DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

DAVID ACHESON, M.D., F.R.C.P.

ASSOCIATE COMMISSIONER FOR FOODS

FOOD AND DRUG ADMINISTRATION

BEFORE THE

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INTRODUCTION

Good afternoon, 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). 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 foodborne illness outbreak associated with fresh produce contaminated with *Salmonella* Saintpaul and the measures we are taking to enhance the safety of fresh produce and to enhance traceability.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA). FDA is committed to ensuring that America's food supply continues to be among the safest in the world.

There is no question that the *Salmonella* Saintpaul outbreak investigation has been one of the most complex investigations in recent memory. I assure you that FDA is committed to working with all our food safety partners to examine ways to remove or mitigate some of the complicating factors to expedite tracebacks. In my testimony, I will discuss some of the factors that made this investigation so complex. I will also 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 traceability when an outbreak occurs.

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 posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan and the Action Plan for Import Safety, which I will discuss later in my testimony.

CHALLENGES OF FRESH PRODUCE

The number of illnesses associated with fresh produce is a continuing concern for FDA, 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, 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, and inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps. The fact that produce is often consumed raw or with only minimal processing, without any type of intervention that would eliminate pathogens (if they are present) 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 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 to develop guidance on ways to prevent or minimize potential contamination, conducting educational outreach to consumers on safe food handling practices, 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. For example, just last month, FDA provided training in good agricultural practices in Costa Rica.

Research is also a critical element of our efforts to improve the safety of fresh produce. 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 to identify contaminants are important for detecting contamination if it is present and minimizing the spread of foodborne disease once it occurs. 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.

I would now like to provide a brief description of the typical traceback process.

TRACEBACK PROCESS

Once CDC, through its epidemiological investigation which involves working with state and local governments, identifies the possible food(s) associated with a foodborne illness outbreak, CDC notifies FDA. At that point, we start our traceback investigation to identify the source of the contamination. We work with industry and with local, state, and Federal officials, and, when needed, with foreign governments, to identify the source of the contamination. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer or restaurant and inspecting or investigating points throughout the

supply chain to determine where the contamination most likely occurred. Tracing food requires us to find and examine documentation (such as bills of lading and invoices) for the product throughout the supply chain. We also obtain information on the practices and conditions under which the product was stored and handled at each point to better determine shipments of interest and whether contamination may have occurred at each point.

Traceback investigations involving fresh produce are more difficult because the food is perishable and is usually no longer available for testing by the time consumers become ill. 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. As each traceback investigation is different, I would like to mention three recent examples which illustrate the different degrees of difficulty.

Peanut Butter

In 2007, CDC notified FDA of a multi-state outbreak of *Salmonella* Tennessee infections associated with the consumption of peanut butter. In this case, because it was not a perishable food, consumers who had become ill still had jars of peanut butter available for testing. This enabled investigators to confirm the presence in that food of the contaminant associated with the outbreak. Further, because the food was packaged, the investigators were able to identify the manufacturer through the information on the jars. This is an example of a rapid traceback in which the necessary information was readily available.

Fresh Spinach

In 2006, CDC informed FDA of a multi-state outbreak of illnesses associated with the consumption of fresh spinach contaminated with *Escherichia coli* O157:H7. Although this outbreak involved a perishable food, the food was sold in a package. The traceback investigation was facilitated because several consumers who had become ill still had packages of fresh spinach in their refrigerators. The information on those packages ultimately led investigators to the spinach processors. By looking at the processor's records, the investigators were able to identify the implicated farms associated with the identified production lot of bagged spinach. This is an example of a traceback of medium complexity that took a little longer than the peanut butter example but which was aided by the information on the package.

Salmonella Saintpaul

The current outbreak investigation, which initially focused on certain types of raw tomatoes, provides an example of one of the most difficult traceback investigations. On May 26, CDC informed FDA of the hypothesis of a possible association between ill persons and the consumption of raw tomatoes. On May 31, CDC formally notified FDA of a significant statistical association between consumption of certain types of tomatoes and a multi-state outbreak of *Salmonella* Saintpaul infections, and FDA decided to initiate investigations attempting to trace the tomatoes reported to have been eaten by ill persons back to their sources. Raw tomatoes are a perishable commodity and, thus, are unlikely to be in the consumer's home after the consumer becomes ill, obtains a diagnosis, and a foodborne illness outbreak is identified. Further, raw tomatoes are often sold loose, without any form of packaging. In this case, we learned that many tomatoes had been shipped to washing, packing, and repacking

facilities where they were or might have been commingled with other tomatoes from many different sources. This commingling has the potential to multiply the quantity of food that is contaminated. It also increases the difficulty in determining which tomatoes were the source of the illnesses. A further complicating factor was caused by entities in the supply chain using different terminology to describe the tomatoes. For example, one party might describe the tomatoes as "hothouse" or "greenhouse" tomatoes while the next party in the chain might describe them simply as "tomato bulk." Yet another party might use a descriptor such as "green six-by-six." This lack of consistency in nomenclature makes it more difficult and more time-consuming to connect the links in the chain and to identify the source of the tomatoes.

SALMONELLA **SAINTPAUL OUTBREAK INVESTIGATION**

Since May 31, many FDA employees in the field and at headquarters have been working continuously on the outbreak investigation to identify the source(s) of the illnesses. To help the public distinguish tomatoes not associated with the outbreak, FDA adopted the policy of specifically designating the types of tomatoes implicated in the outbreak as well as listing growing areas that were not part of the outbreak. Based on information provided by CDC, state officials, and from our own investigations, FDA has been regularly updating the information on its website, conducting media calls, and updating our Federal, state, and local partners, along with the affected industries.

As is our usual course, FDA's recommendations for consumers were focused on protecting public health and were based on epidemiological information from the state agencies and CDC.

From them we learned initially that illness was statistically linked to consumption of raw tomatoes. Ill persons reported consuming red round, red plum, and red Roma tomatoes. Because few ill persons had reported consuming other types of tomatoes, we advised consumers that these other types of tomatoes had not been implicated. We also had information from our ongoing traceback investigation that a limited number of geographic regions were being identified as possible sources of the tomatoes that were associated with the outbreak. A number of states informed FDA that growers within their jurisdictions either were not shipping tomatoes during the period of concern or they would not have shipped tomatoes as widely as would have been required to account for this multi-state outbreak. This aggregated information allowed us to advise consumers that they could eat certain types of tomatoes and all tomatoes from a number of countries and states (or from certain regions within a state) with confidence that they were not from the sources that were identified in the traceback investigation.

On June 30, CDC advised FDA that their epidemiological data from the ongoing outbreak indicated that jalapeño and Serrano peppers also might be implicated in the outbreak. Accordingly, on July 1, FDA expanded its investigation into peppers as well and advised consumers at increased risk of complications from infection (elderly persons, infants, and persons with impaired immune systems) not to consume raw Serrano and jalapeño peppers.

On July 17, FDA lifted its warning to consumers to avoid certain types of raw tomatoes. FDA announced that tomatoes currently on the market are not considered to be a possible source of the continuing *Salmonella* Saintpaul illnesses because the tomatoes coming to market now are harvested from different growing areas than those initially implicated. We also reiterated our

recommendation to consumers at increased risk of infection to avoid eating Serrano and jalapeño peppers while the investigation continues.

On July 21, FDA announced that one of the jalapeño pepper samples we tested is a genetic match with the outbreak serotype, *Salmonella* Saintpaul. This finding is strong evidence that jalapeño peppers were involved in the outbreak; however, it does not exonerate other foods. While this one positive sample does not provide the whole story, this genetic match is an important break in the case that we hope will help us pinpoint the source of the contamination. FDA obtained the jalapeño pepper sample during an inspection of the Agricola Zaragoza produce distribution center in McAllen, Texas. The company voluntarily issued a recall. The pepper was grown in Mexico, but that did not mean the pepper was contaminated in Mexico. We continued to investigate the source of the contamination.

Based on this finding, on July 21, FDA advised consumers to avoid eating fresh jalapeño peppers and foods made with them. This advisory did not include cooked or pickled jalapeño peppers. As the traceback investigation continued into the source of the pepper's contamination, the review of the current traceback investigation and harvesting dates, matched with the dates that people became ill, combined to indicate that the contaminated jalapeño pepper originated in Mexico and not at the plant in Texas. Therefore, on July 25, FDA announced that there was no indication that domestically grown jalapeño or Serrano peppers are implicated in the outbreak. We updated our consumer advisory to indicate that our advice to avoid raw jalapeño and Serrano peppers now applies only to peppers grown, harvested, or packed in Mexico. In addition to domestically grown raw jalapeño and Serrano peppers, canned, pickled, and cooked jalapeño and

Serrano peppers from any and all geographic locations also are not connected with this outbreak. Serrano and jalapeño peppers are often grown together, are often served in the same foods, and often travel along the same distribution routes. The finding of the contaminated jalapeño pepper does not mean that Serrano peppers were not also associated with the outbreak.

We are working with state regulatory agencies and the food industry, including restaurants, grocery store chains, and wholesalers to ensure that this new, more narrowly focused advisory is clearly understood by everyone. Our investigation into the source of the contamination is ongoing. We will continue to refine our consumer guidance as our investigation continues.

I would now like to describe some of our recent activities to improve traceability of fresh produce.

RECENT FDA ACTIVITIES TO IMPROVE TRACEABILITY OF FRESH PRODUCE

The ability to trace pathways of any food, including tomatoes and other fresh produce, 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 formed an internal multi-Center group to meet with external entities (such as industry, consumers, and Federal, state, local, and foreign governments) to better understand the universe of track and trace systems that are currently in use or being developed. FDA has reached out to various organizations, including trade associations and consumer groups, to gain a better understanding of best industry practices for traceability, including the use of electronic and other technologies that speed and enhance the traceback process and the use of systems that connect all the links in the produce supply chain. FDA is using this information to develop recommendations for the fresh produce industry to use to improve its internal traceback systems. We plan to hold a public meeting in the fall to further the exchange of information on available technology and best practices for enhanced traceability.

We have been working extensively with states and the fresh produce industry to encourage incorporation of traceability 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.

Another recent example is the final guidance for the fresh-cut produce industry, which FDA issued this year. The guidance includes a section on tracebacks and a section on documentation and recordkeeping. FDA also has provided industry its "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations," which is used by our investigators.

Last month, FDA issued a Request for Applications to provide funding to six states to establish Food Protection Rapid Response Teams to investigate multi-state outbreaks of foodborne illness. Enhancing the infrastructure of state food protection programs and strengthening joint Federal/state responsiveness at a local level are an important way to protect consumers by expediting traceback investigations.

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-, practice-, or region-specific programs to enhance the safety of fresh produce.

ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN

To enhance safety across the range of imported consumer products, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan, which provides a framework to identify and counter potential hazards with respect to both domestic and imported food. Achieving the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress. Both Plans build in safety measures across a product's life cycle, from the time a food is produced to the

time it is distributed and consumed. They encompass three core elements: prevention, intervention, and response.

The Food Protection Plan identified ten legislative authorities necessary for achieving full implementation. We encourage Congress to provide these authorities, which would:

- Allow FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain;
- Authorize FDA to issue additional preventive controls for certain high-risk foods;
- Require food facilities to renew their FDA registrations at least every two years and allow FDA to modify the current food product categories for purposes of registration;
- Authorize FDA to accredit highly-qualified third parties for voluntary food inspections;
- Require a new reinspection fee from facilities that fail to meet current Good Manufacturing Practice (cGMPS) requirements;
- Empower FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet FDA standards;
- Allow FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products;
- Authorize FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied;
- Empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective; and
- Give FDA enhanced access to food records during emergencies.

Last month, the Secretary announced that the Administration is increasing its Fiscal Year (FY) 2009 budget request for FDA by $275 million. This increase brings the Administration's total proposed increase in FDA's budget, including user fees, for FY 2009 to $406.3 million, a 17.9% increase over FY 2008. A large portion of this increase ($125 million) will be used for food safety and will allow FDA to intensify actions to implement the Food Protection Plan. This is in addition to the $42.2 million increase proposed for food protection in the budget announced in February 2008.

On June 30, the President signed the FY 2008 Supplemental Appropriation into law. This appropriation act provided $150 million for FDA, and these resources will allow FDA to accelerate its transformation of its regulatory strategies to meet the challenges of the evolving global marketplace for food and medical products. The funds in the supplemental appropriations act will allow FDA to further implement the Food Protection Plan, the Action Plan for Import Safety, and important medical product priorities. It will specifically allow FDA to expand its food safety activities, such as increasing inspections, performing research on mechanisms of food contamination, establishing offices overseas to build capacity with our foreign partners, developing and validating more rapid detection tools, enhancing our information technology systems to support interoperable databases, and enhancing FDA's ability to identify and target the greatest threats from intentional and unintentional contamination.

CONCLUSION

FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, tribal, 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. However, the *Salmonella* Saintpaul foodborne illness outbreak underscores the challenges we face. Once our investigation has determined the cause of the *Salmonella* contamination, we will examine what other measures are needed.

In the meantime, we have been making progress and are moving forward to implement the Plans. We recently issued 6-month updates that demonstrate the specific actions we have been taking to implement the Plans. For example, we have formed a Risk-Based Steering Committee with the charge of ensuring that a comprehensive risk-based approach is taken with regard to food protection. We are holding a 50-state meeting in August to share information and develop strategies for implementing the Food Protection Plan and to enhance future collaborations between Federal, state, and local partners. Progress also has been made in identifying food vulnerabilities and mitigation strategies; for example, FDA has identified several natural plant bacteria that are effective in preventing contamination of tomatoes with *Salmonella* Newport. FDA scientists received training and instruments to rapidly detect and accurately identify *Salmonella* serovars using a new molecular method. We have strengthened the response to food safety threats by providing incident command system training to our FDA offices around the country and to states and by developing templates to enhance communication during a food

recall. 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 enhance food safety and traceability. I would be happy to answer any questions.