addressing modern hazards in the food supply:
ensuring the safety of fresh and fresh-cut produce

testimony of caroline smith dewaal
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before the
united states house of representatives
subcommittee on horticulture and organic agriculture

washington, dc
may 15, 2007

my name is caroline smith dewaal, and i am director of food safety for the center for science in the public interest (cspi). cspi is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. cspi is supported principally by the 900,000 subscribers to its nutrition action healthletter and by foundation grants. we accept no government or industry funding.

the center for disease control and prevention (cdc) estimates that 76 million americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards each year in the united states. according to cspi’s database of 5,000 foodborne illness outbreaks, fruits and vegetables caused 13 percent (639) of outbreaks with an identified food and pathogen and nearly 21 percent (31,496) of the associated illnesses between 1990 and 2004. norovirus, salmonella and e. coli 0157:h7 illnesses have been traced to a wide variety of produce, including lettuce, salads, melons, sprouts, tomatoes, and many fruit- and vegetable-containing dishes.1 in fact, foodborne illnesses from these produce outbreaks surpassed those from all other foods, including

1 center for science in the public interest, outbreak alert! (revised and updated – 2006). this database of foodborne illness outbreaks is maintained by cspi. it contains 15 years of data, from 1990–2004. outbreaks are classified by both food vehicle and disease-causing agent. food is classified by which agency regulates the product. during the years 1990 – 2004, there were 3,323 foodborne illness outbreaks from fda-regulated foods (e.g. seafood, produce, eggs, milk); usda regulated-foods (e.g. beef, poultry, pork) caused 1,344 outbreaks.
beef, chicken and seafood. Equally troubling is that the average size of these outbreaks is larger than outbreaks from other foods, thus affecting more people. It is time for Congress to take action to better ensure the safety of our food supply and to protect Americans from these preventable illnesses and deaths.

**Fall 2006 Produce Outbreaks**

A series of produce outbreaks in the fall of 2006 was a wake up call for the public about the critical state of produce safety. Beginning in August, a nationwide outbreak of *E. coli* 0157:H7 from bagged fresh spinach sickened 205 and killed at least three. Then in late September, *Salmonella* found in tomatoes sickened 183 restaurant patrons in 21 states throughout the nation. *E. coli* O157:H7 appeared in produce once more before the year’s end when two separate incidents of contaminated shredded iceberg lettuce sickened a total of 152 individuals at chain restaurants Taco Bell and Taco John.

While many produce outbreaks occurred prior to 2006, the spinach outbreak provided the smoking gun that sourced the cause all the way to the farm. The Food and Drug Administration (FDA) traced the exact strain of the *E. coli* bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig. These findings definitively proved that the *E. coli* contamination that sickened so many people started right on the farm.

**The Case for Produce Regulation**

While the produce outbreaks of fall 2006 have triggered a wake-up call for produce safety, large-scale produce outbreaks are not a new phenomenon in this country. Outbreaks from produce, both imported and domestic, have resulted in deaths, illnesses, both mild and severe, and great market disruptions. Domestic produce is largely unregulated, and FDA has done little more than coax, request, and warn producers to improve produce safety.

- In February 2004, following fourteen outbreaks linked to lettuce and tomatoes, FDA sent a letter to firms that grow, pack, or ship fresh lettuce and/or fresh tomatoes asking them to review their current operations in light of the agency’s guidance.

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• After seeing 18 outbreaks since 1995 involving *E. coli* 0157:H7 in lettuce, FDA sent another letter in November 2005 specifically to California lettuce firms outlining actions the industry should take in order to ensure lettuce safety.\(^5\)

• At a June 2004 public meeting to discuss the proposed Produce Action Plan, Dr. Robert Gravani of Cornell University’s Food Science Department reported that a Good Agricultural Practices Survey of Farm Workers in New York State showed that approximately 30 percent of producers were unaware of Good Agricultural Practices (GAPs) for their particular crop. The numbers show the need for a mandatory regulatory program for fresh produce and the same should go for fresh-cut produce.

• A qualitative study examining food safety practices used by Iowa produce growers was conducted by researchers from Iowa State University. Observational and in-depth interview techniques were used to assess current food safety practices at each operation. Producers were conscious of product safety, but levels of awareness about risk varied. Areas that needed improvement included improved hand washing facilities and practices; provision of employee training; and the development of cleaning and sanitizing protocols for both products and food contact surfaces.\(^6\)

**Imported Produce**

While it is important that we clean up our domestic produce industry, we must also look to improving standards in the countries that export produce to the U.S. as well. Americans seek a variety of fresh fruits and vegetables year-round, and supplying this demand has greatly increased the importation of produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported.\(^7\) A troubling realization is that imported fruits and vegetables have caused numerous large and sometimes deadly outbreaks.

Imports of berries, melons and even green onions, from areas with substandard hygiene practices have sickened thousands of Americans in the last ten years. In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from the parasite, *Cyclospora*, on

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raspberries grown in Guatemala. Then in 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries imported from Mexico and distributed through a U.S. Department of Agriculture (USDA) school lunch program in several states.

Cantaloupe imported from Mexico caused three multistate outbreaks of *Salmonella* serotype Poona infections in the spring of consecutive years during 2000-2002. FDA traceback investigations of the cantaloupe farms identified numerous hygiene failures including contaminated irrigation and processing water and poor hygienic practices of handlers. In the fall of 2003, raw green onions from Mexico spread Hepatitis A to hundreds of people in four different states. In Pennsylvania alone, 555 people became ill from Hepatitis A after eating salsa with the contaminated green onions at a single restaurant.

Most of these outbreaks were traced to imported fruits and vegetables that were grown or processed under substandard and unhygienic conditions. In addition to imposing standards on domestic growers and processors, FDA must ensure that the fruits and vegetables being imported into our country are produced under equally rigorous standards.

**Consumer Confidence**

Consumer confidence in the safety of the food supply, and in FDA’s ability to protect consumers, has declined steadily in recent years. According to the Coalition for a Stronger FDA, a Harris Poll showed that consumer confidence in FDA plummeted by 25 percent in the last six years, with 20 percent of that decline occurring between 2004 and 2006. Those who thought FDA was doing an “excellent” or “good” job went from 61 percent in 2000 to 36 percent in 2006 while nearly 60 percent of respondents ranked FDA as doing only a “poor” or “fair” job.

Consumers want to eat fresh vegetables and fruits and we love the convenience of bagged salads that allow us to have a salad on the table in few minutes. But consumer confidence in the safety of these bagged products has certainly declined since the fall. A January 2007 survey by

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12 In November 2006, the Food Policy Institute at Rutgers University conducted a telephone survey of 1,200 adults to assess consumer attitudes on bagged leafy greens. The survey found that consumers were confused over which products were recalled and that some consumers were hesitant to resume consumption of bagged leafy greens.
the Food Marketing Institute (FMI) reported declines in consumer confidence in supermarket and restaurants foods.\textsuperscript{13} The survey also reported that 38\% of consumers stopped buying certain products; 71\% of these consumers stopped buying spinach and 16\% stopped buying lettuce. The spinach outbreak had as many fatalities as Jack in the Box hamburger outbreak of 1992. It may prove to be a tipping point for consumer confidence – not only in FDA but in the food it regulates – unless the industry and the government act quickly to provide solutions to the risks that are now so evident. Consumers want FDA to put in place a regulatory system that will prevent these outbreaks from occurring.

The American public wants safe food. A 2006 poll from the National Center for Food Protection and Defense at the University of Minnesota revealed that U.S. residents believe that for every $1 spent to protect against a terrorist attack from an aircraft, $1.13 should be spent to protect America’s food supply.\textsuperscript{14} Unfortunately, these sentiments have not translated into a budget reality.

**A Roadmap to Recovery**

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that steps are taken to improve their safety. FDA should consider emergency regulations requiring all fruit and vegetable producers and processors to focus on the hazards associated with their products and have written plans in place to identify where contamination is likely to occur and how to address it. This approach is appropriate for both large and small growers and processors. It targets resources to critical areas and reduces risk by using prevention. The FDA should adopt mandatory hazard control programs for farms and fruit and vegetable processors. These programs should address all major sources of contamination, including the following areas:

**Manure:** The grower must manage the application of manure to ensure that it does not contribute to the contamination of crops, including limitations on the crops where and the times when it may be applied.

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**Water:** Growers and producers should ensure that the water supply used for irrigation and in food processing plants is suitable for its intended use. Growers should assess the microbial and chemical quality of the water used in primary production.15

**Hygiene:** Growers and processors should ensure that employees have close access to bathrooms and that handwashing facilities are visible to supervisors. Employees with direct and indirect access to the production areas should be trained in preventive controls that will help to eliminate or minimize contamination of produce.

**Sanitation:** Processors should establish mandatory standard operating procedures for sanitation, including cleaning procedures for equipment, storage areas, air systems, and water storage areas.

**Traceback:** Processors should mark packaging to ensure easy traceback when fruits and vegetables are implicated in an outbreak. Package markings should be specific enough to extend all the way back to the farm/farms of origin.

Adoption of mandatory regulatory requirements is the best way to ensure that growers and others in the produce supply chain address the risks inherent in the production of fresh produce. FDA should also regularly conduct random inspections of farm fields and facilities that process produce, prioritizing by size and risk potential. Where states or third party auditors are being used, FDA should oversee audits and exercise more rigorous enforcement actions, including product seizure and criminal sanctions whenever adulterated products are sold.

**FDA’s Budget Problems**

Unfortunately the solution to cleaning up the produce industry is not as simple as imposing regulations. Steps taken by industry players, such as the Western Growers Association, are important first steps because FDA currently lacks the funding and authority to act on its own. But FDA alone is empowered to enforce uniform standards across growers in all states and importing countries.

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Last fall’s produce outbreaks are just the latest symptom of an agency that is overwhelmed by responsibility, but lacks the staff and resources to function effectively. The agency 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, there was a 47 percent drop in federal inspections.16

In 2006, FDA’s food program had a funding shortfall of $135 million, which an FDA budget official described as equivalent to a 24 percent budget cut.17 This means that many other parts of the agency’s responsibilities are just not getting attention – things like obesity, dietary supplements, and oversight of new food technologies. In addition, funding shortfalls do not allow the FDA to develop more modern testing technologies and leave the U.S. at a competitive disadvantage compared to other developed countries.

Equally important is the fact that the federal agencies’ food safety expenditures are disproportionate to the risk posed by the foods they regulate. USDA regulates 20 percent of the food supply, which causes 27 percent of outbreaks, yet its food safety appropriations are double that given to FDA.18 This means that while USDA has the resources to inspect meat and poultry plants daily, the FDA inspects food facilities it regulates on average just once every five to ten years.

The Bush Administration’s 2008 budget proposal brings no relief to the ailing agency. The recent budget proposal gives USDA $104 million in new money for food safety.19 The FDA, which regulates 80 percent of the food supply, including produce, will only get $10.6 million in new food safety money.20 It is a food safety budget that defies logic.

Foodborne illness outbreaks related to fresh produce are a major public health problem. Prevention, early detection, and control measures must be in place at every step of fresh produce production to help minimize food safety risks. Voluntary guidelines are not an effective public

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18 Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006).


health response to address the food safety problems related to fruits and vegetables. And while FDA can likely cobble together the authority it needs to regulate on the farm from existing statutes, there is no clear mandate from Congress that ensures food safety oversight all the way from the farm to the table. Food safety is critically important to consumers’ health and to the health of the industries that produce food; yet, it is governed by laws that are 100 years old. It is time to modernize food safety.

**Modernizing the Law: The Safe Food Act**

Following September 11, 2001, Congress enacted the Bioterrorism Act of 2002 but left the most frequent traveler across U.S. borders — imported food — under the supervision of a fragmented system of food regulation. According to the National Academy of Sciences, “[a]t least a dozen federal agencies implementing more than 35 statutes make up the federal part of the food safety system.”  

In response to the problems identified by the National Academy of Sciences, Government Accountability Office, and other agencies, several Members of Congress have introduced legislation—the Safe Food Act—that would modernize the outdated inspection system and give clear authority for on-farm programs. The new system would rely on preventative control systems implemented by the industry and performance standards monitored and enforced by the government.

In a post-September 11 world, with risks of bioterrorism and natural hazards such as *E. coli* O157:H7, the U.S. food safety system has become an issue of national security. The existing regulatory framework is simply insufficient to handle these challenges. The Safe Food Act was introduced February 15, 2007 by Senator Richard Durbin (D-IL) and Representative Rosa DeLauro (D, CT-3rd) as a solution to the myriad of problems in the food system. The Act would streamline food safety at the federal level by consolidating food programs at the FDA, USDA, EPA, and several other key food agencies into a new, independent, unified, science-based Food Safety Administration. In addition, the Safe Food Act would create new authorities to address the development of preventative processing controls, sanitation standards,

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performance standards for contaminants, adequate recordkeeping to monitor compliance, and a sampling program to ensure that the process controls are effective.22

The key to creating a modern food safety system is to implement science-based programs to prevent contamination. The Safe Food Act calls for the implementation of science-based process controls to ensure that food contamination is minimized throughout the production process. The bill would require all food establishments to implement appropriate measures to control and reduce the levels of harmful contaminants in food and meet performance standards for harmful pathogens. The bill builds upon existing Hazard Analysis of Critical Control Points (HACCP) programs, a prevention-based food safety system, but would not limit the agency administrator to rely solely on this program.

In addition, the Safe Food Act would create a system of risk-based inspection, “determined by the type of food handled and the type of processing to which the food is subjected.”23 Food establishments would receive a rating of between one and five, based on public health considerations and strong scientific evidence, to determine the frequency and timing of inspections. The risk-based inspection program would continue the “carcass-by-carcass” inspections by government employees at slaughterhouses and perform daily inspections of high-risk products. All facilities now regulated by the FDA would be inspected at least annually, with many inspected much more often. This system of risk-based inspection would allow for the best use of government resources while still providing safety checks along the entire “farm-to-fork” continuum.

Consumption of imported foods continues to rise exponentially, and the Safe Food Act recognizes and addresses this important component of our food supply.24 Due to limited resources, the FDA currently inspects only about one percent of food entering the U.S., and does little to evaluate foreign food safety systems or inspect foreign plants.25 The Safe Food Act would give the Food Safety Administration the authority to evaluate and certify a country’s food safety program to ensure that it is “at least equivalent to the food safety program in the United

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States.” The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years. The proposed law also requires routine inspections of foreign food imports to ensure that the food is safe and properly labeled. Under the Safe Food Act, foods would no longer have an “open visa” to enter the U.S. without inspection or regulation.

The Safe Food Act further mandates the establishment of a national system for “tracing food and food producing animals from point of origin to retail sale.” The Act would allow companies to issue voluntary recalls should their product be deemed unsafe, but also grants authority for the Food Safety Administration to issue a mandatory recall if the company fails to do so. This will ensure quicker removal of contaminated products from the market and increase consumer confidence in the food supply.

Because our understanding of foodborne illness is constantly evolving, the Safe Food Act recognizes the importance of outbreak investigations and scientific research to improve the safety of the food supply. The legislation would require the CDC and state health departments to share outbreak investigation information with the Food Safety Administration. The bill also would give the Food Safety Administration the responsibility to maintain an “epidemiological system dedicated to food-borne illness identification, outbreaks, and containment.” Detailed food attribution data is critical for risk assessments and also for the identification of emerging foodborne pathogens that could endanger the public.

The Safe Food Act would create a single food agency with the necessary authority to fulfill its mission to put safe food on America’s tables. The Administration could detain imported food and recall tainted food from the market. It would provide the necessary authority to penalize persons or organizations for violating food safety laws, allowing both civil and criminal penalties, and also provide whistleblower protection for individuals who disclose food safety violations.

The Safe Food Act would work to prevent foodborne illness and bioterrorism without grand schemes or an inflated budget. Instead, it ensures a strong national program, outbreak surveillance, and effective, honest public communication. The food industry remains the first

27 id.
28 id
29 id
line of defense, but the Act recognizes that effective industry programs require government monitoring and oversight.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as bioterrorism, antibiotic resistance, or tainted produce. The September 11, 2001 terrorist attacks demonstrated the need for enhanced national security, and the recent produce outbreaks serve as a reminder that much more must be done to protect the food supply. The Safe Food Act draws from these recommendations and creates a program that puts public health at the forefront of food safety in America.