

**THE ROLE AND PERFORMANCE OF FDA IN
ENSURING FOOD SAFETY**

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS
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THE ROLE AND PERFORMANCE OF FDA IN ENSURING FOOD SAFETY

THURSDAY, MAY 6, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 2 p.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman of the subcommittee) presiding.

Present: Representatives Stupak, Christensen, Dingell (ex officio), Waxman (ex officio), Burgess, and Latta.

Staff Present: Phil Barnett, Staff Director; Bruce Wolpe, Senior Advisor; Eric Flamm, FDA Detailee; Dave Levis, Chief Oversight Counsel; Stacia Cardille, Counsel; Erika Smith, Professional Staff Member; Scott Schloegel, Investigator; Ali Neubauer, Special Assistant; Derrik Franklin, HHS-OIG Detailee; Karen Lightfoot, Communications Director, Senior Policy Advisor; Elizabeth Letter, Special Assistant; Mitchell Smiley, Special Assistant; Melissa Bartlett, Minority Counsel, Health; Kevin Kohl, Minority Professional Staff Member; Ruth Saunders, Minority Detailee; and Alan Slobodin, Chief Counsel, Oversight.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing entitled, "The Role and Performance of FDA in Ensuring Food Safety."

The chairman, ranking member, and chairman emeritus will be recognized for a 5-minute opening statement. Other members of the subcommittee will be recognized for a 3-minute opening statement. I will begin.

Today's hearing will mark the 12th hearing of the Oversight and Investigations Subcommittee since January 2007 regarding food safety issues. We have examined an E. coli outbreak traced to tainted spinach, melamine-contaminated pet food, and the industry practice of intentional exposure of meat and seafood to carbon monoxide, among other inquiries. During this Congress, the subcommittee has held hearings on a salmonella outbreak associated with peanut products manufactured by the Peanut Corporation of America; and actions and obligations of food manufacturers and retailers that purchased tainted food products; and the safety of bottled water.

Today, we will continue our oversight role and performance in the food safety system by considering two reports. The first is a Government Accountability Office report entitled, "Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Foods."

GAO found that, despite the efforts and actions of the three Federal agencies that share jurisdiction over imported food—U.S. Customs and Border Protection, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the U.S. Food and Drug Administration—there are gaps in the enforcement and collaboration that could allow high-risk foods to enter domestic commerce without assurance that products are safe.

Specifically, the GAO found: the three agencies failed to collaborate and to share food-related data effectively; FDA's authority to ensure importer compliance is limited; the agencies lacked the ability to assign unique identification numbers for importing firms; and CBP faces challenges managing inbound shipments.

The second report, "FDA Inspections of Domestic Food Facilities," was issued by the Department of Health and Human Services, Office of the Inspector General. The report identifies a number of challenges confronting FDA in safeguarding domestically produced food.

OIG found that, on an average, FDA inspects only 24 percent of domestic food facilities annually and that the number of inspections declined from 2004 to 2008. The report also found that FDA has not inspected 56 percent of the food facilities under its jurisdiction during the past 5 years.

The inspector general found that, and I quote, "When violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied," end of quote. Additionally, the report found that some companies who had violations at their facilities significant enough to warrant regulatory action refused to grant FDA inspectors access to their official records.

I am interested in learning more about these two reports and what proactive steps the GAO and inspector general believes FDA could be taking to ensure the safety of our Nation's food supply. I am also interested in hearing from FDA on the recent steps it has taken to reinvigorate its focus on food safety and to improve and enhance food safety oversight.

The work of this subcommittee, coupled with the work of the Health Subcommittee and the full committee on food safety, culminated the introduction and passage of H.R. 2749, the Food Safety Enhancement Act, which passed the House of Representatives on July 30th, 2009.

The provisions contained in H.R. 2749 would address several concerns raised by GAO. For example, Section 204 of the bill requires all food importers to register with FDA annually, comply with good importer practices, and pay a registration fee of \$500 in order to ship food to the United States. Section 206 requires that registered facilities have a unique facility identifier or they will not be allowed to import food into the country. I am interested in hearing from our witnesses how H.R. 2749 could help address the concerns raised in the two reports before us today.

Our witnesses today include the authors of the two reports. Lisa Shames is the director of the agriculture and food safety at the Government Accountability Office. Jodi Nudelman is the regional inspector general for evaluation and inspections for Region II at the U.S. Department of Health and Human Services, Office of Inspector General.

Joining them on the panel will be Mike Taylor, FDA deputy commissioner for foods, and Steve Solomon, deputy assistant commissioner for compliance policy, from the Food and Drug Administration.

The members of this subcommittee were the first to sound the alarm on the weaknesses of our food safety system. I look forward to hearing from our witnesses today about progress that has been made since we began pushing for reform more than 3 years ago and about the weaknesses that remain until we have an effective food safety bill enacted into law.

We are fortunate that today's hearing was prompted by the HHS and GAO reports rather than another widespread food outbreak like we saw with the spinach in 2007, peppers in 2008, and peanut butter in 2009. But make no mistake about it: Without legislative action, it is not a matter of if but when more lives will be put at risk by another outbreak. We cannot afford to put off action any longer.

Mr. Burgess, opening statement, please?

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for the recognition.

And I am pleased to join you and the other members on the committee as we convene this hearing on the role of the Food and Drug Administration to ensure food safety for the American public. Food safety reform is relatively controversial, yet a critical issue, competing for attention with a long list of domestic priorities.

Last July, in a bipartisan fashion, the House passed food safety legislation. I supported the legislation because, while historically the performance of the FDA has been questioned, I felt this was partly a result of inadequate tools.

But the enduring role of the Food and Drug Administration today still remains a very complex question. The House legislation did not address the future progress of future inspection and whether or not it is the proper role of both the Food and Drug Administration and the United States Department of Agriculture to continue their bifurcated jurisdiction over food. We heard, for instance, that a food such as pizza if it has only cheese on it is wholly the province of the Food and Drug Administration, whereas if it has pepperoni as well, it is in the province of the U.S. Department of Agriculture.

One thing is crystal-clear without controversy: The future of the FDA should not be as a reactive body dictated by the events of yesterday, but rather an effective and efficient, proactive agency preventing the emergencies of tomorrow.

And I agree wholeheartedly with the chairman of this subcommittee when he says it is not a question of if but when. Because, as we were coming into the room for this hearing today,

across the newswire from the Columbus Dispatch, Federal health officials will come to Columbus this weekend to help determine what is responsible for a three-State E. coli outbreak that has sickened at least seven people there. So, as we see, even tomorrow's headlines today are being covered in this committee.

It is important for the Food and Drug Administration as well as the industry to work cooperatively to reduce the number of and help prevent food-borne illnesses and contamination before the tainted products are able to enter the markets.

The Food and Drug Administration should make maximum use of information technologies for risk assessment, but it has come to my attention and the attention of the committee that the Food and Drug Administration has delayed the rollout of the promising new system, PREDICT. PREDICT uses a variety of assessments to rank food import shipments according to risk. The system is currently in use in New York and Los Angeles, but the nationwide deployment was recently postponed indefinitely because of technical problems.

And this is not the first time that we have heard of the failure of the Food and Drug Administration to keep pace with changes in technology. From the failures of the 510(k) medical device process to the backlog of new drug applications to the entire portfolio of food issues, the Food and Drug Administration regulates fully 25 percent of all government activity, yet the Food and Drug Administration remains technologically in the 1990s. This is why scientific innovation and information technology must play a central role in the prevention and the strategic analysis that is essential to a successfully functioning Food and Drug Administration.

We are going to hear from four witnesses today, including two from the agency itself. And although much has been said about the past limitations of the agency and the uptick in funding shortfalls from a year ago, I do not believe that it is simply a resource question and that simply increasing the resources of the Food and Drug Administration will solve the problems outlined before us today. After numerous hearings, we have learned that simply providing more money to FDA will not, by itself, result in a safer food supply.

From our agricultural imports to domestic manufacturing, the Food and Drug Administration must streamline the process and internal controls to identify high-risk products and manufacturers before tainted goods are able to enter the food supply. While continuing to collaborate with their counterparts at the USDA and the Customs and Border Protection, the Food and Drug Administration internal communications between Washington and their regional offices at home and abroad must be increased. Communication may not create the perfect system, but it will create a more reliable and a more efficient one.

I am also interested in an update of the issues that still hinder work of the FDA and any new ideas you may have to foster innovation to improve the agency as a whole. As Commissioner Hamburg recently said, it is simply not possible for FDA to inspect our way to safety.

Congress must advocate for an all-of-the-above approach in addressing food safety solutions. We must support and advocate for the FDA to continue to advocate for risk-based approaches to the inspection and testing processes, as well as support improvements

to modernize scientific standards, safety controls, and information technology.

While these update reports from the Government Accountability Office and from Health and Human Services Inspector General are helpful, their reports do not change the conversation regarding this domestic priority. Food safety is important. Food safety legislation has passed the House. Food safety is now awaiting Senate action.

So I hope today's hearing is not just to continue to put pressure on the Senate to act for food safety. It is my understanding that the Senate is already planning to vote on this issue as soon as the Financial Services bill is finished. I hope, instead, we also ask questions about whether the progress and the evolution of food safety requires more advancements than red-tape bureaucracy than the government will logically allow.

I would like to thank the chairman again, and I look forward to the testimony of our witnesses and to our questions.

I will yield back.

[The prepared statement of Mr. Burgess follows:]

**Opening Statement of the Honorable Michael C. Burgess
Subcommittee on Oversight and Investigations**

Hearing on

“The Role and Performance of FDA in Ensuring Food Safety”

May 6th, 2010

Thank you, Chairman Stupak. I am pleased to join you and the other Members of the Committee as we convene this hearing on the role of the FDA to ensure food safety for the American public. Food safety reform is a relatively controversial yet critical issue competing for attention with a long list of domestic priorities.

Last July the House passed food safety legislation, bipartisanly. I supported the legislation because while, historically, the **performance** of the FDA has been lacking, I felt this was partly a result of inadequate tools, but the enduring **role** of the FDA remains a complex question.

The House legislation did not address the future progress of food and whether it is the proper role of both the FDA and the USDA to continue in their bifurcated jurisdiction over food where, for

instance, if a food such as pizza has only cheese on it, it is wholly the province of the FDA, whereas if it has pepperoni as well, it is also in the province of the USDA.

One thing is crystal clear and without controversy. The future FDA should not be a reactive body dictated by the events of yesterday, but rather an effective and efficient proactive agency preventing the emergencies of tomorrow.

It is important for the FDA as well as the industry to work cooperatively to reduce the number of, and help prevent, food-borne illnesses and contamination before tainted products are able to enter the markets.

FDA should make maximum use of information technologies for risk assessment, but it has come to my attention that FDA has delayed the rollout of its promising new system, PREDICT. PREDICT uses a variety of assessments to rank import shipments according to risk. This system is currently used in NY and LA, but the nationwide deployment was recently postponed indefinitely due to technical problems.

This is not the first time I have heard of the failure of the FDA to technologically advance. From the failures of the 510k medical device process to the backlog of New Drug Applications to the entire portfolio of food issues, the FDA regulates 25% of all government activity yet the FDA remains technologically in the 1990s.

This is why scientific innovation and information technology must play a central role in the prevention and strategic analysis that is essential to a successfully functioning FDA. We are going to hear from four witnesses today including two from the agency itself. Although much may be said about the past limitations of the agency and the uptick in funding shortfalls years ago, I do not believe that simply increasing the resources of the FDA will solve the problems outlined before us today. After numerous hearings, we have learned that simply providing more money to FDA will not by itself produce a safer food supply.

From agricultural imports to domestic manufacturing, FDA must streamline the processes and internal controls to identify high risk products and manufacturers before tainted goods are able to enter the food supply. While continuing to collaborate with their counter-parts at CBP and USDA, FDA must continue to improve

internal communications between Washington and their regional offices at home and abroad. Communication may not create the perfect system, but it will create a more reliable and efficient one.

I am also interested in an update of issues that still hinder the work of FDA and any new ideas you may have to foster innovation and improve the agency as a whole. As FDA Commissioner Hamburg recently said, “It is simply not possible for FDA to inspect our way to safety.”

Congress must advocate for an “all-of-the-above” approach in addressing food safety solutions. We must support and advocate for the FDA to continue to advocate for risk-based approaches to the inspection and testing process as well as support improvements to modernize scientific standards, safety controls, and information technology.

While these update reports from the GAO and the HHS IG are helpful, their reports, substantively, do not change the conversation regarding this domestic priority. Food safety IS important. Food safety legislation HAS passed the House. Food Safety is now awaiting Senate action.

So I hope today's hearing is not just to continue to put the pressure on the Senate to act on food safety. It is my understanding the Senate is already planning to vote on this issue as soon as the Financial Services bill is acted on. I hope instead we also ask questions about whether the progress and evolution of food requires more advancements than the red-tape bureaucracy of government will logically allow.

I would like to thank the Chairman again, and I look forward to your testimony and questioning.

Mr. STUPAK. Thank you, Mr. Burgess.

Mr. Waxman, full committee chairman, opening statement please, sir?

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to commend you for calling this important hearing and to examine the role of FDA in protecting the Nation's food supply.

Today we are going to hear from two reports, one from GAO, the other from HHS Inspector General, about the FDA performance. These two reports tell a story of an agency that is trying to keep the food supply safe but needs new authorities, more effective tools, and increased funding to meet its obligation.

In GAO's report, it found that FDA needs to coordinate its enforcement efforts better with other agencies. For example, FDA and Customs and Border Protection should be able to work together to assign a unique identification number to firms that import our food. This is currently not the case. In fact, there are some that have more than three identifiers, and GAO found one firm had 75. These multiple identifiers make it more difficult for FDA to track foods that are imported.

GAO also questioned whether FDA's current penalties are sufficient to keep an importer from violating FDA requirements.

The OIG report focused on FDA's inspection of domestic food facilities. They found that FDA inspected only 24 percent of food facilities each year between 2004 and 2008. The number of FDA inspections declined during that time, even as the number of facilities increased. Over the course of 5 years, FDA failed to inspect 56 percent of facilities that were subject to its authority and only inspected an additional 14 percent.

These two reports are very disturbing. It is a similar story to what we heard last year. We were told in the two hearings on salmonella outbreak in peanut butter that sickened over 700 people—and the investigators revealed executives at the Peanut Corporation of America knew their peanuts were testing positive for salmonella, but they chose to ship the tainted food anyway.

Many of the concerns raised in these two reports and in the wake of the salmonella outbreak are addressed by the Food Safety Enhancement Act of 2009, which the House passed on a bipartisan basis. The legislation contains critical fixes. I am pleased that we are holding this important hearing. I hope the Senate will act soon and we will have this new legislation in place. And I hope we will see, through the efforts of legislation and oversight, a more comprehensive food safety regimen at FDA.

Thank you for holding the hearing. I yield back my time.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Latta for 3 minutes?

We will try to get them in.

**OPENING STATEMENT OF HON. ROBERT E. LATTA, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Mr. LATTA. Well, thank you very much, Mr. Chairman and Ranking Member Burgess.

First of all, thanks for holding this subcommittee hearing on the Food and Drug Administration ensuring food safety. And it is also an honor being recently appointed on the Energy and Commerce Committee, and I look forward to working with you on the important issues that come before the Oversight and Investigations Subcommittee.

Instances of contaminated food products are a serious concern for the public. Just last week, the FDA announced that contaminated materials were used in production of several lots of pediatric Tylenol products. About 1,500 lots of the bottled products are currently being recalled. Furthermore, as the percentage of U.S. food supply imported from foreign countries increases and bioterrorism continues to be a threat, food safety is a critically important issue.

Last summer, the House debated H.R. 2749, the Food Safety Enhancement Act, and it is expected that the Senate will soon take action on the legislation.

I represent the largest agricultural district in the State of Ohio and am a member of the House Agriculture Committee. I believe that H.R. 2749 did not adequately address the concerns of the agricultural community, nor was it referred to the Agriculture Committee at that time for any hearings. Additionally, the Congressional Budget Office estimates that H.R. 2749 will authorize \$2.314 billion over fiscal years 2010 through 2014 and that it will take \$3.5 billion for the FDA to administer the new regulatory activities under the legislation at that time.

The spending level authorized by H.R. 2749 is of grave concern, especially when the September 2009 GAO report found that gaps in enforcement and collaboration currently undermine food safety efforts among Customs and Border Patrol, the FDA, and USDA's Food and Safety Inspection Service. Furthermore, the same report indicates there is a lack of information sharing between the FDA and States during a recall, which impedes States' efforts to quickly remove contaminated food.

The safety and security of the Nation's food supply is of utmost importance; however, with 15 Federal agencies already administering at least 30 Federal laws concerning food safety, I am concerned of the prospect of an increased size in the bureaucracy, budget, and statutory authority for the FDA when improvements in communication, collaboration, and technology have been recommended by the GAO.

Mr. Chairman, I thank you for this opportunity. I look forward to hearing the testimony from the witnesses on the panel today. And I yield back.

[The prepared statement of Mr. Latta follows:]

Congressman Robert E. Latta
The Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
Opening Statement – For the Record
May 6, 2010

MR. CHAIRMAN; RANKING MEMBER BURGESS: Thank you for holding this subcommittee hearing on the role and performance of the Food and Drug Administration in ensuring food safety. It is an honor to have been recently appointed to the Energy and Commerce Committee, and I look forward to working with all of you on the important issues that come before the Oversight and Investigations Subcommittee.

Incidences of contaminated food products are a serious concern for public health. Just this week, the FDA announced that contaminated materials were used in the production of several lots of pediatric Tylenol products, and about 1,500 lots of bottled products are currently being recalled. Furthermore, as the percentage of the U.S. food supply imported from foreign countries increases, and bio-terrorism continues to be a threat, food safety is a critically important issue.

Last summer, the House debated H.R. 2749, the Food Safety Enhancement Act, and it is expected that the Senate will soon take action on the legislation. I represent the largest agricultural district in the state of Ohio, and am a former member of the House Agriculture Committee. I was displeased that H.R. 2749 did not adequately address the concerns of the agricultural community, nor was it referred to the Agriculture Committee for any hearings.

Additionally, the Congressional Budget Office estimates that H.R. 2749 will authorize \$2.314 billion over Fiscal Years 2010-2014, and that it will take \$3.5 billion for the FDA to administer the new regulatory activities under this legislation during that time.

CBO also estimates that the president's budget plan will increase the public debt to \$20.3 trillion by 2020, and a \$655 billion deficit has been incurred in just the first five months of this fiscal year. Recently the President's Budget Director Peter Orszag, stated that "deficits of this size are serious, and ultimately unsustainable" and that significant changes in policy are required.

The spending level authorized by H.R. 2749 is of great concern to me, especially when the September 2009 GAO report found that gaps in enforcement and collaboration currently undermine food safety efforts among Customs and Border Patrol, the FDA, and USDA's Food Safety and Inspection Services. Furthermore, the same report indicates that there is a lack of information-sharing between the FDA and states during a recall, which impedes states' efforts to quickly remove contaminated food.

The safety and security of the nation's food supply is of utmost importance. However, with 15 federal agencies already administering at least 30 federal laws concerning food safety, I am concerned by the prospect of an increased size in bureaucracy, budget and statutory authority for the FDA when improvements in communication, collaboration and technology have been recommended by the GAO.

Mr. Chairman, thank you for this opportunity, and I look forward to hearing the testimony from the witnesses on the panel today. [Yield Back]

Mr. STUPAK. Thank you, Mr. Latta. Good to have you on board. Look forward to working with you.

Mrs. CHRISTENSEN for 3 minutes, please?

Mr. CHRISTENSEN. Thank you. I will try to be shorter than that. Every year, 300,000 people in this country are hospitalized and 5,000 die after consuming contaminated food or beverages. So thank you, Chairman Stupak and Ranking Member Burgess, for following up on this issue.

It is very important that we explore the weaknesses in the food safety network and the coordination, or lack of it, between CBP, FSIS, and FDA, as well as any new authorities these agencies might need. So I just look forward to hearing the testimony of our witnesses and to working with the subcommittee and the larger committee to address the gaps in our food safety system.

And thank you, Chairman Stupak, once again, for holding this hearing on this issue that is really vital to the safety and health of everyone who lives in this country.

Mr. STUPAK. Well, thank you.

And we have 2 minutes left to vote. We have a series of votes. There are four votes, plus a motion to recommit. So we are going to stand in recess until 3:15.

So this committee will be in recess until 3:15.

[Recess.]

Mr. STUPAK. The committee will come to order.

Mr. Dingell, do you have an opening statement, sir?

Mr. DINGELL. Mr. Chairman, I will dispense with my opening statement. I thank you.

Mr. STUPAK. Very good.

Then that concludes the opening statements by members of the subcommittee. I call our first panel.

On our first panel we have Mr. Michael Taylor, deputy commissioner for foods with the Food and Drug Administration; accompanying him is Mr. Steven Solomon, assistant commissioner for compliance policy at the Food and Drug Administration; Lisa Shames, director of agriculture and food safety at the Government Accountability Office; and Ms. Jodi Nudelman, regional inspector general for evaluation and inspections for the Health and Human Services Office of Inspector General.

We welcome you all.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right, under the rules of the House, to be advised by counsel during your testimony. Do you wish to be represented by counsel?

Everyone is shaking their head "no," so I will take it as no.

Please then rise, raise your right hand, and take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect the witnesses replied in the affirmative.

You are now under oath.

We are going to begin with your opening statement of 5 minutes, please. If you would like to submit a longer statement for the record, it would be accepted.

Mr. Taylor, shall we start with you?

TESTIMONY OF MICHAEL R. TAYLOR, DEPUTY COMMISSIONER FOR FOODS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY STEVEN M. SOLOMON, ASSISTANT COMMISSIONER FOR COMPLIANCE POLICY, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION; LISA SHAMES, DIRECTOR, AGRICULTURE AND FOOD SAFETY, GOVERNMENT ACCOUNTABILITY OFFICE; JODI NUDELMAN, REGIONAL INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, REGION II, HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

TESTIMONY OF MICHAEL R. TAYLOR

Mr. TAYLOR. Yes, sir.

Good afternoon, Mr. Chairman, Ranking Member Burgess, and members of the subcommittee. I am pleased to be here today with my colleague, Dr. Steven Solomon, and to have this chance to talk with the committee about FDA's food safety program.

I also want to really thank you, Mr. Chairman, as well as Chairman Dingell, Chairman Waxman, and all the members of the committee, for your leadership in passing the Food Safety Enhancement Act, which we do hope will soon go to conference with the bill now pending in the Senate.

As you know, food safety is an important priority for the Obama administration. Soon after taking office, the President established a Food Safety Working Group which brought together experts from all Federal agencies with responsibilities related to food safety.

In its July 2009 report, the working group recognized the challenges posed by a rapidly changing and globalized food supply and the need to shift our focus to preventing food safety problems throughout the system. The working group also recognized the importance of inspections, recommending that the government prioritize crucial inspection and enforcement activity, build on and enhance State and local food safety efforts, and utilize better data to guide these efforts and evaluate their outcomes.

In August of 2009, Commissioner Margaret Hamburg created my office, the Office of Foods, to lead a unified FDA foods program and to enhance FDA's ability to meet today's challenges in food safety. We recently launched the One Mission, One Program initiative, which involves over 100 experts from throughout FDA who are addressing topics crucial to the future success of the foods program and the implementation of the anticipated new legislation. This includes an inspection and compliance strategy group that is looking hard at the way we conduct inspections.

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 contributed significantly to food safety over the years, but the preventive control requirements and other new tools provided by H.R. 2749 would greatly enhance the ability of FDA investigators and FDA inspections to protect public health.

We will, of course, continue to act to remove contaminated food from commerce, but our focus will shift 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.

Our goal needs to be high rates of compliance with the prevention-oriented standards envisioned by H.R. 2749. And to achieve 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 recent Office of Inspector General 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 authority, and FDA has already addressed many of the issues noted in the report.

For instance, improving the speed and predictability of follow-up to inspections and strengthening the agency's enforcement program are top agency goals. Last August, Commissioner 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.

FDA appreciates OIG's recognition of the gaps in the agency's inspection authority, and we support their legislative recommendations. These include the use of civil monetary penalties for FD&C Act violations related to food and the authority provided in Section 106 of H.R. 2749 for routine access to all records bearing on whether a food may be in violation of the act.

The GAO report of September 2009 raised some important issues relating to the safety of imported food. The agency agrees with many of GAO's recommendations, and we are working to incorporate them into both short-term and long-term initiatives.

The report looked at FDA's new PREDICT system for targeting import shipments. This technology, which is deployed in Los Angeles and New York, will improve import screening and targeting to better prevent the entry of unsafe foods and expedite the entry of non-violative foods. A pilot test of the prototype system showed that PREDICT works to target shipments that are more likely to be found violative when examined by FDA.

FDA has encountered problems with rolling out PREDICT nationwide due to difficulties with incorporating it into the agency's outdated IT infrastructure, which is now undergoing major upgrades. These problems have delayed the full deployment of PREDICT, but we will continue to move forward as expeditiously as possible, with full roll-out anticipated by the end of the year. And we will continue to evaluate and strengthen PREDICT as the project progresses.

FDA was encouraged that GAO recognized the importance of new legislative authorities as a key to strengthening FDA's oversight of imported foods. In accordance with GAO's recommendations, FDA is working with Congress to obtain authority for civil money penalties and to acquire the use of a unique identifier by food facilities, both of which are provided by H.R. 2749.

The House bill will provide other valuable tools for ensuring that importers reliably verify—and this is really important—reliably verify that the foods they import are produced in accordance and compliance with the same prevention-oriented standards that we

would make applicable to foods produced in the United States. We all know that for our food safety system to be effective, prevention must begin at the point of production, not at the port of entry.

Mr. Chairman, protecting our Nation's food supply remains a top priority for FDA and the administration. We really are at a historic moment for food safety in the United States. As we work collaboratively to improve our authorities, our practices, and our policies, it will enable us to meet the food safety challenges of the 21st century. And we appreciate the support of this committee and look forward to working with you in the future.

Thank you.

[The prepared statement of Mr. Taylor follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

MAY 6, 2010

FOR RELEASE ONLY UPON DELIVERY

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 state 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.

Mr. STUPAK. Thank you.

Mr. Solomon, do you have anything to add?

Mr. SOLOMON. No, thank you.

Mr. STUPAK. Ms. Shames, would you like to do an opening statement?

TESTIMONY OF LISA SHAMES

Ms. SHAMES. Yes, thank you.

Chairman Stupak, Ranking Member Burgess, and members of the subcommittee, I am pleased to be here today to discuss FDA's oversight of imported food.

Effective FDA oversight is critical to public health. About 60 percent of fresh fruits and vegetables and 80 percent of seafood are imported.

My testimony today will focus on three key issues: FDA's overseas inspections of imported food; gaps in import enforcement; and statutory authorities that could further help FDA.

First, regarding the inspections: The number of FDA's overseas inspections has fluctuated since 2001. As shown in Table 1, annual inspections ranged from 95 to 153 out of an estimated 189,000 foreign firms. These inspections were conducted in 56 countries, mostly in Mexico. FDA conducted 46 inspections in China during this time frame.

To augment these inspections, FDA has opened offices in China, Costa Rica, and India and plans to open more in Mexico, Chile, the Middle East, along with the European Union.

In addition, PREDICT, a risk-based computer program is to assist FDA inspectors flag higher-risk food shipments. As Mr. Taylor said, a pilot test of PREDICT was promising. PREDICT nearly doubled the percentage of field examinations that resulted in violations. However, FDA told us that PREDICT's nationwide roll-out has been delayed, primarily because of technical problems.

Second, we identified several gaps in enforcement that could allow food with safety violations to enter U.S. commerce.

One gap is that FDA has limited authority to assess civil penalties on violators. Importers post a monetary bond for shipments to provide assurance that they meet U.S. requirements. However, even though the bond may be up to three times the value of the shipment, this sum may be negligible for a large importer. An unscrupulous importer may consider forfeiting the bond as a part of the cost of doing business. FDA agreed with our recommendation that it seek authority to assess penalties. We note that H.R. 2749 provides for assessing penalties.

A second gap is the lack of unique identification numbers. Importers get computer-generated ID numbers from FDA. Because importers may provide their names and addresses slightly differently for each shipment, multiple identifiers are generated. FDA officials told us that firms have, on average, three unique identifiers, and one firm had 75. In addition, foreign firms are to register with FDA and are assigned a registration number, as well. FDA told us that there may be duplicate registration numbers, as well. FDA agreed with our recommendation to pursue the use of specific identifiers. H.R. 2749 also provides for such a unique identifier system.

A third gap is that FDA does not share product distribution lists with States during a food recall because the information is considered commercially confidential. State officials told us that, without this information, they lose time removing recalled food from grocery shelves. FDA agreed with our recommendation to find ways to share information to the States.

On a positive note, one gap we found appears to be resolved. We were told that FDA now receives the arrival time of imported food shipments. This can help FDA coordinate any further review for high-risk imports.

Finally, we have made several recommendations that would help FDA improve food safety oversight. GAO has called for mandatory food recall authority. Currently, food recalls are voluntary, and FDA has no authority to compel companies to recall contaminated foods except for infant formula. Other government agencies that regulate other products, such as toys or car tires, have recall authority and have had to use it when companies did not cooperate.

FDA should also strengthen its oversight of food ingredients determined to be generally recognized as safe, or GRAS. Companies may conclude a substance is GRAS without FDA's approval and even without its knowledge because companies are not required to inform FDA. FDA generally agreed with our recommendation that it develop a strategy to require companies to provide basic information about their GRAS determinations and, in view of emerging science, to conduct reconsiderations of GRAS ingredients.

We also recommended that FDA seek any statutory authority that the agency determines it needs to implement our recommendations.

And, lastly, FDA agreed with our recommendation that it seek authority to issue regulations for preventive controls for high-risk food. As Mr. Taylor said, FDA already has regulations for preventive controls for seafood and juice which require firms to analyze safety hazards and implement plans to address those hazards. FDA officials told us that issuing regulations for preventive controls might be one of the most important things that they can do to enhance the oversight of fresh produce.

We note that H.R. 2749 contains provisions that address mandatory recall, GRAS ingredients, and preventive controls.

In conclusion, a substantial volume of our food supply is imported. Our work has shown that FDA could strengthen its oversight of imported food and close gaps in its enforcement by assessing penalties, developing unique identifiers, and sharing information with State agencies. Additional statutory authorities to conduct a mandatory recall and to establish preventive controls could further help FDA's food safety.

Mr. Chairman, this concludes my prepared statement, and I would be happy to answer any questions that you or other members of the subcommittee may have. Thank you.

[The prepared statement of Ms. Shames follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Oversight
and Investigations, Committee on Energy
and Commerce, House of Representatives

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FOOD SAFETY

FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities

Statement of Lisa Shames, Director
Natural Resources and Environment



May 6, 2010

G A O
Accountability Integrity Reliability

Highlights

Highlights of GAO-10-699T, testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Food imported from around the world constitutes a substantial and increasing percentage of the U.S. food supply. Ensuring the safety of imported food challenges the Food and Drug Administration (FDA) to better target its resources on the foods posing the greatest risks to public health and to coordinate efforts with the Department of Homeland Security's Customs and Border Protection (CBP) so that unsafe food does not enter U.S. commerce.

This testimony focuses on (1) FDA's overseas inspections, (2) identified gaps in agencies' enforcement efforts to ensure the safety of imported food, and (3) statutory authorities that GAO has identified that could help FDA's oversight of food safety. This testimony is principally based on GAO's September 2009 report, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (GAO-09-973) and has been updated with information from FDA.

What GAO Recommends

GAO previously recommended that FDA explore a unique identifier for firms, among other things. GAO also recommended FDA seek statutory authorities as needed, such as for preventive controls. FDA has agreed with these recommendations and has sought needed authorities.

View GAO-10-699T or key components. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

FOOD SAFETY

FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities

What GAO Found

While the number of FDA overseas inspections has fluctuated, FDA has opened up several overseas offices to address the safety of imported food at the point of origin, and is testing a computer-based system to target high-risk imports for additional inspection when they arrive at ports of entry. Specifically, in 2008, FDA inspected 153 foreign food facilities out of an estimated 189,000 such facilities registered with FDA; in 2007, FDA inspected 95 facilities. FDA estimated that it would conduct 200 inspections in 2009 and 600 in 2010. In addition, FDA opened offices in China, Costa Rica, and India and expects to open offices in Mexico and Chile and to post staff at European Union agencies. Furthermore, FDA's testing of a new computer screening system—the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT)—indicates that the system could enhance FDA's risk-based screening efforts at ports of entry, but the system is not yet fully operational. PREDICT is to generate a numerical risk score for all FDA-regulated products by analyzing importers' shipment information using sets of FDA-developed risk criteria and to target for inspection products that have a high risk score.

GAO previously identified several gaps in enforcement that could allow food products that violate safety laws to enter U.S. commerce. For example, FDA has limited authority to assess penalties on importers who introduce such food products, and the lack of a unique identifier for firms exporting food products may allow contaminated food to evade FDA's review. In addition, FDA's and CBP's computer systems do not share information. FDA does not always share certain distribution-related information, such as a recalling firm's product distribution lists with states, which impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses.

GAO identified certain statutory authorities that could help FDA in its oversight of food safety. Specifically, GAO previously reported that FDA currently lacks mandatory recall authority for companies that do not voluntarily recall food products identified as unsafe. Limitations in FDA's food recall authorities heighten the risk that unsafe food will remain in the food supply. In addition, under current FDA regulations, companies may conclude a food ingredient is generally recognized as safe without FDA's approval or knowledge. GAO recommended that, if FDA determines that it does not have the authority to implement one or more recommendations, the agency should seek the authority from Congress. Finally, GAO reported that FDA has identified a need for explicit authority from Congress to issue regulations requiring preventive controls by firms producing foods that have been associated with repeated instances of serious health problems or death. FDA already has preventive regulations for seafood and juice, which require firms to analyze safety hazards and implement plans to address those hazards.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss findings from our work on the Food and Drug Administration's (FDA's) efforts to ensure the safety of imported food and on our other recently issued food safety work. According to U.S. Department of Agriculture (USDA) data, food imported from more than 150 countries and territories constitutes a substantial and increasing percentage of the U.S. food supply. Imported food constitutes 15 percent of the U.S. food supply, including 60 percent of fresh fruits and vegetables and 80 percent of seafood. Additionally, the volume of agricultural and seafood products imported for consumption increased 29 percent from fiscal years 2003 to 2008, and the value of these products increased 65 percent. Ensuring the safety of imported food challenges federal agencies to better target their resources on the foods posing the greatest risks to public health and to coordinate efforts so that unsafe food does not enter U.S. commerce.

We have reported on the safety of imported food for many years. In 1998, we assessed the federal government's efforts to ensure the safety of imported foods and determined that federal agencies could not be certain that the growing volume of imported food was safe for consumers.¹ More recently, we reported in September 2009 that agencies need to address gaps in enforcement and collaboration to enhance the safety of imported food.² Federal agencies involved in the oversight of food imports include the following:

- FDA—which is responsible for roughly 80 percent of the food supply, including dairy products, seafood, fruits, and vegetables—oversees imported food safety through targeted inspections, sampling, and surveillance, among other things. Owing in part to the volume of imported products it regulates, FDA physically examines approximately 1 percent of imported food; however, the agency is developing the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) computer system to improve its targeted screening efforts.

¹GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCE-98-103 (Washington, D.C.: Apr. 30, 1998).

²GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873 (Washington, D.C.: Sept. 15, 2009).

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- Customs and Border Protection (CBP), under the Department of Homeland Security, is responsible for inspecting food imports for compliance with U.S. law and coordinating with FDA to enforce food safety laws at the border, among other things. CBP's computerized screening system processes all imported shipments, including food. CBP requires importers to (1) give a manufacturer identification number for each imported shipment and (2) post a monetary bond for formal entries to provide assurance that these shipments meet U.S. requirements, among other things.
 - USDA's Food Safety and Inspection Service (FSIS) has responsibility for the safety of imported meat and poultry and relies on an equivalency system whereby exporting countries must demonstrate that their systems meet standards that are equivalent to those of the U.S. system.

Furthermore, food safety responsibility is further divided among the 50 states, which may have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products. This fragmentation is the key reason that we added federal oversight of food safety to our high risk-series in January 2007 and called for a governmentwide examination of the food safety system.³

Several food safety bills have recently been introduced in Congress, and a comprehensive bill, H.R. 2749, passed the House of Representatives in July 2009. The House bill would require importers to register annually with FDA and to submit an appropriate unique facility identifier as a condition of such registration, among other provisions. The bill would also authorize FDA to issue a mandatory recall of foods that may cause serious adverse health consequences or death to humans or animals and would expand the agency's authority to assess criminal and civil penalties. Our September 2009 report made some of the same recommendations.

My testimony today will focus on three key issues: (1) FDA overseas inspections to address the safety of imported food, (2) identified gaps in agencies' enforcement that undermine efforts to ensure the safety of imported food, and (3) statutory authorities that we have identified that could help FDA's oversight of food safety.

³GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

As detailed in our reports, we found the following:

- First, while the number of FDA's foreign inspections has fluctuated, the agency has opened several overseas offices to address the safety of imported food at the point of origin. In addition, FDA testing of PREDICT indicates that the system could enhance FDA's risk-based screening efforts, but the system is not yet fully operational. FDA officials stated that a scheduled nationwide rollout this summer of PREDICT has been delayed primarily because of technical problems, such as server crashes and overloads, which are affecting FDA's field data systems nationwide.
- Second, gaps in FDA's and other agencies' enforcement could allow violative food products to enter U.S. commerce. For example, FDA has limited authority to assess penalties on importers who introduce violative food products, and the lack of a unique identifier for firms exporting food products may allow contaminated food to evade FDA review.
- Finally, we have made several recommendations that would help FDA improve food safety oversight. For example, we recommended that FDA seek additional authorities, such more explicit authority to create preventive controls for high-risk foods, and we have recommended that Congress consider giving FDA additional authority, such as mandatory recall authority. FDA agreed with our recommendations and has sought authority to order food safety recalls and issue additional preventive controls for high-risk foods.

This testimony is largely based on our September 2009 report on imported food safety, as well as other recent reports, and updated with information from FDA. See appendixes I-IV for highlights of our prior work. We conducted our work in accordance with generally accepted government auditing standards.

**While the Number of
FDA Overseas
Inspections Has
Fluctuated, the
Agency Has Opened
Overseas Offices, and
Has Piloted PREDICT**

In 2008, FDA inspected 153 foreign food facilities out of an estimated 189,000 such facilities registered with FDA and estimated that it would conduct 200 inspections in 2009 and 600 in 2010.³ In 2007, FDA inspected 95 facilities. Table 1 shows the number of FDA inspections of foreign food facilities, by country, from fiscal years 2001 through 2008. As the table shows, FDA conducted 1,186 inspections in 56 countries from fiscal years 2001 through 2008; the majority of FDA inspections were in Mexico, followed by Ecuador, Thailand, and Chile. FDA conducted a total of 46 inspections in China during this period.

³FDA was not able to provide 2009 inspection data in time for this statement, according to FDA officials.

Table 1: FDA Inspections of Food Firms in Foreign Countries, Fiscal Years 2001 through 2008

	2001	2002	2003	2004	2005	2006	2007	2008	Total
Mexico	17	15	8	15	7	16	26	29	133
Ecuador	8	0	11	24	0	11	10	0	64
Thailand	4	10	0	10	0	22	0	12	58
Chile	13	0	15	6	7	11	0	5	57
Peru	13	0	0	18	1	9	9	4	54
Brazil	0	12	6	7	21	0	0	7	53
China	0	9	2	6	16	0	0	13	46
Taiwan	9	7	0	9	0	7	0	7	39
Canada	13	0	13	1	0	7	4	0	38
Costa Rica	0	11	0	4	5	7	0	7	34
Honduras	9	8	0	0	7	0	0	8	32
Vietnam	0	9	0	10	8	0	0	4	31
Argentina	7	5	0	0	0	0	19	0	31
India	6	0	10	0	7	7	0	0	30
South Korea	14	0	0	1	7	0	6	0	28
Australia	12	0	6	0	0	9	0	0	27
Jamaica	2	6	0	3	0	3	0	8	22
Fiji	0	0	8	0	0	0	13	0	21
Guatemala	0	10	0	0	6	0	0	5	21
Singapore	10	0	0	8	0	0	0	3	21
Nicaragua	0	8	0	0	0	7	0	4	19
El Salvador	0	0	8	0	6	0	0	4	18
Germany	5	4	4	0	0	1	1	2	17
Estonia	8	0	0	8	0	0	0	0	16
Panama	0	0	7	0	0	0	0	9	16
South Africa	5	0	11	0	0	0	0	0	16
Malaysia	0	0	0	0	9	0	0	6	15
28 additional countries*									
Total number of countries that had firms inspected by FDA during the specific fiscal year listed above	26	22	22	20	16	15	11	24	56
Total inspections	211	169	148	153	132	125	95	153	1,186

Source: GAO analysis of FDA data.

*Countries with a total of 14 or fewer inspections between 2001 and 2008 are not listed in the table. These countries include: Italy (14 inspections), Latvia (14), Uruguay (14), Venezuela (14), Morocco (13), New Zealand (13), Poland (13), Trinidad and Tobago (12), France (11), Norway (11), Romania (10), Surinam (10), Iceland (9), Bulgaria (8), Colombia (8), United Kingdom (8), Cyprus (7), Turkey (6), Belize (4), Spain (4), Belgium (3), Greece (3), Hungary (3), Indonesia (3), Finland (2), Haiti (2), Japan (2), and the Netherlands (2).

For fiscal year 2009, FDA allocated 272 full-time employees to examine imported food shipments at U.S. ports of entry and estimated a budget of approximately \$93.1 million for field import activities.⁵ The total estimated 2009 FDA budget for all FDA products and programs, including food, drugs, medical devices, and other products, was \$2.7 billion. In 2008, we testified that if FDA were to inspect each of the 189,000 registered foreign facilities—at the FDA Commissioner's estimated cost of \$16,700 per inspection—it would cost FDA approximately \$3.2 billion to inspect all of these facilities once.⁶

Since November 2008, FDA has opened overseas offices to help prevent food that violates U.S. standards from reaching the United States. These offices are expected to provide FDA with direct access to information about foreign facilities' food manufacturing practices so that its staff at U.S. ports of entry can make more informed decisions about which food imports to examine. For example, FDA's overseas staff are working with staff at counterpart regulatory agencies overseas, as well as with other stakeholders who may be knowledgeable about certain industries. Overseas staff are also educating local exporters to make sure they understand U.S. food safety laws and regulations and FDA expectations. FDA opened offices in China (Beijing, Guangzhou, and Shanghai); in Europe (Brussels, London, and soon in Parma, Italy); in Latin America (San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico); and in India (New Delhi and Mumbai). The FDA Middle East Office is operating out of FDA headquarters because the Department of State denied its request to locate in Amman, Jordan, due to security concerns.

In addition to having overseas offices assist FDA's oversight of imported food, the agency is developing PREDICT. PREDICT is intended to assist FDA's oversight of imported food and uses FDA-developed criteria to estimate the risk of imported food shipments. These criteria are to incorporate, among other things, the violative histories of the product, importer, manufacturer, consignee, and country of origin; the results of laboratory analyses and foreign facility inspections; and general

⁵This category includes all nonlaboratory activities, such as field examinations and tests, import sample collections, import label exams, Prior Notice Center security reviews, import entry reviews, and other import investigations, as well as associated infrastructure support.

⁶GAO, *Federal Oversight of Food Safety: FDA has Provided Few Details on the Resources and Strategies Needed to Implement Its Food Protection Plan*, GAO-08-909T (Washington, D.C.: June 12, 2008).

intelligence on recent world events—such as natural disasters, foreign recalls, and disease outbreaks—that may affect the safety of a particular imported food product. In addition, agency officials stated that PREDICT will assign higher risk scores to firms for which the system does not have historical data.

PREDICT generates a numerical risk score for all FDA-regulated products. According to FDA, PREDICT is to present the shipment's risk score to FDA reviewers if the score is above an FDA-specified threshold. Shipments that are below the threshold are to receive a system "may proceed" (cleared) message unless other conditions are present, such as an FDA import alert.⁷ FDA intends that reviewers using PREDICT will also be able to view the specific risk factors that contributed to the shipment's risk score, such as whether the product or importer has a history of FDA violations. FDA expects reviewers to use PREDICT to supplement, rather than replace, their professional judgment when deciding what food products to inspect.

A 2007 pilot test of PREDICT in Los Angeles for seafood products indicated that the system could enhance FDA's risk-based import screening efforts. When compared with baseline data from FDA's existing import screening system, the Operational and Administrative System for Import Support (OASIS), PREDICT improved FDA's ability to target imports that the agency considers to be high risk for further examinations and allowed a greater percentage of products the agency considers to be low risk to enter U.S. commerce without requiring a reviewer's intervention. Specifically, PREDICT nearly doubled the percentage of field examinations—and increased by approximately one-third the percentage of laboratory examinations—that resulted in violations, relative to baseline OASIS data. In addition, according to FDA, the violations in shipments that reviewers targeted using PREDICT, on average, posed a greater risk to human health than the violations that OASIS detected.

FDA told us on April 12, 2010, that PREDICT is fully operational in the Los Angeles and New York districts, but due to technical problems, FDA has not determined when the system will be deployed in the Seattle district. In

⁷Import alerts communicate information and policy to FDA field staff. Usually, they provide information that products covered by the alert are subject to detention. If a product is detained, the importer is provided an opportunity to prove that the imported product is compliant, such as by providing FDA with the results of third-party laboratory analysis of the product.

addition, FDA officials stated that a scheduled nationwide rollout of PREDICT this summer has been delayed, primarily because of technical problems, such as server crashes and overloads, which are affecting FDA's field data systems nationwide.

Although the PREDICT pilot produced positive results and demonstrated the system's potential to improve import screening efforts, we reported that further agency actions were needed to help ensure that the system is effective. For example, FDA had not yet developed a performance measurement plan to evaluate, among other things, PREDICT's ability to identify high-risk shipments for manual review while simultaneously returning "may proceed" messages for low-risk shipments and enabling them to enter U.S. commerce. We recommended FDA develop such a plan. According to agency officials, since our report was issued in September 2009, FDA had completed a draft performance measurement plan. However, we have not reviewed this draft plan.

FDA and Other Agencies Face Gaps in Enforcement That Undermine Efforts to Ensure the Safety of Imported Food

We identified specific gaps in enforcement that could allow violative food products to enter U.S. commerce: (1) FDA's limited authority to assess civil penalties on certain violators; (2) lack of unique identifiers for firms exporting FDA-regulated products; (3) lack of information-sharing between agencies' computer systems and (4) FDA's not sharing product distribution information during a recall.

FDA Has Limited Authority to Ensure Importers' Compliance

Importers can retain possession of their food shipments until FDA approves their release into U.S. commerce. However, FDA and CBP officials do not believe that CBP's current bonding procedures for FDA-regulated food effectively deter importers from introducing violative food products into U.S. commerce. Specifically, importers post a monetary bond for formal entries (i.e., all shipments exceeding \$2,000 and certain shipments valued below that amount) to provide assurance that these shipments meet U.S. requirements. According to these officials, many importers still consider the occasional payment of forfeited bonds as part of the cost of doing business. Indeed, as we reported in 1998, forfeiture of the shipment's maximum bond value is often not sufficient to deter the sale of imported goods that FDA has not yet released. In its response to our September 2009 report, FDA agreed with this finding. According to FDA's regulatory procedures manual, the bond penalty is intended to

make the unauthorized distribution of articles unprofitable, but liquidated damages incurred by importers are often so small that they, in effect, encourage future illegal distribution of imported shipments. Even though the bond may be up to three times the value of the shipment, for a large importer, this sum may be negligible, especially when the importer successfully petitions CBP to reduce the amount.

We recommended that the FDA Commissioner seek authority from Congress to assess civil penalties on firms and persons who violate FDA's food safety laws and 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 agreed with this recommendation and was working with Congress to include civil penalty authority in food safety legislation. FDA officials also told us that if the agency had the authority to impose civil penalties on importers, which is also provided for in H.R. 2749, FDA might be better able to deter violations.

**FDA and CBP Do Not
Provide Unique
Identification Numbers to
Firms**

High-risk foods may enter U.S. commerce because the identification numbers that FDA uses to target manufacturers that have violated FDA standards in the past are not unique, and therefore these manufacturers and their shipments, may evade FDA review. Importers generate a manufacturer identification number at the time of import, when, among other things, they electronically file entry information with CBP. (CBP is responsible for validating the manufacturer identification numbers and ensuring they are unique.) CBP electronically sends this information to FDA's computer system. From this new manufacturer identification number, FDA's computer system automatically creates an FDA firm identification number—called the FDA establishment identifier. Officials told us that a single firm may often have multiple CBP manufacturer identification numbers—and therefore multiple FDA establishment identifiers. FDA officials told us that because CBP has multiple identification numbers for many firms, FDA has an average of three “unique” identifiers per firm, and one firm had 75 identifiers.

The creation of multiple identifiers can happen in a number of ways. For example, if information about an establishment—such as its name—is entered by importers incorrectly at the time of filing with CBP, a new manufacturer identification number, and therefore a new FDA establishment identifier, could be created for an establishment that already has an FDA number. In this scenario, an importer may—intentionally or unintentionally—enter a firm's name or address slightly

differently from the way it is displayed in FDA's computer system. This entry would lead to the creation of an additional FDA number for that firm. If an import alert was set using the original FDA establishment identifier, a shipment that should be subject to the import alert may be overlooked because the new number does not match the one identified in the alert.

In addition, foreign facilities that manufacture, process, pack, or hold food for consumption in the United States, with some exceptions, are required to register with FDA. Upon registration, FDA assigns a registration number. FDA calculated that in 2008, 189,000 foreign firms were registered under this requirement. However, some of the firms included in that total may be duplicates because the facility may have been reregistered without the cancellation of the original registration; consequently FDA may not know the precise number of foreign firms registered. As we previously reported, FDA officials told us they are working to address the unique identifier problem by establishing an interactive process in which FDA's systems recognize when a product's identifier does not match its manufacturer's registration number.

As we reported, FDA could consider requiring food manufacturers to use a unique identification number that FDA or a designated private sector firm provides at the time of import. However, the use of this unique number would necessitate collaboration with CBP, since importers would use such a number each time they file with CBP to ship goods to the United States. That is, CBP's computer system would need to be programmed to accept an FDA unique identification number. According to CBP officials, it is unknown if or when CBP's system will have this capability. To improve FDA's and CBP's ability to identify foreign firms with violative histories, we recommended that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier and that the CBP Commissioner ensure that its computer system is able to accept a unique identification number for foreign firms that export FDA-regulated foods. Both FDA and CBP agreed with our recommendation, and CBP officials told us that the agency has developed a plan for implementing a unique identifier. However, we have not reviewed this plan. We observe that H.R. 2749 contains a provision that may allow the Secretary of Health and Human Services, in consultation with the Commissioner of CBP, to specify the unique numerical identifier system to be used, taking into account compatibility with CBP's automated systems. Such actions would help prevent high-risk foods from entering U.S. commerce.

Information Is Not Shared
between Computer
Systems

When we issued our report in September 2009, we reported that CBP's computer system did not notify FDA's or FSIS's systems when imported food shipments arrive at U.S. ports, which increases the risk that potentially unsafe food may enter U.S. commerce, particularly at truck ports. If FDA chooses to examine a shipment as part of its admissibility review, the agency notifies both CBP and the importer through its computer system, OASIS. However, once the shipment arrives at the port and clears CBP's inspection process, the importer is not required to wait at the port for FDA to conduct its examination. Instead, the importer may choose to transport the shipment to the consignee's warehouse or other facility within the United States. The importer might choose to do so because, for example, CBP and FDA do not have the same hours of operation at some ports, and FDA's port office may be closed when the shipment arrives. In such cases, as a condition of the bond with CBP, the importer agrees to hold the shipment intact and not distribute any portion of it into U.S. commerce until FDA has examined it.

CBP and FDA officials told us that, occasionally, an importer will transport the shipment to the consignee's warehouse without first notifying FDA. If this occurs, FDA will not quickly know that the shipment has arrived and been transported to a U.S. warehouse because CBP's computer system does not notify FDA's OASIS computer system when the shipment arrives at the port. Instead, from the perspective of an FDA reviewer using OASIS, it will appear as if the shipment's arrival is still pending. FDA port officials told us that it could be 2 or 3 days before FDA reviewers become suspicious and contact CBP to inquire about the shipment's arrival status. By this time, an unscrupulous importer could have distributed the shipment's contents into U.S. commerce without FDA's approval. As we reported, if CBP communicated time-of-arrival information directly to OASIS, then FDA would be able to quickly identify shipments that are transported into the United States without agency notification and arrange to examine them before they are distributed to U.S. markets. Since our report was issued in September 2009, CBP told us that it had modified its software to notify FDA of a shipment's time of arrival. However, we have not reviewed the effectiveness of these modifications. We are still waiting to see whether CBP has an agreement with FSIS regarding time of arrival modifications.

FDA Does Not Always Share Product Distribution Information During a Recall

One key issue of concern, according to officials we spoke with from several states, is that FDA does not always share with states certain distribution-related information, such as a recalling firm's product distribution lists, which impedes the states' efforts to quickly remove contaminated products from grocery stores and warehouses. According to one state official, because FDA does not provide this information, the state has to spend time tracking it down on its own. Public health may be at risk during the time it takes for the states to independently track distribution information when a product is found to be contaminated. FDA told us that it usually considers such information to be confidential commercial information, the disclosure of which is subject to statutory restrictions, such as the Trade Secrets Act. However, FDA's regulations allow for sharing of confidential commercial information with state and local government officials if, for example,

- the state has provided a written statement that it has the authority to protect the information from public disclosure and that it will not further disclose the information without FDA's permission, and FDA has determined that disclosure would be in the interest of public health, if such sharing is necessary to effectuate a recall, or
- the information is shared only with state and local officials who are duly commissioned to conduct examinations or investigations under the Federal Food, Drug, and Cosmetic Act. In certain circumstances, FDA may also seek a firm's consent to disclose its market distribution information.

Statutory Authorities We Identified Could Help FDA Oversee Food Safety

In our past work, we have pointed out that mandatory recall—the authority to require a food company to recall a contaminated product—would help ensure that unsafe food does not remain in the food supply. We also reported that FDA should strengthen its oversight of food ingredients determined to be generally recognized as safe for their intended use and to seek the authority if the agency deems necessary. Likewise, we reported that FDA has identified a need for explicit authority from Congress to issue regulations to require preventive measures by firms producing foods that have been associated with repeated instances of serious health problems or death.

FDA Lacks Mandatory Recall Authority

We have reported that food recalls are largely voluntary and that federal agencies responsible for food safety, including FDA, have no authority to compel companies to recall contaminated foods, with the exception of FDA's authority to require a recall for infant formula.⁸ FDA does have authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food under its jurisdiction and to disseminate information about foods that are believed to present a danger to public health. However, government agencies that regulate the safety of other products, such as toys and automobile tires, have recall authority not available to FDA for food and have had to use their authority to ensure that recalls were conducted when companies did not cooperate.

We have noted that limitations in the FDA's food recall authorities heighten the risk that unsafe food will remain in the food supply and have proposed that Congress consider giving FDA similar authorities. H.R. 2749 authorizes the Secretary of Health and Human Services to request that a person recall an article of food if the Secretary has reason to believe it is adulterated, misbranded, or otherwise in violation of the Federal Food, Drug, and Cosmetic Act and to require a person to cease distribution if the Secretary has reason to believe the article of food "may cause serious adverse health consequences or death to humans or animals." It also requires the Secretary to order a recall of such an article of food if the Secretary determines (after an informal hearing opportunity) it is necessary. Finally, it authorizes the Secretary to proceed directly to a mandatory recall order if the Secretary has credible evidence that an article of food subject to an order to cease distribution presents an imminent threat of serious adverse health consequences or death to humans or animals. As our previous work has shown, mandatory recall authority would allow FDA to ensure that unsafe food does not remain in the food supply.

⁸GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, GAO-05-51 (Washington, D.C.: Oct. 6, 2004) and GAO, *Federal Oversight of Food Safety: High Risk Designation Can Bring Attention to Limitations in the Federal Government's Food Recall Programs*, GAO-07-755T (Washington, D.C.: Apr. 24, 2007).

FDA Has Limited Oversight of Food Ingredients Determined to be Generally Recognized as Safe

We have reported that FDA should strengthen its oversight of food ingredients determined to be generally recognized as safe (GRAS) for their intended use.⁹ Manufacturers add these substances—hundreds of spices and artificial flavors, emulsifiers and binders, vitamins and minerals, and preservatives—to enhance a food's taste, texture, nutritional content, or shelf life. Currently, companies may conclude a substance is GRAS without FDA's approval or knowledge. We reported that FDA only reviews those GRAS determinations that companies submit to the agency's voluntary notification program. The agency generally does not have information about other GRAS determinations companies have made because companies are not required to inform FDA of them. Among other things, we recommended to FDA that it develop a strategy to require any company that conducts a GRAS determination to provide the agency with basic information about this determination, and to incorporate such information into its public Web site.

We also reported that FDA is not systematically ensuring the continued safety of current GRAS substances. According to FDA regulations, the GRAS status of a substance must be reconsidered as new scientific information emerges, but the agency has not systematically reconsidered GRAS substances since the 1980s. Rather, FDA officials said, they keep up with new developments in the scientific literature and, on a case-by-case basis, information brought to the agency's attention could prompt them to reconsider the safety of a GRAS substance. We recommended that FDA develop a strategy to conduct reconsiderations of the safety of GRAS substances in a more systematic manner. We also recommended that, if FDA determines that it does not have the authority to implement one or more of our recommendations, the agency should seek the authority from Congress. FDA generally agreed with the report's findings and recommendations.

In addition, we reported that FDA has taken steps to make information about its GRAS notification program available to the public by posting its inventory of all GRAS notices FDA has received on its Web site. By placing information about the GRAS notice and its response on its Web site, FDA enhances the ability of Congress, stakeholders, and the general public to be better informed about GRAS substances. H.R. 2749 contains provisions on GRAS substances, including a requirement that the Secretary post on

⁹GAO, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, GAO-10-246 (Washington, D.C.: Feb. 3, 2010).

FDA's Web site information about GRAS notices submitted to FDA within 60 days of receipt of the notice.

FDA Lacks Explicit Authority to Issue Regulations Requiring Food-Producing Firms to Institute Preventive Measures

We have also reported that FDA should strengthen its oversight of fresh produce.¹⁰ For example, we noted that FDA has identified a need for explicit authority from Congress to issue regulations requiring preventive controls (risk-based safety regulations) by firms producing foods that have been associated with repeated instances of serious health problems or death. FDA already has preventive regulations for seafood and juice, which require firms to analyze safety hazards and implement plans to address those hazards. According to FDA, such authority would strengthen the agency's ability to implement risk-based processes to reduce illnesses from high-risk foods. FDA officials told us that issuing preventive regulations may be one of the most important things they can do to enhance their oversight of fresh produce. We therefore recommended that the Commissioner of FDA seek authority from Congress to make explicit FDA's authority to adopt preventive controls for high-risk foods. FDA agreed with this recommendation and has sought authority to issue additional preventive controls for high-risk foods. Furthermore, H.R. 2749 requires FDA to create preventive controls for produce and certain raw agricultural commodities. Such measures could help the agency reduce illnesses from these high-risk foods.

In conclusion, food imports from around the world constitute a substantial and increasing volume of imported foods. Our work has shown that FDA could strengthen its oversight of imported food by improving its enforcement, such as by assessing civil penalties and providing unique identification numbers to firms. Additional statutory authorities, such as mandatory recall authority, could also help FDA oversee food safety. FDA generally agreed with our recommendations and has some taken actions to address them.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions that you or other Members of this Subcommittee may have.

¹⁰GAO, *Food Safety: Improvements Needed in FDA Oversight of Fresh Produce*, GAO-08-1047 (Washington, D.C.: Sept. 26, 2008).

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Appendix I: GAO-09-873 (Food Imports)



Highlights
Highlights of GAO-09-873, a report to congressional committees

September 2009

FOOD SAFETY

Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food

Why GAO Did This Study

Imported food makes up a substantial and growing portion of the U.S. food supply. To ensure imported food safety, federal agencies must focus their resources on high risk foods and coordinate efforts.

In this context, GAO was asked to (1) assess how Customs and Border Protection (CBP), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) are addressing challenges in overseeing the safety of imported food, (2) assess how FDA leverages resources by working with other entities, such as state and foreign governments, and (3) determine how FDA is using its Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system to oversee imported food safety. GAO analyzed CBP, FDA, and FSIS procedures, reports, and regulations and interviewed agency officials and key stakeholders.

What GAO Recommends

GAO recommends, among other things, that FDA seek authority from the Congress to assess civil penalties on firms and persons who violate FDA laws, and that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier. CBP and FDA generally agreed with our recommendations. FSIS provided technical comments only.

View GAO-09-873 or key components. For more information, contact Lisa Shames at (202) 512-3041 or lshames@gao.gov.

What GAO Found

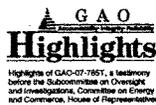
CBP, FDA, and FSIS have taken steps to address challenges in ensuring the safety of the increasing volume of imported food. For example, CBP maintains the system that importers use to provide information to FDA on food shipments; FDA electronically reviews food imports and inspects some foreign food production facilities to prevent violative food from reaching U.S. shores; and FSIS employs an equivalency system that requires countries to demonstrate that their food safety systems provide the same level of protection as the U.S. system. However, gaps in enforcement and collaboration undermine these efforts. First, CBP's computer system does not currently notify FDA or FSIS when imported food shipments arrive at U.S. ports, although efforts are underway to provide this information to FDA for air and truck shipments. This lack of communication may potentially increase the risk that unsafe food could enter U.S. commerce without FDA review, particularly at truck ports. Second, FDA has limited authority to ensure importers' compliance with its regulations. Third, CBP and FDA do not identify importers with a unique number, as a result, FDA cannot always target food shipments originating from high risk importers. Finally, CBP faces challenges in managing in-bond shipments—those that move within the United States without formally entering U.S. commerce—and such shipments possibly could be diverted into commerce.

FDA generally collaborates with select states and foreign governments on imported food safety. FDA has entered into a contract, several cooperative agreements, and informal partnerships for imported food with certain states, and some state officials told GAO that they would like to collaborate further with FDA on food imports. However, citing legal restrictions, FDA does not fully share certain information, such as product distribution lists, with states during a recall. This impedes states' efforts to quickly remove contaminated products from grocery stores and warehouses. FSIS has begun to make available to the public a list of retail establishments that have likely received food products that are subject to a serious recall. FDA is also expanding efforts to coordinate with other countries. In particular, through its Beyond Our Borders initiative, FDA intends to station investigators and technical experts in China, Europe, and India, to provide technical assistance and gather information about food manufacturing practices to improve risk-based screening at U.S. ports.

According to FDA, PREDICT will analyze food shipments using criteria that include a product's inherent food safety risk and the importer's violative history, among other things, to estimate each shipment's risk. A 2007 pilot test of PREDICT indicated that the system improved FDA's ability to identify products it considers to be high risk while allowing a greater percentage of products it considers low risk to enter U.S. commerce without a manual review. However, FDA has not yet developed a plan to measure the system's performance, and GAO previously identified shortcomings in FDA's information technology modernization efforts. FDA plans to begin deploying PREDICT at all ports and for all FDA-regulated products in September 2009.

United States Government Accountability Office

Appendix II: GAO-07-785T (Food Recalls)



Why GAO Did This Study

Each year, about 76 million people contract a foodborne illness in the United States; about 325,000 require hospitalization, and about 5,000 die. The outbreaks of *E. coli* in spinach and *Salmonella* in peanut butter, along with contamination in pet food, have highlighted the risks posed by accidental food contamination. The attacks of September 11, 2001, heightened awareness that the food supply could also be vulnerable to deliberate contamination. This testimony focuses on the (1) role that GAO's high-risk series can play in raising the priority and visibility of the need to transform federal oversight of food safety, (2) fragmented nature of federal oversight of food safety, and (3) limitations in federal food recall programs.

What GAO Recommends

While many of GAO's recommendations to promote the safety of the nation's food supply have been acted upon, others have not yet been addressed. For example, GAO recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination. GAO also proposed that Congress enact comprehensive, uniform, and risk-based food safety legislation; analyze alternative organizational food safety structures; and consider legislation giving agencies authority to order food recalls.

www.gao.gov/cgi-bin/gettr?GAO-07-785T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lisa Shames at (202) 512-3841 or ShamesL@gao.gov.

April 24, 2007

FEDERAL OVERSIGHT OF FOOD SAFETY

High-Risk Designation Can Bring Needed Attention to Limitations in the Government's Food Recall Programs

What GAO Found

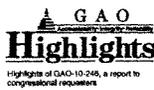
GAO's High-Risk Series is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. These reports also help Congress and the executive branch carry out their responsibilities while improving the government's performance and enhancing its accountability for the benefit of the American people. In January 2007, as part of our regular update of this series for each new Congress, GAO designated the federal oversight of food safety as a high-risk area for the first time.

We designated federal oversight of food safety as a high-risk area because of the need to transform this system to reduce risks to public health as well as the economy. While this nation enjoys a plentiful and varied food supply that is generally considered to be safe, the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety. The two primary agencies are the U.S. Department of Agriculture (USDA), which is responsible for the safety of meat, poultry, and processed egg products, and the Food and Drug Administration (FDA), which is responsible for virtually all other food. We have identified examples where the federal government's resources and enforcement activities can better align with the risks of food contamination. For example, the majority of federal expenditures for food safety inspection were directed toward USDA's programs for ensuring the safety of meat, poultry, and egg products; however, USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA, which is responsible for regulating about 80 percent of the food supply, accounted for only about 24 percent of expenditures.

Among the reasons we designated federal oversight of food safety as a high-risk area is that limitations in the federal government's food recalls heighten the risk that unsafe food will remain in the food supply and ultimately be consumed. Food recalls are voluntary, and federal agencies responsible for food safety have no authority to compel companies to carry out recalls—with the exception of FDA's authority to require a recall for infant formula. USDA and FDA provided guidance for companies to carry out voluntary recalls. We have reported that USDA and FDA could do a better job carrying out their food recall programs so they can quickly remove potentially unsafe food from the marketplace. At the time of our review, these agencies did not know how promptly and completely companies were carrying out recalls, did not promptly verify that recalls had reached all segments of the distribution chain, and used procedures that may not have been effective to alert consumers to a recall.

United States Government Accountability Office

Appendix III: GAO-10-246 (GRAS)



February 2010

FOOD SAFETY

FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)

Why GAO Did This Study

The Food and Drug Administration (FDA), which is responsible for ensuring the safety of most of the U.S. food supply, is not required to review substances, such as spices and preservatives, added to food that are generally recognized as safe (GRAS) for their intended use. Currently, companies may determine a substance is GRAS without FDA's approval or knowledge. However, a few substances previously considered GRAS have later been banned, and concerns have been raised about the safety of other GRAS substances, including those containing engineered nanomaterials, materials manufactured at a tiny scale to take advantage of novel properties. GAO was asked to review the extent to which (1) FDA's oversight of new GRAS determinations helps ensure the safety of these substances, (2) FDA ensures the continued safety of current GRAS substances, and (3) FDA's approach to regulating engineered nanomaterials in GRAS substances helps ensure the safety of the food supply. GAO reviewed FDA data on GRAS substances and interviewed a range of stakeholders, among other things.

What GAO Recommends

GAO recommends that FDA take steps to better ensure the safety of GRAS substances, including developing a strategy to require any company that conducts a GRAS determination to provide FDA with basic information about it. FDA generally agreed, while raising concerns about certain aspects of several of the recommendations.

View GAO-10-246 or key components. For more information, contact Lisa Shimee at (202) 512-3841 or lsimee@gao.gov.

What GAO Found

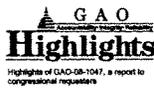
FDA's oversight process does not help ensure the safety of all new GRAS determinations. FDA only reviews those GRAS determinations that companies submit to the agency's voluntary notification program—the agency generally does not have information about other GRAS determinations companies have made because companies are not required to inform FDA of them. Furthermore, FDA has not taken certain steps that could help ensure the safety of GRAS determinations, particularly those about which the agency has not been notified. FDA has not issued guidance to companies on how to document their GRAS determinations or monitored companies to ensure that they have conducted GRAS determinations appropriately. Lastly, FDA has yet to issue a final regulation for its 1997 proposed rule that sets forth the framework and criteria for the voluntary notification program, potentially detracting from the program's credibility.

FDA is not systematically ensuring the continued safety of current GRAS substances. While, according to FDA regulations, the GRAS status of a substance must be reconsidered as new scientific information emerges, the agency has not systematically reconsidered GRAS substances since the 1980s. FDA officials said they keep up with new developments in the scientific literature and, on a case-by-case basis, information brought to the agency's attention could prompt them to reconsider the safety of a GRAS substance. However, FDA has largely not responded to concerns about GRAS substances, such as salt and the trans fats in partially hydrogenated vegetable oils, that individuals and consumer groups have raised through 11 citizen petitions submitted to the agency between 2004 and 2008. In fact, FDA has decided on the validity of these concerns in only 1 of 11 cases. In addition, FDA does not know to what extent, or even whether, companies track evolving scientific information about their GRAS substances.

FDA's approach to regulating nanotechnology allows engineered nanomaterials to enter the food supply as GRAS substances without FDA's knowledge. While some uses of engineered nanomaterials have the potential to help ensure food safety, uncertainties remain about how to determine their safety in food. After reviewing the uncertainties associated with the safety of engineered nanomaterials, FDA has decided that it does not need additional authority to regulate products containing such materials. Rather, FDA encourages, but does not require, companies considering using engineered nanomaterials in food to consult with the agency regarding whether such substances might be GRAS. Because GRAS notification is voluntary and companies are not required to identify nanomaterials in their GRAS substances, FDA has no way of knowing the full extent to which engineered nanomaterials have entered the U.S. food supply as part of GRAS substances. In contrast to FDA's approach, all food ingredients that incorporate engineered nanomaterials must be submitted to regulators in Canada and the European Union before they can be marketed.

United States Government Accountability Office

Appendix IV: GAO-08-1047 (Fresh Produce)



September 2008

FOOD SAFETY

Improvements Needed in FDA Oversight of Fresh Produce

Why GAO Did This Study

In recent years, both domestic and imported produce have been linked to reported outbreaks of foodborne illness. Contamination in produce is of particular concern because produce is often consumed raw. The Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of both domestic and imported fresh produce. GAO was asked to examine (1) the resources FDA has spent on fresh produce safety and how it has allocated those resources, (2) the effectiveness of FDA's actions to oversee fresh produce safety, and (3) the extent to which FDA's planned actions to enhance fresh produce oversight address identified challenges. For this review, GAO analyzed FDA spending data and estimates and FDA activities data, reviewed FDA plans, and interviewed FDA officials and others.

What GAO Recommends

GAO recommends, among other things, that the Commissioner of FDA update its guidance on good agricultural practices and its regulations on current good manufacturing practice for food, and seek explicit authority from the Congress to adopt preventive controls for high-risk foods and authority for enhanced access to records.

FDA agreed with most of GAO's recommendations but believed that it had sought authority from the Congress. FDA should continue to take steps to obtain these authorities so that it can conduct its oversight responsibilities.

To view the full product, including the scope and methodology, click on GAO-08-1047. For more information, contact Lisa Shivers at (202) 512-3841 or lshivers@gao.gov.

What GAO Found

While FDA has considered fresh produce safety a priority for many years, resource constraints and other work—including counterterrorism efforts and unplanned events such as foodborne illness outbreaks—have caused FDA to delay key produce safety activities. FDA has no formal program devoted exclusively to fresh produce and has not consistently and reliably tracked its fresh produce spending. Based on FDA estimates, FDA spent at least \$20 million and 130 staff years on fresh produce in fiscal year 2007—or about 3 percent of its food safety dollars and 4 percent of its food safety staff years. In addition, FDA had few staff dedicated solely to fresh produce safety. Moreover, FDA acknowledged that it has not yet been able to conduct certain fresh produce work crucial to understanding the incidence of contamination of produce by pathogens such as *E. coli* O157:H7 or *Salmonella*, because it has lacked the resources to either fund its extramural research grant program or perform some critical research internally. Finally, FDA delayed issuing final fresh-cut produce guidance at least 5 years because it had to shift staff to counterterrorism and outbreak investigation work.

FDA has provided limited oversight of domestic and imported fresh produce. For example, while FDA has issued guidance for industry on recommended practices for reducing the risk of contamination during the processing of fresh-cut produce, it has not issued regulations requiring firms to take action to prevent contamination, even though some industry groups would like it to do so. FDA's intervention efforts have also been limited. Specifically, domestic fresh produce firms were inspected infrequently. Furthermore, FDA examined less than 1 percent of the 7.6 million fresh produce lines imported from fiscal year 2002 through 2007. Finally, FDA has improved some elements of its emergency response by, for example, partnering with California on outbreak investigations. However, it faces challenges in tracing an outbreak involving fresh produce back to its source because produce is highly perishable and may no longer be available for testing. Also, when product is available, it may be unlabeled or mixed in packages containing products from multiple sources.

FDA has proposed changes through its *Food Protection Plan* that could significantly enhance its fresh produce oversight. However, the agency is still in the planning stages for several enhancements and has not provided specific information on strategies and resources, making it difficult to assess the likelihood of success. To help prevent contamination, FDA plans to update its existing guidance on good agricultural practices and regulations on current good manufacturing practice for food, and has identified a need for explicit authority to issue preventive safety regulations for high-risk foods and enhanced access to records. To enhance intervention efforts, FDA plans to use more rigorous risk-based criteria to target domestic firm inspections and is testing a new import screening software tool. To improve response efforts, FDA is examining best practices for tracing contaminated foods to their source.

United States Government Accountability Office

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Mr. STUPAK. Thank you.
Ms. Nudelman, your opening.

TESTIMONY OF JODI NUDELMAN

Ms. NUDELMAN. Good afternoon, Chairman Stupak, Ranking Member Burgess, and other members of the subcommittee. I am Jodi Nudelman, regional inspector general in New York for the U.S. Department of Health and Human Services Office of Inspector General. I appreciate the opportunity to appear before you today to discuss our most recent review of FDA's food inspections program.

FDA's inspections are an important tool for ensuring food safety. Recent outbreaks, however, such as the salmonella outbreak caused by peanuts in 2009, have raised questions about FDA's inspection process and its ability to protect the Nation's food supply.

Our most recent review focused on FDA's inspections of domestic food facilities. In brief, our review found that more than half of food facilities went 5 or more years without an inspection. We also found that the number of FDA inspections is going down, even as the number of food facilities is going up. In 2004, FDA inspected over 17,000 facilities. In 2008, this number dropped to fewer than 15,000. The number of high-risk facilities inspected also declined during this time. If FDA does not routinely inspect food facilities, it cannot be sure that these facilities are complying with the law and that the food they handle is safe.

Our review also found that FDA's inspectors are identifying fewer violations in food facilities. During an inspection, an inspector may find violations of FDA's regulations or laws. Based on the nature of the violations, he or she may assign the facility a classification. In the most severe cases, the inspector will assign the facility an OAI classification, which means "official action is indicated." Between 2004 and 2008, the number of facilities that received OAI classifications dropped from about 600 to less than 300.

Most commonly, facilities received OAI classifications for unsafe practices and unsanitary conditions in the facility. These classifications resulted from violations such as food not being adequately refrigerated or evidence of rodent infestation. We also found that nearly three-quarters of the facilities that received OAI classifications had a history of violations. Even more concerning, half of these facilities had been cited for the exact same violation in a prior inspection.

Further, our report found that FDA did not always take swift and effective action to remedy the violations. When a facility receives an OAI, FDA should consider taking some type of regulatory action. In the year that we studied, FDA took regulatory action against 46 percent of the facilities that received OAI. For the remaining, FDA either lowered the classification or took no regulatory action.

Moreover, for a third of the facilities with OAIs, FDA did not take additional steps to ensure that the violations were corrected. This means that FDA did not reinspect these facilities in a timely manner or review any other evidence to determine whether the violations were corrected.

Based on these findings, we made six recommendations to FDA. We recommended that FDA increase the frequency of its inspec-

tions, especially its high-risk inspections; provide additional guidance about when to lower OAIs; take appropriate action against facilities with OAIs; ensure that violations are corrected; seek the authority to access facilities' records during an inspection; and, finally, consider seeking the authority to impose civil penalties through administrative proceedings.

In conclusion, our report identified significant weaknesses in FDA's inspections program. We found that many food facilities go without routine inspections. We also found that, when FDA finds violations, it does not always take swift and effective action to ensure that the violations are remedied. Taken together, our findings demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary tools to keep food safe.

This concludes my testimony, and I welcome your questions.

[The prepared statement of Ms. Nudelman follows:]

Testimony of:
Jodi Nudelman
Regional Inspector General for Evaluation and Inspections
Office of Inspector General, U.S. Department of Health & Human Services

Good afternoon, Chairman Stupak, Ranking Member Burgess, and other distinguished Members of the Subcommittee. I am Jodi Nudelman, Regional Inspector General for Evaluation and Inspections of the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss our oversight work as well as the vital role that the Food and Drug Administration (FDA) plays in protecting the Nation's food supply.

Recent high-profile outbreaks of foodborne illness have underscored the importance of food facility inspections. My testimony today will focus on my office's recent review of FDA's inspection program.¹ In short, our report identifies significant weaknesses in FDA's inspections of domestic food facilities. We found that many food facilities went 5 or more years without an FDA inspection. We also found that there was a large decline in the number of food facility inspections conducted by FDA over a 5-year period, as well as a decline in the number of violations identified by FDA inspectors. Further, when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied.

Our recent report is a part of a larger body of OIG work that demonstrates that more needs to be done to ensure the safety of the Nation's food supply. In a report on food traceability, we found that only 5 of 40 selected products could be traced through each stage of the food supply chain.² In addition, more than half of the facilities that handled these food products failed to meet FDA recordkeeping requirements. In another report, we found that 5 percent of selected facilities failed to register their facilities with FDA as required. Of those facilities that did register, almost half failed to provide accurate information in FDA's registry.³ Finally, we completed a report that found that FDA did not always follow its procedures when overseeing certain pet food recalls and noted that FDA does not have the statutory authority to mandate recalls.⁴

OIG'S MISSION IS TO PROTECT HHS PROGRAMS AND BENEFICIARIES

OIG is an independent, nonpartisan agency committed to protecting the integrity of the more than 300 programs administered by HHS as well as the health and welfare of the people served by them. OIG fights fraud, waste, and abuse through a nationwide network of investigations, audits, and evaluations, as well as enforcement and compliance activities.

OIG's work results in recoveries of misspent or stolen funds and in recommendations for program savings and improvements to program efficiency and effectiveness. In FY 2009, OIG investigations

¹ OIG, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080, April 2010.

² OIG, *Traceability in the Food Supply Chain*, OEI-02-06-00210, March 2009.

³ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. The purpose of registration is to provide FDA with reliable information that enables FDA to quickly locate facilities during outbreaks of foodborne illness. See OIG, *FDA's Food Facility Registry*, OEI-02-08-00060, December 2009.

⁴ OIG, *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls*, A-01-07-01503, August 2009.

1 House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: Hearing May 6, 2010.

resulted in \$4 billion in settlements and court-ordered fines, penalties, and restitution. OIG audits resulted in almost \$500 million in expected recoveries. OIG also produced equally important but less quantifiable gains in deterrence and prevention of fraud, waste, and abuse and in improved program operations. Additionally, OIG has raised awareness of critical issues among policymakers, Government agencies, and other relevant stakeholders. Moving forward, OIG is committed to building on our successes and continuing to protect the integrity of Government programs and their beneficiaries.

FOOD FACILITY INSPECTIONS ARE AN IMPORTANT TOOL TO ENSURE FOOD SAFETY

Each year, more than 300,000 Americans are hospitalized and 5,000 die after consuming contaminated foods and beverages.⁵ FDA is responsible for safeguarding the Nation's food supply by ensuring that food is free of disease-causing organisms, chemicals, or other harmful substances.⁶ Recent outbreaks, such as the salmonella outbreak caused by insanitary conditions at a peanut-processing plant in 2009—as well as others that resulted in large recalls of spinach, peppers, and alfalfa sprouts—have raised questions about FDA's inspections process and its ability to protect the Nation's food supply.

FDA inspects food facilities to ensure food safety. During an FDA inspection, an inspector may identify potential violations of the Food, Drug, and Cosmetic Act or other applicable laws and regulations. Based on the outcome of the inspection, FDA assigns the facility one of three classifications: official action indicated (OAI), voluntary action indicated, or no action indicated.

According to FDA guidance, when inspectors uncover violations that are significant enough to warrant OAI classification, FDA should consider taking some type of regulatory action. This regulatory action generally consists of either an advisory action or an enforcement action. Advisory actions usually allow an opportunity for the facility to voluntarily correct the violations found during the inspection, whereas enforcement actions are usually initiated in court and the facility is compelled to correct the violations found during the inspection.

Once an FDA inspection finds violations at a facility, FDA uses several methods of determining whether a facility has subsequently corrected the violations. FDA may review evidence of corrective actions provided by a food facility or FDA may reinspect a facility to verify that corrections were made.

OIG ASSESSED THE FREQUENCY AND RESULTS OF FDA'S FOOD FACILITY INSPECTIONS

Our study assessed the extent to which FDA conducted inspections and identified violations in domestic food facilities.⁷ It also assessed the extent to which FDA took regulatory action against food facilities with violations and ensured that these violations were corrected.

⁵ Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, 1999, pp. 607-625. Available online at <http://www.cdc.gov/ncidod/eid/Vol5no5/mead.htm>. Accessed on December 14, 2009.

⁶ FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture.

⁷ This study includes inspections of domestic food facilities conducted by FDA or by States under contract with FDA.

We based our study on three sources of data: (1) FDA's data on food facility inspections, (2) FDA's documentation of facility violations and followup activities, and (3) structured interviews with FDA staff.

To determine the extent to which FDA conducts inspections, we analyzed FDA's data on all domestic food facility inspections for fiscal years (FY) 2004 through 2008. To determine the extent to which FDA took action against food facilities with violations and ensured that those violations were corrected, we requested from FDA all documentation related to OAI classifications received by facilities in FY 2007. We chose FY 2007 because it was the most recent timeframe that would also allow FDA sufficient time to initiate any actions and to complete any activities designed to ensure that violations were corrected.

MOST FOOD FACILITIES WENT UNINSPECTED FOR AT LEAST 5 YEARS

Our study found that 56 percent of food facilities that were subject to FDA inspection went 5 or more years without an FDA inspection. If FDA does not routinely inspect food facilities, it is unable to ensure that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe. Except in a few instances, there are currently no specific guidelines that govern the frequency with which inspections should occur.

Our study also found that the number of food facility inspections has declined, even as the number of food facilities has increased. In FY 2004, FDA inspected more than 17,000 facilities; in FY 2008, this number dropped to fewer than 15,000. During the same period, the number of food facilities subject to FDA inspection increased from about 59,000 to almost 68,000 facilities. We also identified a decline in the number of high-risk facilities inspected by FDA.⁸

FDA officials attributed the decline in inspections primarily to a significant decrease in staffing levels that resulted from funding cuts. These officials noted that between 2003 and 2008, FDA lost almost a quarter of the staff that performs food facility inspections. They also noted that many of those losses came from the ranks of FDA's most experienced employees.

THE FREQUENCY OF VIOLATIONS IDENTIFIED BY FDA INSPECTIONS DECLINED, AND MOST FACILITIES WITH VIOLATIONS WERE REPEAT OFFENDERS

Facilities receive OAI classifications when inspectors determine that the violations found are significant enough to potentially warrant regulatory action. Facilities most commonly received OAI classifications for unsafe food manufacturing and handling practices and insanitary conditions in the facilities, such as improper handling of food or evidence of rodent infestations.

From FY 2004 to FY 2008, the percentage of inspected facilities that received OAI classifications dropped from nearly 4 percent to less than 2 percent. Further, over this 5-year period, the number of facilities with OAI classifications declined from 614 facilities to 283 facilities.

⁸ Each year, FDA designates certain facilities as high risk. This designation helps FDA determine which facilities should be given a higher priority for inspection. Generally, these facilities handle types of food that have a greater potential to cause harm.

Our study also found that nearly three-quarters of the facilities that received OAI classifications in FY 2008 had a history of violations. Even more worrisome, half of the facilities that received OAI classifications had been cited for exactly the same violations in prior inspections. In one notable example, FDA found that a facility had the same unsafe manufacturing practices and insanitary conditions as it did during the previous four inspections. After each inspection, the facility promised to make corrections; however, each subsequent inspection revealed that nothing had changed.

We also found that a small number of facilities refused to grant FDA officials access to records during an inspection. These records included descriptions of sanitation practices within each facility, lists of customers that received the facility's products, and descriptions of consumer complaints. FDA does not currently have the statutory authority to require food facilities to provide access to these records.⁹

FDA DID NOT TAKE REGULATORY ACTION AGAINST MANY FACILITIES WITH VIOLATIONS

According to FDA guidance, when a facility receives an OAI classification, FDA should consider taking some type of regulatory action. This regulatory action generally consists of either advisory action or enforcement action. In FY 2007, FDA took advisory actions against 44 percent of the 446 facilities that initially received an OAI classification, whereas FDA initiated enforcement actions against 2 percent of these facilities.¹⁰

FDA lowered the classifications of 29 percent of the facilities that initially received OAI classifications. The most common reason for lowering a classification was that other FDA officials did not concur with the inspector's initial classification. The second most common reason for lowering a classification was that the facility either took or promised to take corrective actions. Although FDA guidelines allow inspection classifications to be lowered, FDA district offices appeared to be inconsistent when lowering classifications. For example, some district offices did not lower their OAI classifications after a facility promised to take corrective action, whereas other district offices did this more commonly.

For 25 percent of facilities initially receiving OAI classifications, FDA neither took any regulatory action against the facilities nor lowered the classifications. In just over half of these cases, FDA officials noted that they did not take regulatory action because of their interpretation of FDA's program guidance. For example, FDA guidelines suggest that multiple warning letters should not be issued for the same violations. Several officials reported that they did not issue a warning letter because FDA had previously issued a warning letter to the facility.

FDA OFTEN DID NOT TAKE SWIFT AND EFFECTIVE ACTION TO ENSURE THAT VIOLATIONS WERE REMEDIED

FDA often failed to follow up with facilities to ensure that violations were corrected. In FY 2007, 280 facilities received OAI classifications that were not lowered by FDA. FDA did not reinspect 36

⁹ FDA has access to certain records held by infant formula facilities as well as certain records needed to trace an article of food through the food supply chain. The limited circumstances under which FDA can access these records are described in 21 U.S.C. §§ 374 and 350.

¹⁰ The advisory actions taken by FDA consisted of warning letters, untitled letters, and regulatory meetings. The enforcement actions taken by FDA consisted of seizures and injunctions.

percent of these facilities within a year of the inspection or review evidence to ensure that the violations were corrected.

For the remaining facilities, FDA took additional steps to ensure that the violations had been corrected. Specifically, FDA reinspected 35 percent of the facilities within a year of the initial inspection. For an additional 30 percent of facilities, FDA reported that it reviewed some type of evidence from the facilities demonstrating that they had corrected the violations.¹¹ Examples of this evidence included photographs documenting corrections made in the facility, revised food labels documenting changes made to correct labeling violations, and a description of how employees were counseled.

OIG RECOMMENDS SEVERAL ACTIONS TO STRENGTHEN FDA'S DOMESTIC INSPECTIONS PROGRAM

Based on these findings, we made six recommendations to FDA to improve its domestic inspections program. Specifically, we recommended that FDA:

- increase the frequency of food facility inspections, with particular emphasis on high-risk facilities;
- provide additional guidance about when it is appropriate to lower OAI classifications;
- take appropriate actions against facilities with OAI classifications, particularly those that have a history of violations;
- ensure that violations are corrected for all facilities that receive OAI classifications;
- seek statutory authority to allow FDA access to facilities' records during the inspection process; and
- consider seeking statutory authority to impose civil penalties through administrative proceedings.

IN CONCLUSION, MORE NEEDS TO BE DONE TO PROTECT THE SAFETY OF THE NATION'S FOOD SUPPLY

Our report identified significant weaknesses in FDA's inspections program. If FDA does not routinely inspect food facilities, it is unable to ensure that these facilities are complying with applicable laws and regulations and that the food handled by these facilities is safe. In addition, FDA must take swift and effective action to ensure that all violations are remedied. Taken together, the findings of this report demonstrate that more needs to be done to protect public health and to ensure that FDA has the necessary tools to prevent outbreaks of foodborne illness.

OIG recognizes the importance of ensuring the safety of the food supply and will continue our work in this area. We are currently conducting a review that assesses FDA's oversight of inspections conducted by State inspectors under contract. In addition, we are conducting an audit of selected

¹¹ Note that these percentages do not sum to 100 percent because of rounding.

food recalls to determine whether FDA's oversight was adequate to ensure that the recalls were complete, accurate, and timely.

This concludes my testimony. I welcome your questions.

Mr. STUPAK. Thank you.

And thank you to all the witnesses for your testimony.

And let me just apologize. We got tied up on the floor. I thought we would be back by 3:15. It was about a half-hour later. You never know what happens when you get to the floor.

We will now move to questions.

Mr. Taylor, let me ask you this. The FDA announced a lettuce recall today. Freshway Foods is doing a voluntary recall of shredded romaine lettuce with a use on date by May 12th—or use on or before May 12th. I guess three people have been hospitalized.

In the trace-back, do we have any idea of where that romaine is originating from?

Mr. TAYLOR. Our understanding of the investigation so far is it came from a production site in Arizona, in Yuma, Arizona, where this company had its growing operations. We don't know the cause of contamination, but we do know that there was product contaminated, people got sick. And so this recall is highly appropriate to protect the public health.

Mr. STUPAK. Is the lettuce strictly grown in Arizona, or is it mixed with lettuce from Mexico, as we have seen in the past?

Mr. TAYLOR. Well, this is romaine that is grown just in Arizona. And it is sold to institutions in a bulk sort of form, is the general way in which this product is distributed.

Mr. STUPAK. If I remember correctly, when we were out in California, you were there with us, and we were doing some of the farming there. And I thought Arizona and California had a very good trace-back method. You could almost tell from what field it came from. Would you care to comment on this in the matter of this case?

Mr. TAYLOR. Well, in this case, once we had the company identified, there was not a problem getting back to the source of production.

Mr. STUPAK. OK. So the production field produced right there, and you don't know if it is in machinery or whether it was the growing site.

Mr. TAYLOR. We don't know—yes, we are investigating, we are back at the farm investigating the cause, so that investigation goes on. But, as you know, there can be multiple vectors, avenues for getting this kind of contamination into an open field where product is growing.

Mr. STUPAK. Right. It was for romaine that was used by the May 12th. Today is May 6th. How long has this investigation been going on?

Mr. TAYLOR. The first cases go back to—the first onset of illness goes back to April 6th. But it has been only in the last week or 10 days that we became aware of this. There is that lag factor between people first becoming ill and it getting reported.

Mr. STUPAK. Right.

Mr. TAYLOR. And we found yesterday a positive sample of lettuce, which really confirmed the epidemiological hypothesis that this product was responsible for the problem. So there was actually a very swift recall response once the evidence fell into place.

Mr. STUPAK. And I take it Freshway Foods has been cooperative, no problems there?

Mr. TAYLOR. They have worked closely and responded very quickly when the evidence came into place.

Mr. STUPAK. OK.

Ms. Nudelman, let me ask you this. I am looking at page 10 of your report. That is where you start with Table 1, food facilities inspected by the FDA, fiscal year 2004 through 2008. And I think you testified the average of the inspections were about 24 percent of all the places inspected. Correct?

Ms. NUDELMAN. Yes.

Mr. STUPAK. Now, the one that struck me was, in 2004 you had 59,305 facilities should be inspected; by 2008, it has grown to 67,819. If my math is correct, that is about 8,514 new facilities in less than 5 years.

How is the FDA going to keep up with more and more facilities without the resources?

Ms. NUDELMAN. I think that is a good question. I mean, clearly we document the number of facilities has grown and, at the same time, the number of inspections has declined.

I think the other important factor in this is the number of high-risk inspections that are completed. And that is one way to target resources and target—

Mr. STUPAK. Right. Well, if we jump to the next table, that is Table 2, which is the high-risk facilities inspected by the FDA and, again, through the same years, 2004 to 2008. You have had, again, more high-risk facilities come online, about 565, if my math is correct here. The number of inspections has actually dropped from 77 percent to 63 percent.

Any correlation during that period of time from 2004 to 2008, how many inspectors did the FDA have? Did the number of inspectors go down?

Ms. NUDELMAN. That is correct. And this is one of the things that FDA talked about in terms of the reason why there was a decline in the number of high-risk inspections as well as the number of overall inspections.

Mr. STUPAK. Let me go to your next chart on page 12, again, number of inspections per facility between 2004 and 2008. I take it facilities inspected more than three times, there is 21 percent of them, were probably the greater or high-risk foods.

Ms. NUDELMAN. I am not positive about that. That makes sense to me, but I am not—I can look at that in a little bit more detail for you.

Mr. STUPAK. All right.

Let me go to the bottom of page 14. In your report, you were talking about the FDA OAI classifications—refused to grant FDA officials access to their records. Most of the facilities had a history of violations. Then you say the FDA does not have statutory authority to require food facilities to provide access to these records.

Do you know if the FDA ever received those records in these four or five cases?

Ms. NUDELMAN. In the reports that we looked at, that was for 2008, and it just documented clearly the types of records that they did not receive. I don't know. And maybe FDA has a better sense of that.

Mr. STUPAK. Yes, I was going to ask Mr. Taylor.

Any comment on that? Do you know if they ever received those records?

Mr. TAYLOR. We got what we felt was a satisfactory resolution. Dr. Solomon can walk you through the details of each one. It varied from case to case. But, in some cases, we went ahead and got injunctions to solve the problem or took other forms of enforcement action. And if you would like, we can put—

Mr. STUPAK. Sure. Just quickly, if you could just tell us what would happen on those.

Mr. SOLOMON. In one of those cases, we actually used the authority under the Bioterrorism Act, 414, to meet that threshold to have to request those records. Obviously, that delayed us.

In two of the other cases, we conducted an injunction in order to try and get those records and requesting others for—

Mr. STUPAK. Injunction would stop them from doing what, shipping their product?

Mr. SOLOMON. We were able to stop them from shipping product, and, at the same time, we used that consent decree that was signed to go to the suppliers there and get the information that we needed to control the product.

Mr. STUPAK. OK. So you went to the supplier to find out what the facility was doing?

Mr. SOLOMON. Correct.

Mr. STUPAK. OK.

Mr. SOLOMON. So these were longer processes that took us to try and get the records that were needed.

Mr. STUPAK. Sure. OK.

My time is up. Mr. Burgess for questions?

Mr. BURGESS. Just staying with that concept for a minute, Mr. Taylor and Mr. Solomon, on the food safety bill that we passed out of this committee that is now awaiting activity over in the Senate, there is a provision for emergency recall, which I think you referenced, Mr. Solomon, as part of the bioterrorism defense. But, still, it is a voluntary recall under the bill that we passed.

Is that your understanding, as well?

Mr. SOLOMON. We don't currently have mandatory recall authority, which is part of the Food Safety Enhancement Act.

Mr. BURGESS. And after the passage of this legislation, is that a deficiency that you feel will be corrected? Or will you still be relying on the emergency provisions of the Bioterrorism Act to have that emergency provision?

Mr. SOLOMON. We could use all the tools available, and we would use that mandatory recall authority if that was necessary in order to effectuate getting product removed from the market.

Mr. TAYLOR. If I may add, the bill, 2749, would also give us routine records access, so the company would be obligated to provide the records we need to conduct an investigation and to find and discover the problems and solve the problems.

Mr. BURGESS. Mr. Taylor, congratulations on your new post—

Mr. TAYLOR. Thank you, sir.

Mr. BURGESS [continuing]. I think, I hope, for you.

How many people currently work in your office?

Mr. TAYLOR. Well, in my immediate Office of Foods, it is a very small staff of about 15 people. But we really work within the over-

all foods program. There is the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and then the large field force. So, you know, there are upwards of 5,000 people in the foods program.

But this new office that the commissioner created is a small leadership office, essentially.

Mr. BURGESS. OK. Do you plan on expanding it?

Mr. TAYLOR. The immediate office will grow slightly, but the last thing we want to do is to try to manage the program from the Office of Foods. We have great management teams and people throughout the foods program and these organizations, and our job is to lead and to unify and elevate their work within the FDA.

Mr. BURGESS. So, you just referenced the Center for Veterinary Medicine. Those directors report to you, as well?

Mr. TAYLOR. Yes, sir. The director of the Center for Veterinary Medicine reports to me, as does the director of the Center for Food Safety and Applied Nutrition.

Mr. BURGESS. At this point, are you considering merging the Center for Food Safety as well as the Center for Veterinary Medicine?

Mr. TAYLOR. We have no plans to merge the organizations. We are looking at how we manage this program in a unified way and how we can be sure that we are really able to empower the people in these organizations to accomplish the things they are setting out to accomplish. And so we are looking at how we manage the program, but we have no plan for mergers at this point.

Mr. BURGESS. Let me just ask you a couple of questions about PREDICT since that has come up in your testimony as well as the testimony of the GAO. It holds promise, correct?

Mr. TAYLOR. Yes, sir.

Mr. BURGESS. But there were problems.

Mr. TAYLOR. Yes.

Mr. BURGESS. And those problems were related to the status of the IT systems that are surrounding it?

Mr. TAYLOR. Yes, sir. Really—and I am not the IT expert on the case, but it is really a function of the aging IT infrastructure, the servers, the basic equipment that supports the IT system.

And so what happened, in lay terms, is a combination of things. You put this whole new application onto the system, which put extra demand on the system. And it was happening at about the time that we have grown our field workforce. We have been able, with resources Congress has provided over the last couple of years, to hire additional inspectors and other people in our field force.

So that combination of extra demands on an aging IT infrastructure resulted in slowdowns and some, you know, servers going down. And the IT people realized that that aging infrastructure could not support the new system.

But, again, with resources Congress has provided, we are making the investments to upgrade that infrastructure. So, you know, that upgrade and the imperative to test that carefully and be sure that when we do implement—you know, that is pushing back implementation. But we hope to roll out PREDICT nationwide by the end of the year. That is our goal.

Mr. BURGESS. You anticipated my question. But I was going to ask you, you have developed a strategic plan for dealing with the deficiencies in the IT architecture?

Mr. TAYLOR. Yes, sir. We have the—you know, upgrades are being made; it is being tested. You know, we will test the PREDICT system before we make it operational. But the IT folks are confident that we will have the infrastructure to support this and, you know, make it serve the function that we know it can, which will really be much better targeting of imports.

Mr. BURGESS. So when we have this hearing a year from now, you will be able to report to me—

Mr. TAYLOR. I will be here, yes—

Mr. BURGESS [continuing]. Satisfactorily that it has been up and running for 6 months and it is targeted and in the right place?

Mr. TAYLOR. That is our absolute aspiration and goal. We are working hard to achieve it. And we welcome coming back and giving that answer.

Mr. BURGESS. You can understand the frustration of people who—you know, we are requiring every physician's office across the country to make great investments in information technology, and our own FDA, which is our premiere Federal agency that handles 25 cents out of every Federal dollar, at least domestically, has been unable to meet its own challenge.

Clearly, we have to get our own house in order before we can be too critical of other people who have been slow in that regard, as well.

Mr. TAYLOR. I understand.

Mr. BURGESS. I am going to yield back to the chairwoman.

Mrs. CHRISTENSEN [presiding]. Thank you, Mr. Burgess.

The chair is now really honored to recognize our chairman emeritus, Mr. Dingell, for questions.

Mr. DINGELL. Thank you, Madam Chairman. I commend you for the way you are presiding, and I thank you for being recognized.

I want to begin by commending Chairman Stupak and the committee for this hearing. And I want to observe that this committee has completed a rather remarkable piece of legislation with regard to food safety that rests comfortably in the arms of the United States Senate. As my old daddy used to say, that is the place where good legislation goes to die.

Regrettably, the points made by the witness on behalf of the GAO are very much on point. Her observation of the two statutory methods that need to be added to the arsenal of FDA are included in that legislation.

I know this is going to sound a little hostile to the panel, but I want to begin by commending—and I want you to understand, there is nothing hostile in these questions. But I want to lay the framework of understanding how the events about which we are surrounded affect what it is we are doing.

And I will start by observing that FDA, in 2008, inspected 153 foreign food facilities out of 189,000 such facilities registered with FDA. That is, of course, only a small fraction of the, in fact, number of worldwide sources of foods imported to the United States. But we were able, in each of those years, according to GAO, to in-

investigate only a very small number of the massive numbers of exporters into the United States.

I noted, with regard to China, FDA conducted 46 inspections to China. China is one of the biggest exporters of food to the United States. I observe that that is a country which sends us melamine in milk products, mushrooms, vegetables, fish, shellfish, and other food products that are contaminated, dirty, filthy, or adulterated.

And, frankly, again, the legislation to which we address ourselves sits over there in the Senate. That is a remarkable piece of legislation which came out of this committee unanimously with the full support of every single Member. And the leadership of this subcommittee made it possible for that legislation to move because of the way Mr. Stupak and the members of the committee, including my colleagues on the minority side, worked very hard to see to it that this legislation had not only a proper flooring and support but also a full justification.

Now, having said these things, I would like to make a quick observation and then a question.

Since 2007, FDA has had two major outbreaks linked to peanut butter, involving hundreds of illnesses and nine deaths. That is out of about the 5,000 deaths that exist in this country.

And now I would like to address the types of enforcement action that have been taken against the companies. I would note that the GAO asserts that additional authority to routinely inspect records, detain food, subject violators to civil penalties, subpoena witnesses to help stepped-up enforcement efforts would be significantly helpful.

Am I correct in that, to my witnesses down there, particularly you, Commissioner, and you, ma'am, from the GAO?

Mr. TAYLOR. Yes, sir. Those new authorities are crucial to our doing our job.

Mr. DINGELL. Now, I note FDA's budget anticipates hiring 129 new food and safety inspectors based on revenue from the registration and reinspection fees in H.R. 2749.

What will happen, if you please, to its plans to hire these 129 new inspectors if these fees are not included in the bill that the President signs as they are in the budget?

Mr. TAYLOR. We won't be able to hire those inspectors. And, you know, we need more inspections to ensure the safety of food.

Mr. DINGELL. That means that the ongoing record of dismal ability to investigate or to inspect food processors will continue unabated.

Mr. TAYLOR. Yes, sir.

Mr. DINGELL. Now, I note that the Peanut Corporation of America recall, while it was still ongoing, one of the companies that received the PCA product, Westco Fruit and Nut Company, refused FDA access to important safety records and refused to conduct a voluntary recall, and FDA seized the product of the company.

Now, I note that we should address—in that instance, Food and Drug would be able, had the legislation been passed, to use the mandatory recall authority to remove products that are already on the market. Is that not so?

Mr. TAYLOR. Yes, sir, that is correct.

Mr. DINGELL. Now, how would such mandatory recall authority result in a different outcome in the Westco case?

Mr. TAYLOR. Well, we could have directed that firm to recall that product, to stop distribution, withdraw the product from the market. We wouldn't have to have been in a lengthy discussion and then have to go to court and get a judicial intervention. We could have acted swiftly with those—

Mr. DINGELL. In other words, all of this sawing of the air would have to go on while people were dying of bad peanut butter.

Mr. TAYLOR. Again, if we are delayed in removing product from the market, people are at risk.

Mr. DINGELL. Now, following the outbreak in the recall first linked to tomatoes and later to jalapeno and serrano peppers, the inspector general identified weaknesses in the current one-up/one-down traceability system, including bad record-keeping, lack of access to records, and firms that didn't know about the requirements.

Has FDA's experience in other outbreaks confirmed flaws in the one-up/one-down traceability?

Mr. TAYLOR. Yes, sir. I mean, that requires a lot of shoe leather by FDA. It is an old-fashioned paper system, essentially, when we have electronic alternatives, systems that the industry itself is developing, that can get us this information much more quickly.

Mr. DINGELL. Now, how important is trace-back in containing food-borne illness outbreaks?

Mr. TAYLOR. Trace-back is crucial. Once CDC identifies the food vehicle, we then need to be able to go back to the source of production so we can get to the root of the problem and contain it. So it is really crucial to public health, as well as to protecting the industry, to contain a problem so that the industry, its own business, won't be disrupted any more than need be.

Mr. DINGELL. You can protect honest men and women in the industry from unfair competition by scoundrels and rascals, but you would also protect them against unsafe materials that could enter into the products that they distribute. Isn't that right?

Mr. TAYLOR. Yes, sir. That is exactly it.

Mr. DINGELL. Now, in your report—this is to Ms. Shames. In your report, you state CBP's computer system does not notify FDA when imported food shipments arrive at U.S. ports. It is extremely important that these two agencies coordinate when it comes to imported food. Do you agree with that?

Ms. SHAMES. We agree. We have been able to update that information, and CBP has told us that now it does give FDA the time of arrival. And this should help FDA in terms of coordinating its inspections.

Mr. DINGELL. What additional steps need to be taken by the administration to fully address this concern?

Ms. SHAMES. We feel that CBP should continue to work towards this effort to share time-of-arrival information with USDA. That part of our recommendation has not yet been implemented.

Mr. DINGELL. Thank you.

Madam Chairman, you have been most kind to me with regard to the time. I yield back the balance.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

I now recognize myself for 5 minutes of questions. And I want to ask a question about information sharing, as well.

Ms. Shames, I would like to ask you about GAO's finding that FDA does not always share product distribution information with State regulators during a recall. If food needs to be removed, FDA may not give State regulators important information like which grocery stores and warehouses received the recalled product.

FDA's inadequate coordination with States means that States must duplicate FDA's efforts and track down the same information. You found that public health—and I guess this is a quote—may be at risk during the time it takes for the States to independently track distribution information when a product is found to be contaminated.

So my question, Ms. Shames: FDA's limited provision of information to States during an outbreak seems illogical, so what is the agency's rationale for withholding that information?

Ms. SHAMES. FDA says that this information is commercially confidential. And while we recognize that, we still recognize the public need that the State agencies are often the ones that are actually going into the grocery stores and removing the contaminated product off of the shelf. What we recommended to FDA and what FDA agreed to is that they would explore ways to try to get comparable information to the State agencies.

I should note that USDA, the Food Safety and Inspection Service, does give product name information to the States as a way of trying to expedite any recall.

Mrs. CHRISTENSEN. OK.

So, Mr. Taylor, so you have agreed, and you have the authority to share that information with the States?

Mr. TAYLOR. We are able to share this information with State officers who are commissioned by FDA. And to some extent around the country we have actually commissioned State officials to function as FDA officials, so we are able to do it to that extent. But we do have legal constraints under the laws that govern disclosure of information.

This is a strong feature of the legislation, H.R. 2749, that this committee has passed, that the House has passed, because it would explicitly authorize us to share information with State officials, with other organizations, when necessary to protect public health, and still protecting the confidences of companies but getting the information in the hands of people who need it to protect public health. And we enthusiastically embrace that. We need that clear authority from Congress.

Mrs. CHRISTENSEN. OK. Thank you. You answered the rest of my question.

My next question is on monetary bonds and civil penalties. I am concerned that FDA may not have sufficient authority to keep an importer from violating food safety requirements. Under our current system, the importing company maintains control over their food shipments but is not allowed to release them until FDA approves. Importers post a monetary bond with Customs and Border Protection to guarantee the product will meet all U.S. Requirements, including those of FDA.

At least, that is how the system is supposed to work. But the GAO investigation found that FDA and Customs and Border Protection officials do not believe that the bonding system stops import firms from releasing their goods prior to FDA approval. GAO found that many brokers and importers expect that they will occasionally have to forfeit the monetary bond as part of the cost of doing business.

So, again, my question to you, Ms. Shames, is: Why is the current system of monetary bonds not a sufficient deterrent?

Ms. SHAMES. What we are seeking is for FDA to be able to assess the civil penalties, to make it more of a deterrent for unscrupulous importers who try to do that.

Mrs. CHRISTENSEN. Is the amount of the bond adequate as a deterrent, or does it need to—

Ms. SHAMES. FDA and CBP officials told us that they thought that the amount of the bond really was insufficient.

And this is something that we reported in an earlier report back in 1998. So, well over a decade ago, we were hearing this information from those agencies.

Mrs. CHRISTENSEN. And your testimony stated that GAO recommends that the FDA commissioner seek authority from Congress to assess civil penalties. Can you elaborate? Why does FDA need authority to assess the civil penalties?

Ms. SHAMES. Now it cannot do that; it relies on CBP for any enforcement actions. And giving FDA this authority, again, we feel, would be a deterrent for any unscrupulous importers.

Mrs. CHRISTENSEN. So, Mr. Taylor, if FDA could impose civil monetary penalties for violations of food safety requirements, would that assist FDA in its mission?

Mr. TAYLOR. That would be a big help, to create more accountability for importers.

There is another very important feature of the legislation, though, that would require importers to register with us and to meet requirements for their own practices in order to stay registered, to stay in business as importers. So we would have also the authority to de-register an importer.

So, again, it is critical that we enhance the accountability of importers to play by the rules, essentially.

Mrs. CHRISTENSEN. Is there authority needed to increase the amount of the bond—well, that would be CBP.

Mr. TAYLOR. Right.

Mrs. CHRISTENSEN. Yes. Thank you.

OK, I am out of time. So are we going to have a second—oh, you are back.

I will recognize Mr. Burgess, Dr. Burgess, for a second round of questioning.

Mr. BURGESS. Thank you.

Mr. Taylor, approximately 13 million shipments of food arrive in the U.S. Every year from foreign producers. And, of course, the number is growing, as we have seen from all the graphs.

There are numerous examples of foods that have been problematic. We have heard about the melamine in the milk and the problems with gluten and some of our pet food contamination of a few years ago.

You have opened some stations overseas, the FDA has opened some stations overseas. In addition to that—and the first question is, have we opened enough? Have we done enough in that regard?

And what other measures are we employing to increase or enforce lax safety standards in other countries?

Mr. TAYLOR. Yes. You know, I think it is going to take a combination of tools and efforts to ensure the safety of imports.

Those foreign offices are—they are not inspection posts, but they are critical posts for gathering intelligence about what is happening in other countries, to explain our requirements to foreign governments and to foreign firms.

But that is just one small piece of the toolkit. We do need to do more inspections overseas, but we also need to hold the importer accountable and see that they are policing their own supply chain and being able to provide real assurances to us, documented assurances, that they are producing products overseas or sourcing their product from facilities that meet our standards.

So it is going to take a combination of things. But it is all about building more accountability into the supply chain, all the way back to the point of production.

Mr. BURGESS. And it would seem intuitive that the importer would want that accountability in the supply chain, because, after all, if their products are felt to be unsafe when they get over here, their market share is going to suffer.

But is the FDA working with the importers directly in a collaborative fashion, educational fashion, to try to get more accountability on that end?

Mr. TAYLOR. We do work with the importer community. We have issued guidance to the importer community on good importer practices that we think they should observe to meet that responsibility, to offer food only that meets our standards.

You know, some importers feel the accountability. They are part of a supply chain. The major processor in this country might be the importer, in some cases. But, in other cases, importers don't have a stake in what happens to the food after it passes from them, and so they lack accountability.

And so there is a real gap in the system, you know, if we don't have systematic accountability on importers as a critical part of the safety assurance system.

Mr. BURGESS. So what can you do to impose that degree of accountability if it may not exist naturally as part of the marketplace?

Mr. TAYLOR. We need the passage of H.R. 2749. That is one of the most critical elements of the legislation, to define that accountability, to give us the authority to set the rules that the importers need to play by in order to provide an adequate assurance that the food that they are offering is meeting our standards; again, backed up by our own ability to go inspect, backed up by what foreign governments are doing, backed up by a host of other checks.

But that importer accountability is really a linchpin of the system. And it is lacking now as a really enforceable matter. It is something we urge on the industry, but there is no legal requirement for the importer to really take that responsibility. They only run the risk that we will send the food back. Or, you know, they

may get it into the country under a bond, and, as a cost of doing business, you know, some of them, unscrupulous, will make a decision to let the product go.

So there is a lack of accountability in that part of the system that H.R. 2749 would directly address.

Mr. BURGESS. I have always felt that it really is necessary to have some sort of a stop button that you guys can push in a hurry if you need to, if we find that we have something coming in that we really shouldn't.

Ms. NUDELMAN, let me just ask you a question. And I apologize if Chairman Stupak has already covered this. But, in the report, it found in fiscal year 2007 the FDA took no regulatory action for 25 percent of facilities who received the OAI classification.

Why would the FDA classify a facility as "official action indicated" rather than one of the lesser classifications and then take no action? What would be a possible—that seems counterintuitive to me. What would be a possible rationale for doing that?

Ms. NUDELMAN. Well, in some cases, if the facility agreed to take action or promised to take action, then they did not issue—they did not take any further regulatory action. That was the most common response that we heard.

Mr. BURGESS. And then how is the follow-up for that overseen to ensure that, indeed, the voluntary action was taken and the problem was corrected?

Ms. NUDELMAN. Well, that is one of the things we found. In about 36 percent of the facilities, FDA didn't take any—didn't reinvest to ensure that the correction was made or look at any other evidence. So there is not always the follow-up.

Mr. BURGESS. So that is still inherently a weak spot that needs to be fixed.

Ms. NUDELMAN. Correct.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. STUPAK [presiding]. Mr. Dingell, did you have a question or two on this second round here, please?

Mr. DINGELL. Mr. Chairman, I will impose again briefly upon your patience. And I want to thank for your courtesy to me. And I also want to commend you for the series of hearings you have held on these matters, because they have made it possible for us to move forward in a very significant fashion to protect people and to see that Food and Drug finally has the law and the resources it needs to do its business.

Now, these questions are for Ms. Nudelman. There are 226,373 foreign food facilities registered with FDA. When the inspector general looked at the domestic facilities registered in 2009, it found 48 percent provide inaccurate information; 7 percent either fail to register or failed to cancel their registrations; and 5 percent created multiple registrations.

Now, if domestic registrations are this prone to errors, in your opinion, how reliable is the list of foreign facility registrations?

Ms. NUDELMAN. The numbers that you cite are right on, and it would make—I think it is even more challenging for foreign facilities to have accurate information in the registry.

Mr. DINGELL. Now, what can be done to help FDA improve the accuracy of its registration lists? Obviously, more people; obviously,

more money; obviously, more inspections; obviously, a better computer system.

Do they need, in addition to that, additional authority under law to do the things that need to be done, to induce better cooperation from the people who are supposed to register? What has to be done, in your expert opinion?

Ms. NUDELMAN. I think there is a number of ways FDA can improve the accuracy and the completeness of the information in the registry. We make a recommendation to FDA to consider seeking the authority to have facilities register on a more routine basis. And that would allow the facilities to provide updated information about the foods they handle and about contact information.

Mr. DINGELL. Thank you.

Now, Mr. Taylor, do you have a comment you would like to make?

Mr. TAYLOR. Well, I think that suggestion that Ms. Nudelman made is an excellent one. I think the requirement to have a unique identifier is important. And I think the requirement for the importer, as part of good importer practices, to be able to vouch for the accuracy of the information, identifying the foreign sources of supply, the foreign facilities from which they are sourcing products for import—all of those, I think, would really improve the reliability of the registration list. And those are all addressed in the Food Safety Enhancement Act.

Mr. DINGELL. Now, Ms. Shames, you have talked about the ability to inspect. And, in your very excellent study, you talked about the need for FDA to be able to do a better job of getting the cooperation of Homeland Security and other government agencies.

How could that best be done? Could that best be done by having a memorandum of agreement between the agencies, a memorandum of agreement required by congressional action, or by some other mechanism whereby we could see to it that these two very important agencies, or several very important agencies, talk to each other so that they are able to use the advantages that comes with having several different agencies enforcing different laws but able to work together to address the problems that concern us?

Now, what is your comment, please?

Ms. SHAMES. It will be a multifaceted solution to a very complicated problem, and I wish I could tell you that there will be a single step that could correct that. We found that at the working level that the relationships between FDA and CBP were oftentimes very cordial, that they were able to work around, for example, not getting the time of arrival information.

Mr. DINGELL. Of course, that is a structural failure, is it not?

Ms. SHAMES. Well, yes, in this case it was.

Mr. DINGELL. And whose fault is that, the other agency or is that the importer or the food broker or who?

Ms. SHAMES. Well, there are many players that are involved in the oversight of food safety. FDA is one, and, as you noted, CBP really is the first face for an importer. So one of the challenges that we identified is CBP's own computer system, that that system—

Mr. DINGELL. And that's probably hopelessly out of date, as is the Social Security computer system.

Ms. SHAMES. Well, there are hardware changes that would have to be made, for example, for getting a unique identifier. This is something that FDA feels it needs. We have certainly identified that it's something that is very important, but CBP told us that it would be difficult for its current system to do it, and they really could not offer any sort of timeline of when that might be done.

So it's structural in terms of the many agencies that are involved, but it also gets to the resources in terms of, you know, the computer systems that it has in place as well as the people.

Mr. DINGELL. Thank you. Mr. Chairman, again, thank you for your courtesy to me, and I want to remind everybody that you and this subcommittee have had tremendous leadership in this matter. I want to remind everybody that this committee, working unanimously, together in a bipartisan fashion, has set out legislation that would address the problems we now discuss today, which reside comfortably in the United States Senate.

Thank you, Mr. Chairman.

Mr. STUPAK. Well, hopefully the Senate will move that legislation, get it to conference, and we can go from there.

Let me ask, Ms. Shames, about the unique identifier. How can one firm have 75 different identifiers?

Ms. SHAMES. It can happen very inadvertently, when a company registers for an import shipment, it may identify itself one time as White, Incorporated. The second time the company might identify itself as White Company. So it is something that is done most of the time, very innocently, but it means that there needs to be some sort of scrubbing of the list to make sure that each company has a single—

Mr. STUPAK. So the company enters its information on a computer Web site so it is really the company that enters it, which would then give it a number—

Ms. SHAMES. That's right.

Mr. STUPAK [continuing]. Which could be unique on something as simple as an address, a different address.

Ms. SHAMES. Yes.

Mr. STUPAK. Does Customs and Border Patrol use unique identifiers?

Ms. SHAMES. They do not, no. They also—

Mr. STUPAK. Shouldn't they actually have access to it at the same time? Shouldn't that company give it to Customs and Border?

Ms. SHAMES. Ideally FDA and CBP and would have the same unique identifier.

Mr. STUPAK. Ideally, but reality is they don't, right?

Ms. SHAMES. Right.

Mr. STUPAK. If we would limit the number of ports that food could be imported into this country, would that help?

Ms. SHAMES. Well, that is an approach that USDA takes.

Mr. STUPAK. Right, on meat products.

Ms. SHAMES. Well, that only USDA regulated imports come from food systems that have or are equivalent to ours, only through designated ports. USDA also goes and audits those countries to make sure that their systems are comparable or equivalent.

Mr. STUPAK. Well, is that something we should look at? I was going back to your chart number one that you had in here, you

know, you said 80 percent of our seafood comes from foreign sources, I think she said 60 percent of our fruits and vegetables. And they can come into basically any airport or any trucking location on our border, correct?

Ms. SHAMES. That's true, yes. Stakeholders that we have spoken to said that it would be difficult for FDA to really replicate the same system that USDA has, because—

Mr. STUPAK. I am not saying replicate it, but shouldn't you limit the ports of entry? I mean, how can you control anything if every airport and every truck crossing is basically a port of entry for food or seafood?

Ms. SHAMES. Well, it's an approach that the European Union has taken to limit the ports for its risk-based foods, so it is—there are precedents for it.

Mr. STUPAK. Any comments on that, Mr. Taylor, on either unique identifiers or limit the number of ports?

Mr. TAYLOR. Yes. Again, from a consistent—an ease of implementation by the regulatory agency, that's certainly advantages to that. I think the challenge we face that is different from the USDA is that, you know, we are dealing with a much larger array of commodities coming from a much larger volume of countries, there's a huge volume of trade.

And so I think there would be, you know, big practical questions you would have to work through. I don't think anyone wants to disrupt the trade in food, but we need to be sure it's safe. And how do you do that? It's a really important question.

Mr. STUPAK. Let me ask you this then, Mr. Taylor, you mentioned the shipper's bond. What is the usual amount of a bond? Does it depend on the product and the value?

Mr. TAYLOR. Typically three times the value of the shipment.

Mr. STUPAK. OK. You said many times the shipper will just forego the bond.

Mr. TAYLOR. Again, our understanding is that some shippers, you know, who have a large volume of business are willing to just take that chance of letting a product go out into commerce, even though it's still under bond, because, you know, in the whole course of their business they don't get caught very often or they aren't—there's not a problem that requires that that product be brought back. And so, again, it's the cost of doing business for some of these firms.

Mr. STUPAK. Well, should we make it higher?

Mr. TAYLOR. I think you could try a higher bond. I mean, I think the civil penalty approach is one part of it. I think the importer accountability and the fact that an importer could lose its registration under the Food Safety Enhancement Act would be perhaps even stronger tools, you know, to make them have really something really at stake for playing by the rules. That's what we need to do.

Mr. STUPAK. You know, Mr. Dingell pointed out, and I think we have all pointed out that, you know, it's expensive to keep our food supply safe and the agency needs inspectors, and I think GAO report says, what, \$16,000 per inspection at a food facility. And the IG said that, and I am quoting now, The decline in inspection is largely due to the significant decline in staffing level that resulted from cuts.

And in the legislation that we have pending in the Senate, the Food Safety Enhancement Act, we have an annual registration fee of \$500. These fees would be devoted towards funding a variety of food safety activities. Any idea and what percentage would go towards inspectors?

Mr. TAYLOR. Well, we would envision the fee revenue being used to a significant degree to meet the inspection mandates, or to at least contribute to meeting the inspection mandates in the legislation. But we also have to invest those resources in the tools for the inspectors and the scientific basis for what they are doing, so it would be a mix of activities. And you could also contribute to the import oversight.

So we would distribute it across a mix of activities to meet the objectives of the statute.

Mr. STUPAK. Well, under the Obama administration, did you not receive a substantial increase in money for food safety in the last year?

Mr. TAYLOR. The 2010 budget is, yes, is an increase over 2009, and there's an increase requested in 2011.

Mr. STUPAK. Well, have you hired more inspectors?

Mr. TAYLOR. Yes, sir, the last 2 or 3 years of funding has enabled our field force to add 6- or 700 inspectors, who are completing their training, and we are going to be able to increase our inspections because of that in the coming years. So there has been that step up, you know, through the increases we have gotten. It's not sufficient to meet the inspection mandate in the legislation, but it's a step in the right direction, which we appreciate.

Mr. STUPAK. OK. Mr. Burgess, any questions?

Mr. BURGESS. Yes. Just following up on that last line from Mr. Stupak about the budget, did you, did the FDA receive any money from the stimulus bill or the big health care bill that we just passed?

Mr. TAYLOR. No—there was some money that went into HHS for management matters related to FDA like comparative effectiveness of pharmaceuticals, but there was not money that directly affects the food program.

Mr. BURGESS. Did the Obama administration seek funding for the FDA in either one of these laws?

Mr. TAYLOR. Well, again, the stimulus money was about immediate projects that could stimulate economic activity in the near term and so that we—

Mr. BURGESS. Mr. Taylor, we gave \$10 billion to NIH. Are you any less deserving than they are?

Mr. TAYLOR. We would never say—

Mr. BURGESS. \$10 billion to NIH. Now I love the guys at NIH, but you are important too.

Mr. TAYLOR. Yes, sir, we agree with you.

Mr. BURGESS. Well, do you know why the administration didn't ask for additional funding for the FDA in either of these laws?

Mr. TAYLOR. I would have to get back to you on that. I don't personally—I wasn't involved in that.

Mr. BURGESS. Well, and it's all well and good, just like the Obama budget, and what great things are going to happen as a result of it, but we are not going to pass a budget on the floor of this

House I don't think, unless Mr. Stupak knows something that I don't know—

Mr. STUPAK. It wouldn't be first time getting me wrong on legislation.

Mr. BURGESS. And certainly, we are not going to do any appropriations bills before election day, so your level of funding till some omnibus in the lame duck session, so are you oK with that level of funding at this point?

Mr. TAYLOR. Well, again, we are going to need additional resources to carry out the expectations of the Food Safety Enhancement Act. Again, that's why the fee provision and that—the registration fee provision in that law, that bill is very important to us. We do need a stable, predictable and adequate level of resources to meet the mandates in the legislation.

Mr. BURGESS. Well, and I couldn't agree with you more and that a stable, predictable source of funds is not just true for you but true other agencies as well, but so far we seem to be doing things in fits and starts. And you, in fact, got left out of the fits and starts, unfortunately.

Mr. Chairman, you have been very indulgent. It has been a long day. I am going to yield back the balance of my time.

Mr. STUPAK. Thanks, Mr. Burgess. And as Mr. Dingell has pointed out, you know, the Food Safety Act went through this committee 51–0, and we appreciate our colleagues on the Republican side of the aisle to help us provide a stable funding source for that FDA through that \$500 per facility registration fee. That will provide the stable funding so we do have the resources to get to it.

It's not just resources it's, information sharing. And hopefully we can do that whether it's Customs and Border Patrol or we get the PREDICT program worked out a little more so the high risk foods we can identify.

Well, thank you and thank you to all of our witnesses. Sorry about the delay there on the floor for a while. We appreciate you staying with us and being here today.

That concludes all questioning. I want to thank all of our witnesses for coming today and thank you for your testimony. The rules of the committee provide that members have 10 days to submit additional questions for the record. That concludes our hearing. This meeting of the subcommittee is adjourned.

[Whereupon, at 4:58 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Opening Statement of the Honorable Joe Barton
Subcommittee on Oversight and Investigations**

**Hearing on
“The Role and Performance of FDA in Ensuring Food Safety”
May 6th, 2010**

I thank the Chairman and Ranking Member Mike Burgess for convening this hearing today.

We understand the role the agency plays in protecting the Nation’s food supply, and after more than a decade of bipartisan oversight and investigation, we also understand the FDA’s history of problems.

Today, our subcommittee will hear testimony about many of the inefficiencies found in FDA’s food regulators and inspection protocols. But I would like to highlight my concerns about GAO’s recent findings in a report written for me and the former ranking member, Mr. Walden.

Our request to GAO stemmed from the Committee’s work two years ago looking into FDA’s ability to protect the public from

unsafe food and drugs. We were concerned that FDA's attempts to measure performance and progress had become an over-bearing and useless paper exercise. I regret to inform the subcommittee that we were right.

Specifically, GAO found that the agency's performance measures are inadequate. Rather than focus on outcomes, FDA does little to assess how money spent actually improves safety and public health.

Secondly, FDA cannot show how the employees they hire will be put to effective use in the critical area of IT, which is at the root of FDA's persistent past failures.

Lastly, FDA does not track how employees use their time, so we cannot track whether the agency is actually putting the proper resources toward achieving FDA's public health and safety mission.

The taxpayer deserves a transparent and accountable system =. Americans deserve to know whether their tax dollars are spent effectively by the FDA.

At the same time as I voice my concerns about the FDA, I believe the food safety legislation that passed the House in July of last year provides the agency with many tools to ensure the safety of our food supply. I worked with the other Members of the Committee to create a prevention-based approach to fixing this food safety problem.

One way the legislation does that is by requiring companies to create and properly execute food-safety plans. Experts continue to agree that if companies involved in recent outbreaks had food-safety plans, the crises would not have happened.

Mr. Chairman, I want to thank you for this hearing and your willingness to work with the Republicans on this issue. There is still work to be done, but I am hopeful that we are on a path to improved implementation. I look forward to hearing testimony and questioning from the Members and witnesses here today.

I yield back the balance of my time.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 18 2010

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the May 6, 2010, hearing of the Subcommittee on Oversight and Investigations entitled "The Role and Performance of FDA in Ensuring Food Safety." This letter provides responses to questions for the record, which we received on May 21, 2010.

Please find FDA's responses in the enclosed document. We have restated each question in bold type, followed by our responses.

Thank you again for the opportunity to discuss the Agency's food safety activities. Please let us know if you have further questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Jeanne Ireland".

Jeanne Ireland
Assistant Commissioner
for Legislation

Enclosure

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The Honorable Edward J. Markey

1. On January 15, 2010, the FDA announced that it has public health concerns about BPA¹, and noted that current BPA food contact uses were approved under food additive regulations issued more than 40 years ago. In the announcement, FDA requested that Congress provide it with more flexible and efficient authority to regulate BPA under the more modernized and robust food contact notification system.

Triclosan is another chemical that is commonly incorporated into kitchen-ware, such as knives and cutting boards that come into contact with food. FDA recently announced concerns regarding the potential health effects of triclosan, particularly given research identifying triclosan as an endocrine disruptor.² In fact, Europe recently banned the chemical from being used in things like cutting boards and knives.³

- a. Would it be helpful if Congress gave FDA more efficient and flexible regulatory authority for all food contact substances, and not just BPA, so that Congress can avoid having to separately legislate on triclosan or any other substance that FDA may conclude poses a health risk in the future?

There are no FDA-authorized uses of triclosan in food contact material. The uses of this chemical for its antimicrobial effect on the surface of cutting boards is regulated by the Environmental Protection Agency (EPA). While the Administration has not taken a position on modifying its regulatory authority for all food contact substances, as noted in the January announcement, a more modern framework would give FDA greater flexibility to require individual manufacturers to address safety concerns through changes in manufacturing processes, use limitations, or additional testing as well as to remove a material from the market.

- b. Many chemicals that are used in food and beverage containers were approved decades ago. As a result, there may be new health risks or different uses of the chemical that were not known or anticipated at the time of approval. Do you think it could be helpful to conduct a review of the available science for those chemicals to see whether there are new health risks that should be addressed?

FDA believes that monitoring the safety of food ingredients and food packaging components on the market is an important part of our responsibility regarding the safety of the U.S. food supply. Postmarket monitoring within our current regulatory environment is labor- and resource-intensive. One of the challenges is prioritizing our postmarket monitoring using a risk-based approach. FDA is addressing this challenge by developing the Chemical Evaluation and Risk Estimation System (CERES). CERES is a

¹ <http://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM197778.pdf>

² <http://markey.house.gov/docs/fdatriclosanresponsereduced.pdf>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:075:0025:0026:EN:PDF>

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knowledge-based data management and analysis system for food additives and food contact substances that is intended to modernize how FDA conducts the pre- and postmarket review of chemicals added to food. The system will automate the postmarket review of these chemicals by using computational toxicology capabilities to leverage all the available safety data in our food substance knowledge base. That data is obtained from both internal reviews and outside sources for chemicals that have been authorized for use as well as chemicals that may be related structurally or biologically. The system will provide a suite of computational tools to assess the potential risks of a particular chemical of interest taking into account data on the chemical and data on chemicals with similar physical and biological properties. In addition, computational models will be able to provide FDA scientists with alerts if the data indicate the potential for any safety concerns for an authorized chemical. When fully operational, the CERES system will allow FDA to more efficiently and effectively monitor the safety of authorized food substances on a nearly continuous basis.

CERES has been selected by the Agency as one of the activities that will be monitored through FDA-TRACK. FDA-TRACK is a new Agency-wide program performance management system that monitors over 100 FDA program offices through key performance measures. FDA-TRACK information is available for public review on FDA's website at:

<http://www.fda.gov/AboutFDA/WhatWeDo/track/ucm206221.htm#OFASpm>

2. **Perchlorate is a chemical used to make rocket fuel that is especially dangerous when pregnant women are exposed to it, as it can cause severe mental deficits in children born to these mothers due to its effect on the thyroid gland. Currently there are only 2 states, Massachusetts and California, that regularly monitor for perchlorate and have also set a drinking water standard for the contaminant.**

The EPA is currently exploring whether to develop a nationwide drinking water standard for perchlorate. Some have suggested that EPA should stop any work on developing a health protective drinking water standard, because there are other sources of this same health risk, including sources found in green leafy vegetables.

- a. **Is it true that the FDA advises pregnant women to eat green leafy vegetables in order to prevent birth defects such as spina bifida?**

FDA's advice to consumers is to maintain a healthy diet consistent with the Dietary Guidelines for Americans, which emphasize eating a variety of foods across all food groups each day. The Guidelines contain recommendations that women of childbearing age who may become pregnant and those who are pregnant consume increased amounts of folic acid to reduce the risk of neural tube defects such as spina bifida, from both supplements and food forms of folate, which would include leafy greens. The Guidelines emphasize eating fruits, vegetables, grains, and fat-free or low-fat milk and milk products, and includes lean meats, poultry, fish, beans, eggs and nuts – with more choices

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in these food groups that are nutrient-dense and low in saturated fats, trans-fats, cholesterol, salt and added sugars.

- b. **Do you think it would be confusing to tell these same pregnant women not to eat the same green leafy vegetables because eating them could cause other problems?**

To help prevent consumer confusion, FDA uses risk communication strategies to inform consumers of safety issues in foods otherwise recommended for consumption under the Dietary Guidelines.

- c. **Other opponents of setting a perchlorate drinking water standard suggest that pregnant women could just take iodine supplements as a prophylactic to prevent against the adverse health effects caused by perchlorate exposure. This is similar to telling people they should take antibiotics as a prophylactic measure in case their food was contaminated by *E. coli*. Do you think that FDA should stop issuing guidance to food growers and producers to help them avoid *E. coli* contamination, and instead just tell people to take antibiotics?**

No, FDA does not believe it should stop issuing guidance to food growers and producers. FDA believes that guidance documents are an effective means of aiding industry in their attempt to prevent or decrease the presence of foodborne pathogens, including *E. coli*.

3. **In the past, much of the food safety focus has been on reducing contamination risk during food production and preparation; however, ensuring that food transportation also occurs in a manner that could prevent food-borne diseases is also an important aspect of overall food safety. It seems plausible that damaged wooden pallets can create splinters and protruding shards that can penetrate or otherwise damage food packaging, creating a pathway for contamination.**
- a. **Does FDA intend to investigate the risks that transportation pallets pose to food safety?**

Over the past few decades, there have been persistent concerns about the potential that food might become contaminated during transportation. While only a limited number of such events have been documented, these include multi-state outbreaks of illness in pets, farm animals, and humans.

The 2005 Sanitary Food Transportation Act (2005 SFTA), which requires the Agency to promulgate regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport, provides FDA with broad authority to regulate the safety of food during transportation.

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The significant outbreaks to date have largely been caused by contamination of food during transport by residues of potentially harmful foods such as raw liquid eggs, or non-foods such as industrial chemicals, hauled in prior loads in bulk conveyances, e.g., tankers, bulk rail cars, that remained on the food contact surfaces of those conveyances, e.g., due to inadequate cleaning. Though these incidents have been investigated and documented, generally speaking, data and information available to the Agency on food transportation practices and associated risks are limited.

As part of its implementation of the 2005 SFTA, to obtain more current data and information, FDA contracted with Eastern Research Group, Inc. (ERG) to undertake a study designed to characterize current baseline practices in the sectors involved in food transportation and to identify current areas where food is at risk for adulteration. In 2009, ERG issued a report with its findings. The ERG report describes the results of a comprehensive literature review pertaining to food handling practices in the food transportation industry. The ERG report also presents the findings from an expert opinion elicitation study, which ERG conducted to identify the main problems that pose microbiological, chemical, and/or physical safety hazards to food during transportation and storage, and to determine the preventive controls needed to address each of the problems identified. The ERG report largely discusses its findings from the perspective of food intended for consumption by humans (e.g., raw seafood, meat, poultry, produce, eggs, and refrigerated foods that are ready-to-eat), but also reports some findings related to animal feed.

ERG identified problem areas where food may be at risk for physical, chemical, or biological contamination during transport and storage, which included the "improper packing of transportation units or storage facilities, including incorrect use of packing materials and poor pallet quality." The report also identified preventive controls with the broadest applicability across all food sectors and modes of transport, including "Appropriate packaging/packing of food products and transportation units (e.g., good quality pallets, correct use of packing materials).

As discussed in the answer below to part (b) of this question, FDA recently issued an advance notice of proposed rulemaking (75 FR 22713-22723; April 30, 2010) to request data and information on the food (including animal feed) transportation industry and its practices and to request data and information on the contamination of transported foods and any associated outbreaks. We expect that the data and information we receive will augment the information in the ERG report and assist the Agency in characterizing the significance of potential problem areas where food may be at risk for physical, chemical, or biological contamination during transport and storage and in determining appropriate preventive controls that FDA should consider including in its proposed regulations. We will include in this process the consideration of any potential food contamination issues associated with the use of pallets, whether constructed of wood or another material.

- b. Does FDA plan to put in place enforceable regulations regarding the quality of pallets used?**

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Under the Federal Food, Drug, and Cosmetic Act and current implementing regulations in 21 CFR Part 110, "Current Good Manufacturing Practice for Manufacturing, Packing or Holding Human Food" (cGMP), pallets, when used as equipment or as food contact surfaces in conjunction with the preparing, packing, or holding of food, must not be used under conditions that may result in the adulteration of food, e.g., contamination with filth or any harmful substance. Food contact surfaces under the cGMP are those surfaces that directly contact food or those surfaces from which drainage onto food or food contact surfaces occurs during normal operations. Our understanding of the typical uses of pallets in food transport and storage indicates that most pallets are not used as food contact surfaces. Part 110.35 of the cGMP addresses cleaning and sanitizing requirements for food contact surfaces and Part 110.40 addresses design and construction requirements for equipment used in food operations. Pallets that serve as food contact surfaces must also not impart to food any indirect food additives, e.g., chemicals used in the manufacture of the pallets, or chemicals used to sanitize the pallets, which are not authorized under FDA (or EPA, in the case of sanitizing agents) regulations for the specific use.

In addition, FDA has published additional guidance and research documents listed below that address considerations for the use of pallets in specific types of food operations, such as the handling of fresh produce. These documents contain Agency recommendations to the industry for segregating and cleaning, staging, storing, inspecting, and stacking pallets. These documents include:

Production Practices as Risk Factors in Microbial Food Safety of Fresh and Fresh-Cut Produce:

<http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm091106.htm>

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174171.htm>

Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>

Guidance for Industry: Control of *Listeria Monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods; Draft Guidance:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm>

As we explained above, the 2005 SFTA requires FDA to promulgate regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. As part of its

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implementation of SFTA, FDA recently issued an advance notice of proposed rulemaking (75 FR 22713-22723; April 30, 2010) to request data and information on the food (including animal feed) transportation industry and its practices and to request data and information on the contamination of transported foods and any associated outbreaks. The regulations would address the risks to human or animal health associated with the transportation of food. In promulgating the regulations FDA will consider all aspects of transportation operations that may impact the safety of food in determining what specific provisions should be included therein, including any potential food safety issues associated with the quality of pallets.

