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Food Safety: Federal and State Response to the Spinach *E. coli* Outbreak

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Summary

In September 2006, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) began receiving reports on clusters of patients in various states confirmed to have *E. coli* infections. By early October, 199 people in 26 states had become ill — 102 had been hospitalized, 31 had developed hemolytic uremic syndrome (HUS), a type of kidney failure, and three had died.

Escherichia coli O157:H7 (*E. coli*) is a bacterium found in animal feces that causes diarrhea and abdominal cramps within days of exposure. An infection can lead to HUS and, in some cases, death. Public health laboratories perform a type of DNA fingerprinting to determine whether a sample taken from a patient matches those taken from other patients and contaminated food during an outbreak. The time from exposure to confirmation of an *E. coli* infection can take two to three weeks.

As the number of infections increased, an investigation that included FDA, CDC, and state and local public health officials was launched. Starting on September 14 and continuing into early October, FDA and CDC released nearly daily statements on the status of the investigation, alerting the public to the number of cases, states with confirmed cases, spinach product recalls, agency actions, and consumer advice on consumption of spinach products. Investigators were able to trace the outbreak back to several farm fields in the Salinas Valley of California. While the investigation continues, there is evidence that nearby livestock, feral pigs or other environmental sources may have contaminated one or more of the fields.

Since the outbreak, FDA has advised growers of fresh produce that they need to develop and implement voluntary guidelines to prevent outbreaks of food-borne diseases. FDA has also announced that it will convene a public meeting on the issue once the investigation is complete. Several growers groups have called for their industry to use the best agricultural and processing practices to prevent such outbreaks, not least because losses to the industry from the spinach outbreak have been estimated at \$100 million.

In October 2006, the House Committee on Energy and Commerce asked FDA to explain its role in detecting contaminated food, particularly in the recent tainted spinach case. The request sought details about the agency's food safety procedures used in emergency situations.

Both proponents and opponents of the National Uniformity for Food Act (**S. 3128, H.R. 4167**) have weighed in on how it would have affected the *E. coli* outbreak. Opponents believe that states' ability to act would have been compromised, while proponents claim that the legislation would not have affected state adulteration or inspection authorities.

Legislators may address the recent *E. coli* outbreak during reauthorization of the farm bill in the 110th Congress, when the proposal for a single food safety agency with increased powers may be considered.

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Introduction

In September 2006, government officials were alerted to an outbreak of *E. coli* O157:H7 infections associated with the consumption of tainted fresh spinach. For several weeks, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) investigated the situation as additional cases were identified nearly daily. This report details the events as they unfolded, and includes the number of cases, the detection of the first case, and the process by which relevant agencies acted as subsequent cases were reported. This report will be updated in response to any further developments.

Background

The public first became aware of a new deadly strain of *E. coli* in 1982 during an outbreak associated with ground beef. *Escherichia coli* is a bacterium normally found in the intestines of humans and animals. Most strains of *E. coli* are harmless. Several strains, including serotype O157:H7, may cause serious illness in humans, though they are frequently found in livestock feces, particularly in cattle manure. In humans, infection with *E. coli* O157:H7 can cause diarrhea that is often bloody and accompanied by abdominal cramps. Fever may occur. Symptoms usually develop in two to four days, but may emerge as quickly as a day or up to a week after exposure. Healthy adults can generally recover completely from infection within a week. Some individuals, however, especially young children and the elderly, can develop hemolytic uremic syndrome (HUS) as a result of infection. HUS can lead to serious kidney damage and even death. In terms of treatment, antibiotics are not indicated and may be harmful. Due to the severity of illness, treatment of these infections often requires hospitalization. Patients who experience kidney failure may need dialysis. For the remainder of this report, “*E. coli*” will refer to the *E. coli* O157:H7 strain implicated in the spinach outbreak.

The Process of *E. coli* Case Confirmation

The cases of *E. coli* linked to spinach consumption, as discussed in this report, are “confirmed,” meaning that victims have been shown, by laboratory analysis of specimens, to be infected with the organism. There are a number of reasons why confirmation may not occur for all victims of an outbreak, though for serious illnesses such as *E. coli*, the proportion of cases that are investigated with laboratory testing is generally higher than with milder foodborne illness. The time from the beginning of a patient’s illness to confirmation of whether the patient is part of an

outbreak typically takes from two to three weeks. In the case of the *E. coli* outbreak in spinach, the average time for confirmation of cases was about 15 days.¹

In most cases of *E. coli* infection, public health laboratories in states and some cities perform a type of DNA fingerprinting on *E. coli* samples. Investigators determine whether the DNA fingerprinting pattern of the bacterium from one patient is the same as that from other infected patients and from contaminated food. Bacteria with the same DNA fingerprint are likely to have come from the same source.

A series of steps takes place between the point when a patient is infected and the point when public health officials can confirm whether the patient is part of an *E. coli* outbreak. As a result, there is generally a two- to three-week delay between the start of the illness and confirmation of the patient's connection to the outbreak.

This series breaks down as follows: In the case of *E. coli*, an incubation period from the time of eating contaminated food to the beginning of the first symptoms is typically two to four days. The time from the first symptom until the person seeks medical care, when a diarrhea sample is collected for testing, is generally one to five days. The process of laboratory diagnosis, which begins when a patient provides a sample and *E. coli* is subsequently obtained from the sample, usually takes one to three days. The time required to ship *E. coli* bacteria from a laboratory to state public health authorities who will perform DNA fingerprinting may take up to a week, depending on the transportation system within a state and the distance between a clinical laboratory and public health department. The time required for state public health officials to perform DNA fingerprinting on an *E. coli* sample and compare it with an outbreak pattern is ideally one day. However, with limited staff and space in public health laboratories during a period when other emergencies may occur, the process can take up to four days.

State health departments typically report laboratory-confirmed cases of foodborne illness to CDC on a regular basis. During serious interstate outbreaks such as the *E. coli* outbreak linked to spinach, state health departments would typically notify CDC of newly confirmed cases on a daily basis, to facilitate a swift nationwide investigation. In general, disease reporting by states to CDC is voluntary, but it may be required as a condition of federal funding for certain state public health systems, such as the PulseNet system described below.

The Systems Used to Monitor Foodborne Illnesses

The tracking and reporting of foodborne illnesses are conducted in several ways:

- PulseNet is a national network of public health and food laboratories coordinated by the CDC. The network consists of labs in state and local health departments and federal agencies (CDC, FDA, and the U.S. Department of Agriculture, or USDA). PulseNet experts perform standardized DNA fingerprinting of foodborne disease-

¹ CDC, "Timeline for Reporting of Cases with the Outbreak Strain of *E. coli* O157," Sept. 19, 2006, at [<http://www.cdc.gov/foodborne/ecolispinach/reportingtimeline.htm>].

causing bacteria by *pulsed-field gel electrophoresis* (PFGE). PFGE can be used to distinguish among strains of organisms — for example, *E. coli* O157:H7, *Salmonella*, *Shigella*, *Listeria* and *Campylobacter*.²

- The OutbreakNet is a group of state public health officers who investigate foodborne disease outbreaks and share information throughout an outbreak.
- CDC's Health Alert Network (HAN) is a national program that provides vital health information and the infrastructure to support dissemination of essential information to public health and medical professionals at the state and local levels.
- The Epidemic Information Exchange (Epi-X) is CDC's secure, Web-based communications network that serves as a communications exchange between CDC, state and local health departments, poison control centers, and other public health professionals.

All of these systems have been used in the investigation of the recent *E. coli* outbreak.

Timeline of Cases, Recalls, and Agency Actions³

Federal and State Tracking and Investigation

September 8, 2006. According to FDA and CDC reports, the agencies were first alerted on September 8 to four cases of hemolytic uremic syndrome (HUS) in a call from Wisconsin's state epidemiologist. CDC began an investigation, working collaboratively with state health departments and FDA, to detect infections, identify the cause of the infections, and provide information to the public and health care providers on the treatment and prevention of *E. coli* O157:H7 infections.

September 12, 2006. On September 12, the PulseNet system confirmed that the *E. coli* O157:H7 strains from the patients in Wisconsin all had the same DNA fingerprint pattern, and also identified the same pattern in some *E. coli* patients from other states.

September 13, 2006. By September 13, CDC officials were alerted by epidemiologists in Wisconsin and Oregon that fresh spinach was the suspected source of small clusters of *E. coli* cases. The same day, Wisconsin and Oregon epidemiologists were contacted by New Mexico epidemiologists about a cluster of

² CDC, PulseNet home page, at [<http://www.cdc.gov/pulsenet/index.htm>].

³ The data in this section were taken from the daily alerts issued by FDA and CDC, available at the following sites: [<http://www.fda.gov/oc/opacom/hottopics/spinach.html>] and [<http://www.cdc.gov/foodborne/ecolispinach/>].

E. coli infections that had also been associated with fresh spinach consumption. At this point, the association of illness with spinach consumption was based only on epidemiologic evidence: the common finding, among victims who were interviewed, of a history of recent spinach consumption.

September 14, 2006. FDA and CDC issued the first of nearly three weeks of daily consumer alerts about an *E. coli* outbreak in several states that was believed to be associated with the consumption of fresh produce. At the time, preliminary epidemiological evidence pointed to bagged fresh spinach as the possible cause of the outbreak. FDA advised consumers to avoid consuming bagged spinach. (It is notable that this product-wide advisory was made based solely on epidemiologic evidence, since at this point, the outbreak organism had not yet been identified in any spinach products.) The agencies advised individuals who believed that they had experienced symptoms of illness after consuming bagged spinach to contact their physicians, and physicians were urged to report suspected cases of *E. coli* infection to local and state public health officials as soon as possible.

The federal agencies reported that they were working with state and local agencies to determine the cause and scope of the outbreak. Eight states had reported illnesses: Connecticut, Idaho, Indiana, Michigan, Oregon, New Mexico, Utah, and Wisconsin. A total of 50 infected individuals had been identified — among them were eight cases of HUS, one death, and multiple hospitalizations. The date range of infection was estimated to be from August 25 to September 3, 2006.

September 15, 2006. On September 15, FDA and CDC issued announcements that the outbreak of *E. coli* in multiple states had been associated with the consumption of fresh spinach and fresh spinach-containing products. The statements indicated that Natural Selection Foods LLC of San Juan Bautista, California, had launched a voluntary recall of products that contained spinach marked with “best if used by” dates of August 17 through October 1, 2006. (FDA does not have authority to mandate recalls of most of the foods it regulates, including fresh produce.) FDA reported that it was investigating whether eight other companies and their brands were involved. The products under investigation, and subject to an expanded consumer advisory, included spinach and any salad blend containing spinach intended for retail or food service (restaurant and institutional) use. CDC also noted that 94 cases of illness had been reported, and that 29 people (31%) had been hospitalized, 14 (15%) had developed HUS, and one had died.

By this point, California, Kentucky, Maine, Minnesota, Nevada, New York, Ohio, Pennsylvania, Tennessee, Virginia, Washington, and Wyoming had also reported human infections to CDC, bringing the total number of affected states to 20. Spinach from presumptively affected lots was also reported to have been distributed in Canada and Mexico. The agencies also indicated that they, or state officials, were testing available packages of spinach consumed by victims of *E. coli* infection.

September 16, 2006. On September 16, CDC reported that 102 cases of illness due to *E. coli* infection had been confirmed, and that 52 people (51%) had been hospitalized, 16 (16%) had developed HUS, and one had died. Tennessee was removed from the list of states that had confirmed cases because a case originally

attributed to the state had actually occurred in Kentucky. FDA advised consumers to avoid fresh bagged spinach, and issued company recall information.

FDA also announced that it was expanding its lettuce safety initiative to cover spinach. In response to repeated *E. coli* outbreaks associated with fresh lettuce, the agency had advised growers in November 2005 of its concerns about the safety of fresh greens, and the need for continued efforts to assure good agricultural and processing practices within the industry.⁴ The California Department of Health Services had expressed similar concerns in a letter to California growers in January 2006.⁵

September 17, 2006. On September 17, CDC reported that 109 cases of *E. coli* infection had been confirmed, and that 55 people (50%) had been hospitalized, 16 (15%) had developed HUS, and one had died. FDA announced that a second voluntary recall was under way by the company River Ranch of Salinas, California, which was voluntarily recalling packages of spring mix obtained in bulk from Natural Selection Foods. The FDA's report listed all River Ranch and Natural Selection brands.

September 18, 2006. On September 18, CDC reported that 114 cases of *E. coli* had been confirmed, and that 60 people (53%) had been hospitalized, 18 (16%) had developed HUS, and one had died. CDC added Illinois and Nebraska to the list of states with confirmed cases, bringing the total to 21. The rest of the information reported by CDC and FDA, which was repeated in subsequent notices, was the same as on previous days: consumer advice, symptoms of illness, the two recalls, the lettuce safety initiative and the ongoing investigation.

September 19, 2006. On September 19, CDC reported that the number of *E. coli* cases reported had risen to 131, and that 66 people (50%) had been hospitalized, 20 (15%) had developed HUS, and one had died. FDA stated that products containing tainted spinach had been distributed to Taiwan, as well as to Canada and Mexico (as noted above), but that no illnesses had been reported by those countries.

September 20, 2006. On September 20, CDC reported that the number of reported cases had increased to 146, and that 76 people (52%) had been hospitalized, 23 (16%) had developed HUS, and one had died. Arizona and Colorado had been added to the list of states with confirmed cases, bringing the total to 23. FDA expanded its consumer alert to include fresh spinach in bagged products, spinach in a clamshell, and spinach from farmers' markets. The agency also indicated that it had found no evidence that spinach that was frozen, canned, or an ingredient in pre-made meals manufactured by food companies was tainted. FDA reported a third recall that had been announced by RLB Food Distributors, L.P., of West Caldwell,

⁴ FDA, "Nationwide *E. coli* O157:H7 Outbreak: Questions & Answers," Sept. 16, 2006, at [<http://www.cfsan.fda.gov/~dms/spinacqa.html>].

⁵ California Department of Health Services, "CDHS *E. coli* Information Website," at [<http://www.dhs.ca.gov/opa/ecoli/>].

New Jersey, for certain listed salad products that may have contained spinach with an “enjoy thru” date of September 20, 2006.

The agencies’ alerts also noted that the New Mexico Department of Health had announced that through DNA fingerprinting, it had matched a strain of *E. coli* from a victim’s package of spinach with the outbreak strain taken from infected patients. This marked the first laboratory confirmation of the link between spinach consumption and *E. coli* infections.

September 21, 2006. On September 21, CDC announced that 157 cases of *E. coli* illness had been reported, and that 83 people (52%) had been hospitalized, 27 (17%) had developed HUS, and one had died. FDA reported that it was working closely with the state of California, since it had been determined that the contaminated spinach had come from fields in the California counties of Monterey, San Benito, and Santa Clara. FDA alerts reassured consumers that processed spinach (frozen and canned) and other produce from those counties were not implicated in the outbreak. The same day, CDC held a Clinician’s Outreach and Communication Activity (COCA) conference call with 800 people, who heard experts provide an overview of the current outbreak and FDA’s investigation, the nature of *E. coli* as a pathogen, and treatment options for patients exhibiting symptoms of the infection.

September 22, 2006. On September 22, CDC indicated that 166 cases of illness had been reported, and that 88 people (53%) had been hospitalized, 27 (16%) had developed HUS, and one had died. Maryland and Tennessee were added to the list of states with confirmed cases, bringing the total to 25. FDA reported working closely with the state of California in the three counties in which the tainted spinach may have been grown — investigators were attempting to narrow the geographic area suspected of being the source of the outbreak. FDA repeated the consumer notice that processed spinach, spinach grown elsewhere in the United States, and other produce grown in the three implicated counties were safe to eat, and that the food industry was working to get fresh spinach back on the market.

September 23, 2006. On September 23, CDC announced that 171 cases of *E. coli* infection had been reported, and that 92 people (54%) had been hospitalized, 27 (16%) had developed HUS, and one had died. In addition, FDA reported two more voluntary recalls for products containing spinach supplied from Natural Selection Foods of California. Triple B Corporation, doing business as S.T. Produce of Seattle, Washington, recalled its fresh spinach products with “use by” dates of August 22 through September 20, 2006, that had been distributed to retail stores in Idaho, Montana, Oregon, and Washington, and sold in hard plastic clamshell containers. Pacific Coast Fruits Company of Portland, Oregon, recalled products that might contain spinach with “use by” dates of September 20, 2006, or earlier, and on pizza products with dates of September 23, 2006, or earlier. The company reportedly had stopped making all products with spinach supplied from California on September 14, 2006. Its products were shipped to Alaska, Idaho, Oregon, and Washington. For the 25 states with confirmed cases, the number of cases was reported for each state. Hong Kong was added to the list of places outside the U.S. that had received the affected products.

September 24, 2006. On September 24, CDC stated that 173 cases had been reported, and that 92 people (53%) had been hospitalized, 28 (16%) had developed HUS, and one had died. The agencies indicated that the Utah Department of Health and the Salt Lake Valley Health Department had confirmed that *E. coli* O157:H7, the same strain as the one associated with the outbreak, had been found in a bag of Dole baby spinach purchased in Utah with a “use by” date of August 30, 2006. The tests were conducted by the Utah Public Health Laboratory.

September 25, 2006. On September 25, CDC stated that 175 cases had been reported, and that 93 people (53%) had been hospitalized, 28 (16%) had developed HUS, and one had died. FDA reported that tainted products had been distributed to Iceland.

September 26, 2006. On September 26, CDC reported that the number of cases had increased to 183, and that 95 people (52%) had been hospitalized, 29 (16%) had developed HUS, and one had died. West Virginia was added to the list of affected states, bringing the total to 26. CDC and FDA also announced that Canada had reported one confirmed case of *E. coli* O157:H7 that matched the outbreak strain. In addition, they noted that Pennsylvania Department of Health had reported that the outbreak strain of *E. coli* O157:H7 had been isolated from a bag of baby spinach.

September 28, 2006. On September 28, CDC reported that 187 cases infected with the outbreak strain of *E. coli* had been reported, and that 97 people (52%) had been hospitalized, 29 (16%) had developed HUS, and one had died.

September 29, 2006. On September 29, FDA announced that it had determined that spinach implicated in the *E. coli* outbreak had been traced to Natural Selection Foods LLC of San Juan Bautista, California. The determination was based on epidemiologic and laboratory evidence obtained from multiple states (Colorado, Ohio, Wisconsin, Nevada, Pennsylvania, Utah, New Mexico, and Illinois) and analyzed by CDC, and on product distribution information. One company had recalled its product on September 15 and four others had instituted secondary recalls, because they received the recalled product from Natural Selection Foods. The statement indicated that FDA, the state of California, CDC, and the US Department of Agriculture (USDA) were continuing to investigate the cause of the outbreak through ongoing inspections and sample collections at facilities, in the environment (including irrigation water sources), and through studies of local animal management and water use.

The FDA update indicated that the Grower Shipper Association of Central California, the Produce Marketing Association, the United Fresh Produce Association, and the Western Growers Association had agreed to develop a voluntary plan to improve the safety of fresh produce. FDA and the state of California, however, have not ruled out the possibility of instituting regulatory requirements in the future. In addition, FDA intends to convene a public meeting later in the year to address the larger issue of food-borne illnesses linked to leafy greens once the current investigation is complete.

October 3, 2006. On October 3, CDC reported 192 cases of illness, and that 98 people (51%) had been hospitalized, 30 (16%) had developed HUS, and one died.

October 5, 2006. On October 5, FDA announced that the U.S. Attorney for the Northern District of California had issued a statement on the execution of two search warrants — for Growers Express in Salinas and Natural Selection Foods in San Bautista, California — in connection with the outbreak of *E. coli* O157:H7 that FDA had traced to spinach grown in the Salinas area. The U.S. Attorney stated that there was no indication at that time that leaf spinach had been deliberately or intentionally contaminated. FDA stated that it was working with the U.S. Attorney's office and the Federal Bureau of Investigation (FBI) to determine the facts behind the outbreak, particularly allegations that certain spinach growers and distributors may have failed to take all necessary precautions to ensure that their spinach was safe before it was placed in interstate commerce. The number of reported cases of illness had not changed.

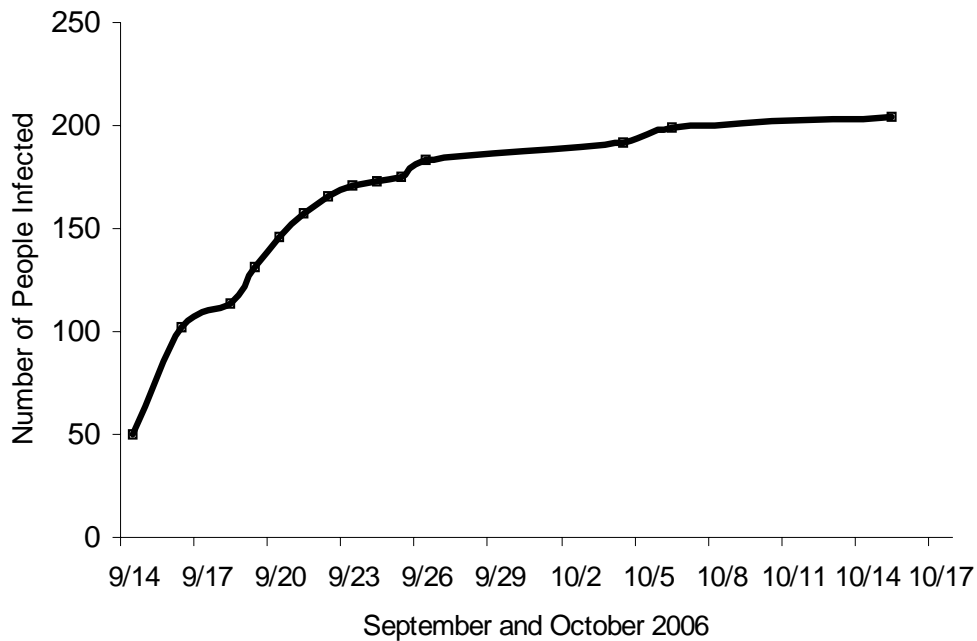
October 6, 2006. On October 6, CDC announced that the number of reported cases had increased to 199 (see **Figure 1**, below) — 102 people (51%) had been hospitalized, and 31 (16%) had developed HUS. On this date, CDC also announced that a total of three people had died in the outbreak — the single case announced earlier, an elderly woman in Wisconsin; and two more victims with *E. coli* infections that matched the outbreak strain on DNA fingerprinting, a child in Idaho and an elderly woman in Nebraska. CDC also reported a fourth suspicious death in an elderly woman in Maryland, but samples to confirm infection by DNA fingerprinting were not available. The two confirmed deaths announced on this date had occurred in September, but required additional time to link to the outbreak by DNA fingerprinting. CDC reported additional findings as follows:

- Of the individuals affected by the outbreak, 141 (71%) were female and 22 (11%) were children under the age of five.
- The proportions of individuals in each age group who developed HUS included 29% of children under age 18, 8% of those aged 18 to 59, and 14 % of those who were 60 years or older.
- The cases were spread across 26 states: Arizona (8), California (2), Colorado (1), Connecticut (3), Idaho (7), Illinois (2), Indiana (10), Kentucky (8), Maine (3), Maryland (3), Michigan (4), Minnesota (2), Nebraska (11), Nevada (2), New Mexico (5), New York (11), Ohio (25), Oregon (6), Pennsylvania (10), Tennessee (1), Utah (19), Virginia (2), Washington (3), West Virginia (1), Wisconsin (49), and Wyoming (1). (See **Figure 2**, below).

In addition, FDA had determined, based on recall audits, that on September 15, Kenter Canyon Farms, Inc., of Sun Valley, California, had instituted a voluntary recall of repackaged spinach as part of the nationwide recall of Natural Selection Foods. The recalled product was only distributed in California, and carried an expiration date of September 20, 2006.

October 12, 2006. On October 12, FDA and the state of California announced test results from the field investigation of the outbreak of *E. coli* O157:H7 in spinach. Samples of cattle feces taken from one of the four implicated ranches tested positive based on matching DNA fingerprints for the same strain that sickened 199 individuals. The announcement stated that while this finding was significant, it was just one aspect of the trace-back investigation that was ongoing for FDA, the state of California, CDC, and USDA. As of November 8, 2006, this alert was the agencies' most recent. (Readers should note that later news reports⁶ have indicated that there were a total of 204 confirmed cases, but this number had not been verified by any available agency documents as of November 8, 2006.)

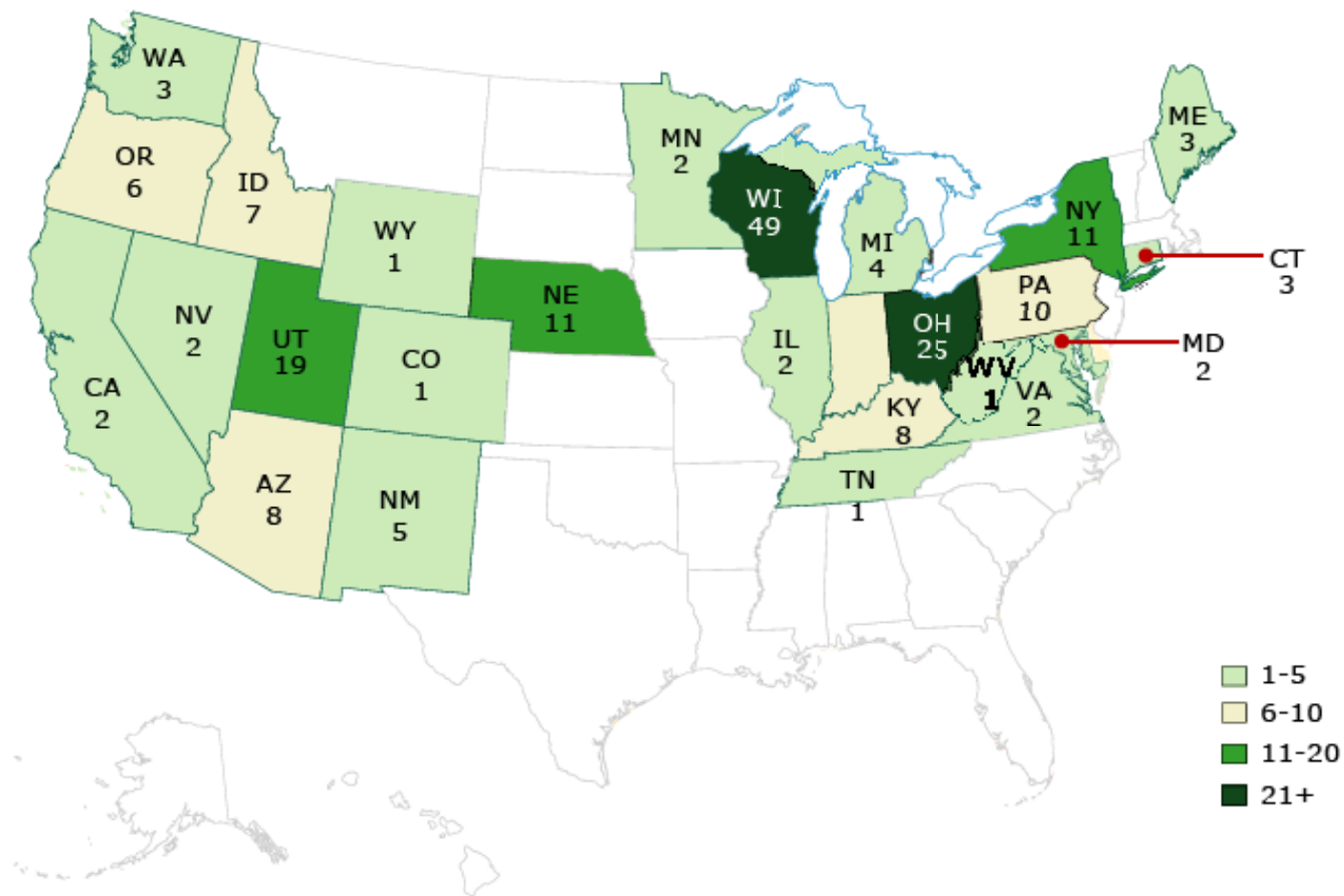
Figure 1. Cumulative Number of *E. coli* Cases Reported by CDC



Source: CDC and FDA data; compiled by CRS.

⁶ “Turning over a new leaf: Produce group wants farmers to foot the bill for inspections.” *The Sacramento Bee*, October 31, 2006.

Figure 2. Number of Confirmed *E. coli* Cases by State as of October 6, 2006



Source: Information provided by CDC. Map adapted by CRS.

Developments Following the Agency Alerts on the Outbreak

On October 22, 2006, a statement issued by the United Fresh Produce Association indicated that it understood that FDA had eliminated all concerns about spinach grown anywhere outside of the three counties in California.⁷ The group indicated its commitment to determining the specific source of the contamination and working to prevent future outbreaks, including the use of the best agricultural practices in the field and the strongest possible Hazard Analysis and Critical Control Points (HACCP) programs in processing facilities.

The Center for Science in the Public Interest (CSPI) petitioned the state of California to adopt stricter food safety procedures because the state has been at the center of the *E. coli* outbreak, and has experienced other problems with contamination of leafy greens.⁸ The petition calls for the California Department of Health Services to establish mandatory regulations relating to manure and water safety on farms, similar to those required of the meat and poultry industries. CSPI suggested that the use of manure as fertilizer should be prohibited during growing season, and that only drinkable water should be used in produce processing facilities.

On October 29, 2006, a news article reported that the investigation of the *E. coli* spinach outbreak had been thorough, although there were no final answers yet.⁹ The article indicated that the codes printed on the bags of spinach had reportedly led detectives to discover when it had been bagged — on August 15 — and other specific details, including worker shift and packing line. Exhaustive testing of the plants' equipment and water supply over several weeks turned up none of the implicated bacteria, according to government officials and company representatives. Company records led investigators to the fields of nine farms in the three counties where the spinach packed on August 15 had been grown. Coding on additional bags of contaminated spinach allowed investigators to narrow the search to four fields. FDA reported that the strain of *E. coli* had been found in manure on a cattle ranch in the Salinas Valley, within a mile of spinach fields. Investigators combed the fields for more samples, including wildlife and cattle feces, stream water, and spinach leaves. Six samples taken from the ranch tested positive for the *E. coli* strain that was being sought, including one found in the gut of a feral pig killed on the property. There were also signs that feral pigs had broken through a wire mesh fence to reach the spinach, indicating that the field was a likely source of the outbreak and that the wild pigs were the probable carriers of the bacteria. However, other fields have not been ruled out as the source. Nevertheless, this investigation has provided the most specific information to date for how a microscopic organism commonly found in an

⁷ "Escherichia coli O157:H7 outbreak investigation narrows," Medical Letter on the CDC & FDA via NewsRx.com & NewRx.net, Oct. 22, 2006.

⁸ Center for Science in the Public Interest, "California urged to monitor farms for food safety," Oct. 25, 2006, at [<http://www.cspinet.org/new/200610251.html>].

⁹ "Spinach probe most thorough ever, but no clear answers yet," *The Associated Press*, State and Local Wire, Oct. 29, 2006.

animal's feces can cause illness and death in consumers thousands of miles away from the primary source of the contamination.

On October 30, 2006, the Western Growers Association proposed that farmers who grow leafy greens be subject to new food safety standards.¹⁰ While a detailed plan has yet to be released, the statement indicated that soil, irrigation water, and farm equipment should be tested for bacteria, workers should be trained in food safety practices, and processing plants should be checked regularly. Violators could be fined or banned from shipping. The association indicated that the produce industry is subject to little oversight by state and federal regulators, an arrangement that is believed to have led to the *E. coli* outbreak. Losses to the spinach industry alone from the recent outbreak have been estimated to exceed \$100 million.¹¹

The association proposes to fund the food safety measures through the novel use of a marketing order. Marketing orders were authorized by state and federal legislation in 1937 as a way to compel producers of a particular crop to follow a common set of rules and pay fees used to fund programs. While marketing orders have never been used to enforce food safety, California Department of Food and Agriculture officials have said that such procedures appear to be within the scope of the law. No information is available on the cost of implementing such a program. Although farmers have to approve marketing orders, they do seem to support the call for increased regulation. The September 2006 outbreak represented the ninth outbreak in California in a decade, and the 20th report of an *E. coli* outbreak in lettuce or leafy greens nationwide since 1995. FDA has reportedly pressed the lettuce and spinach growing industry for more than two years to follow voluntary federal guidelines to prevent outbreaks of foodborne diseases.

On November 2, 2006, a rancher in San Benito County, California, revealed that his operation was one of four farms under investigation by government agencies in connection with the September 2006 *E. coli* outbreak.¹² The rancher indicated that his operation did not grow or process the spinach in question, but that he rented fields to two tenants, one of whom was still under investigation as of November 8. Also on November 2, the Canadian government lifted its ban on U.S. spinach that is grown anywhere outside of San Benito and Monterey counties. Mexico had reportedly lifted its ban on California-grown lettuce in October.

¹⁰ See: Western Growers Association, "Western Growers Board Takes Action To Require Mandatory Food Safety Practices," press release, Oct. 30, 2006, at [<http://www.wga.com/public/active/siteBuilder/templateNewsReleasePopup.php?id=70>]; and "Turning over a new leaf: Produce group wants farmers to foot the bill for inspections." *The Sacramento Bee*, Oct. 31, 2006.

¹¹ *Ibid.*

¹² One of four farms under investigation named. *The Californian* (Salinas, California), Nov. 2, 2006.

On November 2, 2006, several major supermarkets told growers that they had six weeks to establish new safety rules to prevent *E. coli* outbreaks.¹³ The consortium of stores (Vons, Ralph's, and Albertsons grocery chains, and the Costco Wholesale Corporation) wanted growers to work with federal regulators, academia, and industry research scientists to standardize food safety requirements. The group also called for a process for updating food safety rules in response to the emergence of research findings on how diseases are spread from the farm to the dinner table. If growers failed to achieve more stringent and enforceable farming practices, the consortium indicated that it was prepared to set up its own certification system.

Related Congressional Activities

On October 24, 2006, the House Committee on Energy and Commerce asked FDA to explain its role in detecting contaminated food, particularly the *E. coli* strain that tainted spinach in September 2006.¹⁴ The request asked for detailed information about the agency's food contamination preparedness and deterrence assessment, conducted in 2004, and how the assessment was being used in emergencies like the 2006 *E. coli* outbreak. The committee's letter asked the agency for the types of food commodities selected for vulnerability assessments under its 2004 assessment, known as the FDA Security Surveillance Assignment (FSSA), and how the data were collected and analyzed. (FSSA was conducted to determine the safety of food at special security events, such as the G-8 Summit and the national political conventions.)

The recent *E. coli* outbreak led opponents of the National Uniformity for Food Act (**S. 3128, H.R. 4167**), which is scheduled to come before the Senate in the closing days of the 109th Congress, to call for a rejection of the bill. The Association of Food and Drug Officials (AFDO) has indicated that states' ability to react to future bacterial outbreaks would be compromised. While FDA does not have authority to mandate recalls for most of the foods it regulates, the states generally do have this authority. Proponents of the bill argue that the legislation would not affect state adulteration or inspection authorities. Supporters believe that state food regulators are simply wrong to say that the legislation standardizing food warning labels would have hindered states' ability to recall spinach. See CRS Report RL33559, *Food Safety: National Uniformity for Food Act*, by Donna V. Porter, for further information.

¹³ "Grocers enter produce-safety debate: Big supermarket chains tell growers they have six weeks to create rules to avoid E.coli outbreaks." *The Los Angeles Times*, November 2, 2006.

¹⁴ House Committee on Energy and Commerce, "Oversight letter to the FDA concerning the safety of the U.S. food supply and the adequacy of the FDA's food safety and food security efforts," letter to Dr. Andrew C von Eschenbach, FDA Commissioner, Oct. 24, 2006, at [<http://energycommerce.house.gov/108/letters/letters.htm>].

The House and Senate Agriculture Committees may address the recent outbreak of foodborne illness that occurred as a result of spinach contaminated by *E. coli*, possibly from animal manure, when they take up reauthorization of the farm bill in the 110th Congress. Some members have been longtime critics of the division of food safety responsibilities between USDA, which regulates meat, poultry, and processed egg products, and FDA, which regulates all other food products. A proposal for a single food safety agency with increased powers may become part of the debate.

While not mentioned in FDA's reports of its investigation, it is likely that the investigation was streamlined as a result of certain new authorities granted to FDA in comprehensive bioterrorism and public health preparedness legislation in the 107th Congress. P.L. 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, gave FDA the authority to require that food processing facilities register with the agency, which had not been previously required. In addition, processors were required to maintain records that FDA could use to facilitate product trace-backs during outbreak investigations, including in their records information about the source of ingredients coming into their facilities ("one step back") and the customers to whom they shipped products ("one step forward").

Final Observations

The federal and state systems for tracking and investigating the bacterial outbreak seem to have worked well once the clusters of *E. coli* infections were recognized in several states. Investigators were able to trace back to the likely location and source of the problem through a mix of epidemiologic and laboratory investigation, and multi-agency coordination. The FDA and CDC provided alerts to the public and to health officials, and continued to do so through daily updates. In addition, CDC held a conference call for 800 health care professionals on the investigation of the outbreak, *E. coli* testing, and treatment of patients.

A weak point in the system seems to be how best to intercept *E. coli* contamination before it enters the food chain. While procedures are in place to enhance the safety of meat products, the voluntary federal guidelines for leafy greens seem to be ineffective or not fully implemented by growers and processors. Plans to develop a more effective system announced by the produce industry may address this weakness in the food chain. However, mandatory requirements may need to be implemented by regulators to assure the public that leafy greens are safe for consumption. While funding through market orders has been proposed by one group, the question of whether this source of funding or another source is used remains to be resolved. Oversight of the produce safety system will likely be needed.

In the final analysis, the specific cause of the California spinach *E. coli* outbreak may never be known. Investigators were able to develop a fairly good idea of how the contamination and outbreak occurred, thanks to identifying information on bagged spinach, and DNA fingerprinting technology. While livestock and feral pigs were shown to be carriers of the implicated *E. coli* strain, the precise pathway by

which the spinach became contaminated is as yet unclear. Best agricultural practices and HACCP in processing operations are likely to help in preventing such outbreaks in the future.