



**Building a Modern Food Safety System:
For FDA Regulated Foods**

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***“The FDA is an agency in crisis.
We need to act now.”***

Representative Henry Waxman (D-CA)

(May 2, 2007)

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Preface

The food safety system in America is broken. As a result hundreds of thousands of Americans may require hospitalization and as many as 5,000 may die this year from preventable foodborne illnesses.

Foods regulated by the Food and Drug Administration (FDA) have caused a number of recent national outbreaks and recalls:

- August and September 2006: *E. coli* in bagged spinach sickened 204 people in 26 states, killing three.
- September 2006: *Salmonella* found in tomatoes sickened 183 people in 21 states.
- December 2006: Iceberg lettuce contaminated with *E. coli* at Taco Bell and Taco John restaurants sickened 152 people.
- February 2007: Peter Pan peanut butter contaminated with *Salmonella* sickened 425 people in 44 states.
- February and March 2007: One hundred brands of pet food distributed nationwide were recalled after the FDA received thousands of complaints of illnesses and deaths among cats and dogs due to melamine contamination.
- June 2007: Veggie Booty snacks caused 65 illnesses in 20 states from *Salmonella*.
- July 2007: Canned chili and meats containing *Clostridium botulinum* were recalled after causing eight illnesses in three states.
- August 2007: Almost one year after the September *E. coli* outbreak a nationwide recall of fresh spinach followed discovery of *Salmonella* in a test batch.

Foods regulated by the U.S. Department of Agriculture (USDA) have also triggered many nationwide outbreaks and recalls:

- January to October 2007: Illnesses were reported in 31 states before Banquet Turkey and Chicken Pot Pies carrying *Salmonella* were recalled in October.
- September 2007: The second largest beef recall in U.S. history (21.7 million pounds) began after *E. coli* contamination was found in Topps Frozen Hamburgers and Patties.
- June 2007: Ground beef contaminated with *E. coli* caused 14 illnesses leading to a recall of ground beef that had been shipped to 11 western states.

These outbreaks have shaken consumer confidence in the safety of their food supply. Congress must act to create a strong food safety system that has adequate resources and authority to meet the demands of a modern, globalized food system and restore public confidence – before another crisis occurs.

This white paper addresses problems and solutions linked to FDA regulated foods.

“When Americans purchase a snack, eat at a restaurant, or sit down to dinner with their families, they should be able to expect that the food they eat will nourish them, not make them ill.”
Senator Mike Enzi (R-WY)
(September 10, 2007)

Building a Modern Food Safety System

Introduction

Congress has an unprecedented opportunity to fix a broken food safety system. Recent nationwide outbreaks have exposed extensive gaps in protections of the food supply, prompting calls for reform from industry and consumers and hearings in Congress. This white paper examines the issue of food safety, reviews the status of current efforts to address problems in our food safety system, and recommends steps Congress should take to address those problems. Finally, it examines legislation currently pending in Congress covering FDA and discusses how those bills fit into a broader reform effort.

Why Food Safety is Important

Each year 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards in the United States, according to the Centers for Disease Control and Prevention (CDC).¹ Since September 2006, a number of nationwide outbreaks and recalls have exposed gaping holes in the safety net guarding U.S. consumers from contaminated food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; pet food with toxic chemicals; botulism in canned chili that remained on store shelves weeks after the initial recall; 22 million pounds of ground beef recalled due to *E. coli* contamination – each of these tragedies has demonstrated a different problem with our system of regulating the food supply.

“Indeed our current system is broken – it was not designed strategically, and it does not function adequately today.”

**Rep. Rosa DeLauro
(D-CT)
(September 25, 2007)**

The impact of these outbreaks has been devastating. Last year, consumers’ confidence in the food they purchase at restaurants and grocery stores declined by 16 percent, according to the annual survey of the Food Marketing Institute.² USA Today reported in July that 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.³ The food industry has felt the impact of declining confidence as spinach farmers experienced a loss of \$350 million⁴ after the September 2006 outbreak, and more recently Topps shuttered its meat grinding plant.⁵

Cost provides another measure for assessing the need for action on foodborne illnesses. The U.S. Department of Agriculture’s (USDA) Economic Research Service estimated the economic costs of hospitalizations, lost productivity and death from the five most common pathogens as \$6.9 billion in 2000.⁶ The greatest percentage of this cost is from premature death which occurs primarily in people over age 65 for *Salmonella* and children under age five for *E. coli* O157:H7.⁷ The elderly, people with compromised immune systems, pregnant women, children, and infants are most at risk of serious illness from foodborne disease. Many pathogens, including *Salmonella*, *Campylobacter* and pathogenic *E. coli* can lead to chronic illness and reduced life expectancy.⁸

In 2007, the Government Accountability Office (GAO) designated food safety as a high-risk federal government program.⁹ Agriculture, including all food production, constitutes about 13 percent of the gross domestic product and is the largest industry and employer in the U.S.

Yet federal food safety efforts are hampered by inadequate funding and confusion caused by the way 100-year-old food safety laws and their accompanying bureaucracies have evolved. Federal food safety expenditures are not distributed evenly across all the high risk foods, but instead are concentrated on meat and poultry products regulated by the USDA. In fact, while the USDA regulates one-fifth of the food supply causing 27 percent of outbreaks, its food safety appropriations are *twice* that given to the Food and Drug Administration (FDA).¹⁰

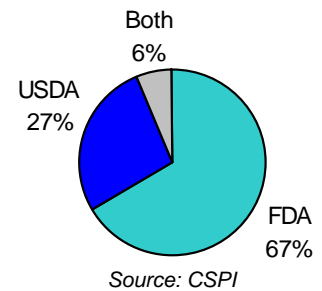
The USDA has the resources to inspect meat and poultry plants daily, as required by law. In contrast, the FDA, which regulates 80 percent of the food supply, inspects food facilities it oversees on average just once every 10 years. The FDA's food program has a current funding shortfall of \$135 million, which an FDA budget official described as equivalent to a 24 percent budget cut.¹¹ Overall consumer confidence in the FDA has plummeted. A Harris Poll has documented that those who thought the FDA was doing an "excellent" or "good" job dropped from 61 percent in 2000 to 36 percent in 2006.

Recent outbreaks are just the latest symptom of an agency that is overwhelmed by responsibility, but lacks the staff and resources to function effectively. The FDA responds to crisis after crisis rather than preventing them. Current FDA funding shortfalls have reached a critical level and budget cuts have left the agency with fewer inspectors even as their workload continues to increase. In fact, since 1972, inspections conducted by the FDA declined 81 percent. Since 2003, the number of FDA field staff dropped by 12 percent and between 2003 and 2006, federal inspections dropped by 47 percent.¹²

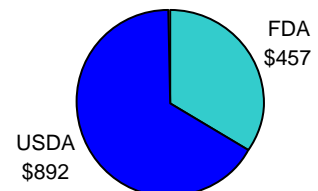
The system is also fragmented among 12 federal agencies that share responsibility for regulating food. This results in a chaotic and inefficient system.¹³ The three main agencies divide duties as follows: the USDA inspects meat and poultry; the FDA oversees the safety of all other foods; and EPA sets tolerances for pesticides in food.

Why Reform is Needed

Foodborne Illness Outbreaks by Regulatory Agency



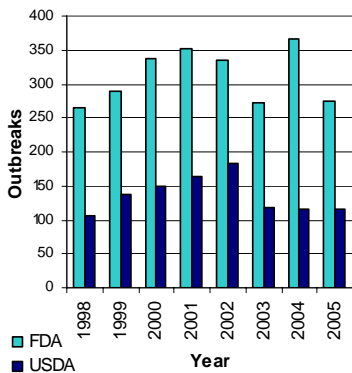
Food Safety Expenditures FY 2007 (\$ Millions)



“What has been made clear by the pet food recall and other outbreaks of foodborne illness is that the FDA is a severely underfunded and understaffed agency.”

**Senator Richard Durbin
(D-IL)
(July 17, 2007)**

Yearly Trends in Foodborne Illness Outbreaks



Why Now

This regulatory system proves confusing, wasteful and highly ineffective. For example:

- A frozen *cheese* pizza is subject to inspection by the FDA, which usually inspects the average food manufacturing facility only once every 10 years. A frozen *pepperoni* pizza falls under the jurisdiction of the USDA, which performs almost daily inspections.
- Imported foods are treated differently depending on whether they are regulated by the FDA or the USDA. While the USDA approves all foreign meat and poultry plants that want to export to the U.S., the FDA cannot even visit the foreign food processors that are linked to outbreaks of illness in this country without the invitation of the foreign government.
- Lettuce and other leafy greens have caused outbreaks from strains of *E. coli* and *Salmonella* previously associated with meats. Although the USDA inspectors visit farms, they do not inspect the crops for safety. The FDA, the food safety agency most likely to regulate the safety of leafy greens, does not inspect on the farm unless there is an outbreak. Fresh vegetables of all kinds thus fall through a huge crack in our current food safety system.

The FDA has authority to implement improvements under both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, but neither of these laws gives the agency clear mandates from farm-to-table when it comes to food safety. The Federal Food, Drug and Cosmetic Act sets up a reactive structure in which the agency is truly empowered only when food is found to be adulterated or misbranded. This is very different from the Federal Meat Inspection Act, for example, which requires government inspectors to approve every meat or poultry carcass before it can be sold.

Recent events are signaling that the time for reform is now. Congress appears ready to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission. The Food and Drug Administration Amendments Act of 2007 includes a Sense of Congress stating this intent. The Senate and the House of Representatives have held numerous hearings on food safety in the past year. (See Appendix A.) The emergence of coalitions of traditionally estranged consumer and industry organizations, such as the Coalition for a Stronger FDA and the FDA Alliance, gives Congress a unique opportunity to appeal to many constituencies as it rebuilds the agency. But the need is great. In fact, the industry and consumers together have estimated that the food program at the FDA needs additional funding of \$115 million¹⁴ to \$140¹⁵ million for that agency to meet its program requirements just for 2008.

CSPI's Recommendations for Improving America's Food Safety System

The heart of a modern food safety system lies in preventing – not merely responding – to food safety problems. Mandatory process controls, coupled with government-enforced performance standards, should be the central features of a new system. These systems can be used from farm-to-table and with both domestic and imported foods.

Most foodborne illnesses are the result of contamination that occurs during production, processing, shipping, or handling. These lapses result in illness, recalls, and loss of public confidence in the safety of our food supply. While in-plant and border inspections form the core of the government's food safety program, inspection is often little more than a spot check on performance. The reality is that the industry holds the key to addressing and preventing food contamination.

The safety and security of the food supply requires an integrated, system-wide approach to preventing foodborne illness, with oversight by federal food safety agencies. Preventing food contamination can be done using programs of quality assurance and preventive process control, such as Hazard Analysis and Critical Control Points (HACCP), that are developed by individual companies. These programs are already widely used, and they can be incorporated into food production systems at all levels.

HACCP systems are already mandated in some segments of the food supply, including seafood, juice, and all types of meat and poultry products – both raw and processed. A modern food safety system mandated by Congress should require the FDA to implement HACCP or HACCP-like systems for all food processors and tie agency inspections to an audit of these systems. These industry-derived programs should be coupled with performance standards, such as limits on the incidence or levels of contamination, or reductions in pathogen levels, that are established by the government. Monitoring and enforcement of the standards are key elements of inspection in a successful food safety program. This includes laboratory testing to ensure that process controls are working effectively.

Process Controls & Performance Standards to Prevent Outbreaks and Recalls

“We want stronger federal oversight. We need more aggressive steps from FDA to see that we’re implementing best practices.”
**Tom Stenzel, United Fresh Produce Association
(September 27, 2007)**

Inspections & State/Federal Cooperation

“Without regular inspections and analysis there is little incentive for food producers and importers to ensure that our food supply is free from harmful and sometimes fatal contaminants.”

Representative John Dingell (D-MI)
September 20, 2007

Congress should require the FDA to set performance standards based on the best-available science on hazards linked to specific food products and other public health considerations. Standards can also be used to ensure that food is produced in a sanitary manner that limits the likelihood of contamination by pathogens, chemicals, or even physical hazards, like glass or metal. The HACCP and performance-standard approaches would focus food safety activities on prevention and would permit more efficient and effective government oversight through analysis of records as well as visual and laboratory inspection.

Unlike for makers of drugs and medical devices, the FDA lacks a minimum inspection mandate for the food companies it regulates, and its current staff is able to inspect food plants on average only once every 10 years. These gaps contributed to the massive peanut butter recall in winter 2007 and the canned food recall in summer 2007, as well as many other outbreaks and recalls that might have been prevented with a stronger oversight program.

Inspections. Inspection of commercial food processors is an integral part of the food safety system. It provides an audit of food safety programs managed by the establishments and ensures accountability for meeting food safety performance standards. The FDA is responsible for overseeing approximately 210,000 domestic food establishments. However, the number of field staff has dropped by 12 percent since 2003, which has resulted in significantly fewer inspections. In fact, between 2003 and 2006, FDA food safety inspections have dropped by 47 percent.

Imported foods receive even less oversight from the FDA. Less than one percent of the food imported into the U.S. is inspected. This leaves the nation’s food supply vulnerable to substandard foods from foreign countries where rules and regulations governing food are often more lax. Under the Bioterrorism Act of 2002, Congress gave the FDA additional authorities including requiring foreign manufacturers and shippers to register with the agency. They are also required to alert the FDA when food is being shipped to the U.S.

Despite these additional authorities, the FDA still lags behind the USDA in inspection authority. The USDA is required by law to do continuous inspections at meat and poultry plants. All meat and poultry products must be inspected and approved for sale by the USDA. The Federal Food, Drug and Cosmetic Act does not require pre-market approval for FDA-regulated food products. Additionally, the FDA does not enforce any requirement that foods imported into the U.S. be produced under food safety systems that are equivalent to or better than those used in the United States.

The FDA must have congressionally mandated authority to create a system of risk-based inspection, based on the type of food handled and the processes used. Under this system, food establishments would receive an inspection classification or rating based on public health considerations and scientific evidence to determine the frequency and timing of inspections. All facilities now regulated by the FDA should be subject to a mandatory inspection frequency, with higher risk facilities inspected much more often (e.g. daily, monthly, or quarterly). This system of inspection would allow for the best use of government resources while still providing safety checks along the entire farm-to-fork continuum.

Over all, CSPI believes the inspection program should:

- Be comprehensive and designed to determine if food establishments have process controls in place and are meeting performance standards;
- Include product sampling at both domestic and foreign food establishments; and
- Be based on a risk-based inspection schedule for the food establishments under FDA's purview and include the authority to go on the farm to address sources of contamination before outbreaks occur.

Federal & state cooperation. State inspection programs are an important component of the nation's food-safety inspection system. The FDA has increasingly relied heavily on states to do inspections of FDA-regulated products because of budget and staff constraints. The agency needs a national food safety plan to assure that state food inspection programs are capable of and in fact provide a level of public health inspection that meets FDA standards. The FDA must have the resources to work with states to carry out food safety activities in a coordinated cost-effective manner. The agency must provide both technical and advisory assistance to the states, while also supporting work on the state level to strengthen inspection programs and recalls.

Each year the average American eats about 260 pounds of imported foods (13 percent of the total diet) that are regulated by the USDA or the FDA. But while the USDA has a multi-tiered, legislatively-mandated program for preventing the importation of unsafe meat and poultry products, the FDA's program is largely reactive and relies on a thin line of inspection to try to catch problems at the port of entry.

Food Imports

***“Foods from abroad
and foods grown at
home have risks.”***
Senator Mike Enzi
(R-WY)
(September 10, 2007)

Weaknesses in FDA’s oversight of imports are causing real problems for consumers. Imported fruits and vegetables, for example, have caused numerous large and sometimes deadly outbreaks. Imported berries, melons and green onions, coming from areas with substandard hygiene practices, have sickened thousands of Americans in the last ten years. More recently, contaminated and mislabeled wheat flour incorporated into pet food and animal feed raised real concerns over the safety of animals.

Each year, the FDA inspects less than one percent of the growing number of imported food shipments. Unlike the USDA, the FDA does not review and approve national programs for countries that want to export to the U.S. or even visit the individual plants before they begin shipments. This is quite different from the program for approving imports of USDA-regulated meat and poultry products, where both national food safety programs and plants must be approved prior to shipping and 100 percent of imported shipments are visually checked at the border.

The FDA must have the authority to establish a system under which governments or foreign food establishments seeking to export food to the U.S. can certify their food safety system. This certification should demonstrate that the food they are exporting meets standards of food safety, inspection, labeling, and consumer protection that are at least equivalent to foods produced in this country.

Prior to approving a certification request by a foreign government or firm, the FDA should review and audit its food safety program. The FDA should be able to withdraw certification from a foreign government or firm if a food product is linked to an outbreak of human illness in the U.S., or if the foreign importer no longer meets equivalency standards. Refusing to allow the FDA to conduct routine audits and investigations of facilities should also be grounds for withdrawing certification.

Certification is very different from the open-border approach that is currently used and would provide much greater assurance of safety for consumers. The ultimate goal of a certification program is to have someone that has reviewed the exporting facility’s food safety program and can vouch for it. It is highly likely that companies would develop new mechanisms, like forming into cooperatives, to become an alternative to firm-by-firm certification. Some have also proposed that certification should be voluntary, but provide a faster route to entering U.S. commerce.

The challenges of approving food coming into the U.S. from all parts of the world are certainly enormous. What is critically important is that the imported food be at least as safe as food produced

domestically, and that the programs both in the U.S. and overseas control for all likely hazards.

Today, the FDA conducts limited research related to pathogenic microorganisms and other food contaminants. More FDA-directed research is needed, however, to support FDA regulatory programs, state food-safety agencies, and the food industry's own efforts.

Public health assessment. The current public health system in the U.S. has limited capacity to identify and track the causes of foodborne illness. FoodNET, an active public health surveillance system run by the CDC, is beginning to produce more information on illnesses associated with foods, but this information needs to be shared on a more timely basis with other governmental agencies as well as the public. More thorough outbreak investigations and analysis of available information is needed to identify the root causes of food safety problems and develop preventive interventions. Additionally, a sampling system is required to assess the nature and frequency of foodborne hazards in food. Such investigation and analysis would allow the public health agencies that regulate food to rank products based on risk to human health and help to identify appropriate industry and regulatory approaches to minimizing hazards in food.

Research. Research is a vital tool in the effort to reduce the incidence of foodborne illness and is integral to the programs of all public health agencies. Research is needed to evaluate the effectiveness of control and prevention strategies and to conduct risk assessments. It is also needed to improve sanitation and food safety practices during processing. The FDA and industry must improve techniques to monitor and inspect food and develop efficient and sensitive methods for detecting contaminants and reducing harmful pathogens.

Public education and advisory system. Public education is another essential component of improved food safety. Rates of illness could be reduced if food preparers and handlers were better informed of risks and related safe-handling practices. Educational programs that promote better understanding and practice of proper food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. Programs are also needed to help health professionals improve their diagnosis and treatment of food-related illness and to advise individuals at special risk.

Research and Education

Solutions to On-Farm Food Safety Issues

“It seems these fresh-produce recalls have become the rule rather than the exception in the United States – and that is unacceptable.”
Senator Tom Harkin
(D-IA)
(September 20, 2007)

Enforcement Authority

Since 1998, fresh fruits and vegetables have been linked to a large number of outbreaks and associated illnesses. Given the importance of produce consumption to a healthy diet, it is imperative that the FDA take concrete steps to reduce the incidence of foodborne illness associated with fresh produce. While many produce outbreaks occurred prior to 2006, last September’s spinach outbreak provided direct evidence that these problems can originate on the farm and therefore require farm-based solutions. In fact, the FDA traced the exact strain of the *E. coli* bacteria that made people sick to a California spinach farm, finding it in nearby manure piles, in a creek, and even in a wild pig.¹⁶

Today, the FDA does not have specific, mandatory standards that apply to farmers who grow food for human consumption. Instead, the agency relies on very general Good Agricultural Practices and other voluntary guidance that is not enforceable under the law.

Due to gaps in the statutes and confusing authority between the FDA and the USDA, Congress must give the FDA a specific mandate to develop and enforce an on-farm food safety program:

- The FDA should require all growers and processors to keep a written food safety plan based on the principles of preventive process control and designed by the farmer to address the specific environmental conditions on the farm.
- The FDA should develop specific, standardized, and enforceable criteria for use by the farmers for such items as water quality, manure use and management, and worker sanitation.
- Processors must mark packaging to ensure easy traceback when fruits and vegetables are implicated in an outbreak. Package markings must be specific enough to extend all the way back to the farm/farms of origin.
- Finally, the written plans should be audited at least once per growing season by the FDA, the states, and/or the buyers (the FDA should review the state and private audits.)

Today, the FDA’s food safety program does not have the modern enforcement tools used by other agencies or even the authorities the agency has to regulate drugs and medical devices. The FDA can take a few limited actions, such as issuing warning letters, urging companies to voluntarily recall product, and getting court-ordered seizures, injunctions, and criminal penalties. These weak tools do not equip the FDA to protect consumers from the threat of foodborne illness. The following new authorities are essential to modernize FDA’s food surveillance and enforcement:

Recalls. Today recalls of contaminated food are voluntary. The Federal Food, Drug, and Cosmetic Act does not give the FDA the power to order a producer to recall a food product, with the exception of infant formula. If a firm does not recall a product, the FDA can go to court to seek an injunction or seizure of the product. But these legal actions waste precious time, and if a food company or importer fails to recall a contaminated product, it can continue to reach consumers. Mandatory recall authority would ensure that recalled foods are removed from the market more quickly and effectively.

Traceback. The FDA needs the authority to identify the source of foods that pose health hazards to consumers. The ability to trace a contaminated product back to the source of production would allow the agency to conduct more rapid and thorough investigations. It would also allow producers to more precisely identify the source of a problem in order to improve production practices and could help narrow the scope of recalls by more quickly identifying the specific plant or country of origin.

Detention. If an FDA inspector has reason to believe that a domestic or imported food is unsafe, adulterated, or misbranded, the agency must have the authority to temporarily detain the food for a reasonable time. If it is determined that the detained food cannot be brought in compliance with food safety requirements, the FDA should be able to condemn the food.

Civil and Criminal Penalties. An essential element of any enforcement capability is the power to penalize manufacturers and producers for violating food safety laws as a deterrent to future violations by the guilty party and others. Food companies must be subject to civil and criminal penalties for violating food safety laws. A person that has been harmed as a result of a violation of food safety law should have the power to commence a civil action.

Whistleblower Protection. Federal employees must be protected from the threat of being fired, demoted, suspended, or harassed as result of providing information or assisting in the investigation of a violation of a food safety law.

Modernizing Food Law: Legislation Pending in the 110th Congress

The following bills incorporate aspects of the reform principles laid out above. (See Table 1 for a comparison of the current legislation to CSPI's food safety principles.)

S. 654 and H.R. 1148, the Safe Food Act. Senator Richard Durbin and Representative Rosa DeLauro. Establishes the Food Safety Administration to administer and enforce food safety laws. The Food Safety Administration would: (1) promulgate regulations to ensure the security of the food supply from all forms of contamination; (2) implement federal food safety inspection, enforcement, and research efforts; (3) develop science-based standards for safe food; and (4) prioritize federal food safety efforts and deployment of resources to reduce food-borne illness. The Food Safety Administrator would be responsible for administering the national food safety program and establishing: (1) standards for processors of food and food establishments; (2) a certification system for importers of food to the United States; (3) requirements for tracing food and food producing animals from point of origin to retail sale; (4) an active surveillance system of food, food products, and epidemiological evidence; (5) a sampling system to monitor contaminants in food; (6) the rank of hazards in the food supply; (7) a national public education campaign on food safety; and (8) research programs relating to food safety. The Administration is provided with tools to enforce the prohibitions in the bill through administrative detention, condemnation, temporary holds, recall, civil and criminal penalties for violations of food safety laws, whistle blower protection, and civil actions.

Representative DeLauro announced plans to introduce a new bill that applies many of the same principles but with less dramatic jurisdictional shifts. It would separate the current Food and Drug Administration into two parts: a Food Safety Administration and a Federal Drug and Device Administration, both housed within the Department of Health and Human Services. It would place a new Commissioner of Food Safety and Nutrition in charge of implementing a modern food safety law with mandatory recall authority, inspection authority, and responsibility for setting and monitoring compliance with science-based performance standards for safe food production. The bill would leave meat, poultry, and egg inspections under the USDA.

H.R. 3624, the Consumer Food Safety Act. Representative Frank Pallone. Establishes a national program to protect human health by ensuring the safety of the food supply through (1) adopting regulations regarding harmful substances in food, registration of facilities, sanitary food processing, proper labeling, process

Table 1. Pending Food Safety Legislation Compared to CSPI's Food Safety Principles

1. Requires secretary to set tolerance levels.
2. Inspection of imports only.
3. Limited to research on testing and detection techniques.
4. Civil penalties only.
5. Covers processors but not farms.
6. Certificate of safety rather than certification.
7. Criminal penalties only.

Bill Name	Process Controls	Performance Standards	Inspections	Imports	Research and Education	On Farm	Enforcement				
							Recall	Traceback	Detention	Penalties	Whistleblower
S. 654/H.R. 1148, Safe Food Act	X	X	X	X	X	X	X	X	X	X	X
H.R. 3624, Consumer Food Safety Act	X	X ¹	X	X	X		X	X	X	X	X
H.R. 3610, Food and Drug Import Safety Act			X ²	X	X ³		X			X ⁴	
S. 1776, Imported Food Security Act			X ²	X	X ³						
S. 1274/H.R. 2108, Human and Pet Food Safety Act				X			X			X ⁴	
S. 2077, Fresh Produce Safety Act	X		X		X	X			X ⁵		
H.R. 3484, SAFER Meat, Poultry, and Food Act							X			X ⁴	
H.R. 3485, TRACE Act								X			
H.R. 2997, Assured Food Safety Act			X ²	X ⁶						X ⁷	
S. 2081, Food and Product Responsibility Act							X				
H.R. 3937, Food Import Safety Act				X			X				
S. 1292, Meat and Poultry Products Traceability and Safety Act								X			

controls, and inspections of registered facilities; (2) setting tolerances to limit the quantity of contaminants in food; (3) establishing a system to ensure the safety of imported food; (4) including food in an active surveillance system; (5) establishing guidelines for a sampling system of food products; (6) ranking food categories based on their health hazard; and (7) designing and implementing a food safety education program. Provides the FDA with mandatory recall authority and allows the FDA to impose traceability requirements on food products to assure the protection of the public health.

H.R. 3610, the Food and Drug Import Safety Act.

Representative John Dingell. Provides for a user fee to fund increased border inspections and research on testing and detection methodologies for identifying adulterants on imported food. To protect the food supply the bill (1) restricts food imports to entry at metropolitan ports with a Food and Drug Administration laboratory; (2) establishes a program to allow

“There's a bipartisan consensus the FDA needs an overhaul,” said Representative Tom Davis, a Virginia Republican.

**Bloomberg News
(May 2, 2007)**

importers to voluntarily agree to abide by specified food and security guidelines in return for expedited movement through the inspection process; (3) provides for certification of foreign governments or importers as meeting U.S. safety standards; and (4) increases civil penalties for the manufacturer or importer of adulterated food.

S. 1776, the Imported Food Security Act. Senator Richard Durbin. Provides for a user fee on food imported into the United States to fund border inspections and research on testing and detection methodologies for identifying adulterants on imported food. Establishes a certification system for a foreign government or foreign food establishment seeking to import food to the United States and authorizes the Secretary to withdraw the certification of any food importer that fails to meet U.S. safety standards.

S. 1274 and H.R. 2108, the Human and Pet Food Safety Act. Senator Richard Durbin and Representative Rosa DeLauro. Requires a person that has reason to believe a food introduced into interstate commerce may be a food safety threat to notify the Secretary of the Health and Human Services of the identity and location of the food. Provides for a mandatory recall of unsafe food, establishes a certification and inspection program for foreign importers and requires recall information to be posted on the Internet.

S. 2077, the Fresh Produce Safety Act. Senator Tom Harkin. Establishes standards for good manufacturing practices for the minimal processing of produce, including standards related to sanitation and water, and requires unannounced inspections of processing facilities to determine if produce processed in the facilities is in compliance with the Act. Establishes general standards for good agricultural practices for the production of raw agricultural commodities, including requirements related to manure, animals, water, and environmental conditions. Creates a national public education program on food safety relating to produce.

H.R. 3484, the SAFER Meat, Poultry, and Food Act. Representative Diana DeGette. Requires a person (other than a consumer) who has reason to believe a meat, poultry, or food product is adulterated or misbranded to notify authorities and provides for a mandatory recall if the distributor refuses to recall the product.

H.R. 3485, the TRACE Act. Representative Diana DeGette. Establishes a traceability system for all stages of manufacturing, processing, packaging, and distribution of food.

S. 1292, the Meat and Poultry Products Traceability and Safety Act. Senator Charles Schumer. Establishes a traceability system for all stages of production, processing, and distribution of meat and poultry products.

H.R. 2997, the Assured Food Safety Act. Representative Marcy Kaptur. Establishes a program to require all food items imported into the United States to bear a certificate of assured safety issued by the government of the country from which the item is imported. If an importer fails to submit a certificate of assured safety, the USDA or the FDA would be required to inspect the production place and determine that sufficient corrective steps have been taken to bring it into compliance with U.S. laws.

S. 2081, the Food and Product Responsibility Act. Senator Sherrod Brown. Provides the USDA and the FDA with mandatory recall authority. Requires the U.S. Customs and Border Protection to develop a program to ensure manufacturers/distributors (of products including food) are able to cover the costs associated with both product recalls and all personal and property damages.

H.R. 3937, the Food Import Safety Act. Representative Rosa DeLauro. Gives the FDA authority to ban imports from countries that have a pattern of food safety violations. Establishes a certification system for a foreign government or foreign food establishment seeking to import food to the United States and authorizes the Secretary to withdraw the certification of any food importer that fails to meet U.S. safety standards. Provides mandatory recall authority.

Conclusion

Key U.S. food safety laws are a century old and were not designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The last several years have demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. Comprehensive reform should draw from these recommendations.

Change is hard, but it has been done abroad. The United Kingdom reformed its food safety program to establish a single Food Standards Agency in 1999. That agency has proven effective in reducing the incidence of foodborne illness and building public confidence. Foodborne illnesses declined 18 percent within the first three years of the new agency, with a reduction from 37 percent to 6 percent in the occurrence of eggs and poultry infected with *Salmonella*. Public confidence in the safety of the food supply rose from 44 percent to 60 percent.¹⁷ The change came after food scares in the 1990's led all sides to recognize the need for change, and that realization built the momentum needed to reach a workable compromise. The U.S. is at the same nexus of crisis and consensus and the momentum for reform is building. We urge Congress to take action this year to modernize food safety laws and to fully fund federal food safety programs.

“The current environment gives me real optimism. A colleague of mine who’s on the Agriculture Committee told me, ‘It [food safety] is the single biggest issue in my district.’”

**Representative Rosa DeLauro (D-CT)
September 25, 2007**

References

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- ⁷ *Id.*
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- ⁹ GEN. ACCT. OFF. REP. NO: GAO-07-785T, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, (Statement of Lisa Shames, Acting Director Natural Resources and Environment) (Feb. 8, 2007) at 2.
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- ¹⁴ Press Release, Coalition for a Stronger FDA, *FDA Coalition Seeks Increases to Agency Budget* (Feb. 6, 2007) at <http://www.fdacoalition.org/inc/Stronger%20FDA%20-%20Budget.pdf>.
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Resources at CSPI

Outbreak Alert Database

<http://www.cspinet.org/foodsafety/outbreak/pathogen.php>

Outbreak Alert Recall Notices

http://www.cspinet.org/foodsafety/outbreak_report.html

Food Safety Legislation

Caroline Smith DeWaal, J.D.

David W. Plunkett, J.D., J.M.

Agency Regulatory Actions

Sarah Klein, J.D., M.A.

Epidemiology

Farida Bhuiya, MPH

Appendix A: Food Safety Hearings 2007

Senate
Committee on Appropriations; Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies -- <i>Field Hearing to Discuss Food Safety</i> , March 12, 2007.*
Committee on Commerce, Science and Transportation -- <i>Safety of Chinese Imports: Oversight and Analysis of the Federal Response</i> , July 18, 2007.*
Committee on Health, Education, Labor, and Pensions -- <i>Developing a Comprehensive Response to Food Safety</i> , December 4, 2007.*
House of Representatives
Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- <i>Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? – Part I</i> , April 24, 2007.
Committee on Agriculture -- <i>Review the impact of Imported Contaminated Food and Feed Ingredients and of Recent Food Safety Emergencies on Food Safety and Animal Health Systems</i> , May 9, 2007.
Committee on Agriculture; Subcommittee on Horticulture and Organic Agriculture - - <i>Review of Industry Response to the Safety of Fresh and Fresh Cut Produce</i> , May 15, 2007.*
Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- <i>Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part 2</i> , July 17, 2007.*
Committee on Appropriations; Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies -- <i>Ensuring the Safety of Imported Foods: What Can the FDA and U.S. Businesses Do Differently to Improve the Safety of Foods Imported into the U.S.</i> , September 25, 2007.*
Committee on Energy and Commerce; Subcommittee on Health -- <i>H.R. 3610, the Food and Drug Import Safety Act</i> , September 26, 2007.*
Committee on Ways and Means; Subcommittee on Oversight, and Subcommittee on Trade -- <i>Joint Hearing on Import Safety</i> , October 4, 2007
Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- <i>Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? – Part III</i> , October 11, 2007

* Center for Science in the Public Interest testified at this Hearing.

Appendix B: Index of Food Safety Bills

Senate		
Bill No.	Title	Sponsor
S. 654	Safe Food Act	Sen. Richard Durbin
S. 1274	Human and Pet Food Safety Act	Sen. Richard Durbin
S. 1292	Meat and Poultry Products Traceability and Safety Act	Sen. Charles Schumer
S. 1776	Imported Food Safety Act	Sen. Richard Durbin
S. 2077	Fresh Produce Safety Act	Sen. Tom Harkin
S. 2081	Food and Product Responsibility Act	Sen. Sherrod Brown

House of Representatives		
Bill No.	Title	Sponsor
H.R. 1148	Safe Food Act	Rep. Rosa DeLauro
H.R. 2108	Human and Pet Food Safety Act	Rep. Rosa DeLauro
H.R. 2997	Assured Food Safety Act	Rep. Marcy Kaptur
H.R. 3610	Food and Drug Import Safety Act	Rep. John Dingell
H.R. 3624	Consumer Food Safety Act	Rep. Frank Pallone
H.R. 3484	SAFER Meat Poultry, and Food Act	Rep. Diana DeGette
H.R. 3485	TRACE Act	Rep. Diana DeGette
H.R. 3937	Food Import Safety Act	Rep. Rosa DeLauro