DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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TESTIMONY OF

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BEFORE THE

COMMITTEE ON AGRICULTURE

U.S. HOUSE OF REPRESENTATIVES

JULY 16, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Peterson and Members of the Committee. I am Mike 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). Thank you for the opportunity to appear before you today to review current issues in food safety, especially pending food safety legislation. I am pleased to be here with my colleagues at the U.S. Department of Agriculture (USDA).

Last week I was appointed as a Senior Advisor to the Commissioner of Food and Drugs. I am happy to be back at FDA to continue my work in the food safety arena. When I served as FDA's Deputy Commissioner for Policy from 1991 to 1994, I was involved in the issuance of regulations to address seafood safety and to implement nutrition labeling requirements. From 1994 to 1996, I served at USDA as the Administrator of the Food Safety and Inspection Service and as Acting Under Secretary for Food Safety. While at USDA, I led the development of new safety requirements for meat and poultry. Since 2000, my food safety work has been in the academic and research arenas. It is an exciting time to be back at FDA, and I look forward to working closely with USDA and all of our food safety partners, including Congress, as we move forward to modernize the nation's food safety system.

By way of background, 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 USDA. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission, and FDA's work on animal drug approvals, animal drug residues, animal feed, and

other issues also supports USDA's vital food safety responsibilities with respect to meat, poultry, and processed egg products.

Food safety is a core public health issue. Every year, millions of our friends and neighbors in the United States suffer from foodborne illness, hundreds of thousands are hospitalized, and thousands die. Public health has been defined by the Institute of Medicine as "fulfilling society's interest in assuring the conditions in which people can be healthy." A precondition for health is having access to safe food.

President Obama has made a personal commitment to improving food safety. On July 7, 2009, the Food Safety 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.

The Working Group noted the need 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. Some of the necessary legislative authorities highlighted in the findings include:

- the ability to require sanitation and preventive controls at food facilities, based on a scientific hazard analysis;
- the ability to access basic food safety records at facilities;

- the ability to use resources flexibly to target food at the highest risk and achieve the maximum gain for public health;
- the ability to establish performance standards to measure the implementation of proper food safety procedures; and
- the ability to require mandatory recalls.

A food safety bill recently passed by the Committee on Energy and Commerce in the House of Representatives, H.R. 2749, the "Food Safety Enhancement Act of 2009," addresses all of the above authorities and includes many of the other key recommendations of the Working Group. This legislation's primary sponsors include Chairman Henry Waxman of the Committee on Energy and Commerce, Chairman Emeritus John Dingell, Chairman Frank Pallone of the Health Subcommittee, and Chairman Bart Stupak of the Subcommittee on Oversight and Investigations.

Another comprehensive food safety bill is H.R. 1332, the "Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009" or "SAFE FEAST Act." Its sponsors include many Members of this Committee, including Representative Jim Costa, Chairman Collin Peterson, and Subcommittee Chairmen Dennis Cardoza, Leonard Boswell, Joe Baca, and David Scott, as well as other Members. H.R. 1332 also includes many of the authorities identified as important by the Working Group, such as preventive controls and mandatory recall authority.

The Chairwoman of the House Appropriations Committee's Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, Representative Rosa DeLauro, also has introduced

legislation, H.R. 875, the "Food Safety Modernization Act of 2009," which provides comprehensive reform to the food safety statutes.

These bills illustrate that there is broad agreement on the general direction of food safety reform toward an improvement of risk-based preventive controls to reduce foodborne illness, a public health goal we all share. These legislative initiatives share the core principles identified by the Working Group: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

A coalition of consumer groups is fighting for improvements in the food safety system so that more families do not have to suffer tragic consequences from foodborne disease. Major sectors in the food industry also support and are advocating for fundamental change.

But even with the President's support … even with the full efforts of HHS and USDA and other federal, state, local, tribal, and territorial food safety partners… and even with the backing of consumer groups and industry, our efforts will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century.

FOOD SAFETY LEGISLATION

From FDA's perspective, there are three key questions to ask about food safety legislation:

- First, does the legislation support a new system focused on prevention?

- Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities?
- Third, does the legislation provide or anticipate resources for the Agency to match its responsibilities?

As H.R. 2749 was recently passed by the Committee on Energy and Commerce, I will focus on that bill for a discussion of these questions. I will address each of these three questions in turn and highlight a few of the many important new authorities in this bill.

Does the legislation support a new food safety system focused on prevention?

The legislation would indeed transform our nation's approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

FDA is eager to further the development of this modern system. Working with USDA, industry, consumers, states, localities, and other key partners, we will establish basic standards for preventive controls. We will then join with states and localities to create an integrated national system of inspection, verification, and enforcement.

Key relevant provisions in the legislation include section 102, which requires facilities to conduct hazard analyses and implement preventive controls. It also requires companies to have a comprehensive food safety plan. Section 104 requires adherence to science-based safety

standards issued by the Secretary for fresh produce and certain other raw agricultural commodities to prevent contamination. Section 112 improves FDA's ability to share key information on food safety between levels of government. These, and other provisions, are critical to modernizing our nation's food safety system.

Does the legislation provide FDA the legal tools necessary to match its existing and new responsibilities?

In a new food safety system, FDA has the fundamental responsibility of overseeing and verifying the implementation of preventive measures by hundreds of thousands of companies. The Agency also retains the existing critical role of protecting the public during an outbreak. FDA needs new legal authorities to be able to succeed in these roles and protect the public health. This legislation would provide these critical tools.

The legislation recognizes the importance of modernizing FDA's efforts to protect the safety of the food supply. Under sections 102, 103, and 104, the failure to comply with preventive controls, the food safety plan requirement, performance standards, or safety standards for produce would result in the food being deemed adulterated. An adulterated food is subject to seizure, condemnation, and forfeiture, and also may be refused admission when offered for import into the United States. Section 132 makes the Agency's administrative detention authority more useful by expanding the circumstances under which the Agency can detain a food, thereby preventing its movement or distribution while the Agency takes appropriate regulatory action. Section 134 increases the criminal penalties for certain "knowing" violations, including distributing violative food, and section 135 provides the Agency with civil penalties

when a person violates the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Together, these authorities underscore the responsibilities of firms to only market safe food and give the Agency essential tools to enforce these requirements to protect American consumers.

The bill also recognizes the importance of providing FDA with improved access to information. Section 101 requires facilities to register annually, deems products of non-registered facilities misbranded and consequently prohibits their sale, and allows FDA to modify the food categories that firms provide during registration. These measures will help ensure that the Agency has accurate information about who is making food for American consumers.

Section 204 will provide FDA with important information about commercial importers and require that they comply with good importer practices as a condition of maintaining the registration. This section also prohibits importing a product without being properly registered, and deems a product misbranded if it is imported by an unregistered broker or importer.

The requirements in this section of the bill represent significant enhancements to FDA's authorities with respect to imported products. At present, importers and brokers are not required to register with FDA. These changes will reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety, and by allowing FDA to take action against importers who do not implement appropriate measures to ensure the safety of the products they import – similar to FDA's ability to target domestic producers and facilities that have not taken these measures.

Section 106 provides FDA with explicit authority to access food records during routine inspections, thereby addressing one of the most significant gaps in FDA's existing authority. The authority provided in this provision is essential to enable FDA to identify problems and require corrections before people become ill. It also enables the Agency to verify during routine inspections that firms are maintaining required records.

Although FDA has routine records access for certain other FDA-regulated products, and USDA has routine records access for USDA-regulated products, FDA does not have explicit authority for routine access to records for the vast majority of foods under its jurisdiction. This provision provides FDA with access to critical information to identify problems before an emergency occurs. Under current limited authority, FDA generally only has access to required records during an emergency situation involving serious threats to health or life. Records access and recordkeeping by all persons in the distribution chain are the key mechanisms of providing regulators with information on plant operations, product safety, and product distribution. Such information is necessary to verify compliance and identify problems.

The requirement in section 107 to implement a product tracing system for food will also provide FDA with enhanced information that will help the Agency trace foods more quickly during an outbreak. The current requirement to keep records for the immediate previous source and immediate subsequent recipient (one up/one back) requires the Agency to go to each point in the distribution chain during an outbreak to trace the source and distribution of the contaminated product, which is not a sufficiently expedient process when trying to prevent more people from becoming ill. The ability to trace the path of any food, including tomatoes, other fresh produce,

and peanut butter, back through every point in the supply chain to the source, or forward through the supply chain to the retailer or food service establishment is crucial for limiting foodborne illness during 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.

Does the legislation provide or anticipate resources for the Agency to match its new responsibilities?

One of the most important elements of the legislation is that it provides FDA, for the first time, a mandate to achieve specified frequencies of inspection. The legislation also provides a funding source to help FDA fulfill its new responsibilities. A greater investment in inspection is critical to ensuring high rates of compliance with the preventive control standards and other food safety performance standards that will help drive improvement in food safety and reduced rates of foodborne illness.

Section 105 proposes a rigorous inspection schedule for food facilities, ranging from at least every six to 12 months for high-risk processing facilities, every 18 months to three years for low-risk processing facilities and food labelers and packers, to at least every five years for warehouses. These requirements start 18 months after enactment. To meet these requirements, section 105 allows the Agency to use inspections conducted by inspectors from recognized state, local, and other federal agencies, and foreign government officials.

FDA supports the bill's inspection goals for domestic food facilities. We also welcome the challenge and opportunity provided by the bill to develop and apply the most modern approaches

to inspection, including wider use of microbial testing, to verify that companies are meeting their prevention responsibilities and to achieve our public health goals.

We also appreciate the flexibility the bill provides to adjust inspection frequencies based on solid information about where we can achieve the greatest public health benefit through wise use of our finite resources. This flexibility would allow for more frequent inspection of foods, facilities, and processes that we find to be high risk and possibly less frequent inspection of facilities that we can have confidence, based on evidence, pose low risk.

Food imports present a significant resource challenge. It is important that food imports meet the same requirements as domestic products, and we are pleased that the bill provides FDA with new tools to help achieve this, including the requirement that importers observe good importer practices and authorization to require certification of compliance for imported food under certain circumstances. FDA plans to increase inspection of foreign food facilities, but we are concerned that the bill's foreign inspection mandate may not result in the best use of FDA's resources, in light of the approximately 200,000 registered foreign facilities and the high cost of overseas inspections. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting strong third-party inspections, and increasing targeted, risk-based foreign inspections.

The bill authorizes three fees that are also requested in the President's FY 2010 budget. For example, section 101 provides for a registration fee. This fee is of critical importance to enable the Agency to increase its inspection coverage of the approximately 378,000 registered facilities

and to enhance its other food safety activities. Section 108 provides for a reinspection fee for a food facility that commits a violation that requires additional inspections by FDA. This will help cover the costs of reinspecting FDA-regulated facilities that fail to meet Current Good Manufacturing Practices (CGMPs) or other FDA requirements. Section 203 authorizes the Secretary to charge and collect a fee for the issuance of export certificates for food and animal feed which would facilitate trade. This fee will help cover the cost of this program, which is necessary for firms to do business with countries that require such certificates.

We are committed to working with Congress to ensure that FDA has sufficient resources, including fees, to carry out its inspection mandate.

CONCLUSION

This is a historic moment for food safety in the United States – a moment for FDA and its sister agencies in the federal government to rise to the challenge of the 21st century. Success means fewer hospitalizations and deaths, fewer economically devastating recalls, and greater health for the American people. As Secretary Sebelius recently noted at a Food Safety Working Group listening session, "with the leadership and commitment by our President and so many Members of Congress, and this renewed partnership across HHS, USDA, and our sister federal agencies, I know that this is the time when we will finally make real progress and strengthen our nation's food safety system."

The legislation is a major step in the right direction toward achieving the recommendations of the President's Food Safety Working Group. I look forward to working with you to address both the issues raised here today and any other matters of concern.

Thank you again for the opportunity to discuss FDA's perspective on pending food safety legislation. I would be happy to answer any questions.