Catherine Woteki, former Undersecretary for Food Safety, stated that USDA “believe[s] that in order to truly protect the public health, USDA needs the authority to mandate a recall when voluntary efforts fail.” Catherine Woteki, Remarks prepared for public meeting to discuss the report, “Improving Recalls at FSIS,” Wash., D.C. (Oct. 5, 1998), available at http://www.fsis.usda.gov/OA/speeches/1998/cw_recall.htm (last visited Dec. 9, 2004).

See GAO, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP (GAO-04-588T) (Mar. 30, 2004) [hereinafter GAO, FEDERAL FOOD SAFETY AND SECURITY SYSTEM]. See also GAO, FOOD SAFETY AND SECURITY: FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD (GAO-02-47T) (Nov. 8, 2001); GAO, FOOD SAFETY: FUNDAMENTAL CHANGES NEEDED TO IMPROVE THE NATION’S FOOD SAFETY SYSTEM (GAO/T-RCED-98-24) (Oct. 8, 1997); and GAO, FOOD SAFETY AND QUALITY: UNIFORM, RISK-BASED INSPECTION NEEDED TO ENSURE SAFE FOOD SUPPLY (RCED-92-152) (June 26, 1992).

See GAO, FEDERAL FOOD SAFETY AND SECURITY SYSTEM, supra note 217, at 2.

Id. at 17-20.

Id. at 13-15.

Id. at 15.

Id.

FSIS Public Meeting, supra note 1, at 5.