



TESTIMONY OF

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HORTICULTURE AND ORGANIC AGRICULTURE

HOUSE COMMITTEE ON AGRICULTURE

MAY 14, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Cardoza and Members of the Subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). With me today is Dr. Steven Solomon, Assistant Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs, which oversees the Agency's field staff. We are pleased to be with you today to discuss issues related to the safety of fresh produce.

FDA is the Federal agency that has statutory responsibility for the safety of almost everything we eat, except for meat, poultry, and processed egg products, which are regulated by our partners at the U.S. Department of Agriculture (USDA). FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

My testimony will describe some of the challenges we face both in preventing fresh produce from becoming contaminated in the first place and in investigating outbreaks associated with fresh produce. I will also discuss some of the specific measures FDA is taking to enhance the safety of fresh produce and other foods to prevent future outbreaks and to improve product tracing when an outbreak occurs or there is a product recall.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both intentional and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local,

tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry, consumer groups, and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports pose challenges that are requiring us to adapt our current food protection strategies.

Improving our food safety system is a high priority for the new Administration. The President has established a Food Safety Working Group and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, strengthening surveillance and enhancing enforcement. FDA is playing an integral part in the working group's efforts.

The President's Fiscal Year (FY) 2010 budget includes an increase of \$259 million for food safety efforts under the "Protecting America's Food Supply" initiative. The level of new funding will increase the number and scope of food inspections, and improve domestic food surveillance, laboratory capacity, and domestic response capabilities to prevent and control foodborne illness. The budget will allow FDA to increase the number of field staff working in the Foods Program

by 404 full-time equivalents (FTEs), an approximate 20 percent increase compared to FY 2009 appropriations.

The overall goal of the Protecting America's Food Supply initiative is to better protect American consumers by preventing intentional and unintentional contamination. This effort invests in priorities that strengthen the safety and security of the supply chain for foods. Supply chain safety and security relies on the principle of risk-based prevention with verification. Under this principle, FDA will hold all segments of industry accountable for ensuring that their products meet U.S. safety standards.

The initiative focuses on foreign and domestic sources of food ingredients, components, and finished products at all points in the supply chain, including their eventual use by the American public. Within this initiative, the budget provides for \$94 million in new user fees to register food facilities and increase food inspections, issue food and feed export certifications, and reinspect food facilities that fail to meet FDA's safety standards.

The budget also will allow FDA to strengthen the safety and security of the supply chain by working with domestic and foreign industry to develop new control measures for all levels of food production and processing, and verify that these control measures are effective when implemented.

The Agency will strengthen food safety by improving the science upon which regulatory decisions and enforcement rely. FDA will conduct risk analysis, modeling and evaluation to

improve risk-based decision-making and better target our resources. This work will also include improving FDA's ability to attribute contamination to specific foods and thereby promote faster response and better resource targeting.

Finally, the budget provides resources for FDA to work with state and other federal agencies to collect baseline data to measure the impact of our food safety efforts and measure the reduction of foodborne illnesses in the United States. This will allow the Agency to adjust food safety priorities and ensure that food programs achieve the best results for public health.

CHALLENGES OF FRESH PRODUCE

Fresh produce presents special safety challenges, and the number of illnesses associated with fresh produce is a continuing concern for FDA. For example, consumption of produce in its fresh (or raw) form, particularly "ready-to-eat" products, has increased substantially during the past decade. The fact that produce is often consumed raw or with only minimal processing, without intervention that would eliminate pathogens (if they are present) prior to consumption, contributes to its potential as a source of foodborne illness. New products and new consumption patterns challenge our food safety efforts.

Because most produce is grown in an outdoor environment, it is susceptible to contamination from pathogens that may be present in the soil, in agricultural water or water used for post-harvest practices (e.g., washing or cooling), in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. Produce also may be vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate

production safeguards, or inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at any one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps.

We also note that traceback investigations for contaminated food, which we discussed with this Subcommittee last year, are more difficult when they involve fresh produce because the food is perishable and the produce item (along with any packaging or labels) is usually no longer available for testing by the time illnesses are reported. In addition, fresh fruits and vegetables are often sold loose without any packaging that could provide information about its source. Further, practices such as packing or repacking produce from multiple sources add complexity to traceback investigations.

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 recent years, FDA has initiated several activities to address safety concerns associated with the production of fresh produce. Some of these activities include: working with industry and others to develop commodity specific guidance on ways to prevent or minimize potential contamination; conducting educational outreach to consumers on safe food handling practices; intensively investigating farms and packing sheds implicated in outbreaks to learn how the produce may have been contaminated; sampling and analyzing both domestic and imported produce for pathogens; and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting, and processing practices.

It also is important to emphasize the critical role of food producers and processors in ensuring the safety of the foods they introduce into commerce. Strong food safety programs in food production facilities begin with the promotion of a strong culture of food safety throughout each farm or firm in the supply chain, including the need for preventive measures and ways to detect and correct problems before they cause harm. Establishing this culture requires a strong sense of corporate responsibility and continuous management oversight.

One of the key messages that FDA has been emphasizing over the last few years is that all food companies, both large and small, must know their suppliers. In today's complex, global market, this may require close interaction with entities throughout the food supply chain, including growers, manufacturers, distributors, retailers, food service providers, and importers.

From the perspective of both public health and the food industry, preventing foodborne illness from occurring is much more desirable than having to minimize the damage caused by such outbreaks by undertaking food recalls, which can often bring production to a halt, disrupt markets, affect consumer confidence, and cause financial loss. It is critical that all segments of the food production industry, from farm to retailer, take measures to ensure the safety of their ingredients and their finished products.

INITIATIVES TO ENHANCE PRODUCE SAFETY

To reduce the risk of foodborne illness at all points in the food chain, FDA utilizes 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 recent produce-related outbreaks.

I will elaborate on the following key areas where FDA has focused its food safety efforts:

- strengthening the research programs that support FDA's food safety program with an emphasis on prevention; and
- enhancing effective partnerships.

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

Strengthening the research programs that support FDA's program to improve food safety is essential to improving the Agency's effectiveness at protecting public health. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and contaminants in a variety of foods. Current research topics include questions related to how and where in the food chain microbiological and chemical contamination of foods takes place, biotechnology and allergenicity issues, seafood safety, dietary supplement safety, color additive safety, and consumer studies. The determination of microbiological and chemical risks and their mitigation drives our research program.

FDA and our regulatory partners are doing extensive research on the detection, characterization, and behavior of foodborne pathogens, microbial genetics, and molecular virology. For instance, the Centers for Disease Control and Prevention (CDC) and FDA have developed rapid methods for serotyping *Salmonella* in produce (such as cantaloupes, tomatoes, and peppers). These rapid methods will aid FDA as we perform analysis of both domestic and imported produce samples.

These efforts also 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. More rapid and precise testing methods to identify contaminants are important for minimizing the spread of foodborne disease once it occurs.

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. In this spirit, we collaborated with ARS and CSREES to analyze water samples from California's 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 the Salinas Valley. Information obtained from this study will be used to inform produce growers about strategies to prevent preharvest microbial contamination.

In addition, we are working with academia, industry, other Federal agencies, 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 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 2006, FDA began working with officials in California and with industry to assess the prevalence of factors in and near the field environment, which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which good agricultural practices and other preventive controls were being implemented as part of a multi-year Leafy Greens Safety Initiative. In 2007, FDA began a similar initiative, in collaboration with state health and agriculture officials from Florida and Virginia, CDC, and several universities, to prevent foodborne illness associated with tomatoes from those states. A significant component of these ongoing initiatives is assessing factors (including irrigation water, drought and flooding events, the proximity of animals to growing fields, and postharvest water use) that are most likely to have been associated with previous contamination of tomatoes and leafy greens. We have made significant progress in our understanding of how *Salmonella* contaminates tomatoes on the farm. We also have improved testing methods to recover *Salmonella* from fresh tomatoes. These findings have already been factored into our regulatory surveillance testing and farm inspections and underscore the importance of our good agricultural practices guidance.

Through the safety initiative, FDA has learned that farms and processing firms are committing resources to implement current Good Manufacturing Practices (cGMPs) and Good Agricultural Practices (GAPs). The initiative also revealed that the extent to which growers implemented GAPs was variable and that improvement could be made. FDA currently is evaluating information that was gathered through the initiative and plans to utilize this information to develop produce safety-related policy and outreach. By identifying practices and conditions that can lead to product contamination, FDA and our safety partners hope to further improve

guidance and policies intended to minimize chances of future disease outbreaks, as well as ascertain future produce-safety research, education and outreach needs.

In 2007, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. Also that year, FDA, the National Center for Food Safety and Technology (NCFST), and the University of Georgia's Center for Food Safety co-sponsored a workshop on microbial testing to reach a consensus on the role of microbial testing in ensuring the safety of produce.

Last year, FDA convened an Interagency Risk Assessment Consortium (IRAC) and, working with JIFSAN, held a workshop to identify and prioritize research needs for conducting a quantitative risk assessment of foodborne illness caused by *E. coli* O157:H7 from the consumption of leafy green vegetables. In September 2008, FDA established the Western Center for Food Safety at University of California in Davis to conduct research, education and outreach that addresses issues that interface production agriculture and food safety. In its first year, the Center will focus on conducting produce safety research addressing the science behind Good Agricultural Practices and develop outcome metrics and an updated literature review related to perchlorate and its impact on food safety. The Center quickly responded to our need for work on the validation of processes to destroy *Salmonella* on pistachios and is working with both the pistachio and almond industries to control *Salmonella* on those tree nuts.

In June 2009, FDA and NCFST will participate in a Food Safety and Technology Day in conjunction with the annual meeting of the International Sprout Growers Association in Chicago.

FDA also has conducted a number of activities to share information with, and solicit information from, our stakeholders. In 2007, FDA held two public hearings concerning the safety of fresh produce 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. In late 2008 and early 2009, FDA held two public hearings requesting data and other information on industry practices and available technologies relevant to improving our ability to more quickly and accurately track fresh produce through the supply chain, especially during a produce-associated foodborne illness outbreak. Through these and other meetings, we are soliciting input from, and actively engaging, all our stakeholders on ways to improve the safety of fresh produce.

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. 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 GAPs and cGMPs that growers, packers, and shippers can take to address common risk factors in their operations. The guide was issued in several languages and FDA has conducted outreach, both domestically and internationally, to encourage its implementation. In September 2008,

FDA published a *Federal Register* Notice soliciting comments and data to inform the agency in updating the 1998 guidance. We are currently drafting revised, proposed guidance based on these comments and other input. 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 will be working with industry on similar guidelines for herbs and green onions in the near future.

In 1999, there were six outbreaks and 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for seed and sprout producers that year. Following release of the sprout guidances, the number of outbreaks associated with the consumption of sprouts and the number of illnesses in an outbreak appeared to decline. There were no reported outbreaks associated with sprouts in 2005, 2006, or 2007. In late 2008, however, there was one sprout-associated *Salmonella* outbreak. In 2009, an ongoing *Salmonella* outbreak linked to sprouts has resulted in more than 200 confirmed cases of illness reported to CDC. Sprouts have also been linked to *Listeria* illnesses in 2009. On May 1, 2009, FDA issued a letter to seed suppliers, distributors, and sprouters urging them to review their operations in light of FDA's guidance and other available information. FDA will be conducting outreach to other industry members, retailers, consumer groups, and state partners. FDA intends to continue to work closely with all parties to identify, and promote adoption of, effective preventive controls.

FDA's efforts in this area are ongoing. In February 2008, FDA finalized its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance complements FDA's cGMPs for food processing facilities. It is intended to assist firms in minimizing the microbial food safety hazards of fresh-cut produce by providing recommendations specific to fresh-cut processing operations. In addition, FDA is leading an effort through the Codex Alimentarius Commission, the international food safety standards body, with support of the Food and Agriculture Organization/World Health Organization (FAO/WHO) to develop commodity-specific annexes to the Codex hygienic code for fresh fruit and vegetable production, starting with an annex for fresh leafy vegetables and herbs.

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, 2007, FDA and California's Department of Health Services (CDHS) released a joint report on an extensive investigation into the causes of the 2006 *E. coli* O157:H7 outbreak 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 offices in San Francisco and Los Angeles and CDHS. Potential environmental risk factors for *E. coli* O157:H7 contamination identified in the report included

the presence of wild pigs and the proximity of irrigation wells to surface waterways potentially exposed to feces from cattle and wildlife. FDA has established agreements with six additional states to establish emergency response teams, similar to CalFERT, around the country.

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 151 laboratories and 19 cooperative agreement laboratories in FY 2009, 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 substantially improved the testing of spinach samples as it allowed for the detection of *E. coli* O157:H7 at lower levels. FDA, with CDC, has provided technical assistance to USDA's Agricultural Marketing Service's Microbiological Data Program by providing information important to the planning of microbiological testing of fresh produce.

LEGISLATIVE INITIATIVES

As noted earlier, the President has established a working group on food safety and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, and enhancing enforcement. FDA's experience with recent foodborne disease

outbreaks and related investigations and recalls have highlighted the need to enhance FDA's statutory authority to better protect consumers. We are reviewing with HHS, as well as other Federal and state food safety partners, prior requests to Congress to strengthen the Agency's ability to protect Americans from foodborne illness. At this time, we want to highlight the previously identified need for new or enhanced authority in several areas:

1. Authority for FDA to require preventive controls for foods;
2. Authority for enhanced access to records during routine inspections to ensure that inspectors have access to all information that bears on food safety; and
3. Authority for FDA to require food facilities to renew their registrations more often, and to allow FDA to modify the registration categories.

In addition, we note that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

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 U.S. food supply continues to be among the safest in the world. We have made progress, but recent incidents of contaminated food demonstrate the challenges we face and the need to enhance our efforts. 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.