

Background Document for Salmonella Rapid Detection Agenda Topic

The following summary is an excerpt taken from a statement by Dr. David Acheson, Associate Commissioner on Foods, Food and Drug Administration, at the U.S. Department of Health and Human Services on FDA Funding to Protect America's Food Supply, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agenc, U.S. House of Representatives, on Wednesday, September 17, 2008. Also available at- <http://www.hhs.gov/asl/testify/2008/09/t20080917a.html>

SALMONELLA SAINTPAUL

There is no question that the *Salmonella* Saintpaul outbreak investigation was 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 the product tracing process. In my testimony, I discuss some of the factors that made this investigation so complex. I 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 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 the product tracing process when an outbreak occurs.

Food can become contaminated at many different steps – on the farm, in packing, 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.

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 irrigation, or processing water, in manure used as fertilizer, and 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 subsequent steps in the chain. 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. One example of recent FDA actions in this area is the June 2008 training in good agricultural practices that FDA conducted 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.

THE PRODUCT TRACING PROCESS

I would now like to provide a brief description of the typical product tracing process. Once CDC, through its epidemiological investigation with State and local governments, identifies the possible food(s) associated with a foodborne illness outbreak, CDC notifies FDA. At that point, FDA starts our product tracing 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 through a supply chain requires us to find and examine documents such as bills of lading, invoices, and other records maintained by the firm. 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.

Product tracing 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 commingling, packing, and repacking produce from multiple sources add complexity to product tracing process investigations. As each product tracing investigation is different, I would like to mention three recent examples that 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 gather much information regarding lot numbers through the information on the contaminated jars. This is an example of rapid product tracing 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 product tracing process investigation was facilitated because several consumers who had become ill still had packages of fresh spinach in their refrigerators. The information from the packages that tested positive for the outbreak strain allowed investigators to narrow the specific lot number that had been responsible for the outbreak. 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 product tracing of medium complexity that took a little longer than the peanut butter example but was aided by the information on the package.

Salmonella Saintpaul: The recent outbreak investigation, which initially focused on certain types of raw tomatoes, provides an example of one of the most difficult product tracing investigations. On May 26, 2008, 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. In response, FDA initiated 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 the same tomatoes simply as “tomato bulk.” Yet another party might use a descriptor such as “green six-by-six.” This inconsistent 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

From May 31, until late August 2008, many FDA employees in the field and at headquarters worked 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 regularly updated the information on its website, conducted media calls, and updated Federal, State, and local partners, and 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 the epidemiological information, we initially learned that illness was statistically linked to consumption of raw tomatoes. Ill persons reported consuming red round, red plum, and red Roma tomatoes. We also had information from our ongoing product tracing investigation that a limited number of geographic regions were 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 certain regions within a State, with confidence that they were not from the sources that were identified in the product tracing investigation.

On June 30, CDC advised FDA that epidemiological data developed by the States and CDC 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 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 were not considered to be a possible source of the continuing *Salmonella* Saintpaul illnesses because the tomatoes coming to market were 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 continued.

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

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 product tracing investigation continued into the source of the pepper's contamination, the review of the current product tracing investigation and harvesting dates, matched with the dates that people became ill, combined to indicate that the contaminated jalapeño peppers 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 were implicated in the outbreak. We updated our consumer advisory to indicate that our advice to avoid raw jalapeño and Serrano peppers then applied 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 were 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.

FDA's investigation of farms, packing facilities and distributors in North Eastern Mexico included collecting numerous samples of peppers and environmental specimens. A sample of Serrano peppers and a sample of irrigation water collected from a farm in Tamaulipas, Mexico contained the outbreak strain of *Salmonella* Saintpaul. FDA announced this finding in a July 30 press release. As a result of these findings, FDA advised consumers to avoid raw Serrano peppers from Mexico, in addition to raw jalapeño peppers from Mexico, and any foods that contain them. FDA worked with State regulatory agencies and the food industry, including restaurants, grocery store chains, and

wholesalers to ensure that this new, more narrowly focused advisory was clearly understood by everyone.

On August 28, 2008, the CDC announced that the outbreak appeared to be over, but that CDC and State health departments were continuing to conduct surveillance for cases of infection with the outbreak strain. Also in late August, FDA completed the product tracing associated with the outbreak of *Salmonella* Saintpaul. FDA is continuing to review the information that we gathered during the outbreak investigation.

One of the lessons learned from this investigation is the importance of the state and local public health infrastructure that we depend on to help identify foodborne illness outbreaks, investigate them and identify the contaminated food.

RECENT FDA ACTIVITIES TO IMPROVE TRACING OF FRESH PRODUCE

I would now like to describe some of our recent activities to improve product tracing 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 tracing 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 product tracing, including the use of electronic and other technologies that speed and enhance the tracing 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 tracing systems. We plan to hold two public meetings in the fall to further the exchange of information on available technology and best practices for enhanced product tracing.

We have been working extensively with States and the fresh produce industry to encourage incorporation of 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 product tracing 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 fresh-cut produce, which FDA issued this year. The guidance includes a section on product tracing and a section on documentation and recordkeeping. FDA also 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 product tracing investigations.

We also are planning to host a workshop at the University of Maryland during 2009 to review the status of a product tracing study on tomatoes and dairy that the European Union is currently conducting. This review will allow FDA to incorporate relevant findings from the EU study in our decision making. The EU began its four-year product tracing study in 2007 with the goal of ensuring total product tracing of food and feed along the whole chain from production to consumption. As part of this effort, the EU is developing, testing, and evaluating two full pilot product tracing systems, including one for the tomato food chain. We will continue to work with Federal, State, local and international food safety partners and with industry to conduct research, develop educational outreach materials, and initiate other commodity-, practice-, or region-specific programs to enhance the safety of fresh produce.