Testimony
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Ensuring Food Safety: FDA's Role in Tracking and Resolving the Recent *E.coli* Spinach Outbreak

Statement of

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INTRODUCTION

Good afternoon, Chairman Enzi and Members of the Committee. I am Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am pleased to be here today with my colleague, Dr. Lonnie J. King, from the Centers for Disease Control and Prevention (CDC), which is also part of HHS. FDA appreciates the opportunity to discuss the recent outbreak of *Escherichia coli* (*E. coli*) O157:H7 linked to fresh spinach and the lessons learned from this outbreak.

Ensuring the safety of the food supply continues to be a top priority for FDA and the Administration. In recent years, we have done a great deal to protect the food supply from unintentional contamination and from deliberate contamination. We have made significant progress in both, but will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

A recent report (April 2006) issued by CDC, in collaboration with FDA and the United States Department of Agriculture (USDA), shows that progress has been made in reducing foodborne infections. This report provided preliminary surveillance data that show important declines in foodborne infections due to common pathogens in 2005 when compared against baseline data for the period 1996 through 1998. The report showed that the incidence of infections caused

by *Campylobacter*, *Listeria, Salmonella,* Shiga toxin-producing *E. coli* O157, *Shigella,* and *Yersinia* has declined. *Campylobacter* and *Listeria* incidence are approaching levels targeted by national health objectives. This report shows that FDA's and USDA's efforts are working, and we are making progress. However, the recent *E. coli* outbreak shows that further progress is needed, particularly with ready-to-eat produce.

Ready-to-eat fresh vegetables, fruits, and prepared salads have a high potential risk of contamination because they are generally grown in a natural environment (for example, a field or orchard) and are often consumed without cooking or other treatments that could eliminate pathogens if they are present. The number of illnesses associated with fresh produce is a continuing concern of the Agency, and we have worked on a number of initiatives to reduce the presence of pathogens in these foods.

In my testimony today, I will first explain FDA's role in food safety. Then, I will discuss FDA's response to the recent *E. coli* outbreak and the ongoing investigation. I also will describe some of the specific efforts that FDA is taking to enhance the safety of fresh produce to prevent future outbreaks. Finally, I will review some of the next steps we plan to take to work with our food safety partners to improve the safety of these foods.

FDA'S ROLE IN FOOD SAFETY

FDA's primary mission is to protect the public health. Ensuring that FDA-regulated products are safe and secure is a vital part of that mission. FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA.

Although FDA has the lead responsibility within HHS for ensuring the safety of food products, CDC has an important complementary and non-regulatory public health role. CDC is the lead Federal agency for conducting disease surveillance and outbreak investigation and routinely monitors the occurrence of specific illnesses in the U.S. attributable to the entire food supply. The disease surveillance systems coordinated by CDC, in collaboration with states, provide an essential early-information network to detect dangers in the food supply and to reduce foodborne illness. Two key surveillance components of our nation's early information network are PulseNet and OutbreakNet. PulseNet is a national network of public health laboratories that perform DNA fingerprinting on foodborne bacteria that result in human illness. The PulseNet network permits rapid comparison of these fingerprint patterns through an electronic database at CDC. OutbreakNet is a network of public health epidemiologists who, under CDC's coordination, investigate suspected foodborne disease outbreaks to determine which foods may be involved and, thus, which control strategies may be needed. Both of these networks provided important information that led to the

early detection of the recent outbreak. CDC's ability to detect and investigate outbreaks of foodborne illness through its networks enable CDC to alert FDA and USDA about implicated food products associated with foodborne illness. CDC also provides expert scientific evaluations of the effectiveness of foodborne disease prevention strategies.

FDA contributes financially and scientifically to the Foodborne Diseases Active Surveillance Network (FoodNet), the principal foodborne disease component of CDC's Emerging Infections Program (EIP). FoodNet is a collaborative activity of CDC, FDA, the Food Safety and Inspection Service (FSIS) of USDA, and ten EIP sites. Through this active surveillance system, these sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. This surveillance system provides important information about changes over time in the burden of foodborne diseases. For example, the CDC foodborne illness report I mentioned earlier used data from FoodNet to identify the decline in the incidence of specific foodborne illnesses. These data help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and develop and plan future food safety activities to prevent and reduce emerging foodborne illnesses. My colleague here today from CDC will provide additional details about CDC's important public health programs.

In addition to working closely with CDC, our sister public health agency, FDA has many other food safety partners – Federal, state, and local agencies; academia; and industry. The government's response to the recent *E. coli* outbreak is a good example of the close and effective working relationships we enjoy with our food safety partners.

RECENT *E. COLI* O157:H7 OUTBREAK LINKED TO FRESH SPINACH

On the afternoon of September 13, CDC informed FDA of a multi-state foodborne illness outbreak, that appeared to be ongoing, of *E. coli* O157:H7 possibly associated with the consumption of fresh spinach. On September 14, CDC notified FDA that the epidemiological data confirmed that fresh spinach was implicated as the source of the illnesses. That day, FDA, CDC, and California and other state officials began holding daily conference calls to share information, coordinate efforts to contain the spread of the outbreak, and investigate the cause.

Also that day, FDA's San Francisco District Office and California Department of Health Services' Food and Drug Branch hosted a conference call with three spinach-processing firms to advise them of the outbreak and to suggest that they consider the possible need to recall spinach products. We informed these firms that FDA would begin on-site investigations of processing facilities that day. FDA, in conjunction with the California Food and Drug Branch, also activated the

California Food Emergency Response Team (CalFERT), a joint California and FDA response team to investigate the source of *E. coli* O157:H7 and determine the extent of possibly contaminated product.

Once CDC notified FDA that they had confirmed that fresh spinach was the source of the outbreak, FDA immediately took action to prevent further illnesses by alerting consumers. On September 14, FDA held a press teleconference and issued a press release alerting consumers about the outbreak, stating that preliminary epidemiological evidence suggested that bagged fresh spinach may be the cause and advising consumers to avoid bagged fresh spinach. Over the course of the next few days, the advisory was expanded to include all fresh spinach to ensure that consumers could adequately avoid eating any tainted product. This revision to the initial advisory became necessary when we learned that bagged spinach was sometimes sold in an un-bagged form at the retail level. This revised advisory remained in effect until September 22, when we were confident that the source of the tainted spinach was restricted to the three implicated counties in California. At that time, we advised consumers that spinach from outside these counties was not implicated in the outbreak and could be consumed.

During the outbreak, on an almost daily basis, FDA held press conferences (that included spokespersons from the State of California), issued press releases, and posted updates on our website to limit the spread of the outbreak by keeping the

public informed. FDA also worked closely with foreign government's food safety officials to provide them up-to-date information regarding the recall.

FDA, the State of California, CDC, and the USDA continue to investigate the cause of the outbreak. The environmental and on-site investigation has included inspections and sample collection in facilities, the environment, and water. In addition, investigators have reviewed and evaluated animal management practices, water use, and the environmental conditions that could have led to contamination of the spinach. The field investigation team has included experts in multiple disciplines from FDA, CDC, USDA, and the State of California.

The joint FDA/State of California field investigation found the same strain of *E. coli* O157:H7 as was involved in the illness outbreak in samples taken from a stream and from feces of cattle and wild pigs present on ranches implicated in the outbreak. The investigation team also found evidence that wild pigs have been in the spinach fields. We continue to look for more information as to the source and mechanism of contamination.

FDA INITIATIVES TO ENHANCE SAFETY OF PRODUCE

As I mentioned earlier, FDA continues to be concerned about the number of foodborne illness outbreaks associated with fresh produce. In the past decade, consumption of produce, particularly "ready-to-eat" products, has increased

dramatically. These products are usually consumed in their raw state without processing to reduce or eliminate pathogens that may be present. Consequently, the manner in which they are grown, harvested, packed, processed, and distributed is crucial to ensuring that microbial contamination is minimized, thereby reducing the risk of illness to consumers.

FDA has initiated several activities to address safety concerns associated with the production of fresh produce in response to the increase in illnesses associated with consumption of fresh produce. Some of these activities include: developing guidance, conducting outreach to consumers, sampling and analyzing both domestic and imported produce for pathogens, and working with industry to promote the use of good growing, harvesting, packing, transporting, and processing practices.

In 1998, FDA and USDA issued guidance for industry, "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance, known as the Good Agricultural Practices (GAPs) guidance, addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. FDA and USDA issued the guidance in several languages and have conducted significant outreach, both domestically and internationally, to encourage its implementation.

After raw sprouts were associated with several outbreaks, FDA issued two guidance documents in 1999 for the sprout industry. The guidance documents contain steps that the sprout industry could use to reduce microbial hazards common to sprout production to ensure that sprouts are not a cause of foodborne illness. Implementation of the guidance has reduced the incidence of outbreaks of illness attributed to the consumption of sprouts.

Since then, FDA has collaborated with industry, in cooperation with state agencies and academia, to develop commodity-specific supply chain guidance for the commodities most often associated with foodborne illness outbreaks. FDA contracted with the Institute of Food Technologists (IFT) to summarize scientific research relating to the various methods of eliminating or reducing pathogens on whole and fresh-cut produce. The 2001 report generated as part of the contract with IFT provided important information that we used to plan and develop future produce safety activities.

In October 2004, FDA announced its Produce Safety Action Plan to help reduce the incidence of foodborne illness attributed to the consumption of produce. The Action Plan has the following four objectives: 1) preventing contamination of fresh produce with pathogens; 2) minimizing the public health impact when contamination of fresh produce occurs; 3) improving communications with producers, preparers and consumers about fresh produce safety; and 4)

facilitating and supporting research relevant to fresh produce. This Plan represents the first time that FDA had developed a comprehensive food safety strategy specific to produce.

Since 2005, as part of the Produce Safety Action Plan, FDA has provided technical assistance to industry in developing guidance for five commodity groups: cantaloupes, lettuce and leafy greens, tomatoes, green onions, and herbs. These commodities account for more than 80% of the foodborne outbreaks associated with produce. Three of the guidance documents (for cantaloupes, tomatoes, and lettuce and leafy greens) have been completed. We have recently made these guidance documents available, and FDA has done outreach and training with the industry to implement the guidance. FDA is still working on the commodity-specific guidance for herbs and green onions. In March of this year, we released draft guidance for the fresh-cut produce industry, "Draft Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables." We are currently working to finalize this guidance document.

In August 2006, FDA met with Virginia officials to discuss outbreaks associated with tomatoes produced on the eastern shore of Virginia. FDA is working with the Florida Tomato Exchange and the University of Florida's Institute of Food and Agricultural Sciences to arrange a forum to discuss ways to improve the safety of tomatoes. The preliminary plan is for the forum to include FDA, state officials including Commissioners of Agriculture and Secretaries of Health, as well as

representatives from institutions and industry in several selected states. Once our investigation of the recent *Salmonella* Typhimurium outbreak linked to fresh tomatoes served in restaurants is complete, we will also reexamine the need for additional safety measures to ensure tomato safety.

We also are working in a broader context to address food safety concerns for all leafy greens. In the past two years, FDA twice wrote to industry to express FDA's concerns with continuing illness outbreaks and to express our expectations for industry to enhance the safety of these products. These letters were a "Notice to Firms that Grow, Pack, or Ship Fresh Lettuce and Fresh Tomatoes" sent in February 2004 and a "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce" (and leafy greens) sent in November 2005.

More recently, in August 2006, FDA and the State of California launched the Lettuce Safety Initiative at the "Forum for Discussion of Lettuce Safety," hosted by the Western Institute for Food Safety and Security (WIFSS). This initiative was developed as a response to the recurring outbreaks of *E. coli* O157:H7 associated with fresh and fresh-cut lettuce and leafy greens, primarily, but not exclusively, from the Salinas Valley area. The multi-year initiative is intended to reduce public health risks by focusing on the product, agents, and areas of greatest concern. The four objectives of the proactive initiative are to: 1) assess current industry approaches and actions to address the issue of improving lettuce

safety and, if appropriate, stimulate segments of the industry to further advance efforts in addressing all aspects of improving lettuce safety; 2) alert consumers early and respond rapidly in the event of an outbreak; 3) obtain information for use in developing and/or refining guidance and policy that will minimize future outbreaks; and 4) consider regulatory action, if appropriate.

Through its investigations of farms implicated in previous outbreaks, FDA has identified many possible factors that contribute to the contamination of fresh produce. These factors include the exposure of produce to poor quality water, manure used for fertilizer, workers with poor hygiene, and animals, both domesticated and wild, on the farm. FDA has been working with the State of California and the industry to promote the adoption of measures to prevent contamination of fresh produce.

NEXT STEPS

In view of this recent *E. coli* O157:H7 outbreak, and after discussions with industry, FDA and the State of California advised the industry to develop a plan to minimize the risk of another outbreak in all leafy greens, including lettuce. Once we have completed our current investigation, FDA will hold a public meeting to address the larger issue of foodborne illness linked to leafy greens. We will also be examining whether improvements in the following four areas could help prevent or contain future outbreaks: 1) strategies to prevent

contamination; 2) ways to minimize the health impact after an occurrence; 3) ways to improve communication; and 4) specific research. We also will be holding a series of meetings with industry groups to discuss ways to improve the safety of fresh produce. As part of our evaluation, we will consider whether additional guidance and/or additional regulations are necessary.

As we continue to look for a better path to improving the safety of fresh produce, research will remain a critical element. This element of a critical path to safer foods will need to include research on analytical technologies that enable faster detection of foodborne pathogens and better intervention strategies. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and toxins in a variety of foods. More rapid and precise testing methods are important to minimizing the spread of foodborne disease once it occurs. We are also studying possible intervention strategies, such as use of thermal treatment and irradiation, which could be applied to fresh produce products to reduce the level of bacteria and viruses that are in or on the product.

In addition, we are working with universities, industry, and state governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end users along the supply chain. We will continue to work with these partners to develop guidance, conduct research, produce educational

outreach documents, and to initiate other commodity- or region-specific programs that will enhance the safety of fresh produce.

CONCLUSION

In conclusion, FDA is working hard, in collaboration with its Federal, state, local, and international food safety partners and with industry, consumers, and academia, to improve the safety of fresh produce. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. This year's report of FoodNet data clearly shows that the preventive measures being implemented by FDA, USDA, and others are achieving significant public health outcomes in the effort to reduce the incidence of foodborne illness. We have made significant progress but will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's food safety programs. I would be happy to answer any questions.