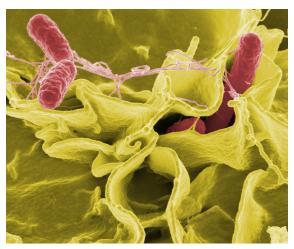
# **Building a Modern Food Safety System For FDA Regulated Foods**









A CSPI White Paper by Caroline Smith DeWaal, J.D. and David W. Plunkett, J.D., J.M.

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"Americans do not need another deadly outbreak to understand that our food safety system is in desperate straits. We have ample proof of that. This is a bad situation not just for the American public, but also for the food industry itself. We must act now to address this problem."

Rep. Henry Waxman (D-CA) (March 11, 2009)



#### **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 food-borne illnesses.

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

- February to April 2009: *Salmonella* Saintpaul linked to raw alfalfa sprouts sickened 181 people in 11 States.
- March to April 2009: Spice recalled by Union International Food Co. because of possible Salmonella contamination that sickened 60 people in 4 States.
- March 2009: Setton Pistachio voluntarily recalled more than 2 million pounds of roasted pistachios due to possible Salmonella contamination.
- September 2008 to March 2009: *Salmonella* contaminated peanut products from the Peanut Corporation of America sickened 691 people, and caused 9 deaths in 46 States and Canada. Over 3,800 products recalled.
- September and October 2008: Dairy products made in China recalled because of intentional melamine adulteration which sickened 300,000 babies and caused 7 deaths in China.
- April to August 2008: Imported Jalapeño and Serrano peppers (and possibly tomatoes) sickened 1,442 people in 43 states, the District of Columbia, and Canada.
- July 2007: Canned chili and meats containing Clostridium botulinum were recalled after causing eight illnesses in 3 states.
- June 2007: Veggie Booty snacks caused 65 illnesses in 20 states from *Salmonella*.
- February and March 2007: One hundred brands of pet food distributed nationwide recalled after causing illnesses and deaths among cats and dogs due to melamine contamination.
- February 2007: Peter Pan peanut butter contaminated with *Salmonella* sickened 425 people in 44 states.
- December 2006: Iceberg lettuce contaminated with *E. coli* at Taco Bell and Taco John restaurants sickened 152 people.
- September 2006: *Salmonella* found in tomatoes sickened 183 people in 21 states.
- August and September 2006: *E. coli* in bagged spinach sickened 204 people in 26 states, killing three.

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.

Source: Outbreak Alert at http://www.cspinet.org/foodsafety/outbreak\_report.html

"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)

#### **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 food-borne hazards in the United States, according to the Centers for Disease Control and Prevention (CDC). (Mead, 1999) 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.

The impact of these outbreaks has been devastating. After the 2006 outbreaks, 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. (Food Marketing Inst., 2007) USA Today reported in July, 2007, that 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico. (Weise, July 2007) The food industry has felt the impact of declining confidence as spinach farmers experienced a loss of \$350 million after the September 2006 outbreak. (Weise, Sept. 2007)

Cost provides another measure for assessing the need for action on food-borne 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. (Crutchfield, 2000) 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. voli* O157:H7. (Crutchfield, 2000) The elderly, people with compromised immune systems, pregnant women, children, and infants are most at risk of serious illness from food-borne disease. Many pathogens, including *Salmonella*, *Campylobacter* and pathogenic *E. voli* can lead to chronic illness and reduced life expectancy. (Schardt, 2002)

#### Why Reform is Needed

In 2007, the Government Accountability Office (GAO) designated food safety as a high-risk federal government program. (GAO, 2007)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.

"Recent outbreaks of foodborne illness and nationwide recalls of contaminated food from both domestic and foreign sources highlight the need for Congress to act to modernize and strengthen our nation's food safety laws.."

> Sen. Judd Gregg (R-NH) (March 3, 2009)

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 USDA. Historically, while USDA regulates one-fifth of the food supply causing 27 percent of outbreaks, its food safety appropriations have been *twice* that given to FDA. (CSPI, 2006) Increased appropriations starting in 2008 have begun to address this disparity, but FDA's funding still lags behind USDA's.

USDA has the resources to inspect meat and poultry plants daily, as required by law. In contrast, FDA, which regulates 80 percent of the food supply, inspects food facilities it oversees on average just once every 10 years. FDA's food program as of 2007 had a current funding shortfall of \$135 million, which an FDA budget official described as equivalent to a 24 percent budget cut. (House Committee on Government Reform, 2006) Overall consumer confidence in FDA has plummeted. A Gallup Poll has documented that confidence in FDA's ability to ensure the safety of the food supply fell 11 percent between 2001 and 2008. (Morales, 2008) Polling after the Peanut Corporation of America outbreak found only half of Americans believe the government does a good job of enforcing the nation's good laws. (ASQ, 2009)

Outbreaks are a symptom of an agency that is overwhelmed by responsibility, but lacks the staff and resources to function effectively. FDA responds to crisis after crisis rather than preventing them. FDA funding shortfalls reached a critical level by 2007 leaving the agency with fewer inspectors even as their workload continued to increase. By 2006, inspections conducted by FDA had declined 81 percent from 1972 levels. The number of FDA field staff dropped by 12 percent and between 2003 and 2006, as federal inspections dropped by 32 percent. (House Committee on Government Reform, 2006) With budget increases in 2008 and 2009, the agency is beginning to rebuild. But, adding inspectors alone will not solve FDA's problems.

The food safety system is also fragmented among 12 federal agencies that share responsibility for regulating food. This results in a chaotic and inefficient system. (National Research Council, 1998) The three main agencies divide duties as follows: USDA inspects meat and poultry; FDA oversees the safety of all other foods; and EPA sets tolerances for pesticides in food.

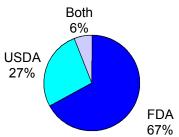
This regulatory system proves confusing, wasteful and highly ineffective. For example:

- A frozen cheese pizza is subject to inspection by FDA, which usually inspects the average food manufacturing facility only once every 10 years. A frozen pepperoni pizza falls under the jurisdiction of USDA, which performs almost daily inspections.
- Imported foods are treated differently depending on whether
  they are regulated by FDA or USDA. While USDA approves all
  foreign meat and poultry plants that want to export to the U.S.,
  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 USDA inspectors visit farms, they do not inspect the

"Over the last year we've seen major recalls of peanut butter spiked with salmonella, spinach laced with e-coli and chili loaded with botulism. These are not isolated incidents and are the result of an outdated, under-funded and overwhelmed food safety system."

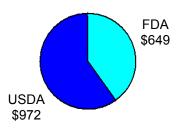
Sen. Richard Durbin (D-IL) (March 3, 2009)

### Food-borne Illness Outbreaks by Agency 1990-2006



Source: CSPI Outbreak Alert!

#### Food Safety Expenditures FY 2009 (\$ Millions)



Source: President's Budget FY2010

"There's a bipartisan con-

sensus the FDA needs an

overhaul,' said Represen-

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

tative Tom Davis. a Vir-

ginia Republican."

crops for safety. 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.

At the heart of FDA's problems is an antiquated statute that is out of step with modern food safety regulation. 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. 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.

#### Why Now

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. (See Appendix A.) The emergence of coalitions of traditionally estranged consumer and industry organizations, such as the Alliance for a Stronger FDA, gives Congress a unique opportunity to appeal to many constituencies as it rebuilds the agency. But the need is great.

To fix FDA Congress must adopt legislation that addresses deficiences in 11 critical areas by establishing (1) process controls implemented by industry, (2) performance standards set by FDA, (3) more frequent inspection schedules, (4) better import controls, (5) stronger research and education programs, (6) an onfarm food safety mandate, (7) mandatory recall authority, (8) traceback systems, (9) administrative detention authority, (10) authority to issue civil penalties, and (11) protection for whistleblowers.

Number of Foodborne Illness Outbreaks by Year and Regulating Agency 1990-2006 400 FDA 350 USDA BOTH Number of Outbreaks 300 250 200 150 100 50 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006

Page 5, Building a Modern Food Safety System

Source: CSPI Outbreak Alert!

#### **Improving America's Food Safety System**

## Process Controls & Performance Standards to Prevent Outbreaks and Recalls

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 food-borne 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 food-borne 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 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.

Congress should require 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.

#### Inspections & State/Federal Cooperation

Unlike for makers of drugs and medical devices, 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

"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)

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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. FDA is responsible for overseeing more than 136,000 domestic food establishments. (FDA, 2007) 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 32 percent. (House Committee on Government Reform, 2006)

Imported foods receive even less oversight from 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 FDA additional authorities including requiring foreign manufacturers and shippers to register with the agency. They are also required to alert FDA when food is being shipped to the U.S.

Despite these additional authorities, FDA still lags behind USDA in inspection authority. 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 USDA. The Federal Food, Drug and Cosmetic Act does not require pre-market approval for FDA-regulated food products. Additionally, 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.

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 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. 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. FDA must have the resources to work with states to carry out food safety activities in a coordinated

"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."

> Rep. John Dingell (D-MI) September 20, 2007

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.

#### **Food Imports**

Each year the average American eats about 263 pounds of imported foods (13 percent of the total diet) that are regulated by USDA or FDA. (Jerardo, 2004) But while USDA has a multi-tiered, legislatively-mandated program for preventing the importation of unsafe meat and poultry products, FDA's program is largely reactive and relies on a thin line of inspection to try to catch problems at the port of entry.

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, FDA inspects less than one percent of the growing number of imported food shipments. Unlike USDA, 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.

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, FDA should review and audit its food safety program. 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 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

"We must empower the FDA... so that the agency can effectively prevent problems from ever occurring, rather than simply reacting once something bad has happened."

Rep. Frank Pallone (D-NJ) (March 11, 2009)

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.

#### Research and Education

Today, 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 food-borne illness. Food-NET, 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 food-borne 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 food-borne 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. 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 food-borne 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.

#### **Solutions to On-Farm Food Safety Issues**

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 FDA take concrete steps to reduce the incidence of food-borne 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, 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.<sup>15</sup>

Today, FDA does not have specific, mandatory standards that apply to farmers who grow food for human consumption. Instead, the agency relies on very gen-

"We need to shift from the current reactive food safety system that depends heavily on product testing to a proactive and preventive strategy that relies on modern scientific standards and safety controls that detect and eliminate food-borne contamination as far up the chain as possible."

Rep. Greg Walden (R-OR) (March 19, 2009) eral Good Agricultural Practices and other voluntary guidance that is not enforceable under the law.

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

- 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.
- 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 FDA, the states, and/or the buyers (FDA should review the state and private audits.)

#### **Enforcement Authority**

Today, 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. 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 tools do not equip FDA to protect consumers from the threat of food-borne 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 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, 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.** 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 detain the food for a reasonable time. If it is determined that the detained food cannot be brought in compliance with food safety requirements, FDA should be able to condemn the food.

"To say that food safety in this country is a patchwork system is giving it too much credit. Food safety in America has too often become a hit-or-miss gamble, and that is truly frightening."

Sen. Tom Harkin (D-IA) (February 5, 2009)

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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. Today, FDA has to pursue a criminal prosecution when it finds a violation because the agency doesn't have authority to assess civil fines. The cost and difficulty of mounting a criminal prosecution makes it more likely food companies will get away with some violations.

Whistleblower Protection. Employees must be protected from the threat of being fired, demoted, suspended, or harassed as result of providing informa-

"If there is any good that can come from this tragic outbreak, it could come from long overdue legislative change to protect the American people from dangers in the Nation's food supply."

Rep. Bart Stupak (D-MI) (February 11, 2009) Whistleblower Protection. 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. Whistleblower protection could have helped prevent illnesses and deaths that resulted from the Peanut Corporation of America outbreak. One story reported that employees who knew of unsanitary conditions at the plant kept quiet because they "wanted to keep their jobs." (Glanton, 2009)

**Civil and Criminal Penalties.** An essential element of any enforcement capability is the power to penalize manufacturers and producers for violating food

#### **Modernizing FDA:**

#### **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.)

H.R. 875, Food Safety Modernization Act. Representative Rosa

**DeLauro.** H.R. 875 separates food safety from FDA's drug approval program, restructuring the Department of Health and Human Services by creating a Food Safety Administration (FSA). The bill also requires food companies to register annually, and implement preventive measures on their production lines so that food they produce is safe and meets performance standards for controlling the most hazardous contaminants. The FSA would be required to inspect high-risk slaughter plants daily and all food companies no less than annually. FSA would also have farm-to-fork coverage. It requires imported foods to meet the same high safety standards as domestic foods. A program for certifying imported food would ensure foreign companies that ship food to the U.S. abide by U.S. laws. It provides for research into new methods of improving food safety, health assessments to identify emerging problems, and educational outreach to consumers. The bill strengthens enforcement authority by allowing the new FSA to:

- Order recalls;
- Require all products to be traceable;
- Detain and destroy unsafe food when inspectors find it;
- Seek longer criminal sentences when people are hurt or killed;
- Assess new civil fines on food companies that break the law; and,
- Detect unlawful conduct by protecting whistleblowers from retaliation.

H.R. 759, FDA Globalization Act. Representative John Dingell. H.R. 759 is a comprehensive FDA reform measure. It has provisions for strengthening regulation of drugs, devices and cosmetics, as well as for reforming regulation of food. Under the bill, food companies would have to register annually. A registration fee is charged to pay for increased inspections of foreign and U.S. food plants, as well as more inspections of imported food at the border. Food companies would be required to conduct a hazard analysis and implement preventive measures on their production lines to ensure the food they produce is safe and meets performance standards set by FDA for controlling hazards. FDA would be required to implement a risk-based inspection system that ensures all food facilities (foreign and domestic) are inspected no less than once every four years. Imported food would have to be certified as meeting U.S. safety standards by FDA accredited certifying agents. Imported foods meeting FDA guidelines for safety would have access to an expedited entry program. The bill provides for research, a public health assessment and educational outreach to consumers. FDA would set standards for the safe production of fresh fruits and produce. The bill strengthens enforcement authority by allowing FDA to:

- Order recalls;
- Require all products to be traceable through electronic records;
- Detain unsafe food when inspectors find it;
- Impose new civil fines on food companies that violate the law; and,
- Detect unlawful conduct by protecting whistleblowers from retaliation.

H.R. 1332, Safe Food Enforcement, Assessment, Standards, and Targeting (FEAST) Act. Representative Jim Costa. H.R. 1332 requires food companies to implement food safety plans. Food companies would be required to register every two years. Food companies would be required to conduct a hazard analysis and implement preventive measures on their production lines to ensure the food they produce is safe and meets performance standards set by FDA for controlling hazards. FDA would be required to inspect high risk food processors at least annually and all other food processors at least once every four years. Food importers of record would be required to ensure their foreign suppliers comply with U.S. food safety laws. FDA may require high risk foods to be certified as complying with U.S. requirements for safety. Certifications would be performed under a program for accrediting third-party certifiers to audit foreign food companies for compliance. FDA would set standards for the safe production of fresh fruits and produce. The bill strengthens enforcement authority by allowing FDA to:

- Order recalls;
- Detain unsafe food when inspectors find it; and,
- Set traceability requirements.

# S. 510, FDA Food Safety Modernization Act. Senator Richard Durbin. S. 510 requires food companies to implement food safety plans. Food companies would be required to register every two years. Food companies would be required to conduct a hazard analysis and implement preventive measures on their production lines to ensure the food they produce is safe and meets performance standards set by FDA for controlling hazards. FDA would be required to inspect high risk food processors at least annually and all other food processors at least once every four years. Food importers would be required to ensure their foreign suppliers comply with U.S. food safety laws. FDA may require high risk foods to be certified as complying with U.S. requirements for safety. Certifications would be performed under a program for accrediting third-party certifiers to audit foreign food companies for compliance. FDA would set standards for the safe production of fresh fruits and produce. The bill strengthens enforcement authority by allowing FDA to:

- Order recalls;
- Detain unsafe food when inspectors find it; and,
- Set traceability requirements.

#### Food Safety Legislation Compared to CSPI's Food Safety Principles

Bill Name	Process Controls	Performance Standards	Inspections	Imports	Research & Education	On Farm	Recall	Traceback	Detention	Penalties	Whistleblower
H.R. 875, Food Safety Modernization Act (DeLauro)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
H.R. 759, FDA Globalization Act (Dingell)	✓	✓	✓	✓	√	<b>√</b>	✓	<b>√</b>	<b>✓</b>	<b>√</b>	✓
H.R. 1332, Safe FEAST Act (Costa)	✓	∜	√/	✓		✓	✓	∜	✓		
S. 510, FDA Food Safety Modernization Act (Durbin)	✓	$\checkmark$	√/	✓		<b>✓</b>	✓	∜	✓	$\checkmark$	

<sup>✓</sup> Includes a version of this provision that is protective of consumer health and safety

Includes a version of this provision that is not as protective of consumer health and safety

#### 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 food-borne illness and building public confidence. Food-borne 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. (Krebs, 2004) 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.

"With every recall the American people grow more concerned and the momentum for reform grows."

> Rep. Rosa DeLauro (D-CT) February 4, 2009

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#### **Appendix A: Food Safety Hearings 2009-2010**

#### **Senate**

Committee on Agriculture, Nutrition and Forestry -- Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall, February 5, 2009.\*

#### **House of Representatives**

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- The Salmonella Outbreak: The Continued Failure to Protect the Food Supply, February 11, 2009.

Committee on Energy and Commerce; Subcommittee on Health -- How Do You Fix Our Ailing Food Safety System?, March 11, 2009.\*

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- The Salmonella Outbreak: The Role of Industry in Protecting the National Food Supply, March 19, 2009.

Committee on Appropriations; Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies -- Food Safety Oversight, March 26, 2009.

Committee on Agriculture -- To Review Current Food Safety Systems, April 2, 2009.

Committee on Agriculture; Subcommittee on Livestock, Dairy and Poultry -- Review Federal Food Safety Systems at the United States Department of Agriculture (USDA), April 23, 2009.

<sup>\*</sup> Center for Science in the Public Interest testified at this Hearing.

#### Food Safety Hearings 2007-2008

#### Senate

Committee on Appropriations; Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies -- Field Hearing to Discuss Food Safety, March 12, 2007 \*

Committee on Commerce, Science and Transportation -- Safety of Chinese Imports: Oversight and Analysis of the Federal Response, July 18, 2007.\*

Committee on Health, Education, Labor, and Pensions -- Developing a Comprehensive Response to Food Safety, December 4, 2007.\*

#### **House of Representatives**

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? - Part I, April 24, 2007.

Committee on Agriculture -- Review the impact of Imported Contaminated Food and Feed Ingredients and of Recent Food Safety Emergencies on Food Safety and Animal Health Systems, May 9, 2007.

Committee on Agriculture; Subcommittee on Horticulture and Organic Agriculture -- Review of Industry Response to the Safety of Fresh and Fresh Cut Produce, May 15, 2007.\*

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? - Part 2, July 17, 2007.\*

Committee on Appropriations; Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies -- 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., September 25, 2007.\*

Committee on Energy and Commerce; Subcommittee on Health -- H.R. 3610, the Food and Drug Import Safety Act, September 26, 2007.\*

Committee on Ways and Means; Subcommittee on Oversight, and Subcommittee on Trade -- Joint Hearing on Import Safety, October 4, 2007

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- Diminished Capacity: Can the FDA Assure the Safety and Security of Our Nation's Food Supply? - Part III, October 11, 2007.

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- Contaminated Food: Private Sector Accountability, February 26, 2008.

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- Regulatory Failure: Must America Live with Unsafe Food?, March 12, 2008.

Committee on Energy and Commerce; Subcommittee on Health -- Discussion Draft of the Food and Drug Administration Globalization Act' Legislation: Food Provisions, April 24, 2008.\*

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- American Lives Still at Risk: When Will FDA's Food Protection Plan Be Fully Funded and Implemented?, June 12, 2008.

Committee on Agriculture; Subcommittee on Horticulture and Organic

Agriculture -- To review legal and technological capacity for full traceability in fresh produce, July 30, 2008.

Committee on Energy and Commerce; Subcommittee on Oversight and Investigations -- *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health*, July 31, 2008.

<sup>\*</sup> Center for Science in the Public Interest testified at this Hearing.

#### **Appendix B: Index of Food Safety Bills**

Senate							
Bill No.	Title	Sponsor					
S. 510	FDA Food Safety Modernization Act	Sen. Richard Durbin					
House of Representatives							
Bill No.	Title	Sponsor					
H.R. 759	FDA Globalization Act	Rep. John Dingell					
H.R. 875	Food Safety Modernization Act	Rep. Rosa DeLauro					
H.R. 1332	Safe FEAST Act	Rep. Jim Costa					

#### Appendix C: Food Safety Resources at CSPI

Food Safety Home Page

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

Outbreak Alert Database

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

Outbreak Alert Recall Notices

http://www.cspinet.org/foodsafety/outbreak\_report.html

Press Releases, Testimony and Reports

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

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Caroline Smith DeWaal, J.D.

Food Safety Legislation

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

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#### **About the Authors**

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David W. Plunkett is a Senior Staff Attorney with the food safety program of the Center for Science in the Public Interest. In this position, he serves as an advocate on behalf of consumers for stronger laws to protect the public from outbreaks of foodborne disease. Mr. Plunkett has more than 20 years experience working with legislatures at the State and Federal level. Since joining CSPI in August 2007, he has represented consumer interests in presentations to FDA, USDA and State regulators, and worked to improve food safety legislation currently pending in Congress. His publications include articles in *Food and Drug Law Journal* and *Food Traceability Reports*. Mr. Plunkett graduated from the University of Georgia and George Mason School of Law. He holds a master's degree (Juris Master) in public policy with an emphasis on law and economics, and a Juris Doctor with a specialty in regulatory law. He is a member of the Virginia State Bar.

# Other Food Safety Publications from the Center for Science in the Public Interest

Outbreak Alert!

(Annual)

Dirty Dining: Have Reservations? You Will Now

(August 2008)

Making the Grade: An Analysis of Food Safety In School Cafeterias

(January 2007)

Mercury Report

(October 2006)

Shredding the Food Safety Net

(April 2006)

Cow Sense

(April 2006)

Name That Cow

(March 2005)

Global & Local: Food Safety Around the World

(June 2005)

Death on the Half Shell

(July 2001)

Unexpected Consequences: Miscarriage and Birth Defects from Tainted Food

(January 2000)

Scrambled Eggs: How a Broken Food Safety System Let Contaminated Eggs Become a Na-

tional Food Poisoning Epidemic

(May 1997)

"In the end, food safety is something I take seriously, not just as your President, but as a parent. When I heard peanut products were being contaminated earlier this year, I immediately thought of my 7-year old daughter, Sasha, who has peanut butter sandwiches for lunch probably three times a week. No parent should have to worry that their child is going to get sick from their lunch."

President Barack Obama (March 14, 2009)

