



Food and Drug Administration
Silver Spring, MD 20993

TESTIMONY OF

MICHAEL R. TAYLOR

DEPUTY COMMISSIONER FOR FOODS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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COMMITTEE ON ENERGY AND COMMERCE

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INTRODUCTION

Good afternoon, Chairman Stupak and Members of the Subcommittee. I am Michael Taylor, Deputy 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). Thank you for the opportunity to appear before you today to discuss the safety of our nation's food supply, and in particular, the Agency's efforts to ensure the safety of imported food and our inspections program for domestic food facilities. I would also like to commend you, as well as Chairman Waxman, Chairman Dingell, Ranking Member Burgess, and other Members of the Committee for your leadership in passing the Food Safety Enhancement Act (H.R. 2749), important food safety legislation that we hope will soon go to conference with the bill pending Senate floor action.

As you know, food safety is an important priority for the Administration. Soon after taking office, President Obama established a Food Safety Working Group (FSWG), which brought together experts from all federal agencies with responsibilities related to food safety, to improve the nation's food safety system by prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. In its July 2009 Report on Key Findings, the Working Group recognized that the nature of our food supply is rapidly changing, presenting new challenges to our food safety system. An increasingly globalized food supply, changes in the U.S. population, and new dietary patterns have combined to create complex supply chains involved in bringing food to tables across the country. The report noted that food imported from over 150 different countries comprises an increasing percentage of the American diet. The Working Group also recognized the importance of inspections, recommending that the

government prioritize crucial inspection and enforcement activity, support safety efforts by states and localities, and utilize better data to guide these efforts and evaluate their outcomes.

In August 2009, Commissioner of Food and Drugs Margaret Hamburg created the Office of Foods to lead a functionally unified FDA Foods Program and enhance the Agency's ability to meet today's challenges and opportunities in food and feed safety, nutrition, and other critical areas.

The mission of the unified Foods Program is to protect and promote public health by:

- Ensuring the safety of foods for humans, including dietary supplements;
- Ensuring the safety of animal feed and the safety and effectiveness of animal drugs, including the human food safety of animal drug residues;
- Setting science-based standards for preventing foodborne illness and ensuring compliance with these standards;
- Protecting the food and feed supply from intentional contamination;
- Ensuring that food labels contain reliable information consumers can use to choose healthy diets.

The Foods Program leadership recently launched the "One Mission, One Program" Initiative, an effort involving over 100 experts throughout FDA, who are organized in 10 core groups that address topics crucial to the future success of the Foods Program. This includes an Inspection and Compliance Strategy Core Group that is looking at the way we think of and define inspections.

Broadly speaking, FDA's food safety inspections have focused traditionally on identifying sanitation, manufacturing and product contamination problems in food facilities, and gathering evidence of regulatory violations for use in possible enforcement cases. These efforts have made important contributions to food safety over many decades. The food safety legislation passed by this Committee, however, would greatly enhance the public health value of FDA's inspections. The requirements in H.R. 2749 that food facilities have food safety plans and implement modern preventive controls, and the new tools provided to FDA to ensure those plans and controls are working properly, will shift the focus of inspections from collecting evidence of food safety problems after they have occurred to ensuring that food companies are doing what is necessary to prevent problems in the first place.

We will of course continue to act to remove contaminated food from commerce, but the ultimate goal of our inspection and enforcement program must be to achieve high rates of compliance with prevention-oriented standards of the kind envisioned by H.R. 2749, and to do this, we envision our investigators conducting a wider array of inspection activities than is common today and targeting those activities in ways that get the maximum compliance and public health bang for the buck.

The Inspection and Compliance Strategy Core Group is developing ideas and options for making this shift. In addition to considering how best to use the anticipated new tools contained in H.R. 2749, the group is critically evaluating how our new inspectional approach can take into account emerging technologies, food product type, the inherent risk profile of the food product, and the

compliance history of the firm, all with a view toward improving the efficiency and effectiveness of our inspections. In exploring these possibilities, we have reached out to other food regulatory agencies within and outside the United States to better understand their approaches toward food safety and industry compliance, what has worked well, and how success was measured.

Realizing that training and education, both for the inspection staff and for the food industry, will be key for successful implementation of the new authorities we hope will be provided in legislation, we are exploring the idea of alliances with universities, associations, and other organizations to help provide training in preventive controls and develop comprehensive, robust food safety plans that can be tailored to a firm's operation. We have learned from past initiatives that the first step toward safer food production is a strong food safety plan, based on a sound scientific approach that identifies the hazards likely to occur and indicates the appropriate preventive controls to minimize food safety risks.

FDA is continuing to develop a risk-informed process to better target our food safety inspections, sampling, and laboratory analysis of food products. In fiscal years (FY) 2008 and 2009, FDA used a risk-informed model to prioritize which food manufacturers it should inspect. The model considered such factors as association of specific food industry types with foodborne outbreaks, recalls and/or reports of serious adverse events, the inherent risk of food products, and the compliance risk of facilities, as determined by past inspection histories. The application of this inspections model has continued in FY 2010.

In September 2009, the Government Accountability Office (GAO) released a report to Congress entitled “Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food.” Additionally, just last month, the HHS Office of Inspector General (OIG) released a report entitled “FDA Inspections of Domestic Food Facilities.” Let me now focus on the findings of these reports and FDA’s response to them.

GOVERNMENT ACCOUNTABILITY OFFICE REPORT

FDA acknowledges that GAO has raised some important issues in its report on imported food. The Agency agrees with many of the GAO recommendations and will incorporate them, as appropriate, into both short-term and long-term initiatives to help ensure the safety of imported foods.

FDA is continually striving to improve our oversight of the safety of imported food. To this end, the Agency is working with our regulatory partners, such as Customs and Border Protection (CBP), the National Oceanic and Atmospheric Administration, and state agencies, to better coordinate our efforts and to find new ways to collaborate. FDA also recognizes the need to continually update its systems and processes. For example, when fully deployed, FDA's new Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system will improve import screening and targeting to better prevent the entry of adulterated, misbranded or otherwise violative foods and will expedite the entry of non-violative foods. The new system will provide additional information to FDA staff to help them optimize decisions about targeting import entry lines. In June 2007, we launched a pilot test of the PREDICT prototype system on seafood lines. An evaluation showed that PREDICT substantially increased

the violation “hit rate,” that is, entries identified by PREDICT with a higher risk score were ultimately found violative through field exams and/or laboratory sample analyses, thus providing a basis for improving the efficiency of our inspection program.

FDA has encountered certain problems with rolling out PREDICT nationwide, due to difficulties with incorporating it into the Agency’s outdated information technology (IT) infrastructure, which is in the process of undergoing major upgrades. While these problems have delayed the full deployment of PREDICT, we will continue to move forward as expeditiously as possible, and continue to evaluate and strengthen PREDICT as the project advances.

We also believe that enacting the pending food safety legislation is critical to strengthening FDA’s oversight of imported foods. H.R. 2749 would, among other things, provide valuable new tools for ensuring that importers reliably verify that the foods they import are produced in compliance with the same prevention-oriented standards that would be applicable to foods produced in the United States. For our food safety system to be effective, prevention must begin at the point of production, not at the port of entry.

FDA’s comments on GAO’s specific recommendations are as follows:

GAO Recommendation: To enhance FDA's authority to oversee the safety of imported food, GAO recommends that the FDA Commissioner seek authority from the Congress to assess civil penalties on firms and persons who violate FDA's food safety laws.

FDA agrees and is working with Congress to include civil money penalty authority in food safety legislation. Section 135 of H.R. 2749 would establish civil money penalties that FDA would be able to impose for violations relating to food.

GAO Recommendation: GAO further recommends that the Commissioner determine what violations should be subject to this new FDA civil penalties authority, as well as the appropriate nature and magnitude of the penalties.

FDA agrees that the Agency should determine whether or not to seek civil money penalties for particular violations under new authority and that FDA would take into account, as appropriate under such authority, the nature of the violation and other factors in determining the magnitude of a penalty.

GAO Recommendation: The FDA Commissioner should explore ways to improve the agency's ability to identify foreign firms with a unique identifier.

FDA agrees with GAO that the use of a unique identifier would improve the Agency's ability to accurately identify foreign firms. Use of unique identifiers would also aid FDA in targeting high-risk shipments, which are currently hindered when a firm that FDA has previously identified and targeted due to a history of exporting high-risk shipments uses a different identifier, or where a new identifier is assigned to the firm by the database that receives the import entry information. FDA supports new authority to require the use of a unique identifier by food facilities and we are working with Congress to include such new authority in food safety legislation. Section 206 of H.R. 2749 would give FDA the authority to specify the unique

numerical identifier system under which persons must submit such unique identifiers as part of the requirement to register their food facilities with FDA. We also support language in section 101 of the bill to require annual re-registration of food facilities, as that will keep information such as the unique identifiers more current.

GAO Recommendation: To enhance agency coordination and to streamline FDA's refusal process with CBP's redelivery process, GAO recommends that the FDA Commissioner and the CBP Commissioner jointly study, with input from agency field officials, ports where a joint initiative would be feasible.

FDA believes that continuing to engage with CBP to develop joint refusal and re-delivery processes is important, but does not believe that a study is necessary. The Agency is working with CBP to develop a national procedure and implement a joint FDA Refusal and CBP Re-delivery form. If approved, the joint notice should:

- Improve importer compliance with FDA refusal procedures;
- Help ensure that violative products are exported or destroyed; and
- Expedite the response time for the entry refusal process.

GAO Recommendation: To better leverage state resources for protecting the safety of imported food, GAO recommends that the FDA Commissioner reach out to states to find opportunities for additional collaboration through contracts, cooperative agreements, and informal partnerships.

FDA agrees with GAO's recommendation to better collaborate with the states, and supporting state and federal cooperation is also a major priority for the FSWG. FDA's Office of Regulatory Affairs has included an option in the state contracts for import work for the past five years. Future planned State Infrastructure and National Integrated Food Safety System Cooperative Agreements would include the sharing of information on imported products and coordination of both import and domestic import surveillance.

FDA has also increased working relationships with our state regulatory partners through a number of initiatives. These initiatives include increased communication with the states by sharing Agency reports of emerging issues with commissioned state officials, distribution of Reportable Food Registry reports with commissioned officials in affected states, state participation in major recalls, and the use of state-generated evidence and data in FDA regulatory actions. FDA is now connecting inspectional data to programs such as eSAF (electronic State Access to FACTS) and other state accessible programs.

All state food contracts have basic inspection requirements with an option for states to perform additional inspections in specific food areas, such as imports. It may be difficult to get states to commit to new or significantly more inspections. Several states, under current food safety contracts, are now requiring furlough days each month because of state budgets and regardless of contract funding. FDA believes that we can effectively leverage state resources to achieve national food safety goals in a cost-effective way, and the Agency is exploring mechanisms for making the relatively modest federal investments in state food safety infrastructure that would make such leveraging most effective.

GAO also recommended that, in a product recall or foodborne outbreak situation, FDA share product distribution lists with the states. The Agency already shares product distribution lists and other confidential commercial information with states in certain circumstances when permitted by law. However, FDA also supports changes to existing law to strengthen the ability of the Agency to share information with states. The Food Safety Enhancement Act includes such legislative changes.

GAO Recommendation: To help ensure that PREDICT is effectively targeting high-risk imported food shipments for field and laboratory examinations, GAO recommends that the FDA Commissioner develop a performance measurement plan prior to deploying the system at additional U.S. ports.

FDA agrees that a performance measurement plan is key to successfully evaluating PREDICT and modifying it as appropriate prior to widespread deployment. FDA is developing such a plan which will assess whether PREDICT improves FDA's screening of import shipments, whether it provides FDA with better information for management and decision-making purposes, and that identifies indications of the system's public health impact. The plan will also assess PREDICT's functionality and quantify and qualify improvements over the current screening module (OASIS) while providing key baseline data for future assessments. The plan cannot be fully implemented until PREDICT has been in use nationwide for a sufficient period of time to allow the necessary data to be generated.

HHS OFFICE OF INSPECTOR GENERAL REPORT

OIG's recent report on domestic inspections is a useful snapshot of FDA's food safety system as it has existed in recent years. OIG has identified areas of opportunity for enhancing FDA's enforcement authorities. The report also highlights the obligation and responsibility of industry for food safety and OIG has noted the need for better industry practices, such as improved traceability and accurate and timely registration. The recommendations in this report reflect FDA activities during the time period in which OIG studied our systems (FY 2004 to FY 2007). The Agency has already addressed many of the issues and recommendations noted in the report, and considerable progress is being made on others. FDA appreciates OIG's support for our continuing efforts to enhance food safety.

FDA also appreciates OIG's efforts to quantify several issues with respect to inspections from FY 2004 to FY 2007. While FDA's internal analyses do not perfectly replicate these findings, we recognize the importance of follow-up on inspectional findings to make sure that public health is protected and to ensure swift and strong enforcement actions are initiated when significant violations are not corrected or present a threat to public health. Improving the speed and predictability of follow up to inspections and strengthening the Agency's enforcement program are top FDA goals.

Better targeting of inspections to ensure the Agency has the greatest public health impact through prevention of foodborne illness is also a central focus of future efforts to improve FDA's food safety program. This includes targeting sectors and facilities that pose the greatest risk and also focusing more of FDA's inspection activity on ensuring that within any facility, the firm is

meeting its responsibility to prevent food safety problems. The Agency believes there is significant opportunity to improve the public health productivity of FDA food inspections.

New Authorities

OIG Recommendation: Consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that do not voluntarily comply with statutory and regulatory requirements.

OIG Recommendation: Seek statutory authority to allow FDA access to facilities' records during the inspections process.

FDA appreciates OIG's recognition of the gaps in the Agency's inspectional authority. FDA is seeking more effective enforcement tools and we support OIG's legislative recommendations. As noted above, section 135 of H.R. 2749 would expand civil penalties for Federal Food, Drug, and Cosmetic Act (FD&C Act) violations related to food, and section 106 would give FDA access to all records bearing on whether the food may be adulterated, misbranded, or otherwise in violation of the FD&C Act. Routine records access is of particular importance to FDA because it will help to determine whether industry is both implementing proper preventive measures and complying with recordkeeping requirements needed to respond to food safety problems or other public health emergencies.

In addition, FDA and the Administration support several new legislative authorities further advancing the Agency's ongoing efforts to prioritize prevention, strengthen surveillance and

enforcement, and improve response and recovery. New food safety legislation, coupled with the necessary resources, including new user fees, will enable FDA to increase site inspections and issue new, more modern and prevention-oriented food safety regulations. In addition to the legislative authorities already noted, additional necessary legislative authorities include:

- Traceability Requirements – H.R. 2749 provides enhancements to FDA’s ability to trace the origin and distribution of tainted food. FDA would issue regulations that require food producers, manufacturers, processors, transporters, or holders to maintain a pedigree of the origin and previous distribution history of the food and to link that history with the subsequent distribution history of the food. Prior to issuing such regulations, FDA would be required to conduct a feasibility study, public meetings, and a pilot project.
- Mandatory recall authority for foods – In cases where a food could cause adverse health consequences or death and a firm does not act promptly, it is important for FDA to have the authority to order a recall to remove the harmful product quickly from consumer channels to minimize illness or injury.

Increased Inspections

OIG Recommendation: Increase the frequency of food facility inspections with particular emphasis on high risk facilities

Since the timeframe of the OIG report, FY 2004 through FY 2007, the Agency has received increased appropriations that have permitted us to increase the number of food facility inspections. For example, in FY 2010, FDA will be able to increase field staff for the Foods Program to 2,505 from 2,166 in FY 2009 and 1,861 in FY 2008. These field staff, once on board

and fully trained, will allow the Agency to increase the number of food facility inspections it performs annually, and also conduct a wider array of inspections activities. FDA has conducted more foreign inspections in FY 2009 than in any other year in the history of the program and expects to exceed that level in FY 2010.

In addition to FDA's efforts to increase the number of food inspections with these new resources, H.R. 2749 and the Food Safety Modernization Act of 2009 (S. 510) both call for increased inspections. FDA agrees that it is important to expand inspection coverage of food facilities. As the Commissioner pointed out, however, in testimony last fall before the Senate Committee on Health, Education, Labor and Pensions, any food safety bill passed by Congress that calls for increased inspections must have a reliable, consistent funding source in order for FDA to fulfill its new inspections mandate and other responsibilities. Registration fees would provide a consistent source of funding.

Improvements in the efficiency of how FDA uses its inspection resources to achieve public health goals will also contribute to meeting inspection targets. FDA needs the ability to rely on inspections by other federal agencies as well as state, local, and foreign governments, and to establish a mechanism for augmenting direct FDA oversight through some international inspections by certification of accredited third parties who can evaluate and certify foreign food facilities, perform inspections, and determine compliance with FDA standards.

In addition to increasing the number of inspections, FDA is applying information learned from the outbreak of *Salmonella* in peanut products to improve the inspection process and to identify

potential food contamination issues. In 2008 and 2009, FDA began proactively approaching the prevention of foodborne illness by conducting intensive environmental sampling during certain FDA and state contract inspections that involved food products and facility operations that are more readily susceptible to pathogen contamination. Prior to this change, environmental sampling was initiated only when specific conditions observed during an inspection indicated that it was appropriate (so called “for cause” sampling). Through this environmental sampling approach, which requires a significant investment in inspection and analytical resources, unsuitable manufacturing conditions have been identified by FDA investigators that have resulted in corrective action at the processing facilities, as well as several product recalls to remove products from the market that were processed under unsuitable conditions prior to the occurrence of a public health incident.

The additional information gathered from environmental sampling also provides FDA with broader situational awareness and will be considered during risk-based targeting and planning of field work. Also, since implementation, FDA has seen a number of firms adopt environmental sampling programs that assist in monitoring the in-plant conditions on a routine basis. Such an industry response is welcomed and encouraged since food safety is primarily the responsibility of the food industry while oversight is ultimately a shared responsibility between FDA, its regulatory partners, and industry.

Strong Enforcement Strategies

OIG Recommendation: Take appropriate actions against facilities, particularly those that have histories of violations.

OIG Recommendation: Ensure that violations are corrected for all facilities that receive Official Action Indicated (OAI) classifications.

To address facilities that have a history of violations, Dr. Hamburg announced six initiatives to ensure that enforcement actions taken by the Agency are swift, aggressive, and will have a positive impact on public health. The initiatives that address the OIG recommendations are:

- establishment of a timeframe for submission of post-inspection responses;
- a shift in the Office of Chief Counsel’s review of Warning and Untitled Letters;
- development of risk control and enforcement strategies with our regulatory partners;
- Warning Letter and recall follow-up inspections;
- swift, aggressive and immediate enforcement action; and
- a Warning Letter close-out process.

OIG Recommendation: Provide additional guidance about when it is appropriate to lower OAI classifications.

FDA agrees with this recommendation and will revise the guidance in the ORA Field Management Directive #86: Establishment Inspection Report Conclusions and Decisions.

CONCLUSION

Protecting our nation’s food supply remains a top priority for FDA and the Obama Administration. We are in a historic moment for food safety in the United States as we work collaboratively to develop better practices, policies, and authorities that will enable us to meet

the food safety challenges of the 21st century. Thank you again for the opportunity to testify before you about our oversight of imported food and FDA's domestic inspections. I will be happy to answer any questions you may have.