DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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STATEMENT OF

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FOOD AND DRUG ADMINISTRATION

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INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss the Agency's efforts to enhance food safety. I am pleased to be here today with my colleague, Dr. Richard Raymond of the U.S. Department of Agriculture (USDA).

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 USDA. FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission--to protect and promote public health.

Food can become contaminated at many different steps along the path from farm to fork – 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 deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, and tribal food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry 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 have posed challenges that required us to adapt our current food protection strategies. The outbreaks in the last year and a half underscored the need to develop multidisciplinary and integrated product safety strategies.

To address these challenges, last November, FDA released a Food Protection Plan which provides a framework to identify potential hazards and counter them before they can do harm. Also at that time, HHS Secretary Michael O. 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. To achieve the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, and tribal governments; industry; academia; consumers; and Congress. We seek the assistance of the Members of this Subcommittee to help obtain passage of the necessary legislative authorities.

I would now like to describe some of the highlights of the Food Protection Plan and the food-related items of the Action Plan for Import Safety and some recent food safety and food defense activities.

FOOD PROTECTION PLAN

The Plan builds in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency.

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA--an increased emphasis on prevention. Outbreaks in the last year and a half that were linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses, (2) identify food vulnerabilities and assess risk, and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

First, to promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, importers, and other critical components of the food supply chain. FDA will continue to work with industry, state and local governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. For example, in December 2007, FDA released self-assessment tools to minimize the risk of intentional contamination of food and cosmetics. The tools enable industry to get a quick and detailed assessment of the security measures they have in place and to identify areas in which improvements are needed.

FDA is requesting new authorities to accomplish this first goal. The Agency is requesting the authority to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals. FDA would use

this authority to issue regulations to require companies to implement practical food defense measures at specific points in the food supply chain. This authority would apply to food in bulk or batch form, prior to being packaged.

FDA is also seeking explicit authority to issue regulations requiring preventive food safety controls for high-risk foods. Such authority would strengthen FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from these foods.

Second, to identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. The components of such an approach include but are not limited to: risk management, risk analysis, risk assessment, risk-based workplanning, and risk communication. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health. By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks.

Working with the Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will be providing CDC with two epidemiologists to work on attribution using CDC's electronic foodborne disease outbreak reporting system data. FDA will also continue to work with the Department of Homeland Security on identifying emerging risks and developing rankings so that we can more effectively allocate our available resources to manage these risks.

Third, in order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about sources, spread and prevention of contamination. We will also develop new mitigation tools and implement appropriate risk management strategies. Building on risk assessments, FDA will initiate focused research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information will inform FDA's efforts to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher risk foods, FDA will continue to conduct research and leverage relationships with outside organizations. FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety. For example, FDA is doing extensive research on molecular virology, microbial genetics, and the detection, characterization, and behavior of foodborne pathogens. These efforts are necessary to develop risk assessment models

for pathogens such as *E. coli* O157:H7, *Listeria monocytogenes,* and *Clostridium botulinum***.** FDA's food safety research program includes an intramural program, extramural program, interagency cooperation, and consortia with industry and/or academia.

To enhance the safety of lettuce and leafy greens, FDA is continuing to work 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 are being implemented. In the fall of 2007, in cooperation with industry, state and local governments, and academia, FDA conducted assessments on farms. By identifying practices and conditions that can lead to product contamination, FDA and its food safety partners hope to improve guidance and policies intended to minimize the potential for future disease outbreaks, as well as to ascertain future produce-safety research, education, and outreach needs. As part of the multi-year Leafy Greens Safety Initiative, FDA has worked with industry, academia, and other government agencies including public health officials to identify and prioritize research; worked with industry to secure industry funding for research and to develop commodity-specific guidance documents; and worked with USDA to make resources available for priority research and to conduct studies examining both the current challenges and future solutions.

FDA is also continuing its collaboration with state health and agriculture officials from

Florida and Virginia, the produce industry, and several universities to prevent foodborne illness associated with tomatoes from those states. As part of its Tomato Safety Initiative, FDA is leading the effort to conduct assessments of the factors (including irrigation water, drought and flooding events, the proximity of animals to growing fields, and post-harvest water use) that are most likely to have been associated with previous *Salmonella* contamination. Last summer, assessments were conducted in the field and at packers. Similar assessments will be conducted in Florida this spring to coincide with the tomato production and harvesting season. Information from these assessments will help inform appropriate preventive measures.

Last October, the Food and Agriculture Organization/World Health Organization conducted an expert panel that concluded that the safety of leafy greens and herbs merits attention by the Codex Committee on Food Hygiene (CCFH). FDA has assembled a group of experts and is currently drafting a leafy greens and herbs annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables to address in more detail specific controls to prevent the presence and growth of pathogens in these foods.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance, and improve the detection of food

system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense. Therefore, legislation to authorize FDA to accredit and use highly qualified independent third parties to evaluate compliance with FDA requirements would be an effective way to further meet the heightened inspection demand. FDA would not be bound by these third-party inspections in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by FDA when setting inspection and surveillance priorities.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving its ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing agreements with key foreign countries.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority. That authority (or an FDA-recognized third party inspector) would certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment. FDA would apply this requirement for imported products that have been shown to pose a

threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with FDA's.

In addition, while FDA currently has the authority to pursue an inspection warrant or initiate criminal investigations if it is denied access to inspect facilities here in the U.S., our ability to enforce the inspection provisions for overseas sites is very limited. In particular, although FDA can refuse admission of food that appears to be adulterated or misbranded, FDA cannot refuse admission of food if FDA is hampered in making this determination because its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable FDA to keep possibly unsafe food from entering U.S. markets.

FDA can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to "map" or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for emerging food protection problems.

The recent pet food recalls showed us that we need to also increase our efforts on animal food and feed, as well as human food. To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA is working with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to identify problems with the pet food supply and alert veterinarians and others.

FDA also is developing a modernized risk-based Animal Feed Safety System (AFSS) that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals. With state assistance, FDA is developing an AFSS framework document that identifies the current major processes, guidance, regulations and policy documents that address feed safety and the documents that should be developed to make the Agency's feed safety program comprehensive and risk-based. We expect to hold a public meeting on the AFSS risk model in the next few months.

To implement a requirement in the Food and Drug Administration Amendments Act of 2007, FDA is developing ingredient, processing, and updated labeling standards for pet food. We are also developing ingredient and processing standards for animal feed.

Response

During the past year and a half, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods.

While FDA's response to these outbreaks was swift and effective, there is always a need to respond faster and communicate more effectively with consumers and other partners. During emergencies, important messages must be communicated clearly and through multiple forms of media to consumers and retailers. FDA will enhance its risk communication program through aggressive, targeted campaigns that disseminate clear and effective messages and provide regular updates to help get contaminated products off the retail shelf and out of homes more quickly. FDA has sought advice from the recently formed Risk Communication Advisory Committee to obtain expert advice in the field of risk communications.

To improve our immediate response, FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track-and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. Although FDA has the authority to pursue seizure of adulterated or misbranded food through a civil judicial action, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct an effective recall. In such situations, public health would be best

protected if FDA has the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is seeking a modification to our records access authority that would give FDA more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health. The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated ***and*** presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related*

articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario.

We are moving forward to implement the Food Protection Plan and are working with other Federal agencies; state, local, tribal, and foreign governments; as well as with industry to develop the food science and tools necessary to better understand the current risks of the food supply, and develop new detection technologies and improved response systems to rapidly react to food safety threats.

To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA is planning to host a meeting in August with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 states. We also have numerous other outreach activities underway to engage our stakeholders in implementing the Food Protection Plan.

ACTION PLAN FOR IMPORT SAFETY

On November 6, 2007, Secretary Leavitt presented the Action Plan for Import Safety (Action Plan) to the President. This Action Plan shares with the Food Protection Plan the organizing principles of prevention, intervention and response. The general thrust of the Action Plan is to broaden our focus from examining products as they enter the U.S. to monitoring imported products throughout their life cycle from production to consumption, paying particular attention to the critical points of risk along the way where safety can be compromised and safety standards are most needed. It recommends many of the legislative authorities identified in the Food Protection Plan.

It also recommends that FDA examine food safety control systems of other countries to provide the Agency with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention, and response activities.

Consistent with the goals of the Action Plan, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of food and animal feed products exported from China to the U.S. The MOA establishes a bilateral mechanism to provide greater information to ensure products from China meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and

certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress.

FDA has also made a commitment to station inspectors and other Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries.

Last month, FDA briefed 62 representatives from 48 embassies to discuss both plans and engage their assistance with implementation.

CONCLUSION

Together, the Food Protection Plan and the Import Safety Action Plan provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We look forward to working with the Members of this Committee and the entire Congress to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Import Safety Action Plan. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.