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TESTIMONY OF

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INTRODUCTION

Good afternoon, Chairman Kucinich and Members of the Subcommittee. I am Michael Taylor, Senior Advisor to the Commissioner 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 with you today to discuss issues related to the safety of fresh produce.

FDA is the federal agency that is responsible for most of the food supply except for meat, poultry, and processed egg products, which are overseen 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.

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 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 dietary patterns, changes in industry practices, changes in the U.S. population, and an increasingly globalized

food supply chain pose challenges that are requiring us to adapt our current food protection strategies.

President Obama has made a personal commitment to improving food safety. On July 7, 2009, the multiagency Food Safety Working Group (Working Group), which he established, issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. FDA is playing an integral part in the Working Group's continuing efforts. I will describe below a couple of initiatives specifically related to fresh produce that FDA is taking to implement the Working Group's initial key findings.

In discussing these initiatives, my testimony also will describe some of the challenges we face both in preventing fresh produce from becoming contaminated 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 to prevent future outbreaks and to improve product tracing when an outbreak occurs or there is a product recall. Finally, I will address some of the legislative authorities the Working Group identified as necessary for modernizing the food safety statutes.

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. Consumption of produce in its fresh (or raw)

form, particularly "ready-to-eat" products such as bagged, prewashed lettuce, has increased substantially during the past decade. These new products and consumption patterns challenge our food safety efforts. Because produce is often consumed raw or with only minimal processing, without intervention that would eliminate pathogens (if they are present) prior to consumption, it has the potential to be a source of foodborne illness.

Most produce is grown in an outdoor environment, and it is susceptible to contamination from pathogens that may be present in the soil, in agricultural water or water used for postharvest 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 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 examination or 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 their 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; working with the states to increase inspections and to develop commodity-specific food safety programs; conducting educational outreach to consumers on safe food handling practices; investigating farms and packing sheds implicated in outbreaks to learn how the produce may have become contaminated; sampling and analyzing both domestic and imported produce for pathogens; developing risk assessment methods and tools to better characterize and understand the effectiveness of controls to reduce hazards in produce; 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 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 economic interests, preventing foodborne illness from occurring is much more desirable than having to minimize not only the adverse public health impact caused by such outbreaks but also the economic damage 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 supply chain, from farm to retailer, take measures to ensure the safety of their ingredients and their finished products.

You asked about the current science on the safety of ready-to-eat bagged leafy greens, especially with regard to the risk of bacterial growth, including *Listeria* and *Escherichia coli* (*E. coli)* O157:H7 pathogens, and about phages. The differences in growth and survival of pathogens on both whole and fresh-cut leafy greens are not sufficiently documented and not fully understood, although some studies have shown the ability of pathogens to survive and grow on fresh-cut products. While comparisons between whole and cut products are scarce in the scientific literature, some studies have demonstrated that pathogens can attach to both cut and intact surfaces of lettuce tissue. Fresh-cut vegetables provide a higher level of moisture, nutrients, and more surface area, which make ready-to-eat/fresh-cut products more susceptible to microbial growth (non-pathogens and pathogens) than the original intact product. Leafy greens that are processed may be exposed to further risk of microbial contamination from workers, surfaces, equipment, water, and aerosols, enabling microorganisms to persist and grow.

Some processes have the potential to reduce microbial risks (e.g., disinfection), control microbial growth (e.g., chilling), and protect the product from further exposure (e.g., packaging). Current technologies or practices do not effectively eliminate all risk incurred during postharvest processing and packaging of fresh and fresh-cut leafy greens, although, some risk reduction is possible. Storage temperature and length of storage time of ready-to-eat leafy greens are of critical importance for the control of bacterial pathogens and ultimately the safety of these products. Growth of *Listeria monocytogenes* (*L. monocytogenes*) at 3-5°C in refrigerated fresh-cut packaged leafy greens has been demonstrated. *E. coli* O157:H7 has also been shown to survive for several days under refrigerated conditions. Viability of viruses is influenced very little or not at all by low temperatures. However studies have shown that naturally occurring viruses were not typically found on fresh vegetables or in the processing environment of these products. Viruses are primarily introduced through human handling processes. Phages infect bacteria and do not pose a public health risk to humans. In fact, certain types of phages are under investigation for biocontrol of pathogens, such as *L. monocytogenes* and *E. coli* O157:H7.

INITIATIVES TO ENHANCE PRODUCE SAFETY

In the short term, FDA's approach is to issue commodity-specific guidance for industry on the measures they can implement to prevent or minimize microbial hazards of fresh produce. To improve compliance with such measures, FDA also plans to work with USDA's Agricultural Marketing Service (AMS) to include these recommended standards in their marketing agreements and orders when appropriate. Our long-term plan is to set enforceable produce safety standards through a regulation. I will discuss these activities in more detail below.

Federal Commodity-Specific Produce Safety Draft Guidances

Soon FDA will be publishing new commodity-specific draft guidances for improving the safety of leafy greens, melons, and tomatoes. The guidances describe preventive controls that industry can implement to reduce the risk of microbial contamination in the growing, harvesting, transporting, and distributing of these commodities. These guidance documents build on FDA's 1998 general guidance on good agricultural practices for fresh produce but go beyond it by tailoring the guidance to these three specific commodities that have been associated with foodborne illness outbreaks and taking into account knowledge gained since 1998.

FDA's guidances recognize and embrace the progress industry has made in establishing quantitative metrics for the control of some of the factors affecting produce safety. FDA is studying the scientific basis for these metrics and will incorporate appropriate metrics in its produce safety regulation.

FDA's commodity-specific draft guidances represent the Agency's current thinking on how to improve the safety of leafy greens, melons, and tomatoes and are a step along the path to enforceable standards and a safer supply of fresh produce. They reflect and promote the best practices for the industry and are an attempt to help both domestic and foreign firms minimize the risk of microbial contamination of their products throughout the entire supply chain.

In addition to the general guidance on good agricultural practices and guidance for safe production of safe sprouts, in recent years, FDA also has published final guidance for industry to minimize microbial food safety hazards for fresh-cut fruits and vegetables (the Fresh-Cut Guide). The Fresh-Cut Guide, which FDA published in 2008, complements FDA's Current Good

Manufacturing Practices for food processing facilities. It is intended to assist firms 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, 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. In June 2009, FDA conducted the first Codex international electronic working group with members of the Codex Committee on Food Hygiene (CCFH) to advance the draft Annex for Fresh Leafy Vegetables to the next stage of completion. In November 2009, CCFH will consider how to proceed with the next tier of priority commodities.

Produce Safety Regulation

As I mentioned earlier, preventing harm to consumers is one of the core principles identified by the Working Group, and it is our first priority. Too often in the past, the food safety system has focused on reacting to problems rather than preventing harm in the first place. The Working Group recommends that food regulators shift towards prioritizing prevention and move aggressively to implement sensible measures to prevent problems before they occur.

As the federal regulatory agency responsible for ensuring produce safety, FDA has begun work on a regulation to establish enforceable standards for produce safety under our current authorities. The regulation will be based on the prevention-oriented public health principles embraced by the Working Group. It will capitalize on what we have learned over the past

decade, since we published our "good agricultural practices" guidelines in 1998. The regulation also will utilize the progress industry has made in establishing quantitative metrics for the control of some of the factors affecting produce safety by incorporating appropriate measures of success. These metrics, or measures, will improve our ability to verify that certain measures or practices are being carried out and are effective.

Together with its federal and state partners, FDA will work to plan and implement an inspection and enforcement program to ensure high rates of compliance with the produce safety regulation. If Congress passes food safety legislation that includes explicit authority to require preventive controls, FDA would modify and update this rulemaking in light of the new authority.

The regulation will include the following key elements:

- clear standards for implementation of modern preventive controls by all participants in the fresh produce supply chain, from farm to market. These performance-oriented standards will recognize that operators must tailor their preventive controls to the particular hazards and conditions affecting their operations, but the regulation will ensure they do so in accordance with modern food safety principles;
- product-specific standards and guidance, where appropriate, for high-risk commodities;
- quantitative measures of the effectiveness of control systems, to the extent they are feasible and valid; and
- microbial testing protocols to verify the effectiveness of preventive controls.

FDA will work with the industry to facilitate compliance with the new regulation through the following ways:

- issuance of a science-based "hazards guide" to assist producers and processors in designing their preventive controls;
- provision of other technical assistance and guidance on how to comply with the new rules;
- establishment of reasonable time periods for implementation of the rules, taking into account firm size; and
- cooperation with USDA extension programs and industry-sponsored education efforts to foster understanding and implementation of the requirements.

FDA recognizes that the produce sector consists not only of large national and international operators but also many small producers, including many who market directly to consumers at roadside stands and farmers markets. FDA will carefully consider the public health and economic impacts of applying the requirements of the new rules to very small producers and will consider appropriate adjustments in the regulation.

Enhancing Product Tracing

Another key finding of the Working Group is the need to build a national tracing and response system. A system that permits rapid tracing to the source of the product contamination will protect consumers and also help industry recover faster. Yet, despite the dedicated efforts of food safety officials across the country, our current capacity to trace the sources of produce-related illness suffers from serious limitations.

The ability to trace pathways of any food, including fresh produce, forward and back through every point in the supply chain is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses. The pathways that fresh produce travels from field to consumer have become increasingly complex, with items sometimes changing hands many times in the supply chain.

FDA has reached out to various organizations, including trade associations and consumer organizations, to gain a better understanding of best industry practices for product tracing. For example, 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. Using this information from our stakeholders, FDA will issue draft guidance within the next three months on the steps the food industry can take to establish product tracing systems to improve our national capacity for identifying the origins of foodborne illness.

FDA also has entered into a contract with the Institute for Food Technology to conduct a mock traceback scenario with tomatoes, with the cooperation of representatives of the tomato industry and two technology companies. The pilot is scheduled for completion in September 2009. FDA plans to pursue additional pilots to focus on other commodity-technology combinations in the future.

We have been working extensively with states and the fresh produce industry to encourage incorporation of product tracing procedures and technology. For example, FDA assisted the Florida Tomato Commission and the University of Florida/Institute of Food and Agricultural Sciences in the development of Florida's Tomato Best Practices Manual. This Manual incorporates Good Agricultural Practices, Good Handling Practices, and traceability recommendations for industry. The Manual formed the basis of the State of Florida's tomato safety rule.

Research

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 food safety 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 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 for our development of risk assessment models for pathogens and intervention strategies to reduce the public health risk that these pathogens present. 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 and Cooperative State Research, Education, and Extension Service to coordinate and mutually support our respective research efforts related to produce safety. 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.

As part of the Center for Excellence program, FDA maintains four topic-specific centers: the National Center for Natural Products Research at the University of Mississippi; the National Center for Food Safety and Technology at the Illinois Institute of Technology; the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland; and the newly established (2008) Western Center for Food Safety (WCFS) at the University of California at Davis, which focuses on the intersection between production agriculture and food safety.

In its first year, the WCFS has focused on conducting produce safety research addressing the science behind Good Agricultural Practices and developing outcome metrics and an updated

literature review related to perchlorate and its impact on food safety. The WCFS 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.

Last year, FDA, working with the Interagency Risk Assessment Consortium and 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. That workshop assisted in the development of risk assessment tools to better characterize the hazards in produce. This effort is being enhanced by our contract with Research Triangle Institute for the development of scientific assessments. Other collaborative projects are planned and currently are being executed to interact with other academic institutions to augment our in-house and Center for Excellence research. Such projects are based on current needs and are meant to provide FDA with resources that may not otherwise be directly available to the Agency.

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.

Marketing Orders and Agreements

You asked FDA to discuss the Agency's regulation of food safety provisions in agriculture marketing agreements. Although FDA has not had a direct role in creating such agreements, we do work collaboratively with our colleagues at AMS, which is the federal agency responsible for

marketing agreements and orders. When AMS has incorporated food safety standards into its marketing orders, FDA has provided technical assistance to AMS on the appropriate safety practices and would provide such assistance for marketing agreements as well. It is our shared goal that any AMS safety standards would incorporate the applicable FDA regulations or guidance documents. I will defer to my colleague from AMS to describe these programs in more detail.

As FDA moves forward to establish science-based standards to improve the safety of produce, the Agency must have a plan to help ensure high rates of adoption. Given the number of producers, FDA recognizes the importance of leveraging its resources with other federal, state, and local agencies to help achieve greater compliance. In particular, FDA plans to continue to work closely with USDA, which has a great deal of experience in agricultural production and which has a significant workforce, including through its contracts with states. We believe that AMS, by incorporating FDA's produce safety standards in produce-related marketing agreements or orders, can help ensure high rates of compliance with FDA's standards.

LEGISLATIVE INITIATIVES

In addition to highlighting measures that the Executive Branch could implement to enhance food safety, the Working Group also noted the need for Congress to modernize the food safety statutes to provide key tools for FDA, the Food Safety and Inspection Service at USDA, and other components of the federal government to keep food safe. Legislative authorities for FDA that would enhance the safety of produce include:

- enhanced ability to require science-based preventive controls;

- enhanced ability to establish and enforce performance standards to measure the implementation of proper food safety procedures;
- access to basic food safety records at facilities;
- enhanced inspection tools to foster compliance with science-based standards;
- new tools to strengthen standards and oversight for food imports;
- the ability to require the establishment of product tracing systems; and to
- require mandatory recalls.

There are several bills in Congress that incorporate many of the authorities listed above. We look forward to working with Congress on this important legislation to strengthen our food safety system.

CONCLUSION

The safety of fresh produce depends on every participant in the farm-to-table supply chain implementing modern preventive controls to minimize and, where possible, eliminate contamination that can cause illness. We look forward to continuing to work with the produce industry, consumer groups, academia, and our food safety partners at the federal, state, local, tribal, and international levels to help us 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.