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 and 5,000 die from foodborne hazards each year in the United States. Many health-conscious Americans consume fresh produce as part of a balanced diet, but in the last decade, produce is too frequently the cause of major outbreaks, resulting in deaths, illnesses, both mild and severe, and great market disruptions.¹

According to CSPI’s database of 5,000 foodborne illness outbreaks spanning 15 years, fruits and vegetables caused 13% (639) of these outbreaks with nearly 21% (31,496) of the associated illnesses. 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

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.
vegetable-containing dishes.\(^2\) In fact, foodborne illnesses from these produce outbreaks surpassed those from all other foods, including 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.

**History of Produce Outbreaks in the U.S.**

Produce outbreaks in the U.S. have been documented from both imported produce and domestically grown produce. Imported fruits and vegetables have caused numerous large and sometimes deadly outbreaks. Here are several examples:

- Both in 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora*, on raspberries grown in Guatemala.\(^3\) *Cyclospora* infects the small intestine and typically causes watery diarrhea, loss of appetite, substantial loss of weight, and persistent fatigue. If untreated, illness may last for a month or longer, and may follow a remitting-relapsing course.\(^4\)
- In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed by U.S. Department of Agriculture (USDA) to school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.\(^5\)
- Three multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico. FDA conducted on-farm investigations in Mexico and found many possible sources of contamination, included irrigation of fields with water contaminated with sewage; processing (cleaning and cooling) with *Salmonella*-contaminated water; poor hygienic practices of workers who harvest and

\(^2\) Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006).
process the cantaloupe; pests in packing facilities; and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.\textsuperscript{6}

- In 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Preliminary traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Other onions from this area were linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier in the fall.\textsuperscript{7}

But problems with domestic produce are also widespread:

- 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 reminding them to review their current operations in light of the agency’s guidance.\textsuperscript{8} FDA sent another letter specifically to California lettuce firms in November 2005 expressing concern over continuing outbreaks of foodborne illness and outlining actions the industry should take in order to ensure lettuce safety.\textsuperscript{9}

- 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\% 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.\textsuperscript{10}

\section*{Fall 2006 Produce Outbreaks}

The 2006 spinach outbreak hit Wisconsin the hardest. The state had 49 confirmed cases, 24 hospitalizations, nine individuals with Hemolytic Uremic Syndrome (HUS) resulting from their \textit{E. coli} poisoning, and one death.\textsuperscript{11}

On September 5, 2006, the Wisconsin Department of Health and Family Services was notified of several cases of \textit{E. coli} O157:H7 in the state. Two days later the state health department contacted the Centers for Disease Control and Prevention (CDC) and the Wisconsin State Laboratory about this suspected outbreak. On September 8, the Wisconsin State Laboratory “DNA fingerprinted” the specific \textit{E. coli} strain and posted the information for the CDC and other state laboratories. This posting allowed the CDC to match the genetic fingerprint of the Wisconsin \textit{E. coli} O157:H7 to victims of an outbreak in Oregon and the multi-state outbreak investigation of \textit{E. coli} began. Investigations by the CDC, the Wisconsin health department, and the Oregon health department identified fresh spinach as the likely culprit.\textsuperscript{12} On September 14, the FDA issued a warning for consumers to avoid eating fresh spinach.\textsuperscript{13} But the warning came after much of the produce was distributed and consumed. Overall, during August and September, \textit{E. coli} O157:H7 in fresh spinach sickened 204 people in 26 states, killing at least three.

While many produce outbreaks occurred prior to 2006, this outbreak provided the smoking gun that sourced the cause all the way to the farm. FDA traced the exact strain of the \textit{E. coli} bacteria to a California spinach farm, finding it in nearby manure piles, in a creek and even in a wild pig.\textsuperscript{14} These findings definitively proved that the \textit{E. coli} contamination that sickened so many people started right on the farm.

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This spinach outbreak was the first of a series of produce outbreaks that swept the nation in the closing months of 2006. In late September, *Salmonella* found in tomatoes sickened restaurant patrons throughout the nation. This time 183 people fell ill in 21 states. *E. coli* O157:H7 appeared in produce once more before the year’s end when shredded iceberg lettuce at Taco Bell and Taco John Restaurants sickened 152 individuals.

Rapid investigations and the quick release of information to consumers are important to lessen the public health impact. In September, FDA’s nationwide consumer notification to avoid spinach likely reduced the illness and death toll, and its continual updates meant that many additional consumers heard the news.\(^\text{15,16}\) Thorough investigations are also essential to prevent reoccurrences of outbreaks. But it is time to do more. Consumers want FDA to put in place a regulatory system that will prevent these outbreaks from occurring.

**Consumer Confidence**

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. 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 unless the industry and the government act quickly to provide solutions to the risks that are now so evident.

In November 2006, the Food Policy Institute at Rutgers University conducted a telephone survey of 1,200 adults to see if consumers had heard about the FDA advisories and the subsequent recalls of spinach and to understand how the outbreaks would affect their future consumption of fresh spinach.\(^\text{17}\) The majority of Americans knew about the recall (87 percent) and most learned of it from television reports (71 percent). Many Americans were unsure which spinach products were affected; only 68 percent knew that, in addition to bagged fresh spinach, bulk spinach was also recalled. Twenty-two percent incorrectly identified frozen spinach as recalled. The survey also documented that public notice is sometimes not enough to warn people


off a high-risk food item. In fact, more than one-in-eight Americans (13 percent) who were aware of the recall continued to consume fresh spinach during the recall.

Many consumers were confused about when the recall ended; at the time of the survey in November 2006, six weeks after the FDA’s initial warning, 45 percent were unsure if the spinach recall had ended. Many consumers surveyed were also avoiding other fresh greens: 18 percent had stopped buying other bagged produce. At the time of the survey 44 percent of consumers resumed eating fresh spinach and 20 percent said they “definitely will eat spinach in the future.” Five percent of Americans who ate spinach before the recall said they “definitely will not eat spinach in the future.” Nearly one in five reported (19 percent) that they will now avoid spinach grown in particular areas of the country and 15 percent said they would avoid specific brands of spinach.

**FDA’s Budget Problems**

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. 18

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. This means that many other parts of the agency’s responsibilities are just not getting attention – things like obesity, dietary supplements, and appropriate oversight of new technologies. Overall consumer confidence in FDA has plummeted. A Harris Poll has documented that those who thought FDA was doing an “excellent” or “good” job went from 61% in 2000 who to 36% in 2006.

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 32 percent of outbreaks, yet its food safety appropriations are double

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that given to FDA. 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 $270 million in new money for food safety and security. The FDA, on the other hand, regulates 80 percent of the food supply, including produce, but will only get $10.6 million in new food safety money. It is a food safety budget that defies logic.

**CSPI’s Proposal**

Fresh fruits and vegetables are at the center of a healthy diet, so it is critical that immediate steps are taken to improve their safety. CSPI has petitioned the FDA to take action to require that all fruit and vegetable producers and processors develop written plans 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. These plans should apply first to the highest-risk products – such as leafy green vegetables that have been repeatedly linked to illness outbreaks and more gradually to other segments of the industry.

Specifically, CSPI proposes a three-prong approach to improve the safety of fresh fruits and vegetables:

- First, FDA should require all growers and processors to keep a written food safety plan, designed by the farmer to address the specific environmental conditions on the farm.
- Second, FDA should develop standardized criteria for use by the farmers for such items as water quality, manure use and management, and worker sanitation.
- Finally, the written plans should be audited at least once per growing season by FDA, the states, or the buyers, and FDA should review these audits.

FDA’s standards should include 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. The use of raw manure on produce during the growing season should be prohibited as currently required under USDA’s Organic Certification.

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19 Center for Science in the Public Interest, *Outbreak Alert!* (Revised and updated – 2006).
Composting of manure intended for use on food crops should be monitored and records should be maintained to ensure effective controls are used to destroy pathogens. Domestic animals should be excluded from fields and orchards during the growing and harvesting season, and growing areas should have wildlife deterrents. Farmers and producers should ensure that animal waste from adjacent fields, pastures, or waste storage facilities do not contaminate growing areas. Manure treatment and storage sites close to fresh produce fields increase the risk of contamination; livestock producers should be required to move or otherwise control these sites.

**Water:**
Growers and producers should ensure that the water supply used for irrigation and in food processing plants is suitable for its intended use. The internationally agreed-upon Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Processors says that growers should assess the microbial and chemical quality of the water used in primary production. Vegetable processors should use only potable water in processing or for cleaning or sanitizing the facility and equipment. Facilities should have an environmental monitoring program that includes sampling for pathogens to detect areas of harborage and to verify the effectiveness of cleaning and sanitizing programs in preventing cross-contamination. Sanitizers used for washing vegetables should be approved by FDA and continuously monitored by the facility to ensure they remain at effective levels in the wash water. If effective sampling programs can be developed, water used for washing produce should be monitored for the presence of pathogens at a rate adequate to ensure highly contaminated batches are identified and eliminated.

**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 sanitation standard operating procedures, including cleaning procedures for equipment, storage areas, air systems, and water storage areas. Facilities should be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, processing, packing, and storage operations. There should be limited access to the facility and to its processing areas; adequate space for operations; adequate drainage of processing and wash water; food contact surfaces that are easy to clean and maintain; and areas and structures designed to protect the product and equipment from contamination.

**Traceback:**

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20 National Organic Program. 5 CFR pt.205.203(c).
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. The ability to identify the source of a product is a critical component of food safety programs intended to prevent the occurrence of microbial contamination. Information gained from a traceback investigation can help limit the impact of an outbreak of foodborne illness and help to identify and eliminate conditions that may have contributed to product contamination.

Written food safety plans would help farmers to focus on hazards associated with their products and the steps taken to address those hazards. These plans are the essential first step in preventing a reoccurrence of the outbreaks from last fall. The plans should be reviewed during random third party and state auditing based on consistent standards. Seasonal audits would allow FDA to monitor that the regulations are being fully implemented and enforced. If states or third party auditors are relied on, FDA should periodically conduct on-site audit reviews to ensure that auditors provide consistently reliable services. Whenever auditors inform FDA or if the agency finds violations, it should bring enforcement actions, including product seizure and criminal sanctions.

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 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.

**Safe Food Act**

While we believe that FDA has authority to implement these improvements under both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, neither of these laws give the agency clear authority from farm-to-table when it comes to food safety. The FFDCA 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, that requires government inspectors to approve every meat product before it can be sold.
In order to bring these disparate food safety laws together, on February 16, 2007, Senator Richard Durbin and Representative Rosa DeLauro introduced The Safe Food Act to streamline food safety at the federal level. This bill creates a strong, science-based Food Safety Administration, ending the current tug-of-war between agencies.

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.” Food establishments would receive a rating (1-5) to determine the number and the time between inspections, based on public health considerations and strong scientific evidence. The risk-based inspection program would continue the “carcass-by-carcass” inspections at slaughterhouses and perform daily inspections of other high-risk products. All food processors 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 department resources while still ensuring the safety of the entire “farm-to-fork” process.

The Safe Food Act addresses imported foods as well. The FDA currently inspects only about one percent of food entering the United States, due to its limited resources and does little to evaluate foreign food safety systems or inspect foreign plants. The Safe Food Act gives 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 States.” Food coming from uncertified countries or plants will not have an “open visa” to enter the United States without inspection or regulation as they do today, while food that are properly certified would move quickly.

When food safety problems do occur, it is vital that the Food Safety Authority has sufficient tools to respond in an emergency. According to the World Health Organization “tracing systems and market recalls are thus critical in responding to food contamination,

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whether deliberate or inadvertent.”

Today, however, the USDA and the FDA rely on voluntary company tracking and recall systems. The Safe Food Act mandates the establishment of a national system for “tracing food and food producing animals from point of origin to retail sale.”

The Safe Food Act works 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 is the first line of defense, but recent outbreaks demonstrate that effective industry programs require government monitoring and oversight.

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