DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

BEFORE THE

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INTRODUCTION

Good morning, Chairman Cardoza and Members of the Subcommittee. I am Dr. David Acheson, Assistant Commissioner for Food Protection 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, Mr. Lloyd Day of the U.S. Department of Agriculture (USDA). FDA appreciates the opportunity to discuss the recent outbreaks of foodborne illness associated with fresh produce and the measures we are taking to enhance the safety of these products.

FDA is committed to ensuring that America's food supply continues to be among the safest in the world. In recent years, we have done a great deal to protect the food supply from both unintentional and deliberate contamination. We have made significant progress in both, but the recent outbreaks of foodborne illness underscore the need to renew our focus on multidisciplinary and integrated food safety strategies.

The Commissioner of Food and Drugs, Dr. Andrew von Eschenbach, recently appointed me to the newly created position of Assistant Commissioner for Food Protection. My first priority in this position is to develop a new strategy for food safety and food defense that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the risks posed by the types of foods we regulate and that focuses on prevention, ensures compliance with preventive controls, and rapidly responds when contaminated food or feed is detected, or when there is harm to humans or animals.

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. Fresh produce presents special challenges. For example, consumption of produce, particularly "ready-to-eat" products, has increased dramatically during the past decade. This is a positive development from a nutrition perspective, but also a new dynamic that challenges our food safety efforts.

Because most produce is grown in an outdoor environment, it is vulnerable to contamination from pathogens that may be present in the soil, in agricultural or processing water, and in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. Produce also is vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate production safeguards, and inadequate sanitation of equipment and facilities. The fact that produce is often consumed raw or with only minimal processing, without any type of intervention that would reduce or eliminate pathogens prior to consumption, contributes to its potential as a source of foodborne illness. Consequently, addressing the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination.

In my testimony today, I will describe HHS's role concerning activities related to food safety. Then, I will describe some of the specific efforts that FDA is taking to enhance the safety of fresh produce to prevent future outbreaks.

HHS'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, the Centers for Disease Control and Prevention (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. CDC's ability to detect and investigate outbreaks of foodborne illness through its networks enables 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, data from FoodNet help public health and food safety agencies evaluate the effectiveness of current food safety initiatives and plan future food safety activities to prevent and reduce emerging foodborne illnesses.

In addition to working closely with CDC, our sister public health agency, FDA has many other food safety partners – Federal, state, and local agencies; international food safety partners; academia; and industry.

INITIATIVES TO ENHANCE PRODUCE SAFETY

To reduce the risk of foodborne illness at all points in the food chain, FDA has adopted a "farm-to-fork" approach to food safety. This approach systematically applies risk management principles at each step as food moves from growers and producers to consumers. While FDA has been working to enhance produce safety for a number of years, the Agency has sharpened its focus in response to the recent produce-related outbreaks.

FDA has focused its food safety efforts in three key areas:

- strengthening the scientific basis for FDA's food safety program with an emphasis on prevention;
- enhancing effective partnerships; and
- improving risk-based targeting of inspection resources.

I will elaborate on these below.

Strengthening the Scientific Basis for FDA's Program to Improve Food Safety

Strengthening the scientific basis for FDA's program to improve food safety is essential to improving FDA's effectiveness at protecting public health. FDA's existing research program includes activities involving microbiological contamination, chemical contaminants, biotechnology/allergenicity issues, seafood safety, dietary supplements safety, color additives safety, and consumer studies. The determination of microbiological and chemical risk and its mitigation drives our research program. In addition, FDA is doing extensive research on the detection, characterization, and behavior of foodborne pathogens, microbial genetics, and molecular virology. These efforts are vital in our attempt to develop risk assessment models for pathogens and intervention strategies to reduce the public health risk that these pathogens present. FDA's research in the area of chemical contaminants focuses on the development of detection methods and toxicology studies.

Collaborative research efforts further strengthen the scientific basis for our food safety programs. For example, for the past decade, FDA has worked closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to

coordinate and mutually support our respective research efforts related to produce safety. This relationship allows FDA to augment its research resources and gain access to facilities and expertise we do not have. In this spirit, we collaborated with ARS and CSREES to analyze water samples from the Salinas watershed for *E. coli* O157:H7, and to relate the location of bacteria to geographical, seasonal, or rainfall variation. An extension of this research will look for sources of *E. coli* O157:H7 in California's Salinas Valley. Information obtained from this study will be used to inform produce growers about strategies to prevent pre-harvest microbial contamination.

We also strengthen the scientific basis for our program by collaborating and learning with others, such as participating in many scientific and technical meetings on food safety. In February, we participated in a forum sponsored by the Western Institute for Food Safety and Security to share information on assessing industry approaches to address the safety of lettuce and leafy greens on the farm and at packing, cooling, and processing facilities. Also in February, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. This month on May 30th and 31st, FDA, the National Center for Food Safety and Technology, and the University of Georgia's Center for Food Safety will co-sponsor a workshop on microbial testing to reach a consensus on the role of microbial testing in ensuring the safety of produce.

In response to the recent outbreaks, FDA recently held two public hearings concerning the safety of fresh produce. The purpose of these hearings was for FDA to share information about recent

outbreaks of foodborne illness related to fresh produce and to solicit comments, data, and additional scientific information on this issue. We are soliciting input from all our stakeholders on ways to improve the safety of fresh produce. The administrative record will remain open until June 13, 2007.

Enhancing Effective Partnerships

To succeed in our science-based efforts to promote food safety, we need to enhance our collaborations with stakeholders interested in food safety, particularly with respect to fresh produce. Fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing and processing chain can be amplified throughout the following steps. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidances. After enlisting the help of the scientific community and industry, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide, published in 1998, recommends good agricultural practices and good manufacturing practices that growers, packers, and shippers can take to address common risk factors in their operations. FDA and USDA issued the guide in several languages and have conducted significant outreach, both domestically and internationally, to encourage its implementation. In addition, FDA has assisted industry in developing a number of commodity-specific food safety guidelines for the commodities most often associated with foodborne illness outbreaks. These include guidelines for lettuce and leafy greens, melons, and tomatoes. We are working with industry on similar guidelines for herbs and green onions.

The example of fresh sprouts illustrates how successful these efforts can be. In 1999, there were 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for sprouts that year. In 2004, only 33 illnesses were reported associated with fresh sprouts and, in 2005 and 2006, there were none. We believe that the decline in sprout-associated illnesses was in large part due to the industry's adherence to the recommendations FDA provided in those guidance documents through our outreach and inspection efforts.

FDA's efforts in this area are ongoing. In March, FDA issued a draft final version of its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance is intended for all fresh-cut produce firms, including, among others, those that process fresh-cut spinach and lettuce/leafy greens, to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards. In addition, based on FDA's efforts, the Codex Alimentarius Commission, the international food safety standards body, has asked the Food and Agriculture Organization/World Health Organization (FAO/WHO) for an expert consultation on the microbiological safety of fresh produce to support the development of commodity-specific annexes to the hygienic code. FAO/WHO just announced that this consultation will occur during 2007 and early 2008.

In August 2006, FDA launched its "Lettuce and Leafy Greens Initiative," which assesses practices and conditions at select farms and facilities in California, in collaboration with California's Department of Health Services and its Department of Food and Agriculture. We will continue to work with Federal, state, local and international food safety partners and with

industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

The close collaboration between Federal and state food safety officials in response to the *E. coli* O157:H7 outbreak associated with fresh spinach is a good example of the effective working relationships we enjoy with our food safety partners. On March 23, FDA and California's Department of Health Services (CDHS) released a joint report on an extensive investigation into the causes of the *E.coli* O157:H7 outbreak last fall that was associated with contaminated Dole brand baby spinach and resulted in 204 confirmed illnesses and three deaths. The inquiry was conducted by the California Food Emergency Response Team (CalFERT), a team of experts from FDA's district office in San Francisco and CDHS. Potential environmental risk factors for *E.coli* O157:H7 contamination identified in the report included the presence of wild pigs, the proximity of irrigation wells used to grow produce for ready-to-eat packaging, and surface waterways exposed to feces from cattle and wildlife. Because the contamination occurred before the start of the investigation, and because of the many ways that *E.coli* O157:H7 can be transferred -- including animals, humans, and water -- the precise means by which the bacteria spread to the spinach remain unknown.

Another important example of a food safety partnership we continue to enhance is the FDA/USDA Food Emergency Response Network (FERN). FERN is a network of Federal, state, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity in case of emergencies. The number of participating laboratories has increased to 134

laboratories in FY 2007, compared to 30 participating laboratories in March 2004 (near FERN's inception). The FERN network proved to be a critical asset in the *E. coli* O157:H7 outbreak associated with fresh spinach. FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli* O157:H7 in spinach. This method allowed for substantially improved testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels.

Improving Risk-Based Targeting of Inspection Resources

FDA is significantly improving its ability to target its inspection resources at the greatest risks to public health. However, inspections cannot and will not identify every potential food safety problem. Improving the processes and operations of all participants in the food production and distribution process offers the greatest protection for American consumers, and inspections are only one component of this activity. To make best use of available resources, FDA uses a targeted, risk-based approach to inspections. For example, we inspect almost all high-risk food establishments on an annual basis. FDA's electronic screening system for imported food shipments also uses a risk-based approach and allows us to focus our physical inspection resources on what appear to be higher risk shipments. In 2006, FDA performed over 89,000 security reviews on shipments of food and animal feed offered for import and flagged as high risk by our screening system. In addition, we performed over 94,000 field exams on imported food products selected for physical examination by our risk-based screening criteria. To enhance our ability to target our inspections, we are working toward a system that will include information from all points on the import life cycle, from production to consumption, in order to better protect consumers.

CONCLUSION

FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, and international food safety partners, and with industry, consumers, and academia. As a result of this effective collaboration, the American food supply continues to be among the safest in the world. We have made progress, but the recent incidents of contaminated food and animal feed demonstrate the challenges we face and the need to enhance our efforts. As I noted at the beginning of my testimony, we are working on a new strategy for food safety and food defense that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework for addressing the challenges we face. We 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 continuing efforts to improve the safety of fresh produce. I would be happy to answer any questions.