

United States Senate Committee on Health, Education, Labor and Pensions
Foods Safety: Current Challenges and New Ideas to Safeguard Consumers.
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Testimony of
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Good afternoon Chairman Enzi, Senator Kennedy, Committee members. I am Dr. Kevin Reilly. I am the Deputy Director of Prevention Services for the California Department of Health Services, which in partnership with the FDA, investigated the processing plant and farm sources of spinach implicated in the recent multi-state *Escherichia coli* (*E. coli*) O157:H7 outbreak that resulted in 204 persons reported ill and 3 deaths. Thank you for asking me here today to discuss that investigation and our recommendations to help prevent such an outbreak due to contaminated ready-to-eat produce from happening again.

California first learned of the outbreak during a national teleconference on September 14, 2006 where CDC, FDA and a number of states participated. At the beginning of the teleconference, the federal agencies reported 39 *E. coli* O157:H7 cases and one possible fatality in 12 states that matched on bacterial genetic testing. By the end of the call, the number had risen to 51 cases in 13 states with many more suspected cases being tested. By the end of that weekend, well over 100 patients infected with the outbreak strain had been reported from 21 states.

Prior to 1993, public health agencies did not have an objective way to link seemingly unrelated cases of illness in different states. In 1993, a large outbreak of foodborne illness caused by *E. coli* O157:H7 occurred in the western United States. In this outbreak, scientists at CDC performed DNA "fingerprinting" of the bacterium using a method called pulsed-field gel electrophoresis (PFGE) and determined that the strain of *E. coli* O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties served at a large chain of regional fast food restaurants. Prompt recognition of this outbreak and its cause may have prevented an estimated 800

illnesses. As a result, CDC developed standardized PFGE methods and in collaboration with the Association of Public Health Laboratories, created PulseNet so that scientists at public health laboratories throughout the country could rapidly compare the PFGE patterns of bacteria isolated from ill persons and determine whether they are similar. PulseNet has significantly enhanced the ability of public health agencies and laboratories to communicate and more quickly identify “clusters” or foodborne outbreaks. As Dr. King with CDC described, PulseNet played a key role in the early detection of this latest spinach associated outbreak of *E. coli* O157:H7.

In California and many other states, local public health and environmental health agencies have the primary responsibility for investigating foodborne illnesses and outbreaks within their jurisdiction. In outbreaks involving multiple jurisdictions, the state health department takes a leadership role in coordinating the investigation. In other states, the responsibility for all outbreak investigation is at the state health department level. The California Department of Health Services’ (CDHS) authority to investigate foodborne illness extends to all levels of food production and distribution – including to the farm level. Under that authority, CDHS partnered with FDA in leading the traceback and environmental investigation to determine the ultimate source of contamination that caused this outbreak.

Following the national teleconference on September 14, the FDA San Francisco district office and the CDHS Food and Drug Branch hosted a conference call with three major fresh prepackaged spinach producers in the Salinas Valley whose products were identified by patients in the outbreak investigation. CDHS and FDA advised the firms of the outbreak and strongly suggested that the firms consider initiating a voluntary recall of spinach products. As discussed during the national teleconference, 22 of 39 patients reviewed during the call reported consuming pre-packaged fresh spinach in the days prior to onset of illness. The majority of patients that reported specific brands of fresh pre-packaged spinach identified a brand manufactured by Natural Selections Foods LLC in San Juan Batista, California. Natural Selections Foods LLC was informed that an on-site investigation of their processing facility would be initiated that day, and that

CDHS and FDA would be requesting distribution information for bagged spinach. Natural Selection confirmed that they pack for Dole, Trader Joe's and other private labels. Natural Selection e-mailed FDA and CDHS a retail distribution data file for product shipped from 8/1/06 to 9/14/06. The following day, Natural Selections Foods announced a voluntary recall of their prepackaged spinach products.

The FDA San Francisco district and CDHS Food and Drug Branch activated the California-Food Emergency Response Team (CalFERT), a specially trained and exercised group of microbiologists, field investigators, epidemiologists, and others with special expertise in farm investigations and produce tracebacks. In the past, FDA and CDHS investigators would conduct parallel but separate investigations, often resulting in duplication of effort, lack of standardized investigative processes and procedures, and confusion for regulated firms. CalFERT members receive advanced training in environmental investigations, develop standardized procedures, jointly conduct the investigations, and share all records and reports. FDA and CDHS established the CalFERT more than a year ago following investigations of other produce-associated disease outbreaks traced back to California products.

Over the week following September 14, information from the epidemiologic investigations going on around the country (including the outbreak strain being isolated from prepackaged spinach first in New Mexico and ultimately in 13 different situations) narrowed the production dates in question. Work in the Natural Selections Foods facility rapidly resulted in the identification of nine farms or ranches in three counties that supplied spinach to the processing plant on the production dates implicated in the investigations. CalFERT team members began on-site field investigations within a week of the first notifications on September 14, 2006. As the investigation continued, the implicated date of pre-packaged spinach production was narrowed to August 15, 2006 during a single shift. Based on this information and a thorough review of records at the processing plant, the number of farms/ranches that supplied spinach for that day's production was narrowed to four locations in San Benito and Monterey Counties. From this point, the environmental investigation concentrated on spinach fields at these

four locations. Two of the implicated fields had no produce growing on the date of the first visit. Produce on the other two fields was voluntarily disked under by the farmers. Produce has not been grown on those fields since.

Traceback and environmental investigations are a lot like detective work. The field investigators are trying hard to solve the mystery; to find out the who, what, when, where, and how of what happened to cause the outbreak. The environmental investigation seeks to identify all possible opportunities for introduction, survival, and growth of pathogens for the associated food vehicle. This includes detailed examination of growing, harvesting, shipping, processing, and final preparation/serving practices as well as testing of food handlers/food workers when appropriate. Unfortunately, these investigations rarely find a definitive source. The environmental investigations are extremely time-consuming (may take several investigators several months to complete) and may include investigations of dozens of sites/facilities (farms, distributors, wholesalers, brokers, manufacturers, retailers) and hundreds of environmental samples. The analogy we sometimes use is to "imagine trying to investigate a multi-vehicle auto accident one month after it occurred." Frequently, by the time the patients have been diagnosed and reported through the public health system, and the epidemiologic and laboratory investigations have implicated a particular food item, several weeks have passed. In fresh produce associated outbreaks, the fields have been replanted in a different crop, the harvest crews are long gone, and there are no more products to test from retail or consumer's homes.

The environmental investigation is conducted in a very standardized manner. The CalFERT team members have specific assignments, interview the farm management and workers utilizing farm investigation questionnaires, and systematically review the field environment and practices on the fields. They carefully documented all findings and conducted extensive environmental sampling for bacteriologic testing. The CalFERT team examined each field's surroundings, irrigation sources, wild and domestic animal presence, fieldworker hygiene, and collected samples. Domestic livestock operations were observed in the vicinity of three of the fields and fecal

samples were obtained from these operations. A hydrology expert with CDC reviewed irrigation and obtained well and water management data for the properties. USDA Wildlife Services staff assisted the CalFERT team in investigating wildlife presence and conducted sampling.

E. coli O157:H7 was identified in fecal and/or water samples taken on or near all four fields. However, only one field has yielded the genetic testing matches to the outbreak strain of the bacteria. To date, ten PFGE matches have been identified in cattle and wild boar feces, stream water, and intestinal content of a wild boar killed in the vicinity of this field. This particular field had features that concerned investigators even before sampling. The field is surrounded by hills and cattle pasture. Investigators saw extensive evidence of wild pig presence in and around the growing fields on the ranch (damage to fencing, burrowing under fencing, tracks, feces and evidence of rooting in produce fields) and established that numerous pigs thrive in the riparian habitat there. Potential avenues of contamination for the spinach crop may have included direct pig presence in the field or contaminated irrigation water, among numerous other possibilities. Investigators continue to investigate the source of the outbreak strain in the area. Since June 2004, USDA Agricultural Research Service working with CDHS has documented extensive periodic *E. coli* O157:H7 contamination in waterways in the greater Salinas Valley, though none of the isolates collected from these studies matched the spinach-associated outbreak strain. The Salinas Valley appears to have systemic *E. coli* O157:H7 contamination in the environment that has led to a number of fresh produce associated outbreaks over time.

In total, more than 800 environmental samples have been collected by CalFERT in this investigation including soil, sediment, water, fecal material, feral pig tissue, drag swabs, plant material, and environmental swabs of harvesting equipment.

This outbreak was unusual in the widespread distribution of cases and in the virulence of the pathogen (more than 50% hospitalizations, three fatalities, and high rates of Hemolytic Uremic Syndrome in young and elderly patients). The investigation of this

outbreak was unusual in the speed with which the traceback and environmental investigation was conducted to find a likely source of the contamination. The investigation illustrates the excellent working relationships between state and federal public health agencies, and an effective use of the scientific tools now available in the study of these pathogens. What still remains to be done is to effectively implement what has been learned to prevent the next *E. coli* O157:H7 outbreak associated with fresh ready-to-eat produce.

FDA has documented 18 outbreaks of foodborne illness since 1995 caused by *E. coli* O157:H7 for which fresh or fresh-cut lettuce was implicated as the outbreak vehicle. In two additional outbreaks including the latest multi-state investigation, fresh-cut spinach was implicated. These 20 outbreaks account for approximately 610 reported cases of illness and five deaths. Although tracebacks to growers were not completed in all 20 outbreak investigations, completed traceback investigations of nine of the outbreaks associated with lettuce and spinach were traced back to California's Salinas Valley.

In 1998, CDHS provided technical assistance to FDA in the development of early guidance to industry entitled "[Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables <http://www.foodsafety.gov/~dms/prodguid.html>](http://www.foodsafety.gov/~dms/prodguid.html)." This Guide recommends good agricultural practices (GAPs) and good manufacturing practices (GMPs) that growers, packers, and shippers may undertake to address common risk factors in their operations, and thereby minimize food safety hazards potentially associated with fresh produce. In 1996, CDHS working with the lettuce industry developed voluntary agricultural production guidelines for lettuce. This document was used extensively in the development of the 1998 FDA GAPs document.

Following an outbreak of *E. coli* O157:H7 illnesses associated with California lettuce in 2002, CDHS began a series of meetings over the next three years with the lettuce industry to encourage the industry to "step forward", develop a comprehensive research plan to identify the likely causes of and possible preventive measures for the outbreaks, and commit significant long term research funding to this plan. Unfortunately, these

meetings did not result in the desired outcome and subsequent *E. coli* O157:H7 outbreaks have occurred.

CDHS has met with the leafy green industry on a number of occasions over the last 2 to 3 years to voice our concerns and to urge the industry to take the next step and develop a comprehensive research plan for identifying the cause of *E. coli* O157:H7 contamination in the fields and potential solutions, along with providing funding to jump start these efforts. We have worked with the industry, FDA, and academia to produce a video entitled "Safer Processing of Fresh Cut Produce." We have encouraged and participated in the formation of a "lettuce steering committee" at the Western Institute for Food Safety and Security at the University of California, Davis and are developing a prioritized research agenda with this working group. We have met with FDA managers to voice our support for their open letters to the industry and our state health officer sent a letter to the California grower industry in January 2006 stating our support for FDA's approach, outlining several other areas that we plan to assess, and urging the industry to continue their recent commitment to solving this problem.

On February 5, 2004, FDA issued a letter to the lettuce and tomato industries to make them aware of concerns regarding continuing outbreaks associated with these two commodities and to encourage these industries to review their practices in light of FDA's GAPs/GMPs guidance and other available guidance. In view of continuing outbreaks associated with fresh and fresh-cut lettuce and other leafy greens, particularly from California, FDA issued this second letter to reiterate their concerns and to strongly encourage the lettuce industry to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards in fresh fruits and vegetables, as well as other available information regarding the reduction or elimination of pathogens on fresh produce.

In April 2006, the lettuce and green leafy industry promulgated a *Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain*. This document represents an excellent start towards Good Agricultural Practices that, if effectively and

uniformly implemented at the farm level, could significantly reduce the potential for bacterial contamination of fresh lettuce, spinach and other leafy greens. The Guidelines are relatively generic and lack specificity for consistent application on the farm. The next significant challenge for this industry and food safety experts is to put specificity and metrics to these practices so that they can be applied in a verifiable manner on all farms and ranches growing, harvesting and packing leafy green produce for consumption in order to assure improved food safety with these products.

In mid-summer 2006, FDA and CDHS Food and Drug Branch kicked off a joint lettuce safety initiative with Salinas Valley lettuce growers and processors to assess the use of the *Guidelines* and good agricultural practices on the farm, and good manufacturing practices in the processing plants. Although the initiative was in place for only a few weeks prior to being suspended with the onset of the multi-state spinach-associated *E. coli* O157:H7 outbreak; preliminary findings on the farms showed that many growers were not implementing GAPs, and several were not aware of recommended GAPs.

We know where *E. coli* O157:H7 comes from. It is a common flora in cattle and perhaps in other ruminants, and can also be found in the gastrointestinal tracks of other wild and domestic animals. The risk factors for contamination of produce include water used for irrigation or possible from flooding, manure used for fertilization, field proximity to infected livestock, access to the fields by wildlife, and farm worker hygiene. Our job during the on-farm investigation is to determine where the fecal contamination came from, and how it ended up on the spinach or other fresh produce in the field. This latest investigation showed *E. coli* O157:H7 matching the outbreak strain in three of these potential sources. Although we may never be able to determine exactly what happened on the fields during or immediately before the harvest of spinach that went into the August 15 production lots at Natural Selections Foods, we can reinforce the idea that good agricultural practices implemented consistently every day on every farm growing fresh ready-to-eat produce will significantly reduce the risk for contamination. GAPs are of critical importance because we have witnessed that even the most state-of-the-art food processing can fail to remove *E. coli* contamination resulting in

outbreaks. We do not know why that is the case, but it is. The best solutions for safer fresh ready-to-eat produce are research to better understand the ecology of these bacterial pathogens in the field and on the plants, the consistent application of Hazard Analysis and Critical Control Program based Good Manufacturing practices in the processing and shipping environments, and universal application of GAPs on the farms and fields.

We still do not have a lot of science about the environment in which these products are grown, how and where pathogens may survive or grow in these environments, the effectiveness of various measures that growers can take to minimize the chances of contamination. What we do know is that there are still a lot of unanswered scientific questions about produce microbiology, how and where these pathogens survive or grow in the environment, and how traditional green leafy produce processing methods deal with low numbers of pathogens. More funding is needed for research in these areas.