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AMERICAN LIVES STILL AT RISK: WHEN WILL FDA'S FOOD PROTECTION PLAN BE FULLY FUNDED AND IMPLEMENTED?

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

JUNE 12, 2008

Serial No. 110–126

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AMERICAN LIVES STILL AT RISK: WHEN WILL FDA'S FOOD PROTECTION PLAN BE FULLY FUNDED AND IMPLEMENTED?

THURSDAY, JUNE 12, 2008

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

The subcommittee met, pursuant to other business, at 10:04 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, DeGette, Melancon, Doyle, Schakowsky, Dingell (ex officio), Shimkus, Whitfield, Walden, Burgess, and Blackburn.

Staff present: John Sopko, Scott Schloegel, Chris Knauer, Keith Barstow, Calvin Webb, Kyle Chapman, Alan Slobodin, Peter Spencer, and Whitney Drew.

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 "American Lives At Risk: When Will FDA's Food Protection Plan Be Fully Funded and Implemented?" Each member will be recognized for a 5 minute opening statement. I will begin.

Today this subcommittee is holding another in a series of hearings examining the adequacy of the efforts of the Food and Drug Administration to protect Americans from unsafe food. In fact, today's hearing is our eighth hearing on this topic since January of last year. The purpose of today's hearing is to receive important testimony from the FDA regarding how the Agency plans to address its many weaknesses concerning its ability to protect our food supply.

To date, our investigation and hearings have uncovered a multitude of problems regarding FDA's food safety efforts, including poor policy choices, questionable management decisions, and lack of resources. Collectively, FDA's failed regulation of domestic food producers, its ill-conceived plan to close laboratories and reorganize staff, and its inability to ensure the safety of imported foods have suggested the Agency's food safety system is broken.

Outside experts have also found that the FDA's food safety system is in trouble. In fact, in January 2007, GAO added the federal oversight of food safety to its High-Risk Series and called for a gov-

ernment-wide reexamination of this country's food safety system. GAO found numerous concerns with the present food safety system including inconsistent oversight, ineffective coordination, and incomplete program planning. Last year FDA's own Science Board issued a scathing assessment of FDA's food protection abilities, concluding the Agency "does not have the capacity to ensure the safety of food for the Nation." In April of this year, Trust for America's Health, a major public health watchdog organization, issued yet another report which also found a number of deficiencies in the ability of the FDA to safeguard the Nation's food supply.

Through all of these evaluations, one common theme has emerged: FDA's resources are so stretched that its ability to protect Americans from unsafe food is seriously jeopardized. Perhaps the Science Board put it best in its report when it concluded, and I quote, "In contrast to previous reviews that warned crisis would arise if funding issues were not addressed, recent events and our findings indicate that some of these crises are now realities and American lives are at risk." Indeed, the events of the last 18 months with recall after recall demonstrate these concerns have now become a reality.

In response to the multitude of foodborne contamination outbreaks and concerns about its ability to protect Americans from unsafe food, in November of last year FDA released a document entitled "Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply." The Food Protection Plan lays out a blueprint for addressing food safety and food defense for both domestic and imported foods. The plan attempts to prevent contamination by pursuing safety measures that will address risk through the life cycle of food products, but more importantly, to identify potential food hazards and counter them before they can do harm.

The Food Protection Plan is very appealing on paper and appears to be a positive first step toward creating a stronger food safety system. Nonetheless, this subcommittee and many experts will testify today that they are concerned that the key specifics and the resources required to implement this plan remain elusive. As reported by GAO at our January 29th hearing, while acknowledging it will need additional funding, "The FDA has not provided specific information on the resources it anticipates the Agency will need to implement this plan." Over 4 months later, this committee, GAO, and others are still attempting to obtain basic data on what resources are needed and how they will be used to implement the plan.

As of Monday, it appeared the President's budget provided only minimal support for making this plan a reality. The President's fiscal year 2009 budget originally asked for a mere $51 million in new budgetary authority for all programs within the FDA. Approximately $42 million of this would go towards food safety. Because of cost-of-living salary adjustments, only about $30 million would be available for implementing the Food Protection Plan.

This is in stark contrast to the Science Board's recommendations. In a letter to members of this committee, it was recommended that an additional $375 million be provided to FDA across all programs in fiscal year 2009 including $128 million for food safety and $75 million for needed IT enhancements. With the President's original

budget offering only $30 million additional for food safety in fiscal year 2009, one had to ponder how serious the Administration was in implementing the Food Protection Plan as experts suggested the Agency would need far, far more.

Fortunately, just days before this hearing, the Administration apparently grasped the obvious: FDA was strapped for resources and $30 million was not enough to credibly advance the Food Protection Plan.

On Monday evening, HHS Secretary and the FDA Commissioner scheduled a conference call to announce the Administration would amend FDA's fiscal year 2009 budget request to Congress and asked for an additional $275 million in new funding. Approximately $125 million of this would go to food safety efforts. I strongly applaud this request but we need to know far more detail about how this money will be spent.

Despite the Administration's revised budget request, a major concern of the Subcommittee and others is the Agency lacks a meaningful strategic plan detailing what the Food Protection Plan will cost to implement, when key milestones will be achieved and what are they expected to accomplish.

Initially, a smattering of spreadsheets and other documents were provided to the Subcommittee by FDA that attempted to detail what parts of the plan would be implemented this year. These plans fell short in that they did not show what the overall plan cost to execute nor did they prioritize which features were most critical in fixing existing food safety shortcomings. Moreover, the vague plans that were provided to the Subcommittee were based on earlier budget requests, not the new request made this week.

To this point, FDA's strategic planning for implementing the Food Protection Plan appears to be almost entirely budget driven. Rather than articulating what really truly needs to be fixed, why it needs to be fixed and how fixing it would positively affect the current food safety system, FDA instead has tailored its implementation plan to match the meager resources offered in the President's original budget proposal of just $30 million for food safety.

Because both the implementation goals and the funding for the Food Protection Plan remain a moving target, I will today seek from Dr. Acheson information on whether the Administration intends to submit a comprehensive strategic plan based not on yesterday's budget request but one based on the expected costs of a plan's full implementation. In short, if the FDA is going to be successful in getting this effort funded, it must be prepared to detail the plan's expected costs, strategies, milestones, and results on food safety. So far the plan proposes a number of lofty ideals but important specifics remain undefined.

Today I look forward to hearing what progress has been made toward implementing the Administration's Food Protection Plan. Additionally, I want to understand what aspects of this plan are most critical to achieve, what they would accomplish, and what they are expected to cost beyond the ever-changing budget requests that come from the Administration. As the Agency stated in its Food Protection Plan, "FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the Nation's food supply." I am hoping today that the FDA will finally

be willing to enter into this partnership with us and provide a credible and honest answer as to what is needed to realistically safeguard the Nation's food supply.

Lastly, I would be remiss if I did not mention the current salmonella St. Paul outbreak that has led to 167 illnesses in 17 States. This outbreak is particularly frustrating, given the fact that today marks the 1-year anniversary of the FDA's Tomato Safety Initiative, which was supposed to lead to better safety standards and improve notification and tracking of tomato outbreaks. It appears that despite 1 full year having passed, we are no safer today than we were a year ago. At a minimum, the FDA and USDA should require immediate implementation of country-of-origin labeling for all fruits and vegetables sold in the United States. Country-of-origin labeling has been passed by this Congress several years ago. Country-of-origin labeling will provide consumers with more information about where their food is coming from and would also help Federal and State officials more quickly narrow down source locations of contaminated fruits and vegetables.

My time is up.

I next turn to the gentleman from Illinois, Mr. Shimkus, for his opening statement, please.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Chairman Stupak.

As we hold this hearing, grocers and restaurants nationwide have been pulling tomatoes from the shelves and menus until the cause of a recent salmonella outbreak in some States can be identified. I tried to get a BLT sandwich in the cloakroom yesterday and no tomato. I had a BL sandwich. There is no evidence that the outbreak is associated with all this produce but in an abundance of caution, the food industry has reacted.

There must be a more efficient way to trace problems and assure safety. There must be a way to harness science and reduce risk from pathogens we know about and perhaps those yet to emerge. There must be a way to effectively deploy and encourage cutting-edge technologies such as irradiation and even gene splicing to achieve greater safety.

As we focus on FDA's reform efforts this morning, it will be helpful to keep in mind the role of science and innovation to reduce risk and disease threats. It will be useful to explain what opportunities a renewed focus on science at the Agency will hold for encouraging innovation that truly prevents disease outbreaks.

Today we will examine the Food and Drug Administration's Food Protection Plan, which promises to improve the Agency's ability to assure the safety of the food supply both domestic and imported. With 7 months passed since the plan's unveiling in November, I look forward to a progress report from the Agency and outside observers to examine whether this plan can achieve what it promised.

During previous food safety hearings by this subcommittee, we have all remarked on the need for the Agency to focus on developing a truly risk-based food safety system that is oriented towards the challenges of a global marketplace. We have established in past hearings that we can no longer rely upon border operations as the

primary line of defense to ensure imported food safety. We have established that domestic or foreign, there must be a systems approach to food safety which can more effectively prevent outbreaks than the current system and trace problems to the source when they are found. We have established the central role of modern, robust IT systems and the scientific know-how needed to keep the Agency on top of emerging health threats. We have also established that simply giving more money alone to FDA will not produce better public health protection. There need to be structural reforms and performance-oriented management to ensure resources are put to cost-effective use.

We have called for a new regulatory model at FDA that no longer relies on outdated domestic-oriented posture towards the food supply. We have called for quicker deployment of smart import tracking systems at the border such as the so-called Predict system and the necessary restructuring for the more robust and effective foreign inspection program than the current model.

The Food Protection Plan along with other internal efforts reflects a positive effort by the Administration to move in this direction. Another positive is Health and Human Services Secretary Leavitt's recent supplemental budget request for an additional $275 million for fiscal year 2009. This boosts the Administration's proposed budget to some $400 million over the current FDA budget with a sizable portion of this for food safety and cross-cutting technology improvements. How much this proposed funding will accelerate FDA reform is open to question, and Mr. Chairman, I would like to submit for the record a letter that the Minority sent to the appropriators in support of the additional request on the supplemental.

Mr. STUPAK. Without objection.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. The proof will be in the pudding. There are many bureaucratic hurdles and imperatives that can impede legitimate efforts to modernize a federal agency. It is critical today that we discuss details associated with implementing the risk-based Food Protection Plan and related technology improvements. Nobody says this is an easy or fast project but it is important that we see the measures and indicators of progress so we can be assured the promised improvements are implemented effectively. It is also important to understand what Congress should do legislatively, and soon, so the Agency has the necessary tools for doing its job.

Fortunately, we have witnesses, several repeat witnesses today, who can assist us. As we move through the hearing today, I look forward to their insights into performing and planning as well as into what innovative and new technologies may hold for improving safety. Will a repostured FDA help foster the genetic technologies needed to inhibit foodborne pathogens? Is this something we should encourage to develop in the Agency? And Mr. Chairman, representing an ag district, I have seen what GMOs have done to help lower pesticide use. I have seen how it has helped to lower fertilizer use, and it may be a way in which we can move in a direction with the FDA.

I just want to end by putting the FDA on notice of a letter that the Minority sent on May 14 requesting a June 6th deadline on

questions in response to this research that we have done on the Office of Criminal Investigation, and I am giving them a heads-up on that.

Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. Did you want to enter the May 14th letter in from the Minority to Commissioner von Eschenbach?

Mr. SHIMKUS. Yes, if that is all right.

Mr. STUPAK. Did you get a response from the Commissioner? Do you want to enter——

Mr. SHIMKUS. We do not have a response. That is why we are going to enter it and ask them about it.

Mr. STUPAK. Without objection, a May 14th letter from the Minority to the Commissioner will be entered and made part of the record.

Mr. SHIMKUS. Thank you, Mr. Chairman.

[The information appears at the conclusion of the hearing.]

Mr. STUPAK. Thank you.

Ms. DeGette for an opening statement, please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman. I surely appreciate your continuing efforts to investigate the obviously broken food safety system in this country.

Little did we know when we scheduled this hearing a couple of weeks ago that we would now be in the middle of another national outbreak of foodborne illness. The salmonella outbreak in raw tomatoes has now expanded, as we know, to at least 17 States with 167 people sick and dozens hospitalized. Businesses nationwide have pulled tomatoes from their shelves, leaving tons of food to rot and an entire industry of farmers, employees and small businesses in trouble, but the FDA, hobbled by dwindling resources, conflicting missions, cuts in staffing and low morale has not been able to identify the source of this contamination. Sadly, we have been here before.

This salmonella outbreak is just the latest in a steady stream of incidents over the past year. I was just remarking to staff, the longer you sit on this committee, the more depressed you get because the issues never get resolved and crop up again and again. We were glad to hear about the Food Protection Plan last November but there is still much desirable language in the document that needs to be fleshed out in its details. So I am hoping that the hearing will help us specify the specifics about what the FDA will do, how much it will cost and, hopefully, how it will help solve outbreaks like this most recent tomato outbreak.

I would also like to know if the Agency has learned anything from the previous outbreaks that it is putting to use in the current tomato incident. To be frank, it doesn't seem to me like it is because we still can't trace the source of the salmonella contamination in the tomatoes. I am encouraged that the FDA submitted to Congress this week a supplemental budget for the Agency. I know many members of the Committee were dumbfounded when the Administration originally denied a need for additional resources but

I am glad the FDA is seeking more. The question is, will this be sufficient to carry out its mission? And I hate to sound like a broken record in this subcommittee, but we need to create a comprehensive food traceability system so we don't experience delays like we are seeing right now in the tomato outbreak.

The events of the last few days have once again shown that the FDA is incapable of quickly identifying the source of contamination when it occurs. What exists right now in all of these industries is a complicated system of going through records of individual companies to locate suppliers, the suppliers' suppliers, wholesalers, distribution centers, processing facilities, gathering warehouses, and farms. As we have learned this week, this process began in April with the tomato outbreak. Given the advanced technology today, this information should be easily accessible in an instant.

In fact, traceability is already being done by individual companies and I think we should build on their successes to form a comprehensive national system. For example, we all know that UPS and FedEx can instantaneously locate a package anywhere in the world. In the food industry, Dole Foods and many beer distributors can trace their products throughout the supply chain. Many large and small businesses have developed high-tech tracing systems from bar coding, GPS, laser technology, and one of my companies in Colorado has even pioneered a process to laser numerical codes onto individual eggs. You can even put codes on produce like tomatoes, allowing consumers to trace the farm-to-fork distribution from their home computer. INM consulting is advising its clients that food traceability is a sound business investment, given the importance of brand preservation and risk management.

Exciting things are happening in the field literally but sadly, the Federal Government has not gotten on board. Instead, once again, we have a food salmonella outbreak, this time with tomatoes, people getting sick around the country, but the FDA is still in its third month of trying to trace the source of the contamination. And what this does, it ripples around the industry. As I have said many a time, not only is traceability and mandatory recall a good thing to do for the consumer, it is also good for business because it avoids these massive recalls that really hurt production. And so obviously I think that we should pass my bill, H.R. 3485, the TRACE Act, but I also think, Mr. Chairman, that we should consider putting it in the draft that we are looking at in the other committee on food safety.

I look forward to hearing from the witnesses this morning. Given the recent outbreak, I not only want to hear about general progress but also the progress about how we can improve food traceability around the country. Thank you, Mr. Chairman.

Mr. STUPAK. I thank the gentlewoman.

Mr. Walden for opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you very much, Mr. Chairman. I appreciate your due diligence in holding these hearings and holding the FDA accountable.

Obviously there are probably few things more important to parents than the safety of the food that their kids ingest, and it is almost like a conspiracy against parents. You know how hard it is to get your kids to eat spinach and tomatoes to begin with, and it seems like we are fighting over the very staples of the diet you are trying to get kids to eat over whether or not it is even safe. Kids don't need any more excuses on that front.

It is very disturbing that we are seeing more and more firms regulated by the FDA and fewer and fewer inspections occurring. It just seems backwards. At a time when our supplies, much like our fuel supply, is coming from other countries, it is imperative that we modernize and update the FDA to be able to deal with this new dynamic we face. There was a day in this country where we raised what we ate, and that day has sadly changed and gone. We still grow a lot of things. There is no doubt about it and that is important but I think if we are going to have security in the family and in the food supply, I personally believe we need country-of-origin labeling, and I think we need a new regulatory framework so that we can identify the source of an outbreak as quickly as possible. I have perhaps five of my fellow Oregonians who have fallen victim to this salmonella outbreak, three of whom are from Umatilla County, a rural part of my district, an agricultural part of my district, they believe have been diagnosed with this rare form of salmonella.

So, Mr. Chairman, it strikes me that this Congress needs to take seriously as we do the recommendations of the science panel and the findings of the GAO and give the resources necessary to the FDA to do their job. We control the purse. It is up to us to get it done.

With that, I will yield back the remainder of my time.

Mr. STUPAK. I thank the gentleman.

Mr. Dingell for an opening statement, please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, first, thank you for holding this hearing. It is important and it is the eighth in our series of hearings on food safety, and sadly, also upon the inadequacy of our food and drug laws and the inadequacy of the performance of the Food and Drug Administration, the Department of Health and Human Services, the inadequacy of their budget and the shoddy and shameful performance which they have so badly carried forward.

A common theme of each of these hearings has been a major food recall or outbreak of illness linked to food and the Food and Drug Administration's inadequate resources and incompetent management. We now can look back just with regard to food and we can see tomatoes, spinach, grapes, mushrooms, seafood, and dozens of other items which have gotten on to poison and sicken the American consumer.

Today's processes are no different. We face another food crisis. Since mid-April, there have been 145 cases of salmonella poisoning associated with fresh tomatoes. I am hearing some complaints from people who say, well, we don't want to pay the cost of this. I would

ask how many would rather pay a modest increase in cost to avoid bloody diarrhea or something like that associated with salmonella, and do we want to pay a little bit more to get a competent Food and Drug Administration that properly carries out its responsibility and has the capacity to protect the American consumers? And we must ask, what is the point of having the best food and drug laws in the world if they are not enforced and if we cannot reach abroad to address other countries which are shipping foods, drugs, cosmetics, and other things into this country which threaten the well-being of the American consuming public.

The outbreak that we are talking about has extended to 16 States, 23 hospitalizations. It has sickened people. It has devastated an industry. It has cost consumers, producers, and retailers millions of dollars. Tragically, similar food crises have occurred in the past, as I have mentioned. Food and Drug cannot even identify the source of contamination or to know where the tomatoes which are poisoning Americans have originated. These continued outbreaks are unacceptable. To have Food and Drug come up and say they don't know what to do about it or how much money they need or what resources they require is a shame and a disgrace, and this committee, in a bipartisan fashion, is not going to tolerate that kind of nonsense and we are going to come forward with legislation which is going to do the job of protecting the American people and we will begin addressing the problem plaguing the Nation's food safety system.

My colleagues and I have proposed in an April draft discussion legislation outlining comprehensive changes needed to improve the safety of domestic and imported food as well as drugs and medical devices. This proposal will give FDA the resources and the authority necessary to protect Americans, something which I believe that they want and something, Mr. Chairman, which your hearings are shining a spotlight upon so the people may understand the choices that are before them on this matter.

Today's hearing examines the Administration's proposed Food Protection Plan announced last November, which illustrates the challenges we face in protecting this Nation from foodborne illnesses. On paper it looks good. It calls for preventing contamination by pursuing safety measures that address risks through the life cycles of food protects and countering food hazards before they do harm, admirable goals that no one will oppose. Unfortunately, the plan lacks the details of what is needed to meet these goals, including the money that is needed to pay for them. Since this plan first surfaced, this committee and the Government Accountability Office at our direction have made repeated requests for details about this effort but to no avail. If the President's initial budget for the fiscal year 2009 allocation was any indication of how seriously the Administration takes this plan, I fear for the plan's success and I seriously question the bona fides of the makers of the plan. The President's original budget asked for a mere $51 million in new budgetary authority for the FDA programs while requesting only $30 million in a new budget authority for implementing the Food Protection Plan, an amount that everyone who has looked at it views as inadequate.

My concern that the Administration's plan may be smoke and mirrors was heightened by Tuesday night's hastily arranged conference call between Secretary Leavitt, Commissioner von Eschenbach, and select members of the press. It was only then, within just a few days of this hearing, that the Administration announced that they would seek an additional $275 million in new funding including $125 million specifically for food safety, a rather laughable process, I would observe, criticized by my good friend, Senator Specter, in a letter which is now available in the press, and in a rather excellent commentary in the Wall Street Journal, which says, "Senator Specter says FDA can't even ask for money properly." What a shame.

The Food Protection Plan may be a solid first step in how to protect our people and to fix a broken food safety system but it won't work worth a whoop if the Administration does not see to it that we have enough money and does not show greater signs about being serious about this plan. The Administration is going to have to work with us to provide the details and to assist us in drafting the legislation to fix the current system, including a realistic assessment of its resource requirements.

I do look forward to the testimony from today's expert witnesses about what is really needed to protect Americans from unsafe food and I commend you, Mr. Chairman, for this hearing. We are also going to hear from the FDA's food czar, who we hope will not provide us with more Potemkin villages but rather will be candid and forthcoming in giving us and the American people the truth about what is needed to fix a difficult system which is crowned by incompetence, indifference, inadequacy, and a gross shortfall in funding and leadership.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Dingell.

Ms. Blackburn for an opening statement, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. I thank you for the hearing and for updating the Subcommittee on the Administration's Food Protection Plan. I am sure the public is very much aware of the issue that is before us with salmonella and the tomatoes. We are hearing about it from so many members on this committee this morning. I think it is worth noting that U.S. growers produced $1.3 billion worth of tomatoes last year and that this current outbreak will devastate that industry. So yes, indeed, it is an issue that is of concern to us for the health of our citizens but it also is an issue of economics for our agricultural community and, fortunately, our good Tennessee-grown tomatoes are safe and we will be able to enjoy those.

We have held a lot of hearings on this, Mr. Chairman. I think this is our seventh or eighth hearing, and we know it is time for action. People are so weary of rhetoric and talk and saying we have a plan but nothing gets done. I was sitting here reading the Wall Street Journal and here we go, A4, there is another story about the FDA and your inability to take action. My goodness gracious, cer-

tainly this issue should rise to a level of importance to you, and you have had time. It was November 2007 when the FDA released its Food Protection Plan and how you were going to improve your food safety and surveillance system, and we are still waiting. The FDA needs to shift its focusing from reacting to food safety breaches following contamination and instead start looking at implementation and prevention policies. Your fiscal year budget for food safety was over $560 million. The agency would benefit from increased resources to meet the demands of globalization on the Nation's food and drug supply but we need to see some action from you.

I hope that you will show that this rises to a priority for you and I will say, Mr. Chairman, it continues to be troubling to me that we continue to hear about a lack of interagency communication, a lack of 21st century IT systems and a lack of best practices to streamline safety review efforts. We have asked for those best practices, and I am curious if they exist because they tend to not be presented to us. This is an issue of accountability. We know you have the ability to perform these tasks. We would seek from you recognition of the need for this to be a priority and recognition that accountability is required.

Mr. Chairman, I thank you for the time. I yield back the balance of my time and look forward to the hearing.

Mr. STUPAK. Thank you.

Mr. Doyle for an opening statement, please.

OPENING STATEMENT OF HON. MIKE DOYLE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. DOYLE. Thank you, Mr. Chairman. As you mentioned in your opening statement today, this marks our eighth hearing on food safety, and Mr. Chairman, I want to thank you for your tenacity and engagement into ensuring our Nation's food supply is as safe as possible.

I have to say that I am pleased the Administration is amending its FDA funding request in this year's budget. The extra $275 million will be great to help ensure the safety of our food, drugs, cosmetics, and medical devices but it is worth pointing out, as others have, that it falls $100 million short of the amount FDA's own advisory board determined is needed.

Mr. Chairman, as a member of the Subcommittee on Telecommunications and the Internet, I must say that I am dismayed at the many problems FDA is having updating its antiquated information technology infrastructure. IT is the backbone of an information-based workforce. It is the work you have to do first before you can get any other work done. When your computers are down, it is hard to get work done. When you are not giving employees the right technological tools, it is hard to encourage them to be entrepreneurial about their work. Those failures make doing the important day-to-day work critical to our Nation's safety extremely difficult. It is no wonder that the FDA performed more than double the number of foreign and domestic food establishment inspections in 1973 as they performed in 2006. It is no wonder that the folks

at GAO have outlined dozens of suggestions and recommendations to improve FDA that haven't been acted upon.

Mr. Chairman, I look forward to their testimony this morning as I do for all the witnesses, and hopefully with suggestions to improve our food supply. With that, Mr. Chairman, I won't take up too much more of the Subcommittee's time. I would rather listen to what the witnesses have to say and ask some questions, and I will yield back.

Mr. STUPAK. I thank the gentleman.

Mr. Burgess for an opening statement, please.

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

Mr. BURGESS. Thank you, Mr. Chairman, and I too will try to be brief because most of this stuff we have heard already. It is our eighth Subcommittee hearing.

The title of this hearing is interesting: "When Will the FDA's Food Protection Plan be Fully Funded and Implemented." It is kind of ironic. I may only be a third-term Member but from my recollection of civics, funding of federal agencies is partly our job in Congress. So we know what the problem is. We have had eight hearings. We had a lot of testimony. We have seen the consequences. Let us start addressing them. That is what the American people want and what they deserve, and the issue of protecting people and products is not always easy.

We live in a free society and the government is faced with certain challenges and tradeoffs when it comes to safeguarding the public and ensuring their freedom. One of the biggest is, how do we protect people without encroaching upon their freedom? It is a complex challenge but it doesn't lessen our obligation of keeping Americans safe. It is right there in the first sentence of the Constitution. It is time that this Congress start living up to that core responsibility.

I hope the committee today can take some of the first steps to protect our food supply and protect our citizens. We are pretty well past the point of more finger pointing. I think there is enough culpability on all sides to go around but this committee needs to get down to work in a truly bipartisan manner and fill in some of the details of this FDA Food Protection Plan. Based on the title of this hearing, I wonder if both sides of the dais see great merit in this food safety proposal. Let us move forward in two simple steps. First is to legislate, and two, put the pen in the appropriators' hands and let them write the check.

Yesterday, myself and several members on this side of the dais signed a letter supporting the inclusion of the $275 million for the Food and Drug Administration in the supplemental appropriations bill that we are reportedly, allegedly going to vote on some time this month. This plus the additional requested sums in the baseline budget should meet the needs of the FDA, and I would just point out that the dollar amount requested for food protection by the science panel was $128 million, and with the baseline budget and the supplemental money, this will be $125 million, pretty close to what they requested. So there is no excuse. We know what the

problem is. We know what the target funding is. Again, let us put the pen in the appropriators' hands and write the check.

It is impossible to regulate the food safety system down to zero percent foodborne illness. We all know that. It is also possible to change some of our technologies so we are not always having to be reactive but we can be a little bit more proactive, but for whatever reason, we have chosen to leave those technologies on the shelf and not use them. Maybe we need to rethink some of those processes. Are there ways? We understand that the salmonella organism in the tomato problem is not just on the surface of the tomato but maybe in the vasculature of the tomato so washing won't always solve the problem. Is there another method for eradicating the salmonella in the tomato before it reaches the consumer? We could irradiate. Some people have a problem with that. Well, we have to have the discussion and the debate and get past that problem.

This Committee should be about solutions. It should be 21st century results-oriented. The innovation is out there, whether it be irradiation, some of the activities that can be done with gene splicing. There are additional methods of prevention that we could be taking and that we just elected not to. It has been stated over and over again. This is the eighth oversight hearing. Really, it is time to stop talking. This is a bipartisan issue. We all agree that there needs to be a solution. Let us legislate, authorize and then write the check and get this problem solved.

I yield back.

Mr. STUPAK. I thank the gentleman. I take it by your opening statement you will cosponsor Mr. Dingell's FDA globalization safety bill——

Mr. BURGESS. Will the gentleman yield?

Mr. STUPAK. Sure.

Mr. BURGESS. I have some problems with the legislation that Mr. Dingell has outlined and I prepared a letter to the chairman on that and so we can work on those issues. I don't think I am prepared to cosponsor the legislation at this point. There are, as I see it, some problems within the legislation. One of the problems is, it is a bipartisan committee. I mean, both sides should sit down and work on this legislative product before it just gets given to us. It is a whole lot easier to work through this process at the staff level rather than trying to amend the product. You know, we get the legislation and take it or leave it. Well, I am going to try to help as best I can but the reality is, it would have been far better if Mr. Dingell, Mr. Barton and some of us on the Subcommittee had sat down and worked out those problems before the legislation was delivered, and I yield back.

Mr. STUPAK. Well, thank you. We look forward to your letter because we have been working with Mr. Barton and we are making progress on it but we always value your input into the process. Thank you.

Ms. Schakowsky for an opening statement.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I want to commend you for holding this hearing regarding the crucial legislation and for all your hard work on improving our Nation's food safety.

I have been proud to participate in the seven hearings on food safety the Subcommittee has held this Congress which have revealed a number of truly shocking revelations about the major gaps in our food safety system. Once again, it is clear that the FDA is unable to ensure that the food that we serve on our dinner tables each night won't make us sick.

Americans are more and more worried about the safety of the food they eat and rightly so. Last week's tomato salmonella scare sickened 167 people in 17 States, and every week another food recall is announced, it seems. Jars of Peter Pan peanut butter containing salmonella, cans of green beans containing botulism, spinach tainted with E. coli, poisoned pot pies, the largest meat recall in the history of our country, 143 million pounds of recalled beef of which 50 million pounds were sent to the school lunch program in February. Earlier this month salmonella was found in Puffed Rice and Puffed Wheat cereals produced by Malt-O-Meal. Tainted cantaloupes caused a scare in March. As a mother and a grandmother, I should not have to worry about whether I am serving my family contaminated food.

That there are 76 million foodborne illnesses in this country each year is simply unacceptable. It demonstrates that there are real gaps in our food safety system, a system which doesn't come close to reflecting the technological advancements in the wealthiest and most powerful nation on earth, and given its track record and lack of resources, I am concerned about FDA's ability to enact the Food Protection Plan. I am particularly concerned about FDA's lack of willingness to share their plans with Congress and the public. The FDA Modernization Act, which we are beginning to consider in the Energy and Commerce Committee, has strong language which gives the FDA greater authority and more resources to perform their mission. This is especially true of food manufactured overseas, by giving the FDA the tools it needs to conduct inspection of foreign facilities. This legislation takes bold steps to prevent problems before they occur on U.S. soil. And by finally giving the FDA mandatory recall authority, we are giving the Agency the teeth it has been missing to stop corporations and companies that do not stand up to their responsibilities to follow the law and keep the public safe.

So I am looking forward to working with the committee to strengthen that legislation. If the FDA had this authority now, perhaps hundreds of people would not have been exposed to salmonella and millions of tomatoes would still be on the store shelves. Consumers expect no less from their government.

Mr. Chairman, I thank you again for convening this hearing and I look forward to hearing from our witnesses and yield back the balance of my time.

Mr. STUPAK. Thank you.

That concludes the opening statements of all members. I want to thank all members for being here promptly. We did the business

meeting and now we will start this meeting. I realize there is another Subcommittee meeting at this same time, the Environment and Hazardous Materials Subcommittee, so members will be moving in and out, and we welcome their participation.

Since that concludes the opening statements by members of the Subcommittee, I now call our first panel of witnesses to come forward. On our first panel we have Dr. Gail Cassell, Vice President of Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases at Eli Lilly and Company. Dr. Cassell is also chair of the Subcommittee on Science and Technology of the FDA's Science Board. Dr. J. Glenn Morris, Jr., Director of the Emerging Pathogens Institute at the University of Florida. Dr. Morris is also an external advisor to the FDA's Science Board's Subcommittee on Science and Technology. Mr. Michael R. Taylor, Research Professor of Health Policy at the George Washington University School of Public Policy and Health Services. Dr. Jeffrey Levi, Executive Director of the Trust for America's Health, and Ms. Lisa Shames, Director of Food and Agricultural Issues at the Government Accountability Office.

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? With the nodding of heads, I indicate no one wishes to be represented by counsel. Therefore, I am going to ask the witnesses to please rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. Each of you is now under oath. We will now hear 5 minute opening statements from our witnesses. You may submit a longer statement for inclusion in the record.

Ms. Shames, we will start with you, please. We will go from my left to the right. We will go right across.

STATEMENT OF LISA SHAMES, DIRECTOR, FOOD AND AGRICULTURE ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. SHAMES. Chairman Stupak, Ranking Member Shimkus and members of the Subcommittee, I am pleased to be here today to discuss FDA's progress in implementing its Food Protection Plan. As you will recall, we testified last January before the subcommittee that FDA's plan proposes positive first steps. However, we expressed concerns that it would be difficult for Congress to assess the likelihood of the plan's success without a clear description of the resources and strategies needed to implement it.

I would like to make three points today. First, since January, FDA has added few additional details on the resources and strategies it needs to implement the plan. Second, FDA has implemented few of GAO's recommendations that could help it leverage resources and improve enforcement, and third, in terms of FDA's current resource level, its proposal to focus inspections based on risk has the potential to be an efficient and effective approach, especially since FDA's inspections have decreased while the number of food firms under its jurisdiction have increased.

First, regarding resources and strategies, we testified last January that FDA had not provided specific information on the resources and strategies needed to implement the Food Protection Plan. Since then, FDA has added few details. FDA acknowledges that additional resources are required to implement the Food Protection Plan, and is directing a portion of its 2008 and 2009 budget to that end. However, FDA's overall resource needs are unclear and those resource needs could be significant. For example, if FDA were to inspect the over 65,000 domestic food firms under its jurisdiction, it would cost approximately $524 million. This figure underscores the need for FDA to focus on a risk-based approach. Based on our review of draft internal documents, FDA appears to be refining its planning process. These internal documents provide some additional information. Nonetheless, we continue to have concerns about the lack of specificity. For example, we were told the Food Protection Plan would take an estimated 5 years. However, FDA has not provided us with the timelines for the plan's strategic actions and their associated action steps and deliverables. Without this type of information, we are not able to assess whether FDA's estimated time frame is feasible.

We also testified in January that FDA planned to keep the public informed of its progress in implementing the Food Protection Plan. To date, FDA has not done so. While we were provided a list of various accomplishments, they were compiled from numerous public sources. Having such information in a consolidated document that is readily accessible reassures Congress and the public that actions have been taken. Ultimately, at a minimum, the information we are seeking is along the lines of a results-oriented strategic plan that identifies long-term and interim goals and identifies necessary resources including funding, human capital and information technology to achieve them. Publicly reporting on progress made against those goals facilitates congressional oversight, fosters accountability and promotes transparency.

Second, regarding GAO recommendations, FDA has implemented few of our past food safety-related recommendations. Of the 34 recommendations we made since 2004, FDA has fully implemented seven. It should be noted that FDA has started to take some steps on most of the remaining recommendations. Among our recommendations was for FDA to make it a priority to establish equivalence agreements with other countries. We found such agreements would shift some of FDA's oversight burdens to foreign governments. We also recommended that FDA consider an accreditation program for private labs and a certification program for third-party inspectors. None were fully implemented. In light of the Federal Government's long-term fiscal challenges, agencies including FDA need to seek out opportunities to better leverage their resources. The Food Protection Plan's proposals could help address several of these recommendations. For example, it requests Congress to allow FDA to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards.

Lastly, regarding risk-based inspections, the Food Protection Plan identifies the need to focus safety based on risk. Conducting inspections along these lines has the potential to be an efficient

and effective approach for FDA to target scarce resources, which is particularly important as the number of food firms has increased, while inspections have decreased. For example, between 2001 and 2007, the number of domestic firms increased from about 51,000 to over 65,000 while the number of firms inspected declined, albeit slightly. More significantly, the number of foreign food firm inspections that FDA conducted has declined from 211 in 26 countries to 96 in 11 countries.

To conclude, FDA's Food Protection Plan can only be as effective as its implementation. Additional detail along with public reporting on the progress that has been made provides FDA a valuable opportunity to reassure Congress and the public that it is doing all it can to protect the Nation's food supply.

Mr. Chairman, this concludes my prepared statement and I would be pleased to respond to any questions that you or members of the Subcommittee may have.

[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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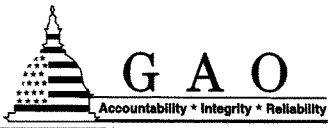
FEDERAL OVERSIGHT OF FOOD SAFETY

FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan

Statement of Lisa Shames, Director
Natural Resources and Environment



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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Food and Drug Administration's (FDA) progress in implementing the *Food Protection Plan*, which articulates FDA's plans to improve the oversight of food safety. FDA is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply—virtually all foods except for meat, poultry, and processed egg products—including $417 billion worth of domestic food and $49 billion in imported food annually. As you know, in January 2007, we designated the federal oversight of food safety as a high-risk area needing urgent attention and transformation.[1] A key reason for that designation is that FDA is one of 15 agencies that collectively administer at least 30 laws related to food safety. Around the time of this designation, consumers faced several outbreaks of foodborne illnesses, including *E. coli* from spinach and *Salmonella* from peanut butter. Subsequently, the U.S. has seen more outbreaks of foodborne illnesses, such as *Salmonella* from imported cantaloupes and raw tomatoes. Not surprisingly, public trust in FDA's ability to protect the food supply has fallen. A 2008 Harris poll showed that U.S. adults have little confidence—and less confidence than last year—in the safety of packaged or prepared foods that have been imported from countries like China, India, or South Africa. In addition, a recent public opinion poll conducted by the Trust for America's Health[2] found that 67 percent of Americans are worried about food safety, ranking it higher than concerns about, for example, pandemic flu or natural disasters.

Concerns about food safety oversight are not new. GAO and others have consistently reported on a lack of adequate oversight of food safety by FDA, and have provided many recommendations for better leveraging FDA's limited resources and suggestions for additional authorities that would allow FDA to better fulfill its responsibilities. In 1998, we reported that limitations in FDA's authority and its need to more effectively target limited resources could adversely affect its ability to ensure food safety.[3] A decade later, the story remains the same and has only taken on a greater sense of urgency due to changing demographics and consumption patterns that, according to FDA, have put more of the U.S. population at risk of contracting foodborne illnesses. Populations at high risk of foodborne illnesses—older adults, young children, pregnant women,

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

[2] Trust for America's Health is a non-profit, non-partisan organization dedicated to protecting the public's health.

[3] GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103 (Washington, D.C.: April 30, 1998)

and immune compromised individuals—now make up 20 to 25 percent of the U.S. population. In addition, U.S. consumers are increasingly eating raw or minimally processed foods, which are often associated with foodborne illnesses. For example, the consumption rate of leafy greens—the category of produce most likely to be associated with an outbreak—increased 180 percent between 1992 and 2005, according to the U.S. Department of Agriculture. Compounding the challenges, the number of FDA-regulated domestic food establishments has increased more than 10 percent in the last five years and the number of food import entry lines has tripled in the past ten years.[4]

To respond to the need for better oversight of food safety, FDA released its *Food Protection Plan* in November 2007, which articulates FDA's framework for overseeing the safety of food and outlines three core elements—prevention, intervention, and response—that are the focus of FDA's efforts to improve oversight.[5] At the same time, a twelve-agency working group presented to the President its *Action Plan for Import Safety*,[6] which contains, among other things, recommendations for improving the safety of food imports entering the United States. Both plans spell out numerous actions FDA plans to take to enhance food safety, including writing new food protection guidelines for industry and helping foreign countries improve their regulatory systems. The plans also request new legislative authorities, such as enhanced access to a food company's records during food safety emergencies.

Also, in November 2007, FDA's Science Board, an advisory board to the agency, released a report entitled, *FDA Science and Mission at Risk*.[7] This report concluded that FDA is not positioned to meet current or emerging regulatory needs, and stated that FDA does not have the capacity, such as staffing and technology, to ensure the safety of the nation's food supply. According to the Science Board report, FDA's resources have not kept pace with its increasing responsibilities, and this disparity has made it increasingly "impossible" for FDA to maintain its historic public health mission. In addition, the report finds that

[4]According to FDA, an entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

[5]Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C., 2007).

[6]Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C., 2007).

[7]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

food safety resources have increasingly been diverted away from routine surveillance and other tasks to managing crises as they arise and the nation's food supply is at risk. In February 2008, the Science Board estimated that, to implement its recommendations to protect the nation's food supply, FDA's base budget would need to increase by a total of $755 million by fiscal year 2013, phased in over time starting with $128 million in fiscal year 2009.

In response to these concerns, Congress has expressed considerable interest in enhancing FDA's oversight of food safety, and the House Energy and Commerce Committee has held hearings to consider a draft bill entitled The Food and Drug Administration Globalization Act of 2008 which, in part, would provide some of FDA's requested authorities.[8] This draft bill also contains provisions that are consistent with several past GAO recommendations to FDA and matters for congressional consideration regarding FDA's food safety programs. For example, the draft bill contains provisions that would allow FDA to leverage resources using outside organizations, such as third-party inspectors.

As part of its congressional oversight of FDA's challenges in meeting its responsibilities, we testified in January 2008 before this subcommittee and reported that FDA's *Food Protection Plan* proposes positive first steps for FDA.[9] For example, FDA requests authority to order food recalls and issue additional preventive controls for high-risk foods, both of which we previously recommended. However, we expressed concerns about FDA's capacity to implement the plan and noted that more specific information about its strategies and the resources FDA needs to implement the plan would facilitate congressional oversight. We recognized that without a clear description of resources and strategies, it would be difficult for Congress to assess the likelihood that the plan will achieve its intended results.

In this context, my testimony today focuses on FDA's progress in implementing the *Food Protection Plan*, FDA's proposal to focus inspections based on risk, and FDA's implementation of previously issued GAO recommendations intended to improve food safety oversight. In summary, we have found (1) FDA has added few details on the resources and strategies required to implement its *Food*

[8]Committee on Energy and Commerce, U.S. House of Representatives, Discussion Draft: The Food and Drug Administration Globalization Act of 2008 (Apr. 16, 2008), *available at* http://energycommerce.house.gov/FDAGlobalAct-08/index.shtml

[9]GAO, *Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical*, GAO-08-435T (Washington, D.C.: Jan. 29, 2008).

Protection Plan, (2) FDA's proposal to focus inspections based on risk can help target scarce resources, and (3) FDA has implemented few of our recommendations intended to help leverage resources and improve operations. This testimony is based on new and previously issued work.

To assess FDA's progress in implementing the *Food Protection Plan*, we reviewed FDA documents, such as FDA's operations plan and work plan, and FDA data related to the plan. In addition, we interviewed FDA officials regarding the progress made to date in implementing the *Food Protection Plan*. To review FDA's proposal to focus inspections based on risk, we analyzed FDA's data on past domestic and foreign food firm inspections. To determine actions that FDA has taken on our past recommendations, we obtained and analyzed information from FDA on the status of these recommendations. We conducted our work between May and June 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FDA Has Added Few Details on the Resources and Strategies Required to Implement Its *Food Protection Plan*

In light of the federal government's long-term fiscal challenges, it is critical that agencies can justify the needed resources and develop effective, efficient strategies to achieve their mission. We testified in January 2008 that, while FDA officials had acknowledged that implementing the *Food Protection Plan* would require additional resources, FDA had not provided specific information on the resources it anticipates the agency will need to implement this plan to improve its oversight of food safety. For example, the *Food Protection Plan* proposes to enhance FDA's information technology systems related to both domestic and imported foods which the Science Board report suggests could cost hundreds of millions of dollars. At that time, FDA officials stated they would provide specific information on how much additional funding would be necessary to implement the *Food Protection Plan* when the President's budget was publicly released in the coming weeks.

In its fiscal year 2008 budget, FDA received approximately $620 million for food protection, an increase of about $56 million over fiscal year 2007, and directed $48 million of that amount toward implementing the *Food Protection Plan*, according to FDA. FDA requested approximately $662 million for food safety for fiscal year 2009, an increase of about $42 million over fiscal year 2008. According to the Department of Health and Human Services' budget justification, FDA plans to direct the $42 million to strategic actions described in its *Food Protection Plan*. As shown in table 1, the plan outlines spending on all

three core elements of the *Food Protection Plan*—a total of about $21 million for prevention, about $34 million for intervention, and about $23 million for response for fiscal years 2008 and 2009. FDA also reported that, in fiscal year 2008, the agency intends to hire nearly 1,500 full time equivalents (FTE), including approximately 730 to fill vacant positions. Of these, 161 will be new FTEs funded by congressional increases dedicated to food safety activities. In addition, in fiscal year 2009, FDA plans to hire 94 new FTEs for food safety activities.

Table 1: Current and planned spending for *Food Protection Plan* Core Elements and Strategic Actions, Fiscal Years 2008 and 2009

Food Protection Plan core elements and strategic actions	Fiscal year 2008 increase	Fiscal year 2009 increase	Total current/planned spending for fiscal years 2008 and 2009
Total for core element 1: prevention	**10,024,000**	**11,414,000**	**21,438,000**
1.1: Promote increased corporate responsibility to prevent foodborne illnesses	3,108,000	6,311,000	9,419,000
1.2: Identify food vulnerabilities and assess risks	5,580,000	4,302,000	9,882,000
1.3: Expand the understanding and use of effective mitigation measures	1,336,000	801,000	2,137,000
Total for core element 2: intervention	**18,509,000**	**15,606,000**	**34,115,000**
2.1: Focus inspections and sampling based on risk	16,187,000	14,864,000	31,051,000
2.2: Enhance risk-based surveillance of imported foods at the border	2,322,000	742,000	3,064,000
2.3: Improve the detection of food system "signals" that indicate contamination	0	0	0
Total for core element 3: response	**19,589,000**	**3,174,000**	**22,763,000**

Food Protection Plan core elements and strategic actions	Fiscal year 2008 increase	Fiscal year 2009 increase	Total current/planned spending for fiscal years 2008 and 2009
3.1: Improve immediate response	19,589,000	2,954,000	22,543,000
3.2: Improve risk communications to the public, industry and other stakeholders	0	220,000	220,000
Sub-total	**48,122,000**	**30,194,000**	**78,316,000**
Cost of living pay increase for onboard food protection employees	0	12,038,000	12,038,000
Total for entire *Food Protection Plan*	**48,122,000**	**42,232,000**	**90,354,000**

Source: FDA.

Furthermore, in May 2008, FDA's Commissioner of Food and Drugs provided his professional judgment in response to a congressional request of FDA's immediate resource needs to implement key initiatives across the core elements of the *Food Protection Plan*. The Commissioner called for an additional $125 million for food protection in fiscal year 2008 beyond the $48 million that FDA had already allocated for implementing the *Food Protection Plan* in this fiscal year. According to the Commissioner, this increase will allow FDA to address some of the plan's strategic actions, such as identifying and targeting the greatest threats from intentional and unintentional contamination and conducting more risk-based inspections. The Commissioner's assessment also calls for 250 additional FTEs to accomplish the goals of the *Food Protection Plan*. After the Commissioner provided his assessment of FDA's resource needs, the Senate passed an Iraq War Supplemental that included an additional $119 million for food safety to be available through fiscal year 2009. In addition, on June 9, 2008, the Department of Health and Human Services announced that the Administration is amending its fiscal year 2009 budget request to include, in part, a $125 million increase for food safety. This amount would add to the $42 million increase originally proposed in the fiscal year 2009 budget justification (see table 1) and appears to be consistent with the Commissioner's professional judgment response. To accompany this amendment, FDA has posted information on steps it is taking to invest in its transformation in areas such as domestic medical products, import products, and domestic food safety. For example, under transforming domestic food safety, FDA reports that it issued final fresh cut produce guidance to limit contamination of fresh-cut fruits and vegetables. In addition, FDA conducted inspections and took action against processors of low acid canned foods that were deviating from required standards.

In addition, in January 2008, we testified that the *Food Protection Plan* does not discuss the strategies it needs in the upcoming years to implement this plan. When we asked FDA for more specificity on the strategies for implementing the plan, FDA officials told us that they have internal plans for implementing the

Food Protection Plan that detail timelines, staff actions, and specific deliverables. More recently, a senior level FDA official provided us with an estimate of 5 years for fully implementing the plan. However, FDA has not provided us with timelines for the various strategies described in the plan. For example, under the plan's strategic action 2.3—to improve the detection of food system "signals" that indicate contamination (see table 1)—FDA has recently identified three additional action steps with deliverables that will be needed to identify, develop, and deploy new screening tools and methods to identify pathogens and other contaminants. However, FDA could not provide us with an estimate of how long it would take to implement these steps or the overall strategic action. Without this type of information, we are not able to assess whether FDA's estimated 5-year time frame is feasible.

Similarly, while FDA's *Food Protection Plan* recognizes the need to partner with Congress to obtain 10 additional statutory authorities to transform the safety of the nation's food supply, FDA's congressional outreach strategy is general. When we asked FDA officials if they had a congressional outreach strategy, FDA officials told us that they had met with various congressional committees to discuss the *Food Protection Plan*. When asked if they had provided draft language to congressional committees on the various authorities, FDA officials explained that they only provided technical assistance, such as commenting on draft bills, to congressional staff when asked.

FDA appears to be refining its implementation plan over time. Most recently, in June 2008, FDA provided us with a draft work plan that it characterizes as a dynamic document that changes on a daily basis to implement the *Food Protection Plan*. While this draft work plan provides more information on the action steps and deliverables to achieve the core elements, we continue to have concerns about FDA's lack of specificity on the necessary resources and strategies to fully implement the plan. For example, as part of the plan's strategic action 1.1—to promote increased corporate responsibility to prevent foodborne illnesses (see table 1)—FDA has identified a goal of analyzing food import trend data and focusing inspections based on risk, and the draft work plan shows six deliverables, such as analysis of import data sets and an import risk ranking, associated with this goal. However, the timelines for these deliverables are unclear. In addition, the agency plans to dedicate a total of $673,000 to this goal in fiscal years 2008 and 2009, and FDA officials told us that the agency considers this funding to be a down payment toward achieving this goal. However, it is unclear what the total cost will be to meet this goal. While the work plan provides some basic information, more specific information, such as estimated resources needed to implement the various strategies—the core elements, goals, and deliverables—as well as the overall plan and timeframes for

implementing the strategies, are needed to assess FDA's progress in implementing the plan or in acquiring the resources and authorities it needs.

Anticipating the cost of the overall plan is important because, while some activities, such as meeting with industry experts to discuss corporate responsibility, may be accomplished within one budget cycle, others, such as the establishment of an FDA field office in China will likely require a long-term commitment of agency resources. From the information we have obtained on the *Food Protection Plan*, it is unclear what FDA's overall resource need is for implementing the plan. The overall resource need could be significant. For example, if FDA were to inspect each of the approximately 65,500 domestic food firms regulated by FDA, at the Commissioner's May 2008 estimate of $8,000 for a domestic food safety inspection, it would cost approximately $524 million to inspect all of these facilities once. Similarly, if FDA were to inspect each of the 189,000 registered foreign facilities (which includes facilities that manufacture, process, pack, or hold foods consumed by Americans) at the Commissioner's estimated cost of $16,700 per inspection, it would cost FDA approximately $3.16 billion to inspect all of these facilities once. These figures underscore the need for FDA to focus safety inspections based on risk.

Ultimately, a results-oriented organization needs to take a long-term view of the goals it wants to accomplish and describe them in a strategic plan. To facilitate congressional oversight, strategic plans should discuss (1) long-term goals and objectives for all major functions; (2) approaches to achieve the goals and objectives, and in particular the required resources including human capital and information technology; (3) a relationship between the long-term goals and the annual performance goals; and (4) an identification of key factors that could significantly affect achievement of the strategic goals. Such discussions in the *Food Protection Plan* could help clarify FDA's organizational priorities to the Congress, other stakeholders, and the public.

Lastly, when we testified before this subcommittee in January, we reported that FDA planned to keep the public informed of their progress on implementing the *Food Protection Plan*. In addition, in March 2008, FDA officials indicated that a progress report on actions taken to implement the *Food Protection Plan* would be issued in April 2008. In May, FDA officials told us that they had prepared a draft progress report, but as of June 4, 2008, FDA had not made this report public. FDA officials told us that the progress report is still being cleared by the Department of Health and Human Services, and they could not provide us with the report until it was cleared by the department. Instead, FDA officials provided us with a broad overview of FDA's actions and, subsequently, provided us with a list of accomplishments drawn out of numerous public documents. For example,

FDA issued a Federal Register Notice to solicit stakeholder comments on the implementation of the *Food Protection Plan* as part of a broad outreach plan.

We have noted that public reporting is the means through which the federal government communicates the results of its work to the Congress and the American people. Such reporting is in the public interest and promotes transparency in government operations. While it is important to show what progress has been made, having such information in a consolidated document at a readily accessible location reassures Congress and the public that actions have been taken.

FDA's Proposal to Focus Inspections Based on Risk Can Help Target Scarce Resources

The *Food Protection Plan* identifies the need to focus safety inspections based on risk, which is particularly important as the numbers of food firms have increased while inspections have decreased. In its *Food Protection Plan*, FDA has identified some actions to better identify food vulnerabilities and assess risks. For example, FDA plans to use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful. According to FDA officials, the agency has assigned a risk-based steering committee to identify models for ranking and prioritizing risk.

Conducting inspections based on risk has the potential to be an efficient and effective approach for FDA to target scarce resources, particularly when the number of inspections has not kept pace with the growth in firms between 2001 and 2007. Specifically, while the number of domestic firms under FDA's jurisdiction increased from about 51,000 to more than 65,500, the number of firms inspected declined slightly, from 14,721 to 14,566. FDA also reported declines in the number of inspections at overseas firms between 2001 and 2007—even as the United States has imported hundreds of thousands of different food products from tens of thousands of foreign food firms in more than 150 countries. Appendix I has information on the number of FDA inspections of food firms in foreign countries from fiscal years 2001 through 2007.

GAO Has Issued Recommendations Intended to Help Leverage Resources and Improve Operations, but FDA Has Implemented Few of Them

FDA has implemented few of our past recommendations to improve food safety oversight. Our recommendations are designed to correct identified problems and improve programs and operations. We have made 34 food safety related recommendations to FDA since 2004 and, as of May 2008, FDA has implemented 7. For the remaining recommendations, FDA has not fully implemented them, however, in some cases, FDA has taken some steps. As shown in table 2, these recommendations fall into two broad categories: improving monitoring and enforcement processes and leveraging resources. The planned activities in the *Food Protection Plan* could help address several of these recommendations.

Table 2: FDA's Implementation of GAO's Food Safety Recommendations, Since 2004

Category of recommendation	Total recommendations	Recommendations FDA has implemented	Recommendations FDA has not fully implemented
Improving monitoring and enforcement processes	21	3	18
Leveraging resources	13	4	9
Total Recommendations	**34**	**7**	**27**

Source: GAO and FDA.

In light of the federal government's long-term fiscal challenges, agencies, including FDA, need to seek out opportunities to better leverage their resources. We have made 13 recommendations to help FDA better leverage its resources since 2004, and FDA has implemented 4 of them. In a January 2004 report regarding seafood safety, we recommended that, among other things, FDA make it a priority to establish equivalence agreements with other countries.[10] We found that such agreements would shift some of FDA's oversight burden to foreign governments. FDA did not concur with this recommendation, and as of May 2008, has not yet established equivalence agreements with any foreign countries. In the same report, we recommended that FDA give priority to taking enforcement actions when violations that pose the most serious health risk occur;

[10]GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements are Needed,* GAO-04-246 (Washington, D.C.: Jan. 30, 2004).

consider the cost and benefits of implementing an accreditation program for private laboratories; and explore the potential of implementing a certification program for third-party inspectors. Although FDA concurred with these recommendations and has taken some limited action such as requesting public comments on the use of third-party certification programs, none were fully implemented. The *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of high-risk products comply with FDA standards.

Since 2004, we have made 21 recommendations to FDA to improve monitoring and enforcement processes, and FDA has implemented 3 of them. For example, in October 2004, we recommended that FDA develop a sound methodology for district staff to verify that companies have quickly and effectively carried out recalls.[11] At the time of our review, we found that FDA was not calculating the recovery rate for recalls. As a result, the agency did not know how much food was actually recovered, although the agency told us recovery was an important indicator of a successful recall. FDA initially commented that we had not demonstrated that weaknesses in FDA's recall process resulted in little recovery of food, but as of May 2008, the agency is in the process of conducting a quality management system review of its recall activities and, once the review is completed, it will include recommendations for verifying that a company's recall was effective, according to FDA.

To conclude, FDA's release of the *Food Protection Plan* is a positive first step toward modernizing FDA's approach to food safety to better meet the challenges of an increasingly global food supply and respond to shifting demographics and consumption patterns. Given that FDA's resources have not kept pace with its increasing responsibilities, FDA's plan to take a risk-based approach to inspections could help FDA make the most effective and efficient use of its limited resources. However, FDA's *Food Protection Plan* can only be as effective as its implementation, and without specificity on the resources and strategies needed to fully implement the plan—and in the absence of public reporting—neither Congress nor the public can gauge the plan's progress or assess its likelihood of success in achieving its intended results. In addition, no one is better poised than FDA to identify the resources and authorities needed to implement the plan; therefore, FDA's capacity to provide such information can be questioned. Meanwhile, as foodborne illness outbreaks continue, FDA is

[11]GAO, *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).

missing valuable opportunities to reassure Congress and the public that it is doing all it can to protect the nation's food supply.

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

Contact and Staff Acknowledgments

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. For further information about this testimony, please contact Lisa Shames, Director, Natural Resources and Environment at (202) 512-3841 or shamesl@gao.gov. Key contributors to this statement were José Alfredo Gómez, Assistant Director; Kevin Bray; Candace Carpenter; Alison Gerry Grantham; Thomas McCabe; Alison O'Neill; and Barbara Patterson.

Appendix I: Number of FDA Inspections of Food Firms in Foreign Countries, as of December 2007

FDA Inspections of Foreign Food Firms, Fiscal Years 2001 - 2007								
	2001	2002	2003	2004	2005	2006	2007	Total
Mexico	17	15	8	15	7	16	26	104
Ecuador	8		11	24		11	10	64
Chile	13		15	6	7	11		52
Peru	13			18	1	9	9	50
Brazil		12	6	7	21			46
Thailand	4	10		10		22		46
Canada	13		13	1		7	4	38
China		9	2	6	16			33
Taiwan	9	7		9		7		32
Argentina	7	5					19	31
India	6		10		7	7		30
South Korea	14			1	7		6	28
Australia	12		6			9		27
Costa Rica		11		4	5	7		27
Vietnam		9		10	8			27
Honduras	9	8			7			24
Fiji			8				13	21
Singapore	10			8				18
Estonia	8			8				16
Guatemala		10			6			16
South Africa	5		11					16
Germany	5	4	4			1	1	15
Nicaragua		8				7		15
31 additional countries[a]	58	61	54	26	40	11	8	258
Total number of countries inspected	**26**	**22**	**22**	**20**	**16**	**15**	**11**	**54**
Total inspections	**211**	**169**	**148**	**153**	**132**	**125**	**96**	**1034**

Source: GAO analysis of FDA data.

Note: [a]Countries with a total of 13 or fewer inspections between 2001 and 2007 are not listed in the table. These countries include: El Salvador (14 inspections), Jamaica (14), Latvia (14), Uruguay (14), Venezuela (14), Italy (13), Morocco (13), New Zealand (13), Poland (13), Norway (11), France (10), Romania (10), Suriname (10), Iceland (9), Malaysia (9), Bulgaria (8), Columbia (8), Cyprus (7), Panama (7), Trinidad and Tobago (7), United Kingdom (6), Turkey (5), Spain (4), Belgium (3), Greece (3), Hungary (3), Finland (2), Haiti (2), Japan (2), and the Netherlands (2). FDA also inspected food firms in Hong Kong (8).

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GAO
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Highlights

Highlights of GAO-08-909T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

FEDERAL OVERSIGHT OF FOOD SAFETY

FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. Changing demographics and consumption patterns along with an increase in imports have presented challenges to FDA. At the same time, recent outbreaks, such as *E. coli* from spinach and *Salmonella* from tomatoes, have undermined consumer confidence in the safety of the food supply. In November 2007, FDA released its *Food Protection Plan*, which articulates a framework for improving food safety oversight. In January 2008, GAO expressed concerns about FDA's capacity to implement the *Food Protection Plan* and noted that more specific information about the strategies and resources needed to implement the plan would facilitate congressional oversight.

This testimony focuses on (1) FDA's progress in implementing the *Food Protection Plan*, (2) FDA's proposal to focus inspections based on risk, and (3) FDA's implementation of previously issued GAO recommendations intended to improve food safety oversight. To address these issues, GAO reviewed FDA documents, such as FDA's operations plan, and FDA data related to the plan. GAO also interviewed FDA officials regarding the progress made. GAO also analyzed FDA data on domestic and foreign food firm inspections. GAO also analyzed the status of past recommendations.

To view the full product, including the scope and methodology, click on GAO-08-909T. For more information, contact Lisa Shames at (202) 512-3841 or ShamesL@gao.gov.

What GAO Found

Since FDA's *Food Protection Plan* was first released in November 2007, FDA has added few details on the resources and strategies required to implement the plan. FDA plans to spend about $90 million over fiscal years 2008 and 2009 to implement several key actions, such as identifying food vulnerabilities and risk. From the information GAO has obtained on the *Food Protection Plan*, however, it is unclear what FDA's overall resource need is for implementing the plan, which could be significant. For example, based on FDA estimates, if FDA were to inspect each of the approximately 65,500 domestic food firms regulated by FDA once, the total cost would be approximately $524 million. In addition, timelines for implementing the various strategies in the plan are also unclear, although a senior level FDA official estimated that the overall plan will take 5 years to complete. Importantly, GAO has noted that public reporting is the means through which the federal government communicates the results of its work to the Congress and the American people. FDA officials told GAO that they had prepared a draft report on progress made in implementing the *Food Protection Plan*, but as of June 4, 2008, FDA told GAO that the Department of Health and Human Services had not cleared the report for release.

The *Food Protection Plan* identifies the need to focus safety inspections based on risk, which is particularly important as the numbers of food firms have increased while inspections have decreased. For example, between 2001 and 2007, the number of domestic firms under FDA's jurisdiction increased from about 51,000 to more than 65,500, while the number of firms inspected declined slightly, from 14,721 to 14,566. Thus, conducting safety inspections based on risk has the potential to be an efficient and effective approach for FDA to target scarce resources based on relative vulnerability and risk.

FDA has implemented few of GAO's past recommendations to leverage its resources and improve food safety oversight. Since 2004, GAO has made a total of 34 food safety related recommendations to FDA, and as of May 2008, FDA has implemented 7 of these recommendations. For the remaining recommendations, FDA has not fully implemented them, however, in some cases, FDA has taken some steps. However, the planned activities in the *Food Protection Plan* could help address several of the recommendations that FDA has not implemented. For example, in January 2004, GAO recommended that FDA make it a priority to establish equivalence agreements with other countries. We found that such agreements would shift some of FDA's oversight burden to foreign governments. As of May 2008, FDA has not yet established equivalence agreements with any foreign countries. The *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards.

Mr. STUPAK. Thank you for your testimony.

Dr. Cassell, your testimony, please.

STATEMENT OF GAIL H. CASSELL, PH.D., VICE PRESIDENT, SCIENTIFIC AFFAIRS AND DISTINGUISHED LILLY RESEARCH SCHOLAR FOR INFECTIOUS DISEASES, ELI LILLY AND COMPANY

Ms. CASSELL. Good morning, Mr. Chairman, members of the Committee. I appear before you today, as you have stated, as a member of the FDA's Science Board, the advisory committee to the Commissioner, and as the chair of the subcommittee of the Science Board that was asked in December of 2006 to assess the state of science and technology at the Agency for its ability to address their current responsibilities as it relates to the protection of the public's health.

On December 3, 2007, the Science Board subcommittee presented the results of our findings to the full Science Board. The Science Board accepted the report as final and dissolved the subcommittee. The record of the proceedings of that meeting will show that due to the seriousness of the deficiencies found and the urgency of the situation, the Science Board was adamant that the report be broadly disseminated among the public and policymakers. The level of concern by all members of the subcommittee and the Science Board to a person was and remains very high, and thus the intensity of our commitment to this review and to see that in fact the recommendations of this committee are fully understood and the urgency appreciated. On behalf of our subcommittee, I again want to thank this committee for your interest and attention to the report.

As you have heard me say before, this subcommittee review was unique in many respects. First, it is only the second time in over a century that the Agency has been reviewed by an external committee as a whole entity. Second, the committee was composed of leaders not from a single sector but industry, academia, other governmental agencies. I won't belabor that. You have heard me say that before. It is in my written testimony. But I would point out on this committee that we did have a former Assistant Secretary of Health, a former Under Secretary of Agriculture responsible for food safety, a former Chief Counsel of the FDA, and almost 50 percent of the members were members of the National Academy of Sciences, including one Nobel laureate. We worked for over a year. It was the rule, not the exception, that almost all members were actively engaged and present in our deliberations. Let me assure you one more time that this level of engagement by a committee is not the norm. Trust me. I have served on enough committees of this type.

I would just say that also it is very rare that a committee would reach consensus so rapidly. You might ask then why were we able to achieve consensus and why the committee to this exercise, and quite simply, it was, it became readily apparent that FDA suffers, as you have heard this morning, from serious scientific deficiencies and is no way positioned to meet current or emerging regulatory responsibilities. It is agency-wide. It is not limited to a single program or center. Since every regulatory decision must be based upon the best available scientific evidence in order to protect public

health, we concluded lives were at risk and that there was an urgent need to address the deficiencies. Quite simply, we concluded that FDA can no longer fulfill its mission without substantial and sustained appropriations.

Many of you this morning have suggested that you are eager to hear what we would tell you about the new scientific technologies that would be applied to the food safety system. I am here to tell you today that in the hearing you may remember that was held by your committee on January 29, that in fact Dr. Porter from the congressional Research Service presented a slide to you which showed that the resources for the FDA for conducting research has declined by 50 percent since 1993. For food safety, you should appreciate that that amount has declined 67 percent. It is absolutely essential if in fact the Agency is to have the best and most up-to-date technologies that they do have the resources.

For that reason, when we were asked by this committee to provide our best judgment in terms of resources needed, you have already alluded to the fact that we requested $375 million in 2009. This was in great contrast, of course, to what you have already heard of the $50.7 million requested by the Administration. We are encouraged that the Administration's fiscal year 2009 budget amendment acknowledges the FDA's needs for $275 million to address serious safety issues but unfortunately, this amount is not sufficient to address all the deficiencies we found including the IT deficiencies and drug safety issues, and most importantly, with respect to food safety, it does come very close to what we recommended but appreciate it doesn't include the IT component in that $128 million we recommended for food safety.

We also wanted to point out that if it were not to become available until 2009, this is not in time. As we have all just heard about the tomato outbreak with salmonella, 23 hospitalizations, over 145 people sickened, and plus over $51 million lost in the space of just a few weeks. I also would point that in fact we also have had the 81 deaths from the heparin contamination. Therefore, it is urgent and we urge you to include the $275 million for FDA in the supplemental appropriations bill currently being considered by the House and Senate in order to get the critically needed funds flowing.

You will hear this morning from Dr. Glenn Morris, a member of the subcommittee, in detail about what the specific findings were that relate to food safety. You will also hear our concern about the lack of specificity in the Agency's Food Protection Plan and the fact that we need a strategic implementation plan. We need to know what technologies are going to be utilized, how long this will take, and I thank you for your attention and conclude my comments.

[The prepared statement of Ms. Cassell follows:]

STATEMENT OF GAIL H. CASSELL, PH.D.

Mr. Chairman and Members of the Subcommittee, I am Gail H. Cassell, Vice President for Scientific Affairs and a Distinguished Research Scholar for Infectious Diseases of Eli Lilly and Company and Professor. I am also Professor and Chairman Emeritus of the Department of Microbiology of the University of Alabama Schools of Medicine and Dentistry. I am a member of the Institute of Medicine of the National Academy of Sciences and am currently serving a second term on the governing board of the IOM. Of relevance to my testimony today, I have previously been a member of the Advisory Committees of the Directors of both the Centers for

Disease Control and the National Institutes of Health. I also co-chaired the congressionally mandated review of the NIH intramural program. I appear before you today as a member of the FDA Science Board, Advisory Committee to the FDA Commissioner as I have done so twice before this year. As you know I served as Chair of the Subcommittee on Science and Technology of the Science Board, which authored the report "FDA Science and Mission at Risk".

In December 2006, the Commissioner charged the Science Board with establishing a subcommittee to assess whether FDA's current science and technology can support the Agency's statutory mandate to protect the Nation's food and drug supply. The subcommittee was comprised of three Science Board members and 30 other experts. The subcommittee formally presented its report to the Science Board and FDA on December 3.

The report was unanimously endorsed by each of the 33 members of the subcommittee and the full Science Board. On December 3, the Science Board accepted the report as final and dissolved the subcommittee. The record of the proceedings of that meeting will show that due to the seriousness of the deficiencies found and the urgency of the situation, the Science Board was adamant that the report be broadly disseminated among the public and policy makers. The level of concern by all members of the subcommittee and the Science Board members was, and remains, high.and thus the intensity of their commitment to this review. On behalf of our subcommittee, I again want to thank you Mr. Chairman and members of your committee for your attention to our report.

The subcommittee review was unique in many respects. First, it is only the second time in over a century that the Agency has been reviewed by an external committee as a whole entity. Second, the committee was composed of leaders, not from a single sector, but from industry, academia, and other government agencies. The expertise and level of accomplishments of the members are almost unprecedented in a single committee, especially considering their breadth and knowledge in regulatory science and understanding of the mission of the Agency.

The subcommittee included expertise ranging from a Nobel laureate in pharmacology, 14 members of the National Academy of Sciences (including two engineers), a renowned economist and specialist in workforce issues, a leader in health care policy and technology assessment, a former CEO of a large pharmaceutical company, a former Assistant Secretary for Health and Human Services who also headed global regulatory affairs within a large company for over 20 years, a former Chief Counsel for the FDA, and the first Under Secretary for Food Safety at the U.S. Department of Agriculture overseeing the Food Safety and Inspection Service and coordinating U.S. Government food safety policy.

For over a year, this group of experts worked intensively for thousands of hours, including many nights, weekends, and holidays conducting their review. It was the norm, not the exception, that when we met, even by teleconference, we would have as many as 30 members actively engaged in discussion for over 2 hours. Let me assure you, this level of engagement by so many very busy people with diverse expertise is rare in such a committee let alone that there would be such rapid consensus about its findings. How then do you explain the consensus and commitment to this exercise?

It became rapidly apparent that the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. It is agency-wide, i.e. not limited to a single program or center. Since every regulatory decision must be based upon the best available scientific evidence in order to protect the public's health, we concluded that American lives are at risk and that there is an urgent need to address the deficiencies. Quite simply we concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations.

On February 25, in response to your request, we submitted a summary of the estimated resources required to implement the recommendations made by our Subcommittee which included $375M in FY 2009. This was in great contrast to the $50.7M requested by the Administration for FY 2009. We are encouraged that the Administration's FY 2009 budget amendment acknowledges the FDA's need for $275M to address serious safety issues. Unfortunately, we do not believe this amount is sufficient and most importantly, even if it were, it would not be available until March or April of 2009 at the very earliest.

Just within the past 2 months there have been 81 deaths in this country from contaminated heparin. Just this past week, the Centers for Disease Control has reported there have been 23 hospitalizations and 145 people sickened from salmonella contamination of fresh tomatoes. The later alone has cost the food industry over $51M in the last few days. Mr. Chairman, if we do not act now to address the deficiencies at FDA, we will see more lives lost and greater economic losses. We there-

fore urge you to include $275M for FDA in the Supplemental appropriations bill currently being considered by the House and Senate in order to get the critically needed funds flowing rapidly.

You will recall in the hearing held by your committee on January 29, we summarized the overall findings of our subcommittee. In the hearing you held, April 22, findings concerning drug safety and foreign inspections were extensively discussed. However, our subcommittee found the most serious deficiencies to be in the area of food safety. Today you will hear from Dr. Glenn Morris, a member of our review group about our specific concerns and recommendations about food safety. In addition, you will hear about our concern that the Agency's current Food Protection Plan lacks specificity regarding the actions to be taken, technologies to be utilized, and mechanisms of implementation. I will now defer to him and the other panel members to discuss these issues in greater detail.

Mr. STUPAK. Thank you, Doctor.

Dr. Morris for an opening statement, please.

STATEMENT OF J. GLENN MORRIS, JR., M.D., M.P.H., T.M., DIRECTOR, EMERGING PATHOGENS INSTITUTE, UNIVERSITY OF FLORIDA

Dr. MORRIS. Mr. Chairman, members of the Committee. It is a pleasure to have the opportunity to speak before you today to review the findings of the report of the FDA's Science Board Subcommittee on Science and Technology on which I had the pleasure of being a member. In the second part of my testimony I would like to expand my remarks beyond the report to deal at a more general level with the ability of FDA to identify and control risks in our U.S. food supply.

The subcommittee's report was entitled "FDA Science and Mission at Risk," which I think correctly emphasizes the critical nature of the current situation at FDA. To quote from the report, "FDA does not have the capacity to ensure the safety of food for the Nation. Crisis management at FDA's two food science centers, Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine, has drawn attention and resources away from FDA's ability to develop a science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance and conduct emergency outbreak investigation activities to protect the food supply." I would say that I very strongly support these conclusions.

As highlighted in the committee report, the current situation reflects decades of neglect of CFSAN and CVM resource needs, and again, this has been noted multiple times already this morning. Just to note one, to me, particularly insightful point: since 2003, CFSAN's workforce has declined from 950 FTE to 771 FTE, and this is at a time when there have been increased demands on the Agency brought on by an increasingly complex food supply, rapidly expanding internationalization of markets as well as increasing regulatory responsibility. The problems in CFSAN and CVM have been further exacerbated by major outbreaks and recalls which, of necessity, divert resources away from "routine" scientific surveillance and regulatory activities.

In the absence of a clearly articulated vision for food safety in this country, it is difficult to come up with a dollar amount for what it is going to take to get everything working again. However, the subcommittee, in response to the request of this committee, de-

veloped cost estimates for beginning the rebuilding process in the Agency, and again, as has already been mentioned, the numbers that we put forth were approximately $128 million for fiscal 2009 with a cumulative increase of $775 million in annual budget by 2013. Again, I would strongly emphasize that that does not include the IT component, which is an absolutely critical component. The increase that is being proposed by the Agency at this point in time begins to move toward the number we put forward, but without the IT component. We are still not there yet.

Food safety remains a critically important area of concern to the U.S. public as has been demonstrated by the current problems with tomatoes. The latest outbreak always gets the headlines, and is what we tend to focus on. What I would comment on, speaking as an epidemiologist, is that the reported incidence rates for the major foodborne pathogens, based on 2007 FoodNet data, have remained relatively constant during the past several years with some actual increases. FoodNet was a system we put in place back in the mid-1990s to give us a means of monitoring the outcome of the new HACCP food protection plan at USDA. I was with USDA at the time and was instrumental in putting the plan in place. FoodNet showed that we had an initial drop in incidence of foodborne disease in this country after implementation of the HACCP rules, which suggests that there was a definite public health impact resulting from these landmark regulatory changes. However, this decrease has leveled off over the last several years, underscoring the need for new and innovative approaches to protect the health of the American people. We did a good job at USDA. We need to do something at FDA to really begin to address these concerns.

There is a broad consensus that the Agency must develop a proactive risk-based and science-based preventive approach to food safety. Some of the key elements of such an approach have been articulated by the Agency with the announcement of their Food Protection Plan. However, as has already been noted, questions remain about implementation and the extent of the FDA vision. I would highlight three specific areas.

First of all, development of a risk- and science-based approach to prevention requires science. To quote from the initial subcommittee report, "There is a critical need to develop a cadre of professionals capable of applying the new biology, chemistry, and bioinformatics to the regulation of foods that exist in the manufacturing, distribution and consumer use environment of today's global marketplace." We need to have the scientists in place. We need to have the ideas and the vision to set the priorities and to be able to develop the risk-based system we have talked about. This is both laboratory science but it also a need for epidemiologic capabilities. It is a need for high-quality surveillance.

This also has to be combined with a strong analytic capability both to guide the original data collection and to make sense of the data when they are collected. In this regard, many of the European countries such as the Netherlands and Denmark are well ahead of us, having in place well-designed surveillance systems that are used to regularly tweak the approaches and focus areas of the associated food safety regulatory agencies. Development of public health-based performance standards which long term are a critical

element of a risk-based prevention system requires an even higher level of sophistication and surveillance and analysis. Unfortunately, the capacity at FDA for such analysis is limited and there is at best a clouded vision of what is needed for actual implementation of such systems.

The second thing, no matter how good the science, the Agency will not be able to move forward in the absence of an appropriate legislative mandate. Again, I will leave that to the comments made by other members of this panel and others this morning.

And of course, finally, the third point, there is a need for a substantial increase in the budgets for CFSAN and CVM. The estimates that we provided again are a starting point. The actual amounts necessary will almost certainly change depending on the extent of the Agency's vision and their approaches to implementation. In the long run, prevention is unquestionably cost effective. However, we have a great deal of rebuilding to do before we can begin to realize such cost savings.

FDA science is at a critical juncture with the negative impact of declining resources being felt perhaps most strongly in the food safety area. I would urge the Committee to work to rebuild its resource base and provide the necessary underlying legislative mandate as part of an ongoing effort to decline and implement a national vision for the future of food safety.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Morris follows:]

STATEMENT OF J. GLENN MORRIS, JR., MD, MPH *

Mr. Chairman, members of the Committee: it is a pleasure to have the opportunity to speak before you today to review the findings of the Report of the FDA Science Board's Subcommittee on Science and Technology, on which I was a member. In the second part of my testimony, I would like to expand my remarks beyond the report to deal at a more general level with the ability of FDA to identify and control risks in our U.S. food supply.

The Subcommittee's report was entitled "FDA Science and Mission at Risk," correctly emphasizing the critical nature of the current situation at FDA. In discussing food safety, the report concluded that "FDA does not have the capacity to ensure the safety of food for the Nation. Crisis management in FDA's two food safety centers, Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM), has drawn attention and resources away from FDA's ability to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply." ** I would strongly support these conclusions.

As highlighted in the Subcommittee report, the current situation reflects decades of neglect of CFSAN and CVM's resource needs. Since 2003, CFSAN's workforce has declined from 950 FTE to 771 FTE, at a time when there have been increasing demands on the Agency. This includes demands brought on by an increasingly complex food supply, with rapidly expanding internationalization of markets, as well as increasing regulatory responsibilities related to new legislative mandates. Problems

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** Report of the Subcommittee on Science and Technology, FDA Science and Mission at Risk, November, 2007, p.3.

in both CFSAN and CVM have been further exacerbated by major outbreaks and recalls, which, of necessity, divert resources away from "routine" scientific, surveillance, and regulatory activities.

In the absence of a clearly articulated vision for food safety in this country, it is difficult to come up with estimates for what it will cost to optimize the FDA food safety program. However, in response to a specific request of Representatives Dingell, Waxman, Stupak, and Pallone, our Subcommittee developed cost estimates for beginning the rebuilding process in the Agency; responses were submitted by Dr. Cassell on February 25 of this year. To summarize, our Subcommittee estimates called for an increase in the annual budget of food-related components of FDA of approximately $128 million for FY2009, with a cumulative increase of $755 million in annual budget by 2013. This figure includes $350 million to strengthen imports and $100 million to strengthen work with nutritional supplements, animal health, and cosmetics. Separate from this total is an additional $450 million cumulative 5-year increase in annual budget for enhancement of FDA Information Technology, an enhancement which is critical for FDA to be able to deal with the massive data flows necessary for its activities, including appropriate surveillance and food protection.[***]

Food safety remains a critically important area of concern to the U.S. public. While attention always tends to focus on the latest outbreak, it is perhaps most concerning, from an epidemiologic standpoint, that reported incidence rates for the major foodborne pathogens (based on 2007 FoodNet data) have remained relatively constant during the past several years, with some actual increases. This follows initial declines in incidence rates seen after implementation of the USDA HACCP rules in 1995, suggesting that the impact of these landmark regulatory changes over a decade ago has "leveled off," and underscoring the need for new and innovative approaches to protect the health of the American people.

FDA, with responsibility for overseeing an estimated 80% of the Nation's food supply, must take the major leadership role in the development and implementation of such new approaches. There is a broad consensus that the Agency must develop a proactive, risk-based (and science-based) preventive approach to food safety. Some of the key elements of such an approach have been articulated by the Agency, with the announcement of their Food Protection Plan. However, questions remain about implementation, and about the extent of the FDA vision. I would highlight three key issues:

1) Development of a risk- and science-based approach to prevention requires science. Going beyond laboratory science, there is a need for high quality surveillance, both microbiologic and epidemiologic, to clearly identify and delineate problem areas. This, in turn, must be combined with a strong analytic capacity, both to guide the original data collection and to "make sense" of the data when they are collected. In this regard, many of the European countries (such as the Netherlands and Denmark) are well ahead of us, having in place well-designed surveillance systems that are used to regularly "tweak" the approaches and focus areas of the associated food safety regulatory agencies. Development of public health-based performance standards, which, long-term, are a critical element of a risk-based prevention system, requires an even higher level of sophistication in surveillance and analysis. Unfortunately, the capacity at FDA for such analysis is limited, and there is at best a clouded vision of what is needed for actual implementation of such systems.

2) No matter how good the science, the Agency will not be able to move forward in the absence of an appropriate legislative mandate. In particular, if we are to develop performance standards, there must be a regulatory structure in place that can make appropriate use of such standards as part of a flexible, risk-based performance system. The legislation before this committee moves in this direction, and I applaud these efforts.

3) And, as previously noted, there is a need for a substantial increase in the budgets for CFSAN and CVM. The estimates provided by our subcommittee are a starting point: the actual amounts necessary will almost certainly change, dependent on the extent of the Agency's vision, and their approaches to implementation. In the long run, prevention is unquestionably cost-effective. However, we have a lot of rebuilding to do before we can begin to realize such cost savings.

FDA science is at a critical juncture, with the negative impact of declining resources being felt perhaps most strongly in the food safety area. I would urge your committee to work to rebuild this resource base, and provide the necessary under-

[***] FDA Science and Mission at Risk. Estimated Resources Required for Implementation. Submitted by Gail Cassell, PhD, on behalf of the Subc0mmittee and its Members. February 25, 2008.

lying legislative mandate, as part of an ongoing effort to define and implement a national vision for the future of food safety.

Mr. STUPAK. Thank you, Doctor.

Professor Taylor, your opening statement, please.

STATEMENT OF MICHAEL R. TAYLOR, J.D., RESEARCH PROFESSOR OF HEALTH POLICY, THE GEORGE WASHINGTON UNIVERSITY, SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES

Mr. TAYLOR. Mr. Chairman, Mr. Shimkus, members of the Subcommittee, I thank you for this opportunity to testify on the resource challenges facing FDA in implementing its Food Protection Plan.

Americans have long looked to FDA as the focal point for food safety leadership in the United States and internationally but FDA's ability to provide that leadership or even meet its basic food safety responsibilities is now badly impaired, in large part because society simply has not given FDA the tools it needs to do the job society expects it to do. These tools include adequate resources, the focus of today's hearing, but also a modern statutory mandate and an institutional structure that is capable of national and international leadership on food safety.

Mr. Chairman, the time for food safety reform has come, as you and others today have indicated, and as the result of recent events surrounding tomatoes so graphically remind us once again. I consider FDA's new Food Protection Plan an important step toward the food safety reform we need. It marks a shift in strategic direction for FDA. The plan would move FDA from primarily reacting to food safety problems after they occur to taking an integrated systems approach that focuses on prevention and on the risk-based targeting of initiatives and resources to reduce the risk of foodborne illness. I think Dr. Acheson and his FDA colleagues deserve credit for this new direction.

The issue now of course is implementation and substantial questions certainly remain. The Food Protection Plan contains eight broad initiatives and a total of 38 specific actions to strengthen FDA's food safety program. In every case, these initiatives and actions involve either an entirely new effort by FDA or significant enhancement of something FDA is doing now. These proposed actions are all worthy, all should be pursued, as should other food safety initiatives that are not included in the plan such as increasing the overall frequency of FDA inspection and establishing and enforcing mandatory on-farm standards to ensure the safety of fresh produce. But the question is how. How is FDA going to do the work called for in its plan? FDA has issued its plan, as we have heard already this morning, at a time when its own Science Board has said that FDA lacks the resources and science base to do its food safety job, yet the plan itself does not address the resources needed to implement it or provide a timeline or priorities for implementation, and until earlier this week, the Administration had not proposed a budget for FDA that would even begin to address the Agency's food safety funding crisis.

It is important to note that the total increase for food safety now proposed by the President for fiscal year 2009 is just a down payment on the more than doubling of FDA's food budget that the Science Board and other experts say is needed over a 5-year period, and under the most optimistic scenario, when Congress will act on the 2009 appropriations, the new resources would first be available to FDA almost a year after the Food Protection Plan was issued. I think we all agree here today that FDA needs resources now.

So given this harsh budget reality, what should FDA do? One of the first things to do, again, as others have said, is to lay out for the Congress and the public an implementation plan for the rebuilding and reform of its food safety program. This should include a detailed resource plan and clear priorities and timelines to implement the Food Protection Plan. Now, making such a plan is hard for an agency like FDA to do in the context of an annual budget process that does not lend itself to long-term planning, but the food safety transformation that is needed and that FDA is calling for demands a long-term effort and plan. Congress should require such an effort and plan from the Administration. In addition, I think FDA should identify some specific actions that it can take now to begin the shift from reaction to prevention and address some of today's most pressing safety problems. In my written testimony, I suggest four such actions, which I will touch on briefly here.

First, to begin the shift to risk-based priority setting and preventive risk management, FDA should identify the most significant food safety hazards within its jurisdiction and begin devising targeted strategies to reduce them. We can't solve food safety problems without naming them first. Identification of the most significant hazards in the food supply can not only guide FDA's actions but also inform the industry about risks that companies should be addressing in their own food safety plans whether or not those risks are being addressed immediately by FDA.

Now, while we know enough to begin this kind of risk-based priority setting, FDA and industry alike have a pressing need for better and more timely information about the actual burden and root causes of human illness associated with foodborne pathogens and other hazards. FDA is dependent for this information, however, on the efforts of State and local health departments and the Centers for Disease Control and Prevention which have their own budget constraint, priorities, and limitations that have been obstacles to FDA getting the information it needs.

Thus, the second immediate action I recommend is that FDA and the Department of Health and Human Services make it a high priority and take affirmative steps to improve the quantity, quality, and timeliness of the food safety epidemiology data available to FDA and others who need it to improve food safety.

Third, I believe FDA should conduct a compliance and effectiveness audit of FDA's seafood HACCP program. This program, established in 1996, foreshadowed the approaches to prevention and improved oversight of imports contained in the Food Protection Plan and in pending food safety legislation. It does this by requiring all seafood processors, domestic and foreign, to implement a preventive control plan and requires importers to take affirmative steps to ensure that the seafood they import was produced under condi-

tions that meet the HACCP requirement. Because seafood safety is an important issue in its own right and because preventive control plans and strengthened industry responsibility for prevention are important elements of FDA's new strategy, FDA should assess the overall effectiveness of the seafood HACCP role in preventing violations of U.S. food safety standards. It should identify legal, resource, and other constraints on the effectiveness of the rule and it should draw lessons for FDA's development of preventive controls for other commodities in sectors of the food supply. FDA should learn from that experience.

Finally, FDA should begin rulemaking now on the safety of fresh produce. Over a year ago, the United Fresh Produce Association and the Produce Marketing Association called on FDA to establish produce safety standards that are, and I quote, "federally mandated, risk-based and allow for commodity-specific regulation." I agree that FDA should establish such standards and I think FDA should begin the rulemaking as soon as possible.

With these actions, FDA can begin down the path of reform but Congress needs to do its part as well. FDA needs a stable and adequate resource base. It needs a modern food safety legislative mandate and it needs an organization structure that unifies and elevates the food safety program within HHS. Only then will FDA be equipped to do the food safety job that Americans expect and deserve.

I thank you again, Mr. Chairman, and I look forward to questions.

[The prepared statement of Mr. Taylor follows:]

STATEMENT OF MICHAEL R. TAYLOR *

Mr. Chairman, Mr. Shimkus, members of the subcommittee, I appreciate this opportunity to testify on the resource challenges facing the Food and Drug Administration in implementing its Food Protection Plan. I applaud the subcommittee for tackling this important topic.

INTRODUCTION

FDA has long been looked to as the focal point for food safety leadership in the United States and internationally. It oversees 80% of the U.S. food supply (including an even greater share of imported food) and is the steward of a long tradition of effective, science-based regulation to protect public health. Unfortunately, FDA's ability to provide food safety leadership, or even meet its basic food safety responsibilities, is now badly impaired, in large part because society simply has not given FDA the tools it needs to the job society expects it to do. These tools includes a modern statutory mandate, an adequate and stable resource base, and an institutional structure capable of national and international leadership on food safety.

The focus of this subcommittee, and the Committee on Energy and Commerce as a whole, on giving FDA the tools it needs to do food safety right is thus timely and important. Getting food safety right at FDA is essential to the public's health, to the confidence people want to have in the food they feed themselves and their families, and to the economic success of the food system. The subcommittee's leadership will be essential to achieving these outcomes.

I consider FDA's new Food Protection Plan an important step toward the food safety reform we need. It marks a shift in strategic direction for FDA, from primarily reacting to food safety problems after they occur to taking an integrated systems approach that focuses on prevention and on the risk-based targeting of initia-

* Mr. Taylor is Research Professor of Health Policy at The George Washington University School of Public Health and Health Services and chair of the Food Safety Research Consortium. He served formerly as Administrator of USDA's Food Safety and Inspection Service (1994–96) and as Deputy Commissioner for Policy of the Food and Drug Administration (1991–94).

tives and resources to reduce the risk of foodborne illness. The FDA plan embodies many of the elements of a more effective and efficient food safety program that have been recommended over the last decade in a series of reports by the Government Accountability Office (GAO) and expert committees of the National Academy of Sciences (NAS).

It is thus appropriate that Congress address FDA's implementation of its Food Protection Plan, including the resources FDA will need to put the plan into practice. In my testimony, I will identify some specific activities that I believe deserve priority management attention and funding to begin the shift to a prevention paradigm, as well as address the scale of FDA's resource needs for food safety in the long term.

It is important, however, to consider the implementation of FDA's Food Protection Plan and resource needs in the context of the broader statutory and organizational problems that must be addressed for FDA's food safety program to succeed. I will thus note briefly how the obsolete food safety laws and fragmented organizational structure under which FDA operates stand in the way of full and effective implementation of the new plan and how these problems can be solved.

FDA'S FOOD SAFETY FUNDING CRISIS

FDA's Food Protection Plan is based on four "cross-cutting principles," all of which are sound and all of which have significant resource implications. These are:

1. Focus on risk over a product's life cycle from production to consumption.
2. Target resources to achieve maximum risk reduction.
3. Address both unintentional and intentional contamination.
4. Use science and modern technology.

Building on these principles, the plan includes three core operational elements: (1) Preventing foodborne illness in the first place; (2) Intervening with risk-based FDA actions at critical points in the supply chain; and (3) Responding rapidly when contaminated food or feed is detected. Under these three core elements, FDA lays out eight broad new initiatives and a total of 38 specific actions to strengthen its food safety program.

In every case, these initiatives and actions involve either an entirely new effort by FDA or a significant enhancement of something FDA is doing now. Under the critical first element of prevention, for example, the plan calls for FDA to, among other things, work with the food industry to promote corporate responsibility and best practices for food safety, increase FDA's presence overseas, generate new data and develop new models for prioritizing risks, and develop and implement a research plan on sources of contamination and methods to prevent it.

These activities are all worthy, as are the 34 other activities called for in the plan. All should be pursued. Moreover, the Agency should be pursuing food safety initiatives that are not included in the plan, such as increasing the overall frequency of FDA inspection and establishing and enforcing mandatory on-farm standards to ensure the safety of fresh produce.

And legislation being developed by Chairman Dingell and other leaders in Congress would give FDA responsibility for implementing two major and needed new programs: the first involves mandatory adoption of preventive controls by all food facilities (domestic and foreign) that produce food for the U.S. market; the second makes importers accountable for assuring that foreign produced products meet U.S. standards.

These efforts to strengthen FDA's food safety program all require investment in such essential inputs to an effective program as increased scientific expertise and staffing levels, research and data collection to guide the new science- and risk-based preventive approach, new information management systems, and the operating funds needed to establish a leadership presence nationally and internationally. FDA has issued its Food Protection Plan and Congress is considering major new initiatives at a time, however, when the Agency lacks the resources to meet even its base food safety responsibilities, much less fund the worthy new initiatives.

The seriousness of FDA's food safety funding crisis was made crystal clear by the December 2007 report of the FDA Science Board, which found, starkly, that "FDA does not have the capacity to ensure the safety of food for the nation" and that "[t]he Nation's food supply is at risk." The Science Board report said further that FDA's food program lacks the resources "to develop the science base and infrastructure needed to efficiently support innovation in the food industry, provide effective routine surveillance, and conduct emergency outbreak investigation activities to protect the food supply." The Science Board also noted "an appallingly low inspection rate" for FDA-regulated food facilities.

The Science Board is not alone in its concern about the current state of FDA's resources for food safety. In its January 2008 testimony before this subcommittee, the GAO found that staffing levels and funding had "not kept pace with the Agency's growing responsibilities." GAO pointed out the Science Board findings that the number of domestic establishments and food import entries for which FDA is responsible has grown significantly; yet, from 2003 to 2006, staffing levels in FDA's Center for Food Safety and Applied Nutrition (CFSAN) and in the field force responsible for food safety inspection and enforcement, actually declined, by 14 percent and 11.5 percent, respectively. Some 200,000 overseas food facilities are registered with FDA, but the Agency expects to conduct only 125 foreign food inspections this year.

FDA's funding constraints and downward trends provide a weak foundation on which to build a modern, science- and risk-based food safety program. Recognizing the need to re-build FDA's scientific base and both headquarters and field capacity, the Science Board recommended in February 2008 substantial increases in FDA's budget for overseeing the food supply, to be phased in over a 5-year period. FDA's FY 2008 budget for overseeing the food supply (which includes resources for all of CFSAN, part of the Center for Veterinary Medicine, food-related field functions managed by the Office of Regulatory Affairs, and elements of the Office of the Commissioner and the National Center for Toxicological Research) is about $620 million. The Board recommended this be increased by $128 million in FY 2009, $283 million in FY 2010, $441 million in 2011, $598 million in 2012, and $755 million in 2013.

This would bring FDA's food-related budget in FY 2013 to $1.375 billion, which is not much more than the approximately $1.1 billion the President requested in his FY 2009 budget for USDA to oversee the safety of just 20 percent of the food supply. I agree that FDA needs resources on this scale to transform its food safety program from the current paradigm of reacting to problems to a paradigm of risk-based prevention.

The President's original FY 2009 budget requests for FDA included an increase of less than $43 million over the 2008 budget, which would just barely keep pace with FDA's core inflation rate of 5.8%. This would mean keeping FDA's actual operating capacity for food safety at essentially the same level that the Science Board found inadequate "to ensure the safety of food for the Nation."

I was pleased that on June 9, 2008, HHS Secretary Leavitt announced that the President's FY 2009 budget request for FDA is being amended to add $275 million, of which $125 million would be available for food safety-related work, for a total FY 2009 increase for food safety of $168 million, which exceeds the Science Board proposal. This is a good sign that the administration has recognized FDA's food safety funding crisis.

I am concerned, however, about when these additional funds, if agreed to by Congress, would become available. The earliest possibility, of course is October 1, 2008, the beginning of FY 2009, but that assumes Congress will pass FDA's FY 2009 budget on time, as opposed to a continuing resolution, which could extend FDA's 2008 funding level well into calendar year 2009. This would substantially delay implementation of the Food Protection Plan.

Regardless of the prospects for the FY 2009 budget, FDA needs immediate budget help to get started with its prevention-oriented food safety strategy, as today's ongoing and widespread outbreak of illness associated with salmonella-contaminated tomatoes so graphically demonstrates. I thus hope Congress will providing FDA additional food safety funds in the pending 2008 supplemental appropriations bill and that Congress will commit itself to a long-term funding plan for food safety at FDA, in keeping with the recommendations of the FDA Science Board.

NEAR-TERM PRIORITIES TO IMPLEMENT FDA'S FOOD PROTECTION PLAN

The magnitude of the transformation that FDA's Food Protection Plan envisions, coupled with inevitably finite management capacity and budgets, means that FDA must set priorities for how it invests its time and money to implement the plan, regardless of what action Congress takes on the 2008 supplemental and FDA's FY 2009 appropriation.

To this end, the first thing FDA should do is determine the resources it needs to implement the Food Protection Plan and develop a detailed resource plan, including priorities, for their deployment. Clearly, based on the Science Board report, FDA needs to build its scientific base and information infrastructure for food safety, in addition to having the operating funds to take the many specific actions called for in the Food Protection Plan. The Plan was silent on resource needs but can be credible and effective only if accompanied by a realistic resource plan that Congress funds.

Beyond that, I'd like to suggest four specific actions that FDA can pursue now. I think these deserve high priority because they would both begin the shift to the prevention paradigm and address some of today's most pressing food safety problems. Though all can be pursued under current law, they would also help lay the foundation for implementing new legislative mandates, such as contained in the discussion draft circulated by Chairman Dingell and on which Chairman Pallone held a hearing on April 24, 2008.

BEGIN RISK-BASED PRIORITY SETTING AND RISK MANAGEMENT

The essential starting point for a risk-based, preventive approach to food safety is knowing what the most important risks are and systematically devising affirmative strategies to reduce them. FDA has not taken this approach in the past, but the Food Protection Plan's initiatives 1.2 (Identify Food Vulnerabilities and Assess Risks) and 1.3 (Expand the Understanding and Use of Effective Mitigation Measures) signal FDA's intention to move in this direction.

This is not, however, a small undertaking. It involves: (1) identifying the most significant hazards in the food supply, meaning the specific combinations of foods and microbial or chemical contaminants that are likely to have the greatest adverse impact on public health; (2) prioritizing these hazards based on the magnitude of the potential risks they pose and the availability, likely effectiveness, and cost of measures to reduce the risks; and (3) developing risk reduction strategies for the highest priority hazards, including appropriate safety standards for each hazard, an inspection and enforcement plan to ensure the standards are met, and a plan to monitor the effectiveness of the strategy in reducing risk to the public.

At the outset, FDA could, for example, identify the 20 most significant hazards within its jurisdiction and commit initially to devising prevention strategies for the top five. As this work progresses, FDA should regularly update its assessment of the hazards and, as appropriate, select additional hazards for priority risk management attention.

In addition to guiding FDA's priority setting and resource allocation, regular assessment and reporting by FDA on the most significant hazards in the food supply has the important advantage of informing the industry about risks companies should be addressing in their own food safety plans, whether or not those risks are being addressed immediately by FDA.

Sufficient information exists today to begin risk-based priority setting and risk management. It is also clear that more complete information and better tools for analyzing and managing information will improve the efficiency and quality of the effort. FDA should, therefore, draw on its current knowledge and early experience with risk-based priority setting to map out a plan for obtaining and managing the information it needs. The plan should address institutional roles and responsibilities and resources for meeting FDA's information needs.

STRENGTHEN THE CONTRIBUTION OF FOOD SAFETY EPIDEMIOLOGY TO PREVENTION

One of FDA's most critical information needs is better knowledge of the actual burden and root causes of human illness associated with foodborne pathogens and other hazards. Such information is essential to the risk-based prevention approach of the Food Protection Plan and to the individual efforts of food companies to prevent the risks arising in their operations. FDA should thus make it a high priority to improve the quantity, quality and timeliness of the food safety epidemiology data it receives.

FDA is dependent for this information, however, primarily on the efforts of state and local health departments and the Centers for Disease Control and Prevention (CDC). These agencies operate under their own budget constraints and have other priorities and limitations that have been obstacles to FDA getting the information it needs in a timely fashion. The Food Protection Plan implicitly recognized this reality in calling for FDA to work with CDC to better attribute pathogens and illnesses to particular foods and identify where in "the production life cycle" the foods became contaminated.

FDA should thus work through the Office of the Secretary of Health and Human Services to make the nation's food safety epidemiology enterprise as responsive as possible to FDA's information needs and the needs of other federal and state agencies and the food industry in their efforts to prevent foodborne illness. A focal point for leadership should be established within the Office of the Secretary to coordinate the efforts of FDA, USDA, CDC, and state and local health officials for this purpose, and FDA should have resources to finance specific enhancements in the way food safety epidemiological data are collected, analyzed and made available to better sup-

port implementation of the risk-based prevention strategy embodied in the Food Protection Plan.

CONDUCT A COMPLIANCE AND EFFECTIVENESS AUDIT OF FDA'S SEAFOOD HACCP PROGRAM

The seafood HACCP (Hazard Analysis and Critical Control Points) program that FDA established in 1996 foreshadowed the approaches to prevention and improved oversight of imports contained in the Food Protection Plan and pending food safety legislation. It requires all seafood processors, domestic and foreign, to prepare and implement a preventive control plan (specifically a HACCP plan), and it requires importers to take affirmative steps to ensure that the seafood they import was produced under conditions that meet the HACCP requirement. The HAACP rule's provision for imports is particularly important since a large majority of the seafood consumed in the United States is imported.

For resource reasons, FDA's oversight of importers and inspection of foreign processing facilities is very limited, and, as seafood imports have grown, state and federal laboratories have documented a growing problem with chemical contaminants and antibiotic residues in farm-raised fish products, especially those coming from Asia. This raises questions about the reliability of the "affirmative steps" being taken by importers and the overall effectiveness of FDA oversight of seafood. Last year, FDA banned certain seafood imports from China.

Because seafood safety is an important issue in its own right, and because preventive control plans and strengthened industry responsibility for prevention - through preventive control plans - are important elements of FDA's new strategy, FDA should conduct a compliance and effectiveness study of the seafood HACCP program for both domestic and imported seafood. The purposes should be to: (1) assess compliance rates and the overall effectiveness of the seafood HACCP rule in preventing violations of U.S. food safety standards, (2) identify legal, resource and other constraints on the effectiveness of the seafood HACCP rule, and (3) draw lessons for FDA's development of preventive control plans for other commodities and sectors of the food supply.

BEGIN TARGETED RULEMAKING ON THE SAFETY OF FRESH PRODUCE

Over a year ago, the United Fresh Produce Association and the Produce Marketing Association called on FDA to establish produce safety standards that are "federally mandated, risk-based and allow for commodity-specific regulation." I agree FDA should establish such standards, and I believe FDA should begin the rulemaking process as soon as possible.

It will be a challenge for FDA to develop workable, science-based standards that can evolve as the science of produce safety evolves. I also recognize that most of the pending food safety legislative proposals would mandate FDA establishment of produce safety standards. I support such legislation. Nevertheless, FDA should begin the process now with respect to one or more specific categories of produce—such as leafy greens and tomatoes—by gathering and analyzing the relevant scientific and technical information, beginning serious dialogue with experts in the produce industry and academia, and proposing regulatory options.

In my view, the basic elements of the new standards should include a mandatory preventive control plan developed by each grower and tailored to local hazards and conditions, and, as appropriate and feasible, enforceable criteria or standards for key risk factors, such as microbial quality of irrigation, manure management, and control of livestock and other animal vectors for contamination. FDA should also evaluate the feasibility and reliability of utilizing state inspectors or private audit firms to review the sufficiency and implementation of these food safety plans and accompanying records on a regular basis and report their findings to FDA.

By beginning the rulemaking process now, FDA will be acting to protect public health and will begin making the shift from reaction to prevention a reality for this important sector of the food supply.

MODERNIZING FDA'S LEGISLATIVE MANDATE AND AUTHORITY

FDA's Food Protection Plan is a good start, and solving FDA's food safety funding crisis is essential, but it is equally essential that Congress modernize the food safety laws under which FDA operates. The basic provisions of the Federal Food, Drug, and Cosmetic Act under which FDA addresses the central public health problem of hazardous food contaminants and food imports were enacted in 1938, well before today's understanding of the public health importance of microbial pathogens and the globalization of the food supply that continues to accelerate.

FDA's core statutory tools consist primarily of a few broad definitions of "adulteration," authority to inspect food facilities (but not, in general, food safety records), and a set of cumbersome-to-pursue judicial enforcement tools (seizure, injunction and criminal prosecution). FDA has made creative use of its authorities to set informal action levels and other de facto performance standards and adopt the seafood HAACP rule, but there is no mandate in the law, and thus no accountability for FDA to implement, a systematic science- and risk-based program to prevent foodborne illness.

FDA should have such a mandate and, assuming adequate funding, should have clear accountability for carrying it out successfully. Otherwise, I question whether the new strategic direction presented in the Food Protection Plan will be sustained.

ORGANIZATIONALLY UNIFYING AND ELEVATING THE FDA FOOD SAFETY PROGRAM

In addition to providing a modern statutory mandate and adequate resources, Congress should ensure that FDA has an organizational framework that enables the Agency to provide national and international leadership on food safety and to run a coherent, well-planned program that makes the best use of available resources to improve food safety. For several reasons, FDA lacks such a framework.

First, within FDA, the food program has historically taken a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products and is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the Agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent appointment in the Office of the Commissioner of an Associate Commissioner for Foods reflects the Agency's awareness of the problem but does not solve it. I have great respect for Associate Commissioner David Acheson, but his position lacks budget or line authority for programs and thus in some ways further clouds responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the Nation's premier food safety program needs to have the greater clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

In my view, the solution to this structural weakness in FDA's food safety plan is to unify the food-related components of FDA into a single organization and elevate that organization within HHS under the leadership of a presidentially-appointed official reporting directly to the Secretary.

CONCLUSION

Thank you again, Mr. Chairman, for the opportunity to testify on these important issues. I look forward to answering your questions and the questions of your colleagues on the committee.

MAJOR POINTS

- I consider FDA's new Food Protection Plan, with its integrated and risk-based systems approach to preventing illness, to be moving in the right direction toward the food safety reform we need.
- FDA's ability to implement the Food Protection Plan is seriously constrained by FDA's food safety funding crisis.
- From 2003 to 2006, FDA's headquarters and field resources for food safety actually declined as the number of domestic establishments and food import entries grew significantly, leaving FDA with a weak foundation on which to build a modern,

science- and risk-based food safety program, as envisioned by the Food Protection Plan.

• I support the FDA Science Board's call for a long-term commitment to re-build FDA's science base and food safety oversight capacity both at headquarters and in the field, as well as the Science Board's specific recommendation to more than double the FDA food safety budget over a 5-year period from the current $620 million to $1.375 billion in 2013.

• FDA should move forward now, however, to begin implementing the Food Protection Plan by developing a detailed a resource plan and pursuing the following high priority actions:

o Risk-based priority setting and risk management for the most significant hazards;

o Strengthening the contribution of food safety epidemiology to prevention;

o Conducting a compliance and effectiveness audit of FDA's seafood HACCP program; and

o Targeted rulemaking on the safety of fresh produce.

• In addition to providing FDA needed resources, Congress should modernize FDA's food safety legislative mandate and direct that FDA's food safety program be unified and elevated organizationally with the Department of Health and Human Services.

Mr. STUPAK. Thank you, Professor Taylor.

Dr. Levi, if you would, please, your opening statement.

STATEMENT OF JEFFREY LEVI, PH.D., EXECUTIVE DIRECTOR, TRUST FOR AMERICA'S HEALTH

Mr. LEVI. Thank you, Chairman Stupak, Ranking Member Shimkus, and members of the Subcommittee. I appreciate the opportunity to testify before you today.

Trust for America's Health is a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We applaud the committee for continuing its thorough examination of the food safety functions at the FDA.

This hearing could not be more timely. The current outbreak of salmonella associated with tomatoes is a perfect demonstration of our need for a modernized food safety system. It shouldn't have taken so many people getting sick from salmonella poisoning for the government to start taking nationwide action to protect the American people, but it did. Not only has it taken us too long to recognize the threat, we are still struggling to find its source and we should have had systems in place to prevent it in the first place. A truly successful food safety system is one that we don't read about in the newspapers because it is working so well, but as we have seen over the last week, instead we have a system that places the lives of Americans at risk, undermines overall public confidence in our food supply and threatens the economic stability of farmers.

At the end of April, TFAH released a report entitled "Fixing Food Safety: Protecting America's Food Supply from Farm to Fork." Our report finds that food safety represents a significant public health threat. The food safety system is fragmented, depending on archaic laws, and chronically underfunded. The current system is reactive, not preventive, meaning we are wasting millions of dollars on responding to such threats rather than building proper controls into the production system.

A major investment is necessary to prepare FDA's food safety function for the 21st century marketplace. However, Congress should not provide the significant additional appropriations with-

out a clear strategy of how that money will be spent. We believe that the FDA's Food Protection Plan is a good start. The plan represents a consensus document outlining broad concepts for modernizing the food safety system, and we are very pleased that the Administration has asked for an additional $125 million for the FDA's food safety work. But increased funding must be sustained over time to allow for effective strategic planning, and before Congress acts on this request, we also believe it should know how the $125 million request is crosswalked to the protection plan and what long-term funding will be needed to implement each element of the plan.

TFAH has long been a watchdog for responsible government spending. While we advocate for a stronger investment in the public health system, we also expect accountability and transparency with respect to that investment. The FDA's food safety system should be no different. Thus, we urge FDA to articulate the steps it will take to achieve each element of the plan including the personnel, laboratory capacity, information technology and research necessary to carry out each concept in the document. FDA should regularly report to Congress and the public with measurable benchmarks, data sharing and the resources necessary to move forward with its plan.

Indeed, if the Administration is serious about modernizing the food safety system, each step of the implementation plan would carry with it a professional judgment number describing the appropriations necessary to achieve the goal, not just the legislative authority needed. We make this recommendation not simply for the sake of transparency but to strengthen FDA's argument for additional funding. There are precedents for such an approach. For example, the Administration released a national strategy for pandemic influenza along with a request for $7 billion to carry out the strategy 2 years ago. The initial strategy articulated brought concepts and principles for pandemic preparedness just as the Food Protection Plan does, but as Congress moved forward with appropriating funding for pandemic influenza preparedness, the strategy was followed by an implementation plan which contains actionable steps from multiple federal departments including interim milestones against which Congress and the public can measure progress.

In addition, several agencies within HHS are legislatively mandated to provide directly to Congress so-called bypass budgets that reflect their professional judgment of funding that is needed without having to receive OMB clearance. In fact, Dr. von Eschenbach had that experience with this process during his tenure at the National Cancer Institute. Each year, both the National Cancer Institute and the Office of AIDS Research provide Congress bypass budgets which include the resources necessary to maintain existing research and the money required to achieve specific expanded or new initiatives. The recent dance we saw leading to the formal request for an additional $125 million for the FDA's food safety work was in a way an ad hoc version of this approach. The Subcommittee may want to consider enacting a regular bypass budget for the FDA as it embarks on its important process of modernization.

Just as policymakers are attempting to transform America's healthcare system form a sick-care system to a well-care system, we must convert our food safety policy from reactive to a preventive system. The Federal Government can save money and lives by investing in technology, information networks and research. This effort will require leadership from Congress and the Administration to assure that both financial and human resources are devoted to this critical public health problem. The end result should be a safer food supply from farm to fork.

I ask that my written testimony be included in the record, and I look forward to your questions.

[The prepared statement of Mr. Levi follows:]

STATEMENT OF JEFFREY LEVI, PH.D.

SUMMARY

I am Dr. Jeffrey Levi, Executive Director of Trust for America's Health (TFAH), a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. At the end of April, TFAH released a report entitled "Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork". Our report finds the food safety system is fragmented, dependent on archaic laws, and chronically underfunded. The report can be found in its entirety at www.healthyamericans.org.

Food safety represents a significant public health threat. According to FDA's Web site, since January of this year alone, FDA has issued over 80 recalls, alerts, withdrawals, and warnings of unsafe or mislabeled food. These numbers are far too high, and major gaps in our Nation's food safety system are to blame. The current food safety system is reactive, not preventive, meaning we are wasting millions of dollars on responding to such threats rather than building proper controls into the production system. Indeed, if we had a modernized food safety system focused on prevention, we would not need to be issuing this number of alerts and recalls. That said, given the disjointedness and underfunded nature of our food safety surveillance system, we cannot be sure that the alerts and recalls issued by FDA truly even reflect the extent of the problem today.

Clearly, a profound investment is necessary to prepare FDA's food safety function for the 21st Century marketplace. However, Congress should not provide significant additional appropriations without a clear strategy showing how that money will be spent. We agree that the FDA's Food Protection Plan is a good start. However, the document lacks the specificity necessary to fund or to implement such a plan. Instead of broad principles, we urge FDA to articulate the steps it will take to achieve each element of the plan, including the personnel, laboratory capacity, information technology, and research necessary to carry out each concept in the document. FDA should regularly report to Congress and the public with measurable benchmarks, data sharing, and the resources necessary to move forward with its plan. This would not be unprecedented for this Administration: its National Strategy for Pandemic Influenza: Implementation Plan contains actionable steps for multiple federal departments to take to achieve an adequate level of preparedness, including interim milestones against which progress can be measured.

In addition to lacking detail, the Food Protection Plan remains abstract because there is no budget request associated with it. Each step of the implementation plan should carry with it a professional judgment number describing the appropriations necessary to achieve the goal. This would be similar to the bypass budgets of the National Cancer Institute and the NIH Office of AIDS Research.

Just as policymakers are attempting to transform America's healthcare system from a sick-care system to a well-care system, we must convert our food safety policies from a reactive to a preventive system. The Federal Government can save money and lives by investing in technology, information networks, and research. This effort will require leadership from Congress and the Administration to assure that both financial and human resources are devoted to this critical public health problem. The end result should be a safer food supply from farm to fork.

TESTIMONY

I am Dr. Jeffrey Levi, Executive Director of Trust for America's Health (TFAH). Trust for America's Health is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We applaud the Committee for continuing its thorough examination of the food safety functions at the Food and Drug Administration (FDA). At the end of April, TFAH released a report entitled "Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork". As we know, recent tragedies have shed a light on glaring gaps in the Nation's federal food safety system, but we now have the opportunity to build a better system for the future. My comments today will discuss the report's findings as well as additional concerns we have with the current food safety system. The report can be found in its entirety at www.healthyamericans.org.

Food safety represents a significant public health threat. One in four Americans is sickened by foodborne disease each year, and an estimated $44 billion is lost each year in medical and lost productivity costs. According to FDA's website, since January of this year alone, FDA has issued over 80 recalls, alerts, withdrawals, and warnings of unsafe or mislabeled food. These numbers are far too high, and major gaps in our Nation's food safety system are to blame. Indeed, if we had a modernized food safety system focused on prevention, we would not need to be issuing this number of alerts and recalls. That said, given the disjointedness and underfunded nature of our food safety surveillance system, we cannot be sure that the alerts and recalls issued by FDA truly even reflect the extent of the problem today.

The public is deeply concerned about this issue. A 2007 public opinion poll conducted on behalf of TFAH found that 67 percent of Americans are worried about food safety. This number ranked above the threat of pandemic flu or natural disasters, illustrating just how strongly food safety truly touches every American. The food supply is vulnerable to a variety of pathogens, toxic metals, and other pollutants, product tampering, and emerging diseases. The current food safety system is reactive, not preventive, meaning we are wasting millions of dollars on responding to such threats rather than building proper controls into the production system.

TFAH's report identifies several problems with the government's food safety system: inadequate federal leadership, coordination and resources; outdated laws and policies; and inadequate Federal, State and local collaboration.

INADEQUATE FEDERAL LEADERSHIP, COORDINATION AND RESOURCES

The Federal food safety system is fragmented. According to the 2007 GAO report, there are 15 agencies collectively administering over 30 laws. Even among lead agencies, the government's ability to prevent illness is undermined by the segmented responsibilities among many agencies, which often use differing regulatory approaches. No agency has statutory authority to forge an integrated strategy, and no agency or person has final authority over food safety. This results in overlapping inspections by FDA and USDA's Food Safety and Inspection Service (FSIS) and food companies having to follow different regulations from each agency within the same plant. Clearly, FDA could use its resources better through increased collaboration and coordination with USDA.

The current system is not just fragmented, but also experiences misaligned priorities and resources. FDA regulates 80 percent of the U.S. food supply, and an estimated 85 percent of known foodborne outbreaks are associated with FDA-regulated food. However, FDA receives less than 40 percent of the overall federal dollars devoted to food safety programs. In addition, funding for food safety programs at FDA and FSIS has barely kept pace with inflation. Even as these agencies must take on new challenges, such as those laid out in the FDA Food Protection Plan, they are barely able to pay for their existing food safety system.

Furthermore, within both FDA and USDA, food safety is not the top priority. At FDA, pharmaceuticals and medical devices—the "drug" part of the Food and Drug Administration—receive priority attention. At USDA the focus is on promoting U.S. farm commodities abroad and helping farmers and agribusiness at home.

We agree with the Science Board's assessment that weaknesses in the FDA's food safety function are directly related to its inadequate resources. Trust for America's Health recommends at least doubling FDA's food budget in real terms over the next 5 years. The need for additional appropriations has been echoed by the National Academy of Sciences Institute of Medicine, the Government Accountability Office, and the Health and Human Services Inspector General. TFAH believes FDA needs a consistent source of funding to keep up with its mandate. We were pleased to see additional food safety money in the Senate's supplemental, but appropriators should

bear in mind that increased funding should be rolled into baseline appropriations in FY 2010, rather than returning to previous funding levels. It is nearly impossible for the Agency to adequately plan and hire full-time staff if it is unclear whether money will be stable from year to year.

In addition to funding, FDA needs to ramp up its personnel levels. According to former FDA Commissioner Mark McClellan, the President's FY 2009 budget "does little to make up for the steady loss of staffing that the Agency has endured for the past decade." We were pleased that FDA recently announced plans to hire 1,300 science and medical staff, including 600 new positions, and we are eager to see how they are used to implement the FDA's Food Protection Plan. However, given the broad consensus among experts who doubt the FDA's ability to fulfill even its existing food safety mandate given current funding levels, we are reluctant to view this announcement as an end to the Agency's problems.

OUTDATED LAWS AND POLICIES

Increased funding for food safety is a start. But our report notes that the Federal Government is spending existing funds on outdated, inefficient practices. TFAH has long been an advocate for accountability within the public health system, and the federal food safety system is an example of misallocated funds due to adherence to an archaic framework. The USDA's FSIS spends most of its resources visually inspecting every beef, pork, and poultry carcass in ways not too different from practices used 100 years ago, although the health of animals has greatly improved and most foodborne illnesses cannot be detected visually. Likewise, FDA's food safety statutes date to 1906 and 1938. FDA's law developed a system that is reactive to problems prevalent in early 20th Century food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur.

Our report finds that Congress has not provided the Agency with a modern, public health mandate to prevent foodborne illness; has not updated the Agency's legal tools to meet the challenges of a high-tech, globalized food supply; nor has it provided the funding stream necessary to carry out research and inspection.

America's food supply faces new threats, and the safety system needs to reflect changes in the market. A 21st Century production and distribution system means that instead of a single contaminated head of lettuce affecting one family, that lettuce may be divided among a dozen prepackaged bags of salad shipped across the country. The centralization of agribusiness means there is significant contact between livestock and crops, which can lead to a single infected product causing pervasive damage.

Deliberate contamination of the food supply for economic or terroristic reasons could also have a widespread, devastating impact on the Nation before the Federal Government even has time to react. We saw this in 2007 when imported pet food killed thousands of cats and dogs in the United States after being deliberately contaminated with melamine for economic profits. It is not science fiction to believe such action could occur again, with malicious intent. The Administration's Homeland Security Presidential Directive 9 called for a coordinated national approach to deliberate threats to the food supply. HSPD–9 tasked the Department of Homeland Security to work with USDA, HHS, and EPA to coordinate a national response, but FDA has not received additional funding and USDA has received only additional $150 million. FDA needs more authority to implement measures against agroterrorism, including increased surveillance.

INADEQUATE FEDERAL, STATE, AND LOCAL COLLABORATION

The existing governmental food safety system is decentralized, so state and local departments have authority that extends beyond federal jurisdiction. State and local health departments are the frontlines in the fight against unsafe food, as they investigate outbreaks, inspect restaurants, and coordinate communication up the chain. The vast majority of foodborne diseases are detected and investigated at the local level. Yet, the capacity of states to conduct appropriate safety surveillance and communicate that back to the Federal Government varies dramatically. Federal support (through the CDC) for such critical state activities is minimal. In a 21st Century food economy, outbreaks are not limited to one state; early detection of what could become a national problem is dependent on the capacity of the state with the weakest surveillance system.

The relationship between Federal and State regulators is also not well defined, so jurisdiction and communication may be hindered. In addition to a lack of resources to quickly respond to outbreaks, there are no mandatory national standards for state and local governments to adopt in their communities. Instead, most states

adhere to voluntary standards such as the FDA's Food Code, a model to assist governments in regulating the retail and food service industry. Although these standards are updated every other year, the vast majority of states have not adopted the most recent guidelines. The Voluntary National Retail Food Regulatory Program is another voluntary guideline for states to develop science-based measures of performance that will lead to more effective and uniform regulation of the food industry. Only 12 states have fully enrolled and achieved verification by external evaluators of the program. TFAH recommends creating uniform standards and practices across the federal, state, and local levels. States should be encouraged and incentivized to adopt and comply with uniform standards of the most recent FDA Food Code and the National Retail Food Regulatory Program.

The systems used to monitor food disease outbreaks are also a patchwork of various government agencies at the federal, state, and local level working largely independently with limited coordination. Government surveillance, or detection of foodborne diseases, exists alongside food safety practitioners from the private sector, public interest groups, and academia. As Michael Taylor, former FDA Deputy Commissioner for Policy, addressed in his recent report on the Food Safety Information Infrastructure, these data sources remain isolated, without the legal, logistical, or cultural means to share information. At a recent congressional briefing hosted by TFAH, Dr. Tim Jones, state epidemiologist for Tennessee, noted that communication of hazards is highly variable among states, which often lack the personnel, technology, and data sharing systems to react quickly to detected outbreaks. TFAH contends that a person's protection from disease should not depend on where he or she lives, and the fragmented food surveillance system is an example of such disparity.

OPPORTUNITIES FOR MODERNIZATION

TFAH believes that we need a comprehensive approach to update and strengthen the Federal food safety system. The institution of Hazard Analysis and Critical Control Points (HACCP) is a good example of a promising approach to modernization within FDA and FSIS. Such a system first requires companies to identify potential hazards and critical control points throughout the production process, and then establish preventive procedures to monitor and ensure those hazards are avoided. However, FDA has not implemented HACCP across the food production chain, and where it exists in many cases it is only on a voluntary basis. Widespread implementation of HACCP and other preventive systems could save money in the long run by identifying potential problems before they occur.

Imported food presents a new, troubling frontier for food safety. Fifteen percent of the food we eat is imported, including 60 percent of produce and 75 percent of seafood. Yet, only 1 percent of shipments are inspected by the FDA each year. The Administration released the Import Safety Action Plan and the Food Protection Plan in November. These plans called for working with foreign governments to ensure compliance with U.S. safety standards, but as Mr. Taylor notes in our report, the FDA does not have the resources to ensure the safety of imports without harnessing the expertise and resources of the private sector. In addition to providing resources for implementing the Import Safety Action Plan and the Food Protection Plan, Congress should require food importers to be legally accountable for assuring that foreign producers are shipping goods to the U.S. that meet U.S. food safety standards.

As mentioned earlier, surveillance is a key component to identifying foodborne outbreaks. Congress can support this mission through removing legal restrictions on data sharing, mandating coordinated data collection among government agencies, and improving the collection of and accessibility to data. Data collection and improving networks among all actors, including private sector and academia, is critical to mitigate the effects of unsafe food. TFAH recommends government food safety officials and food companies should be given the tools to keep track of information about disease outbreaks in humans, plants, and animals and results of food inspections so they can quickly detect and contain problems. CDC's surveillance program should also be able to function in a way that not only monitors outbreaks and investigates preventive strategies, but also provides accountability to gauge how well U.S. food safety systems are working.

In order to develop a dynamic, evolving food safety system, greater investment in research is a prerequisite. Ongoing research is needed to identify emerging threats and up-to-date ways to contain them, as well as to rank relative risks and the health impacts of those hazards. The FDA Food Protection Plan echoes the need to strengthen the Agency's research capacity, but the document does not clarify how it will implement the mission or how it will work with other federal agencies to coordinate a research agenda. As the Science Board report tells us, FDA does not have the funding to conduct its existing research requirements and lacks a clear vision

of new areas of research needed. Funding and planning are vital to carrying out a modern research program, which should serve as a basis for FDA's regulatory framework.

PLANNING AND RESOURCES

Clearly, a profound investment is necessary to prepare FDA's food safety function for the 21st Century marketplace. However, Congress should not provide significant additional appropriations without a clear strategy of how that money will be spent. We agree that the Food Protection Plan is a good start. The Plan represents a consensus document, outlining broad concepts for modernizing the food safety system. However, it lacks the specificity necessary to fund or to implement such a plan. TFAH has long been a watchdog for responsible government spending. While we advocate for a stronger investment in the public health system, all of our reports insist on accountability and transparency with respect to that investment. FDA's food safety system should be no different. Before Congress appropriates significant funds to modernize the food regulatory system, FDA must demonstrate exactly how it intends to spend those funds. Instead of broad principles, we urge FDA to articulate the steps it will take to achieve each element of the plan, including the personnel, laboratory capacity, information technology, and research necessary to carry out each concept in the document. FDA should regularly report to Congress and the public with measurable benchmarks, data sharing, and the resources necessary to move forward with its plan.

In addition to lacking detail, the Food Protection Plan remains abstract because there is no budget request associated with it. If the Administration is serious about modernizing the food safety system, each step of the implementation plan should carry with it a professional judgment number describing the appropriations necessary to achieve the goal. We make this recommendation not simply for the sake of transparency, but to strengthen FDA's argument for additional funding. As an example, the Administration released a National Strategy for Pandemic Influenza along with a request for $7 billion to carry out the strategy. The initial strategy articulated broad concepts and principles for pandemic preparedness, just as the Food Protection Plan does. But as Congress moved forward with appropriating funding for pandemic influenza preparedness, the strategy was followed by an Implementation Plan, which contains actionable steps for multiple federal departments to take to achieve an adequate level of preparedness, including interim milestones against which Congress and the public could measure progress. The implementation plan gave credence to the President's funding request.

Developing a comprehensive strategic plan with a corresponding budget request is not a novel concept. Several agencies within HHS are legislatively mandated to provide Congress with so-called by-pass budgets that reflect their professional judgment of funding that is needed without having to receive OMB clearance. In fact, Dr. von Eschenbach had experience with this process during his tenure with National Cancer Institute. Each year, both the National Cancer Institute and the Office of AIDS Research provide Congress and the President with their annual budgets, which include the resources necessary to maintain existing research and the money required to achieve specific expanded or new initiatives. The Subcommittee may want to consider enacting a similar mandate for the FDA as it embarks on this important process of modernization.

CONCLUSION

Just as policymakers are attempting to transform America's healthcare system from a sick-care system to a well-care system, we must convert our food safety policies from a reactive to a preventive system. The Federal Government can save money and lives by investing in technology, information networks, and research. This effort will require leadership from Congress and the Administration to assure that both financial and human resources are devoted to this critical public health problem. The end result should be a safer food supply from farm to fork.

Mr. STUPAK. Thank you, Doctor. Your written statement, as all written statements, will be part of the record.

I will begin with questions. We will go 5 minutes so we can move the rounds along here. Let me ask you this question. We have all touched on it today, the tomato, salmonella in the tomatoes. If you take a look at the timeline, mid-April, people started getting sick

from tomatoes. On June 3, the FDA issued its first warning in the States of New Mexico and Florida for certain types of tomatoes. On June 7, the FDA put out its warning nationwide for certain types of tomatoes. And we know it is the first year anniversary of the FDA's Tomato Safety Initiative. Why hasn't this initiative worked to stop the salmonella in tomatoes if we knew it was a problem, we implemented a plan a year ago, but here we are, a year later, having nationwide warning? Anyone care to tackle that? Professor Taylor.

Mr. TAYLOR. Well, I will put the answer to that question in an even broader context. We knew 10 years ago that there was a significant increase in outbreaks associated with fresh produce. FDA put in place a so-called guidance for good agricultural practices, which was a worthy thing to do at the time. It reflected what was known at the time but it was very broad guidance. It said pay attention to microbial quality of the water but there were no standards or criteria for what is appropriate microbial quality of the water that is used in irrigation and other risk factors were addressed only in these very broad sort of terms. A properly funded and mandated FDA would have had a leadership responsibility and the resources behind it to drive the research and develop the criteria, to set the standards that should have been in place long ago to ensure the safe production of tomatoes and other fresh produce on the farm. So I think the tomato safety plan was another effort with the best information available but it was not linked with the focused research base and the scientific knowledge needed, coupled with an actual regulatory intervention to create accountability for implementing these control measures.

Mr. STUPAK. But this safety initiative would also have to be initiated not just here in this country but also like Mexico and other places where we import tomatoes, would it not? It doesn't make any sense to have a tomato initiative just confined to the domestically produced crop but would have to be for imports too, would it not?

Mr. TAYLOR. Absolutely. I think there is wide agreement that as we put in preventive control requirements and measure domestically, we have to make importers accountable for ensuring that the imported product meets those standards. It should be a condition of entry into the United States because it demonstrated compliance with the same preventive control measures in foreign fields as we would expect to have in U.S. fields.

Mr. STUPAK. Dr. Morris?

Dr. MORRIS. Just to add, again, I think what the tomato outbreak points out is the difficulty of being purely in a reactive mode, and I am highly sympathetic with FDA, having been in similar positions in government. It is extremely difficult to do these trace-backs, but having said that, the whole point of this is to put in place a system where we don't have to do the trace-backs.

Mr. STUPAK. Sure. Wouldn't the year-ago tomato initiative make us proactive or preventive, not reactive? I mean, reactive, we still don't even know where the tomatoes are coming from.

Dr. MORRIS. Exactly.

Mr. STUPAK. Let me ask you this. This is the report we have all referred to, the Food Protection Plan, put forth by the FDA last No-

vember, and then the request for $50 million to implement it. Dr. Levi, I take it that the newest request that came Monday, which was $125 million, you would not give even the $125 million based on this report. What else would you look for before Congress would just throw money at a situation?

Mr. LEVI. Well, I would be loathe to say don't give them the money. I would say that there is enough opportunity in the appropriations process to do a back-and-forth to get a lot more specificity associated with the spending of this money but——

Mr. STUPAK. What specificity would you like to see in that report?

Mr. LEVI. I would want to see dollar figures associated with each element of the report, and I think we have heard from others here that even that money, the $125 million, may not be sufficient, but we can't really judge what is missing and what we are going to get for that $125 million until that request is crosswalked to the protection plan. If the Administration says this money is to implement the plan, they should at least be able to tell us what parts of the plan we are buying with $125 million.

Mr. STUPAK. Professor Taylor, we will go right down the line.

Mr. TAYLOR. I just want to add that it is a matter of priorities and sequence of activities. Those 38 very significant actions can't all be done at once. They shouldn't all be done at once. FDA should identify what are the priority things needed to get this process going. I suggested a few in my testimony. There may be better ones that that but it is a matter of priorities and sequence.

Mr. STUPAK. Dr. Morris?

Dr. MORRIS. And I would also, as I noted in my testimony, the $128 estimate from the Science Board subcommittee is a very loose estimate. I mean, essentially it is a starting point and a ballpark figure, and there is clearly a need to link this with specifics because that is going to drive what the real costs are.

Mr. STUPAK. Dr. Cassell?

Ms. CASSELL. I don't have anything to add. I like Glenn said it——

Mr. STUPAK. OK. Now, on that $125 million they asked for on Monday night, that does not include any IT, which would certainly help us try to figure out where tomatoes are coming from. Ms. Shames, would you like to comment on that? What would you like to see? And GAO has been very critical of it. What would you like to see in that Food Protection Plan?

Ms. SHAMES. The Food Protection Plan really is the rudiments of a strategic plan, and there is a statutory precedent for the sort of information that Congress has asked for from executive agencies to do the oversight that is needed. Information should include the long-term goals, which are laid out in terms of the core elements in the Food Protection Plan. But then beyond that, we would want those long-term goals to be segmented into interim goals and with those interim goals to know exactly what the associated resources are in terms of dollars, in terms of people, in terms of technology.

Mr. STUPAK. You said long-term goals. This report, I get the impression there is no limit, no time. What kind of plan——

Ms. SHAMES. There is no——

Mr. STUPAK. A 1-year, 3-year, 5-year plan? What should it be?

Ms. SHAMES. There is no stated time frame to the plan. You are right about that. We have been told that it is envisioned to be a 5-year plan.

Mr. STUPAK. My time is up. I will turn to Mr. Shimkus.

Mr. SHIMKUS. Thank you.

Mr. STUPAK. Wait a minute. Dr. Cassell had her hand up. If it is a 5-year plan, we should at least have 5 years worth of data, should we not, and budget requests, Dr. Cassell?

Ms. CASSELL. I personally would like to know more about the technologies that will be applied and the plan to ensure that in fact there is professional development of those individuals responsible for food safety, getting back to our original report, so that we can always be sure they are on the cutting edge and are aware of emerging new technologies.

Mr. STUPAK. Thank you.

Mr. Shimkus, please.

Mr. SHIMKUS. Thank you, Mr. Chairman. Reforming a federal bureaucracy is a difficult challenge. It doesn't have the market forces of bankruptcy and so that is an inherent challenge.

I want to focus on some broad issues. You know, this is really a lot of specificity that to the layman is touch. That is why you are here and I appreciate it. All you mentioned a focus on risk-based approach. I think everyone mentioned the importance of doing that. We are in discussions on an FDA authorization bill, and there is still not acceptance that a risk-based approach is an appropriate way to go because I think there are feelings from some of my friends on the other side that this means going soft on industry. Can some of you chime in on that? I don't believe it is true. I think it is a cost-benefit way of identifying problems, but just respond to that concern. Go ahead, sir.

Mr. TAYLOR. I think it is very important to distinguish between the industry role in food safety and the government role, and when we talk about a risk-based approach, it is not about going soft on industry's duty to ensure that every product that they market meets safety standards. And in fact, the proposals to require every food facility to have a preventive control plan stands for the idea that every company should be sure that they have got a plan in place to meet standards. Regardless of whether it is a high-risk product or a low-risk product, everybody should have a preventive food safety plan. When we use the term risk-based effort by the government, we are really talking about how the government can then deploy its resources, whether they are inspection resources or research or new rulemaking, standard setting. ow does the government deploy its inherently finite resources to address the most significant hazards in the food supply and mount the preventive initiative that do often require government initiatives. So it is risk based in terms of priority setting and use of government resources and targeting those significant hazards that are out there that we know about and that require a concerted effort to address through research, technological innovation, standard setting, education, whatever the appropriate tool might be.

Mr. SHIMKUS. Anyone else want to—Ms. Shames.

Ms. SHAMES. The government and FDA in particular can only afford a risk-based approach to its inspections. For example, if FDA

were to inspect every single domestic facility dealing with food, it would come to over $500 million. That figure is astounding. If FDA were to inspect every foreign facility, it would come to over $3 billion.

Mr. SHIMKUS. I have tried to raise this in some of my discussions. If you have good actors who have zero defects across their whole product line, it doesn't make sense to be in there twice a year and focus those resources and maybe go to once a year but that is kind of—Dr. Morris, do you want to add something?

Dr. MORRIS. Just to further expand on this idea, one cannot inspect safety into a product, and you can't inspect every single thing that goes by, every single apple. Again, the concept is to create a preventive system that minimizes the risk, puts in place multiple hurdles to minimize risk. But again, you come back to, what is the government's role, and the government needs to target its role so that it hits the areas where there is the greatest risk of occurrence of human disease. And again, this is where some of the difficulties arise and that ultimately our goal is to keep people from getting sick, but to figure out how to put in place a plan that minimizes the risk for human disease is difficult and it requires some science, it requires some work, and it requires some resources to be able to do that, and that is where the vision gets cloudy. To be able to really do what needs to be done to appropriately prioritize resources, government resources, to maximize the impact of government to be able, you know, to get the safest possible product.

Mr. SHIMKUS. Because we are a reactive body, especially even on a 1-year spending budgetary cycle, would a 2-year budgetary cycle be helpful in this whole reform debate? I will just allow anybody that wants to—Dr. Taylor.

Mr. TAYLOR. Anything that can be done to extend the planning horizon and planning of use of resources is to the good, so——

Mr. SHIMKUS. Yes, the idea is, you pass a budget for 2 years, and the second year you use to do oversight and investigation and do evaluation. If you are every year fighting on just the spending end—because I look at this. You look at, this is a chicken and the egg debate. We have a plan, then we have to fund, then we have to execute, then we have to evaluate through the execution process and then we have to revise, and you can't do that if you are limited by a 1-year budgetary cycle.

Mr. LEVI. I also think it is important to keep in mind that a lot of the problem at FDA is personnel, that they need more scientists to do the work, and if there is not predictability for funding, then it is very hard to recruit scientists to come and work there because they don't know whether they are going to have a job from one year to the next, and I think that is also the challenge with focusing on a supplemental. We should get as much money as we can into the supplemental but that is even more unpredictable, especially if for fiscal 2009 we are at least starting probably all predictions are for a continuing resolution and that creates even more instability and uncertainty and makes the hiring process that much more difficult.

Mr. SHIMKUS. And I appreciate that comment, because I did have a question on this whole staffing issue and where it is good to get the additional money but there is uncertainty there, and Mr.

Chairman, that is all I have because you answered the question, Dr. Levi. Thank you.

Mr. STUPAK. Thank you, Mr. Shimkus.

Ms. DeGette for questions, please.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Well, I have been looking at this plan, and it has happened before when I have looked at agency plans, it seems to me to be more of an idea than a plan, because in reading it, principles of the plan focus on risk, target resources, address both unintentional and deliberate contamination and use science. Well, I think this is what most of you are saying. We all support those hortatory goals but my question is, how do we get from point A to point B? So I am wondering if very briefly, starting with Ms. Shames, you could maybe give us two or three ideas, and one of them you have already testified, many of you, about, is put specific price tags on specific portions of the so-called plan. I am wondering if there are a couple of other specific suggestions you can make as to what we can do to make this dream a real plan. Ms. Shames?

Ms. SHAMES. We testified in January that many of their proposals were consistent with the recommendations that GAO had made, so I would say that that would be a starting point in terms of FDA's priorities to take.

Ms. DEGETTE. The GAO recommendations?

Ms. SHAMES. Exactly.

Ms. DEGETTE. Thanks.

Dr. Cassell?

Ms. CASSELL. It all goes back to having the right people with the right skills, and quite honestly, I believe that the CFSAN and CVM have been so underfunded in the area of research, as I pointed out, now for over a decade as well as their overall funding. Personally, I don't think they have the right set of people with the right skills to maybe——

Ms. DEGETTE. And what could we do to help that to happen?

Ms. CASSELL. I think to immediately request the supplemental funding and then hold the feet to the fire in terms of getting more specificity around the plan and to also guard against the possibility that you wouldn't have recurring funding so that you will have difficulty recruiting the individuals.

Ms. DEGETTE. Dr. Morris?

Dr. MORRIS. I would strongly concur with Dr. Cassell's statement. I would also add though that one also needs the expertise at the top levels of management to really understand how to approach these problems. If you really want to get concrete with some of this, to my mind the top priority is to identify what the problem areas are. We have to have good surveillance. Right at the moment, FDA surveillance is woefully inadequate. We don't even know what our problems are out there. We can't really identify what the major products are that are creating problems, where the pathogens are. There is just—there is a significant lack of knowledge, and in particular when we compare our knowledge base with the knowledge base of what is present in Europe, for example——

Ms. DEGETTE. Dr. Morris, I am sorry to cut you off. I have a very limited amount of time.

Dr. MORRIS. Certainly.

Ms. DEGETTE. And now we have a vote on the Floor.

Professor Taylor?

Mr. TAYLOR. I can be quick because I agree on the capacity points and also very much agree on the need for information, to know what the problems are and to know what the preventive solutions are, but then it is a matter of acting, and again, I think there are hazards out there, whether it is imported seafood or produce, where it is time to act to put in place preventive controls. Congress can legislate to make that easier. FDA has some authority. We should get action on that front.

Ms. DEGETTE. Thank you.

Doctor, is it Levi or Levi?

Mr. LEVI. Levi.

Ms. DEGETTE. Levi.

Mr. LEVI. And I will be brief as well. I agree with my colleagues. Long-term funding for people, for technology, and give the FDA the authority that we want them to have so that they can really create a modernized system.

Ms. DEGETTE. Now, Dr. Levi, one of the things that the FDA has said is they can't talk about a multi-year plan because of statutory limitations, but in your testimony, you noted that in your oral and written testimony you said that we did exactly that with the pandemic flu plan. Do you see any barriers in doing it with food safety as well?

Mr. LEVI. Absolutely not. I mean, it is a policy choice on the part of the Administration to project out into the future. They were able to do it for pandemic flu, and Congress actually did it in a way that provided almost $7 billion so that it could be carried out as milestones were reached. It is a very similar scientific challenge that you can only move just so fast because you have certain milestones that need to be reached before you can take the next step and invest the next set of money.

Ms. DEGETTE. OK. I have one last question and 18 seconds. My question is, maybe for you and also Professor Taylor, do we have the technology right now in private industry to start exploring a food traceability system?

Mr. LEVI. I am not an expert on that.

Ms. DEGETTE. Maybe Professor Taylor?

Mr. TAYLOR. Yes. I mean, when the market creates an incentive, industry has plenty of technology available to implement traceability. There are economic issues but again, that picture is changing as well see the impact of some of the problems where we don't have traceability and the ability to——

Ms. DEGETTE. It costs money to do traceability but it costs a lot more money not to have any tomatoes being distributed, correct?

Mr. TAYLOR. Absolutely. The market can compel it or you can compel it, you know. It could go either way if the capacity is there.

Dr. MORRIS. If I could make the point again that perhaps rather than investing large sums in traceability, if we put the money in prevention.

Ms. DEGETTE. Well, I actually think——

Dr. MORRIS. Both are important.

Ms. DEGETTE. I actually think both are important. I completely agree with you that you are. That is why I also support mandatory

recall because I don't really want to have to do mandatory recall, but I think it holds a hammer over the head and——

Dr. MORRIS. We need both.

Ms. DEGETTE. They both work hand in hand. Dr. Cassell?

Ms. CASSELL. I don't want to frighten you but I do want you to appreciate that I believe we have the technologies today to apply to be able to detect parasitic and viral infections that are foodborne that we are not yet even screening for, and this is something that the new technologies, the new expertise would bring to bear, but I am quite honestly not convinced we are doing it, and that is what frightens me the most.

Ms. DEGETTE. Dr. Cassell, if you are in this job long enough, nothing frightens you anymore. You just expect the worst. Thank you very much.

Mr. STUPAK. Well, thank you. We have five votes on the Floor. We are going to recess until 12:30. I am going to ask this panel if they can stay. I know Mr. Doyle and others were here and wanted to ask questions. I know we may go another round because it is a very good panel.

Thank you. We are in recess until 12:30.

[Recess.]

Mr. STUPAK. I call the Subcommittee back to order. A couple of members are going to come back for questions. I have a few more and then we will go back and forth, see who shows up.

Let me ask Ms. Shames, let me ask you, if I may, you say on, I believe it is page 10 of your report, since 2004, 4 years, the GAO has been asking or made specific recommendations back in 2004 for the FDA to implement a strategy for food safety and 7 of those 34 have been implemented, and part of it was improving monitoring, enforcement processes. And there were 21 recommendations you made with three of them being implemented or about 14 percent. If you take the 34 and seven of them have been implemented, that is about 20 percent. It has been 4 years. Why haven't the other 80 been implemented, or 80 percent of them, I should say, the other 27. Any idea?

Ms. SHAMES. Most of them FDA has started to take some initial steps but I think that is a very good question. I don't have an answer for you.

Mr. STUPAK. Back in 1998, the GAO also recommended, highly recommended, in fact, very forcefully recommended that the IT at FDA be improved upon. Have any recommendations from 1998, 10 years ago, been implemented to bring the IT into compliance?

Ms. SHAMES. There are others back at GAO who can talk more knowledgably about FDA's IT system. I do know, of course, that if they are going to undertake a risk-based approach, data is absolutely important. Data are underpinnings to be able to make those priority decisions, and of course, IT systems would be absolutely necessary for that.

Mr. STUPAK. And I think we established this earlier, but the extra money that Secretary Leavitt and Commissioner von Eschenbach asked for Monday night did not include any money for IT, for information technology. Is that correct?

Ms. SHAMES. That is the way we understand it, yes.

Ms. STUPAK. You also note in your testimony that while FDA's Food Protection Plan recognizes the need to partner with Congress to obtain 10 additional statutory authorities to transform the safety of the Nation's food supply, you say, "FDA's congressional outreach strategy is general." What do you mean when you say that their outreach strategy is general?

Ms. SHAMES. What we mean is that we would expect that FDA would know best the impediments that it has to conduct its regulatory authority. It would be presumptive on FDA to outreach to the Hill, to be able to provide draft legislation, to provide other technical assistance, to more proactively undertake to get the tools that FDA needs to be able to meet its mission.

Mr. STUPAK. In other words, they need the legislative language to implement part of this?

Ms. SHAMES. I would say that that would be one thing that they would do, yes.

Mr. STUPAK. Professor Taylor, if I may, on page 13 of your testimony you say, "Over a year ago, the United Fresh Produce Association and Produce Marketing Association called on the FDA to establish produce safety standards that are federally mandated, risk-based and allow for commodity-specific regulation." Did the FDA ever work with the produce associations to put forth this risk-based alternative?

Mr. TAYLOR. My understanding is that there was work done within FDA to develop ideas for beginning that rulemaking, and I must say, I rely on press reports for my knowledge of the process but that effort was rebuffed in the Office of the Secretary so that a decision was made that at a level above FDA within the department not to proceed with that rulemaking.

Mr. STUPAK. So the fresh produce producers said let us do something and it is your understanding they went to the FDA, the FDA thought it was a good idea but the Secretary, that would be the Secretary of HHS then, rebuffed the idea?

Mr. TAYLOR. That is my understanding.

Mr. STUPAK. On page 16, you say on the bottom of page 16, "I have great respect for Associate Commissioner David Acheson, but his position lacks budget or line authority for programs and thus in some way further clouds responsibility and accountability for food safety within FDA." Is that your assessment of the food czar situation now?

Mr. TAYLOR. Well, yes, I think that creating that position was an effort to recognize that food safety and responsibility for it is lodged in multiple components of FDA. There is a Center for Food Safety and Applied Nutrition, which people think is the lead agency. There is also the Center for Veterinary Medicine, which has significant food safety responsibilities. And then the Office of Regulatory Affairs at FDA, which manages the field functions, all the inspectors, and the laboratories, and actually consumes the majority of resources that are labeled food safety resources at FDA. All three of those major components are managed separately. They report to the Commissioner but the Commissioner has more than one full-time job looking after the drug supply and the medical product side of the Agency, and so we have got a institution where food safety leadership is fragmented internally, and I think the effort to coordi-

nate out of the Commissioner's office, which Dr. Acheson has been asked to do, is a worthy step, but anyone who has run a government program knows that if you don't have line authority and resource allocation authority over the programs you are expected to coordinate; coordination is a very difficult thing. Management is what is necessary and the leadership that comes with the actual tools of leadership and management.

Mr. STUPAK. So the food czar should really have direct authority, budgetary and line authority over veterinary and the Office of Regulatory Affairs?

Mr. TAYLOR. I mean, my view is that these elements of FDA ought to be unified into a single functioning entity that is responsible for the food side of FDA's jurisdiction, and with direct accountability to a single person who is in charge of food safety at FDA and has that as their full-time responsibility and can manage all the resources of FDA to do food safety.

Mr. STUPAK. I see a lot of nodding of heads. Does anybody else want to comment on that? Dr. Cassell, Dr. Morris, Dr. Levi, Ms. Shames?

Dr. MORRIS. I would just strongly second the need for this type of authority. From a scientific standpoint, one of the major problems that arises is the lack of coordination among the agencies, and having a single line authority is absolutely critical. We are just not getting anywhere because there isn't that. I will say there is a larger problem and that there is further dissemination of responsibility in USDA and CDC, but that goes beyond what we are talking about today.

Mr. STUPAK. Dr. Cassell, would you care to comment?

Ms. CASSELL. I was actually just going to refer back to one of the other comments that you asked. I don't want to be misleading. It is possible that maybe FDA in their request and the Secretary in his request, in their $275 million, were thinking that they would apply monies from that for IT. What we estimated is that $128 million would be needed for food safety, an additional $75 million for IT and an additional $172 million for drug safety and also to address the emerging science issue and the management issues. So I just didn't want to mislead anybody. I don't know what their intentions were but clearly, in our opinion, it would not address all of the needs that are as critical that need to be addressed.

Mr. STUPAK. Right. In the June 9th request for the additional money, it was $125 million protecting America's food supply, $100 million safer drugs, devices, and biologics, and $50 million, modernizing FDA's science and workforce. I didn't see any breakdown for IT so that is why I was asking the question. Thank you.

Mr. Shimkus for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Ms. Shames, there is a briefing binder. Dr. Morris, I think it is in front of you, not the Science Board one but—because I want to refer to tab 11 to begin with, and tab 11 has the business case paper for the Food Protection Plan. Have you seen this or reviewed this?

Ms. SHAMES. Yes.

Mr. SHIMKUS. What information do you feel is lacking in this document that Congress would need to evaluate FDA's justification for spending this money?

Ms. SHAMES. This is the information that was released with the President's budget in February of this year, and it does describe what FDA intends to do with the $42 million for this fiscal year, but beyond that, what we are looking for—and there is a statutory model for it—is to lay out over, let us say, a 5-year period, just what the long-term goals are for food safety, break those long-term goals down into interim goals, and to be able then to discuss the associated resource needs for both the interim goals and the long-term goals. And resource needs should be considered very broadly—dollars, people, technology, in other words, everything that is brought to bear to be able to accomplish that. That really is the minimum information, but under the Government Performance and Results Act, departments are to provide more information. What are the external factors, for example, that they identify that could somehow impede accomplishing their goals. And likewise, there is call for evaluations. If you haven't achieved your goals, why not? Conduct some sort of formal evaluation to show that.

Mr. SHIMKUS. And Dr. Levi, in the pandemic influenza thing, is that similar to the approach that we did with that, and that is—does that sound——

Mr. LEVI. The pandemic strategic plan, implementation plan actually does agency across the government agency by agency 6-month, 12-month, 18-month, 2-year, 3-year goals for a variety of activities.

Mr. SHIMKUS. So we are saying that is a good model to move in this direction?

Mr. LEVI. Yes.

Mr. SHIMKUS. Let us go back to the briefing binder, Ms. Shames, on tab 10, 5 pages in, which is number 2, there is a quote, "Use enhanced modeling capability, scientific data and technical expertise to evaluate and prioritize relative risk." From your information, do you know what this will cost to achieve or when the Agency will accomplish this task?

Ms. SHAMES. Certainly not from this information. Now, we have received some internal documents that provide a little more detail on some of the deliverables associated with the strategic components, but there is nothing more publicly available.

Mr. SHIMKUS. Should this be public?

Ms. SHAMES. Yes, we believe that this sort of public reporting is useful for congressional oversight, reassures the public, especially at a time like this when there is a food outbreak. Public reporting, I think is a very healthy thing.

Mr. SHIMKUS. It is transparent. People can evaluate and hold people accountable based upon the standards established, and I would agree with that. I am going backwards, sorry, but tab 7 now, which is a letter from Commissioner von Eschenbach to Senator Arlen Specter. We kind of talked about it today in some opening statements. He stated in his professional judgment that FDA needs the $275 million immediately to accelerate its reforms. You have reviewed that, I am sure.

Ms. SHAMES. We are familiar with this as well. The progression that you are presenting obviously gets more and more detailed so we do see some associated dollars here with the activities. I think what is interesting here is that this was the Commissioner's professional judgment. We didn't see this accompanying information with the amendment that the Administration just asked for. So I think it is reasonable to assume that this would be applicable but that is only because we have evaluators who are doing a side-by-side comparison.

Mr. SHIMKUS. And we are legislators and we deal in public policy. We are always schizophrenic because on one hand, you know, we are—I think most of us understand FDA more money but we want to it to be accountable. We want it to be directed in the right ways. But of course, I am a fiscal conservative that doesn't want to spend any more money, doesn't want to raise any more taxes, and so it is a dilemma but it is easier for us to go to our constituents if there is a credible plan, if we can have goals and objectives that are attainable and then especially with all these problems that we have had. I mean, there is public awareness of the need to move more aggressively.

Tab 13, this will be my last, at least in the binder, shows a menu of IT programs associated with different levels of funding, page 11 in tab 13. Have you seen this information in the Food Protection Plan?

Ms. SHAMES. I can't say offhand. It certainly is aligned by the core elements that is in the Food Protection Plan.

Mr. SHIMKUS. But this is the kind of stuff that we would hope to see in budgetary information that we are all kind of addressing.

Ms. SHAMES. Absolutely. It lays out the dollars going forward and just what some of the activities are.

Mr. SHIMKUS. Great. And while we go, you all are welcome to page through this in those tabs, but my time is expired. I will turn back to the chairman.

Mr. STUPAK. Seeing no other members available for questioning, I would like to thank this panel again for your expertise and your input into this process, and I will dismiss this panel. Thank you again, and thank you for bearing with us. I said that we had five votes. We ended up having six so we went a little longer than what we thought, but thank you again for being here and thanks for your help.

Ms. CASSELL. Mr. Chairman, as we are leaving, can I just make one statement?

Mr. STUPAK. Yes.

Ms. CASSELL. And that is that our committee certainly struggled with the issue, Mr. Shimkus, that you just described, i.e., the need for the plan and wanting the Agency to be accountable, and what we concluded was, in the absence of additional resources and significant resources, even if you had a plan, I think that there would be no hope and so I think that we concluded that the first thing that had to happen was to get those resources to the Agency and then to begin to help address the issues and to perhaps solidify the plan.

Mr. SHIMKUS. Mr. Chairman, if I can follow up, and when I talk about the schizophrenia of public policy folks, that is why I focus

on this risk-based approach also because we are always going to have—we are never going to have enough money, but the question is, directing it into the area that we need, and really I like to incentivize the good actors. I really want the good actors to get patted on the back. Some will fall through the cracks somewhere down the line, we understand that, but if you can incentivize the good actors, go after the bad actors, I think that is a better application of our resources, and I appreciate those comments, Dr. Cassell.

Mr. STUPAK. Thank you again.

I now call our second panel of witnesses to come forward. On our second panel, we have Dr. David W.K. Acheson, Assistant Commissioner for Food Protection at the Food and Drug Administration, also known as the drug czar—food czar. Sorry. I gave you a promotion, drug czar. I just want to make sure you are paying attention.

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

Dr. ACHESON. No.

Mr. STUPAK. The witness indicated no. Then I will ask you to please rise and raise your right hand to take the oath.

[Witness sworn.]

Mr. STUPAK. Let the record reflect that the witness replied in the affirmative. You are now under oath, Doctor. We will now hear your opening statement. You may submit a longer statement for inclusion in the record. Please begin, sir.

STATEMENT OF DAVID W.K. ACHESON, M.D., ASSISTANT COMMISSIONER FOR FOOD PROTECTION, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. ACHESON. Good afternoon, Chairman Stupak and members of the subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at the Food and Drug Administration, which is part of the Department of Health and Human Services. I would like to thank you for the opportunity to discuss our ongoing activities to implement the Food Protection Plan to enhance food safety.

As we all know, food can become contaminated at many different steps along the path from farm to fork. In recent years, FDA has done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies.

To address these challenges, last November Secretary Leavitt presented to the President an Action Plan for Import Safety, or Action Plan, to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan, which provides a framework to identify and counter potential hazards. Together, these Plans provide an updated and comprehensive approach to assure that the U.S. food supply remains one of the safest in the world. The plans encompass three core elements: prevention, intervention, and response. The prevention element means

promoting increased corporate responsibility to build safety in from the start so that food problems do not occur. The intervention element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain to verify that the preventive measures are being implemented. The response element bolsters FDA's emergency response efforts by allowing for better communication and increased speed and efficiency.

To expedite implementation of both Plans, the Administration has amended its budget request for fiscal year 2009 to include an additional $275 million for FDA. This increase includes an additional $125 million to intensity efforts to implement the Food Protection Plan. This adds to the increase of $42.2 million proposed in the fiscal year 2009 budget announced in February. The $275 million increase also includes $65 million to modernize FDA's information technology infrastructure, $25 million of which will specifically support our food safety and food defense programs.

With the funding requested in the President's amended fiscal year 2009 budget, we will hire an additional 353 FTEs to accelerate our Food Protection Plan implementation activities. These resources will allow FDA to achieve priorities, such as identifying and targeting the greatest risks for intentional and unintentional contamination; conducting essential research on mechanisms of food contamination and deploying new rapid screening technologies to detect microbial and chemical contaminants; conducting more risk-based inspections and strengthening our emergency response; establishing more rapid response teams; expanding FDA's international presence to include offices in China, India, Latin America, Europe, and the Middle East; establishing IT systems to support interoperable databases that will enhance research, threat assessment, and surveillance; and improving our ability to conduct tracebacks.

We are moving forward to work with partners to develop the necessary scientific foundation. FDA has established a number of cross-cutting implementation teams and is working with our external food safety partners to focus on key areas to support our implementation efforts. I would like to take a couple of moments to describe five of these key cross-cutting areas of focus that are current priorities.

First, the risk-based approach. FDA has been using a risk-based approach for setting priorities for many years. However, there are new models relating to risk assessments and new mechanisms that could improve our risk-based approach. FDA has developed an internal steering committee and is working on defining appropriate models, examining product/hazard combinations, and ranking foods by their risk to public health. These will enhance our ability to maximize effectiveness of our resources by focusing on food products that pose the greatest risk.

Secondly, outreach. FDA has undertaken a number of specific outreach activities. For example, we have met with representatives of many foreign governments, state, and local partners, industry and consumer groups. The agency recently opened a docket to collect comments from all stakeholders on implementation of the Food Protection Plan. To provide a forum for local, State and Federal partners to exchange information and ideas about implementing

the Plan, FDA will host a meeting on August 12–14, 2008, in St. Louis, Missouri, with officials from the departments of health and agriculture from all 50 States.

Thirdly, traceability. FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track-and-trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. FDA will use this information to develop key attributes for a successful track-and-trace system. In addition, FDA plans to issue a request for applications to providing funding to six states to establish rapid response teams to investigate multi-state outbreaks of foodborne illness.

Fourthly, FDA Beyond Our Borders. Consistent with the goals of the Action Plan and the Food Protection Plan, HHS and the People's Republic of China signed an agreement to enhance the safety of food and feed exported from China to the United States. The agreement establishes a bilateral mechanism to provide greater information to ensure products exported from China to the United States meet U.S. safety standards. As part of its Beyond Our Borders Initiative, FDA has also made a commitment to station agency representatives in China. We are considering similar endeavors in other countries, as I mentioned earlier.

Finally, voluntary third-party certification programs. In April, FDA published a notice in the Federal Register to solicit public comments on the use of voluntary third-party certification programs for foods and feeds including pet foods. Third-party certification could provide FDA with additional assurances of safety and with valuable compliance information that would allow FDA to allocate inspection resources more effectively. The public comments will assist FDA in the design and development of such programs.

These are just a few of our current high-priority areas of focus as we implement the Food Protection Plan. In my written statement, I also provided numerous examples of specific implementation activities.

In closing, FDA remains committed to working closely with all of its partners to implement the Plan's measures to protect the Nation's food supply. The degree of progress and the overall success are dependent on both resources and new legislation. As you know, the Food Protection Plan identifies legislative authorities that are necessary for achieving full implementation. We commend this committee for its work on drafting legislation and look forward to working with you on this important legislation as we move forward. We also urge Congress to provide the funding requested in the amended fiscal year 2009 budget.

Thank you for the opportunity to discuss FDA's activities to implement the Food Protection Plan. I would be happy to answer any questions.

[The prepared statement of Dr. Acheson follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

DAVID ACHESON, M.D., F.R.C.P.

ASSOCIATE COMMISSIONER FOR FOODS

FOOD AND DRUG ADMINISTRATION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. David Acheson, Associate 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). FDA appreciates the opportunity to discuss our ongoing activities to implement our Food Protection Plan (FPP) to enhance food safety.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the United States Department of Agriculture (USDA). FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more

quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies and to develop the Food Protection Plan.

ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN

To address these challenges across the range of imported consumer products, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released the Food Protection Plan which provides a framework to identify and counter potential hazards with respect to both domestic and imported food. Achieving the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress.

On June 9, the Secretary announced that the Administration is increasing its Fiscal Year (FY) 2009 budget request for FDA by $275 million. This increase brings the Administration's total proposed increase in FDA's budget for FY 2009 to $404.7 million, a 17.8% increase over FY 2008. A large portion of this increase ($125 million) will be used for food safety and will allow FDA to intensify actions to implement the Food Protection Plan. This is in addition to the $42.2 million increase proposed for food protection in the budget announced in February 2008. $100 million of these funds will be used to strengthen safety of drugs, biologics, and medical devices from product development and pre-approval testing, through approval, and post-approval safety

surveillance. Finally, $50 million of the increase will be employed to strengthen FDA's initiatives in emerging science such as nanotechnology, cell and gene therapies, robotics, genomics, and advancing the critical path initiative. Across these program areas, $65 million will be used to modernize FDA's information technology (IT) infrastructure.

We are moving forward to implement the Food Protection Plan and are working with all our partners to develop the science foundation and necessary tools to better understand the current risks in the food supply. We are developing new detection technologies and improved response systems to rapidly react to food safety threats.

The Plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach encompasses three core elements: prevention, intervention, and response. The *prevention* element means working to encourage producers to build safety into their processes from the beginning for both domestic and imported foods and promoting increased corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for better communication and increased speed and efficiency.

IMPLEMENTATION OF FOOD PROTECTION PLAN

Key Themes

Implementing the Food Protection Plan requires not only a major focus on many specific deliverables, but also a cross-cutting approach to a number of key areas that will support the implementation efforts. To this end, FDA has established a number of cross-cutting implementation teams within FDA to focus on key areas. These working groups include participants from FDA's Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine, the Office of Regulatory Affairs (ORA), the Office of Chief Counsel, the Office of Policy, the Office of International Programs, the Office of Crisis Management (OCM), the Office of the Chief Information Officer, the National Center for Toxicological Research, and other offices as needed to ensure full integration and participation across FDA. We are also working with our external food safety partners to gain valuable input and expertise from all our stakeholders. I would now like to describe five of the key, cross-cutting themes.

Risk-Based Approach

FDA has been using a risk-based approach to setting priorities for many years. However, there are new models relating to risk assessments and new mechanisms that could improve our risk-based approach. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. The Agency needs to apply a risk-based approach to many activities such as research, determining where and what to inspect, and developing detection, prevention, and mitigation tools. FDA will work with the food industry, consumer groups, and

Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our risk-based approaches. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

Working with the Centers for Disease Control and Prevention (CDC) and state and local officials, FDA will also build the capacity to better attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will also continue to work with the Department of Homeland Security (DHS) and other partners on identifying emerging food defense risks and developing rankings so that we can more effectively allocate our resources to manage these risks.

Outreach

As part of implementing the FPP, FDA has undertaken a number of specific outreach activities. For example, FDA has met with representatives from many foreign governments. This has allowed FDA to gain insights into how other countries have addressed many of the same problems. Meetings with state and local partners, industry, and consumer groups have also contributed significantly to the implementation strategy. To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA will host a meeting on August 12-14, 2008, in St. Louis, Missouri, with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 States. We also recently established a docket and are soliciting comments from our stakeholders on the Food Protection Plan and on specific questions related to its implementation.

The comment period will remain open until July 31, 2008. We have numerous other outreach activities underway to engage our stakeholders in implementing elements of the Food Protection Plan.

Track and Trace

The ability to trace products both forwards and backwards is critical for protecting consumers. FDA has formed an internal multi-Center group to meet with external entities (such as industry, consumers, and foreign governments) to better understand the universe of track and trace systems that are currently in use or are being developed. FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. FDA will use the information to develop the key attributes for a successful track and trace system. In addition, FDA plans to issue a Request for Applications to provide funding to six states to establish Rapid Response Teams to investigate multi-state outbreaks of foodborne illness.

FDA Beyond Our Borders

Agreement with China

Consistent with the goals of the Action Plan and the FPP, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China signed an Agreement to enhance the safety of food and animal feed products exported from China to the United States. The Agreement establishes a bilateral mechanism to provide greater information to ensure products exported from China to the United

States meet U.S. safety standards. The key terms of the Agreement include enhanced registration and certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress.

The first formal bilateral meeting under the Agreement between FDA and Chinese regulators was held the week of March 17, 2008, in Beijing. Initially, the focus is on six species of aquacultured fish and three specific ingredients that could be used in foods for humans or animals (wheat gluten, corn gluten, and rice protein).

FDA's Beyond Our Borders Initiative includes increased collaboration with foreign regulators to expand FDA's capacity for the regulation of food and other FDA-regulated products. As part of this initiative, FDA has also made a commitment to station Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries. For example, we have had discussions with government officials in India regarding an FDA presence there. FDA is also exploring the possibility of expanding FDA's presence in the Middle East, Europe, and Central and South America.

Voluntary Third Party Certification Programs

On April 2, 2008, FDA published a notice in the *Federal Register* to solicit public comments on the use of voluntary third-party certification programs for foods and feeds, including pet foods. Third-party certification could provide FDA with additional assurances of safety and with

valuable compliance information that would allow FDA to allocate inspection resources more effectively. FDA would not be bound by the information from these third-party organizations in determining compliance with FDA requirements. The public comments will assist FDA in the design and development of third-party certification programs.

Additional Implementation Activities

Implementing the FPP is a long-term, multi-year process. Using the funding increases provided by Congressional appropriations in FY 2008, FDA will be hiring additional staff to assist in addressing the highest priority action items. FDA will hire 161 new full-time equivalents (FTEs) in FY 2008. Of these, ORA will hire 130 new FTEs to conduct food field examinations, inspections, and sample collections. CFSAN will hire 29 new FTEs to assist with research, the development of guidance and regulations, and other food safety-related work. OCM will hire two new FTEs to assist in rapidly responding to and mitigating food safety threats.

The President's FY 2009 Budget requests $167.2 million to implement the FPP. These funds, which include the $42.2 million requested by the President in February 2008 and the $125 million added to that request this week, will allow FDA to advance important food defense and food safety priorities. FY 2009 prevention activities include performing essential food research, determining the greatest threats of intentional and unintentional contamination to the food supply, and expanding food protection activities beyond our borders. Our intervention activities include conducting more risk-based inspections and surveillance and deploying new food defense and food safety screening tools. FY 2009 response activities include establishing more

rapid response teams, strengthening emergency response, and improving our ability to conduct food tracebacks.

To achieve these objectives and safeguard American consumers, FDA will also improve its IT systems that support our research, risk assessment, inspection, and surveillance activities. Finally, FDA's FY 2009 food protection initiative includes $12 million for the cost-of-living pay increase for FDA's food safety and food defense programs. These funds allow FDA to retain its professional workforce. With the funding requested in the President's amended FY 2009 budget, we will hire an additional 353 FTEs to accelerate our food protection plan implementation activities.

I have described above some of the actions we have taken to implement the FPP. I would now like to provide a few more specific examples of our ongoing implementation activities. Under the *Prevention* category, recent accomplishments include:

- FDA held a public meeting to solicit input on ingredient, processing, and updated labeling standards for pet food. We also asked for input on ingredient and processing standards for animal feed generally.

- FDA held a public meeting regarding a modernized risk-based Animal Feed Safety System (AFSS) and the ranking of feed hazards according to the risk they pose to animal and public health. AFSS describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals.

- FDA has been working in collaboration with the State Health and Agriculture departments in Virginia and Florida, several universities, and the produce industry on a multi-year Tomato Safety Initiative.

- FDA released self-assessment tools for industry to minimize the risk of intentional contamination of food and cosmetics.

- FDA issued a draft Compliance Policy Guide to provide guidance for FDA staff on the Agency's enforcement policy for *Listeria monocytogenes* in ready-to-eat food. FDA also issued draft guidance on controls that processors can use to minimize contamination of food with *Listeria monocytogenes*.

- FDA completed an Inter-Agency Agreement with USDA and DHS to determine the survivability of *Bacillus anthracis* (anthrax) in processed liquid egg products which includes whole eggs, egg yolks, and egg whites. Further studies are being conducted to determine the role of lyzozyme in *Bacillus anthracis* inactivation.

- FDA developed an assay to assess the stability of two bioterrorism agents in high-risk foods. This assay can be used to assess other chemicals that may be used by terrorists to contaminate the food supply.

- FDA has established a research coordinating committee to provide a collaborative and integrated FPP research agenda.

- FDA is using genetic analysis to identify hundreds of *Salmonella enterica* strains from seafood imports. The analysis provides information that can be used to trace outbreaks of *Salmonella enterica* and implement surveillance programs to ensure the safety of imported seafood.

- FDA has initiated a collaborative multi-institutional study to reduce the risk of *Escherichia coli* O157:H7, funded by USDA under the National Integrated Food Safety Initiative. The work will examine pathogen risk mitigation strategies for leafy greens from field to table.

- FDA assessed and published data on the microbiological load of bagged, ready-to-eat produce. FDA is planning a follow-up study.

- FDA recently announced the availability of approximately one million dollars in research funds and issued a Request for Applications. The funds will be used to support research efforts to advance the safe transportation and preparation of produce to improve the safety of fresh-cut produce.

- FDA established a Memorandum of Understanding with DHS and the Department of Justice (DOJ) to develop forensic tools to allow the identification and differentiation of individual strains of foodborne bacteria. This will assist in rapid identification of the source of contamination.

- FDA has initiated research on the susceptibility of pathogens found in raw and processed meats and imported seafood to antimicrobial agents and mechanisms by which these pathogens develop a resistance to antimicrobial agents.

Looking ahead:

- FDA plans to issue a *Federal Register* notice this year announcing the availability for comment of draft modified industry guidance documents for leafy greens and melons.

- FDA plans to issue a *Federal Register* notice this year to solicit comment on updating the 1998 Good Agricultural Practices (GAPs) guidance document.

- FDA expects to publish a Final Rule this year on requirements to prevent *Salmonella enteritidis* contamination of shell eggs during egg production.

- FDA plans to release this year the 4th Edition of Fish and Fishery Products Hazards and Controls Guidance with updates to the previous editions to incorporate the current scientific and technical information regarding hazards associated with the harvest, processing, and storage of fish and fishery products.

Some examples of activities to implement the *Intervention* components of the FPP include:

- FDA has completed a pilot test of the prototype system, PREDICT (Predictive Risk-Based Evaluation of Dynamic Import Compliance Targeting), for seafood imported through the ports of Los Angeles. PREDICT is a tool to better target food safety threats at the border. It has been developed under contract with New Mexico State University. We are working to develop the necessary technical requirements to expand the application of this system.

- FDA has developed a rapid detection method using flow cytometry to identify *Escherichia coli* and *Salmonella* in food. This system is being used in poultry processing facilities to detect and prevent bacterial contamination during food processing.

- FDA microbiologists attended training at CDC's Salmonella Reference Laboratory and learned a new molecular method for rapidly and accurately identifying *Salmonella* serovars. The instruments have been purchased by both CFSAN and ORA laboratories.

Additional examples of actions to implement the *Response* components include:

- FDA has completed four Incident Command System training courses that have included state representatives.

- FDA has developed additional Farm Investigation Courses for Federal, state, and international investigators.

LEGISLATIVE AUTHORITIES

Finally, I would like to just mention the legislative authorities identified as necessary for achieving full implementation of the FPP. These authorities would:

- Allow FDA to require preventive controls against intentional adulteration at points of high vulnerability in the food chain;
- Authorize FDA to issue additional preventive controls for certain high-risk foods;
- Require food facilities to renew their FDA registrations at least every two years and allow FDA to modify the registration categories;
- Authorize FDA to accredit highly-qualified third parties for voluntary food inspections;
- Require a new reinspection fee from facilities that fail to meet Current Good Manufacturing Practice (cGMPS) requirements;
- Empower FDA to require electronic import certificates for shipments of designated high-risk products from countries with which FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet FDA standards;
- Allow FDA to charge export certification fees for food and animal feed to improve the ability of U.S. firms to export their products;
- Authorize FDA to refuse admission of imported food if FDA inspection access is delayed, limited or denied;

- Empower FDA to issue a mandatory recall of food products if voluntary recalls are not effective; and
- Give FDA enhanced access to food records during emergencies.

We appreciate the work of this Committee in drafting legislation intended to help provide these authorities. We look forward to working with you to develop this important legislation.

CONCLUSION

Together, the Food Protection Plan and the Action Plan for Import Safety provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. The approach involves some fundamental changes and, as such, requires a comprehensive implementation strategy. This implementation will be built on a sound risk-based foundation and will not be a rapid endeavor. The degree of progress and the overall success are dependent on both resources and new legislation.

FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We commend this Committee for its efforts and look forward to working with Congress to develop and obtain passage of the necessary legislative authorities identified in the Food Protection Plan and the Action Plan for Import Safety. Thank you for the opportunity to discuss FDA's activities to implement the Food Protection Plan to enhance food safety. I would be happy to answer any questions.

Mr. STUPAK. Thank you, Doctor. Let me begin.

In the President's proposal for fiscal year 2009, you received $30 million for food safety. What made the FDA realize that you need another $125 million for food safety here in the last 6 months? What made the light go on that you needed more funds for food safety?

Dr. ACHESON. I think as we were beginning to address the implementation of the Food Protection Plan, based, as you pointed out earlier in this hearing, in November we published the strategy, a high-level document, and as we have driven that down to specific implementation and what it is going to cost in the 2008–2009 time frame, it was very clear that more money was going to be needed, and that helped drive it.

Mr. STUPAK. So in November you said you put forth your Food Protection Plan and as you began to implement it, you realized you needed more money. Do I understand that right?

Dr. ACHESON. Not exactly. When we put the Food Protection Plan out, it was clear, we stated publicly at the time that we would need more resources in order to specifically implement the full components of the Food Protection Plan. You asked specifically what drove us to come up with that number and that was as we were defining what we could accomplish in the 2008–2009 time frame. That helped drive where did that specific $125 million come from.

Mr. STUPAK. OK. Because I am a little confused now, because when Commissioner von Eschenbach sat where you sat at our April 22nd hearing I asked him about implementing this and if the total budget, the $59 million that was requested in 2009, was enough, and he thought that would be fine to implement this program. What happened between April 22nd and June 10th that you put forth the plan?

Dr. ACHESON. I think as we moved forward and had further internal discussions, the Commissioner recognized that there were other areas where we could usefully use additional resources.

Mr. STUPAK. Do you have any idea then what would it cost to implement the Food Protection Plan as written in November of 2007?

Dr. ACHESON. In its totality?

Mr. STUPAK. Yes.

Dr. ACHESON. We have thought this through over a period of 2008, 2009 in a fair degree of specificity. Beyond that, it gets a little difficult to actually determine what resources it will take because so much of what you would do in the second and third year of the plan is dependent on the progress you make in the first year. To give you a specific example, if legislative proposals are enacted to require preventive controls, which is one of the things that is in the plan, to be able to enact that and make it happen and increase the levels of inspection and guidance required, that is going to require resources, and at this point I don't know what those would be.

Mr. STUPAK. All right, but how would you put forth a plan for food safety for the Nation but have no idea what it is going to cost after the first year of implementation and you are only off by $30 million for food safety and you come back and you ask for $120 some, so you are only off by four times. So if your initial assess-

ment was you only need $30 million for this when you submit the budget on April 22 besides our hearing to make you run up those numbers, Commissioner von Eschenbach says you only need $30 million. Six weeks later you are coming up and saying no, we need $125 million, but after that, you don't know what else you need. So how can you put forth a proposal to protect the American people and not even know what it is going to cost 1 year, 2 years, 3 years, 4 years, or 5 years out? Do you have any ideas what it is going to cost 5 years out?

Dr. ACHESON. At this stage, I couldn't tell you what it is going to cost 5 years out. The key part here is to develop a strategy, a vision, lay out the plan, and as the hearings illustrated earlier, put more granularity and specificity into it.

Mr. STUPAK. I agree, but you must have some guesstimation what it is going to cost. I mean, you would have to know it took 4 or 5 years to do it, right? When you were doing this, you had to come up with some guesstimation. The Science Board, there is their binder right there, they gave estimations for 5 years out. Did you even look at their numbers and say they are probably in the right ballpark?

Dr. ACHESON. I did look at their numbers and I don't have any argument with them.

Mr. STUPAK. So we should take the Science Board's number then to help you implement this Food Protection Plan for the country?

Dr. ACHESON. Well, as we both understand, there is a budget process that is followed in terms of FDA seeking funding.

Mr. STUPAK. Correct.

Dr. ACHESON. And in that context, we only take it out in terms of the money that we ask as far as the budget process allows. If you choose to take the Science Board's numbers——

Mr. STUPAK. You were so wrong with your first request. It was only $30 million for food safety and 7 months later, now it is $125 million for food safety. But yet the Science Board came up with $128 million for food in 2009, $283 million in 2010, $441 in 2011, $598 million in 2012, $755 million in 2013. As I think we heard Mr. Shimkus and others, we are willing to help out but we are not just going to throw money at a problem but we need some concrete estimates of what it is going to cost, where are we going with this whole process. If we go to the appropriators and say here is $128 million, that is what we want next year, they are going to say what are we going to have for the following year and thereafter. I mean, it is a sizable amount of money. We are not even talking about information technology which everyone says you are very lacking in that area too. So I guess I am just trying to get some kind of sense of where we are going with it.

Dr. ACHESON. Well, let me try to provide a little clarity. Certainly the number that is in the Science Board proposal for 2009 is absolutely on track with where we now are for 2009 for food safety. It is essentially the same number. There is a couple million difference but it is the same number.

Mr. STUPAK. Sure, that is just for food, but the Science Board for IT had $75 million. You don't even bring that into play.

Dr. ACHESON. No. As I said in my oral statement, there is new money in the 2009 request for IT, $25 million specifically for food

safety. So there is $125 million for food safety and on top of there that there is an additional $25 million for food safety-related IT in the 2009 request. So there is an IT component built on top of that $125 million for food safety in that 2009 additional request.

Mr. STUPAK. My time is up, but let me ask you this. We got the Food Protection Plan, which I have said earlier was tailor-made to the President's budget, original budget, and I have asked about a couple years out. So as the Agency's food czar, do you plan to submit to Congress an implementation plan which shows milestones, costs for the period that it would roughly take to implement this Food Protection Plan roughly 5 years? Will you do that? Will you submit that to the Congress so we have some idea on where we are going with this process?

Dr. ACHESON. I have the ability to submit to you milestones and an implementation plan and a more specific set of timelines as we have heard. In terms of what I can provide in resource requests around that, what I can tell you is that I will work within our Administration to provide you the maximum amount of information that we can provide you around the resources. I can only commit to provide you with details of how we will implement this plan.

Mr. STUPAK. But you are the czar, you put together this plan. Why can't you tell Congress, the American people what it is going to cost for the next 5 years, what milestones are going to be achieved? How are we going to address that, and if you could do that for us? Why do you have to stay within the Administration's constraints? Why not do the job as food czar and say here is what we need, here is what it is going to take, here is my request for the Congress? Isn't that sort of your authority as the food czar?

Dr. ACHESON. Well, if you are asking me to go outside of my authority within the Administration, then that might put me in a bit of a bad place.

Mr. STUPAK. But isn't it really what we need to do to get at food safety? Whatever the next Administration, shouldn't they submit a plan for 4 or 5 years so we know where we are going with this whole process?

Dr. ACHESON. There needs to be a realistic assessment of what is this going to take, both in terms of an implementation strategy, FTEs, and obviously you are right, ultimate cost, but working within the constraints of the process——

Mr. STUPAK. But here is our problem. We heard the same thing in 1998 from the GAO. In 2004, GAO laid out 34 recommendations to be implemented, hasn't been done. Then we had this food plan in November of 2007. You had the Science Board plan right there. We have so many plans floating around that never get implemented because no one ever has the courage to step forward and ask what needs to be done; here is what needs to be done, here is what it is going to cost us, and I think the American people would really like to say someone is finally addressing the issue. As Mr. Dingell said in his opening statement, they are tired of being sick, but if it is going to cost us a few pennies more if we can see results, we could probably implement it.

Dr. ACHESON. Let me commit to giving you at least greater specificity on timelines, plans, short- and medium-term goals, longer-term goals that I will commit to do, and I will also commit to work

with the Administration to provide you whatever I can within my authority as associate commissioner in terms of resources. I can't go beyond that.

Mr. STUPAK. When can we expect that detailed plan?

Dr. ACHESON. It is going to evolve. I think we can provide you a detailed plan over the next—for the next year to 18 months, probably within 6 to 8 weeks. We have gotten most of it. Part of the strategy here is trying to apply the logic. As you are building this plan, you have a lot of complex issues going on with a lot of activities, and we have captured much of that, but what you have got to do is, if you are going to set up a risk-based approach, you have to determine what is the logic flow through that, what do you have to do first, and we made a lot of progress there, so I would hope that within 6 to 8 weeks we can provide you something for at least the first 2 years, and then looking out beyond that in a——

Mr. STUPAK. Six to 8 weeks or a year to 18 months you are going to provide that to us?

Dr. ACHESON. I hope within 6 to 8 weeks to be able to provide——

Mr. STUPAK. Because you gave us one year's worth. This is the first year. This is your 2009 request, which had some details, but it is only—and that was the $42 million plan. We would like to see a full plan for a couple of years out.

Dr. ACHESON. I would like to go into greater detail than what you are holding in your hand there for the next year.

Mr. STUPAK. We would appreciate that. Should your budget, if you reach a milestone, should you get the money, I think Professor Morris said that we should tie it into a process where you do not receive the money unless you reach a milestone. Would you be in favor of that?

Dr. ACHESON. I think you need to look at—there is always a danger that you won't reach a milestone for some unspecified or unpredicted reason. Part of this process is transparent and exploratory. You can't map out 5 years of how do we fix the food supply. This is the eighth hearing that you personally have held on this.

Mr. STUPAK. Right.

Dr. ACHESON. It is really complicated, as illustrated by the number of hearings, and the problems that we have got to address are multiple: they are domestic, they are international, and I am not going to commit to saying we will set a milestone 2 years out. We may or may not make that. That is just reality. That is life.

Mr. STUPAK. Well, the Science Board right there, they have it all laid out right there for you, all you have to do. That is from A to Z, how best to do it. It is already laid out for you if you care to try it.

Mr. Shimkus for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I am going to page back here because I would—well, before I do that, I need to ask you to take back to Dr. von Eschenbach, I said in my opening statement, response to this Office of Criminal Investigations letter, and if you would see that you relay that request from me. I think Ranking Member Barton would appreciate it and it would help us with our good friends in the Majority who might

think we have to go to other extremes to get the information versus just a nice, polite letter.

Dr. ACHESON. I apologize that you don't have that I will most certainly take that back.

Mr. SHIMKUS. Great. I always keep going back to this—have you looked at this national strategy for pandemic influenza and their implementation plan and looked at how the perception of the plan at least, the first panel seemed to think it did a couple things. It set out goals. It set out milestones. It set out funding. Have you all looked at that to look at a way in which—when corporate America wants to build hopefully a lot more coal-fired power plants in this country, they have to plan 10 years out to get through all the permitting, to get the land acquisition, to fight the environmental groups, hopefully win, and then build the project, buy the coal. Everybody has long-term plans. That is our frustration. So, one, have you looked at that as a guide, and then if so, what have you determined and there is legislative action that we need to do to help you do that? When we do our budget, and I have problems with our budgetary process. Like I said, I like to have really the cost structure be a 2-year cycle but we do a 5-year. Ours is a 5-year budget plan. Now, we know we are not going to achieve it. We know there are going to be different areas that are going to be skewed, but at least we have an idea of what is going to happen, where tax cuts may be required to expire or other things. So talk to me about the influenza analysis and then again the whole budgetary cycle.

Dr. ACHESON. In terms of your question about the pandemic plan, I personally have not looked at that for quite some time. I was certainly interested in following it when it was being developed. The discussion earlier today has illustrated that I need to go back and have a look at that specifically in terms of the way it was laid out and structured and see if it applies to the Food Protection Plan or at least if elements of it can be applied to the Food Protection Plan. It is clearly a model that you all feel works and is successful and we should pay attention to that and go and look but at this point I need to make that assessment. In terms of the budget process, essentially it is what it is and what we do——

Mr. SHIMKUS. But the submission by the Administration is not—I mean, we don't pass that and it doesn't go back to the President. It is not signed into law. When we pass out budget, it is not—we don't send it back up to the President to get signed into law. It is a guide that directs our appropriators to spend money a certain way and they have to do the allocations and that is how the process kind of begins. It is very frustrating.

Dr. ACHESON. Well, we are under constraints within FDA in terms of the budget process and we have to follow that. That is the way the law is written and that is what we have to do. So within that, we certainly operate within those constraints and clearly if you were to change those, then we would respond accordingly.

Mr. SHIMKUS. We have a lot of million-dollar numbers floating around here, trying to get a handle on. The request, the Administration has added a $275 million request to the 2009 budget with $125 million of that for food protection. Is that your understanding?

Dr. ACHESON. Yes.

Mr. SHIMKUS. And that is on top of the $42 million and then the—so there is $42 million and $125 million of the $275 million that is food protection addition dollars?

Dr. ACHESON. Correct.

Mr. SHIMKUS. How are you going to use that money to accelerate the plan's implementation?

Dr. ACHESON. Probably the easiest way for me to answer that is I think in the book that you had here, you have a copy of the professional judgment from our Commissioner which lays out in some detail how it would fall under prevention and intervention and response. But within that, we have got essentially money and FTEs allocated to increasing FDA's presence beyond the borders, as an example, setting up the office in China, trying to set up, establish the offices in India and Central and South America, those sorts of things. Also, increasing our ability to provide technical assistance to foreign countries that need it, that requires resources and people. And developing the tools, IT tools and others for international information exchange to help inform the risk-based process. There is a lot ofyou probably don't want me go through——

Mr. SHIMKUS. Let me then add to, now we also have the additional $275 million in new resources through the proposal of the budget supplemental, correct? The emergency supplemental. That is—

Dr. ACHESON. Through the fiscal year 2009 addition, $125 million added in the fiscal year 2009 change.

Mr. SHIMKUS. Yes, but the response to Senator Specter on the 2008, in this emergency supplemental requested an addition of $275 million?

Dr. ACHESON. Well, are we talking about a supplemental or are we talking about the——

Mr. SHIMKUS. I am talking about both, and that is the problem, because the basic—if the emergency supplemental of $275 million gets approved, can you deal with that money?

Dr. ACHESON. Absolutely, no question.

Mr. SHIMKUS. And what will you do with it?

Dr. ACHESON. We will do exactly what we will do with it if we got it in 2009. We would just do it sooner.

Mr. SHIMKUS. Mr. Chairman, my time is expired. Thank you.

Mr. STUPAK. Thank you, Mr. Shimkus.

Ms. DeGette for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Acheson, when Commissioner von Eschenbach appeared in front of this committee almost a year ago, Tuesday, July 17, 2007, and announced your appointment as the new czar, he said, "This plan will enable FDA to be engaged in quality assurance through the total life cycle of food from its very production all the way to consumption. If you will, FDA's commitment is to be engaged from farm to fork, and to do that in the context of a comprehensive, well-developed plan that includes prevention so we can eliminate food safety problems by building quality into our very production of food." Would you agree that is the general purpose of what you are supposed to be doing with this new plan?

Dr. ACHESON. It is heavily focused on prevention but with intervention and response built in as well.

Ms. DEGETTE. OK. So this plan now that came in out in November 2007, would you say that this is a comprehensive, well-developed plan?

Dr. ACHESON. It is a comprehensive, well-developed strategic vision of where to take food safety.

Ms. DEGETTE. Correct. As I said when I talked to the previous panel, there is nothing really very specific in here. It is general goals, right?

Dr. ACHESON. It is a strategic vision.

Ms. DEGETTE. OK. Now, we also have under tab 10 of your notebook the Food Protection Operations Plan. I am sure you are familiar with that as well, correct?

Dr. ACHESON. Yes.

Ms. DEGETTE. So my question is, would you say that is a comprehensive, well-developed plan?

Dr. ACHESON. It does not give specific timelines and metrics.

Ms. DEGETTE. It doesn't give specific timelines, metrics, or price tags, does it?

Dr. ACHESON. No.

Ms. DEGETTE. So you wouldn't say that is a comprehensive, well-developed plan, would you?

Dr. ACHESON. I have already committed to provide that.

Ms. DEGETTE. OK. And you have committed to provide that within 6 to 8 weeks from now, you say?

Dr. ACHESON. For the next——

Ms. DEGETTE. For the next 2 years?

Dr. ACHESON. Yes.

Ms. DEGETTE. For the next how long a period? Because first you said 18 months, then you said 2 years.

Dr. ACHESON. No, I said 18 months to 2 years.

Ms. DEGETTE. OK. Great. So my question to you is it has now been 7 months since we received this whatever you called it and we haven't had a specific detailed plan. Now you are saying another 6 to 8 weeks before a detailed plan. Is that going to have the breakdown with the metrics, and the price tags and so on and so forth?

Dr. ACHESON. To the greatest of our ability, yes, it will have the breakdown of the metrics.

Ms. DEGETTE. What does that mean?

Dr. ACHESON. Pardon?

Ms. DEGETTE. What does that mean and what do you need to get the ability to put metrics and price tags to all of the specific items in both of your Food Protection Plan and your Operations Plan?

Dr. ACHESON. Well, the first point is what are the priorities over the next 18 months to 2 years?

Ms. DEGETTE. Well, I would think the priorities would be to stop food outbreaks like the new outbreak that we have got with the tomatoes right now.

Dr. ACHESON. That is the ultimate priority, to improve the safety of food.

Ms. DEGETTE. Well, how long is it going to take for the ultimate priority to be achieved?

Dr. ACHESON. To rule out outbreaks?

Ms. DEGETTE. Well, to prevent outbreaks.

Dr. ACHESON. We will never completely prevent outbreaks. The goal is to minimize——

Ms. DEGETTE. OK, that is not productive. Let me ask you another question. In your Food Protection Plan, there are many sections that talk about additional legislative authority needed, correct?

Dr. ACHESON. Yes.

Ms. DEGETTE. Has the FDA come to Congress with any draft language for legislation needed to implement the plan?

Dr. ACHESON. In the Food Protection Plan itself, the document you have there, there is a fair degree of detail in terms of what the specific legislative proposals would be.

Ms. DEGETTE. OK. But has the FDA actually developed language to support those proposals?

Dr. ACHESON. We have not provided legislative language——

Ms. DEGETTE. Does the FDA intend to develop language to support those proposals?

Dr. ACHESON. At this stage, there is a great deal of language already developed by many members of Congress that we are providing technical assistance and look forward to doing more of that as we go on.

Ms. DEGETTE. Which specific legislation are you referring to, sir?

Dr. ACHESON. Yours, for one.

Ms. DEGETTE. OK.

Dr. ACHESON. There are many that are out there.

Ms. DEGETTE. Now, isn't it the case that the Administration did submit accompanying language with a number of recent legislative efforts including the Medical Device User Fee Act, the Animal Drug User Fee Act, the Generic Animal Drug User Fee Act, and the reauthorization of PADUFA?

Dr. ACHESON. I was not familiar with any of those, but if you say that, I have no reason to——

Ms. DEGETTE. All right. But as far as you know, the FDA's intent for these recommendations in your plan is to simply provide technical support to Congress but not to provide language. Is that correct?

Dr. ACHESON. At this stage, there is no intent to provide specific legislative language.

Ms. DEGETTE. Now, you had told Mr. Stupak that you cannot exceed the authority given by the Administration in terms of the budget. Is that correct?

Dr. ACHESON. That is my understanding of my role, yes.

Ms. DEGETTE. And what specifically are the parameters of that authority that you have been given by the Administration?

Dr. ACHESON. My understanding of that is that during the development of a budget for 2009 or 2010 or wherever we are going, there is internal discussion that I take a major role in in terms of determining what are we going to need to move forward on whatever it is we are working on in the next stage of the Food Protection Plan. That is turned into a specific budget document, which is forwarded up through the departments, subsequently OMB, the President, and finally to Congress.

Ms. DEGETTE. And it is your understanding then that your authority does not include projecting out over 5 years or even 2 years budget numbers?

Dr. ACHESON. My understanding of our ability, our authority is that if I was to do that, it would be for internal use only and I would not be allowed to share it.

Ms. DEGETTE. And who told you that?

Dr. ACHESON. That is my understanding of the law, and if I am incorrect, please correct me.

Ms. DEGETTE. You believe that is according to the statutes?

Dr. ACHESON. That is my understanding.

Ms. DEGETTE. OK. And so how is it that you think you are going to be able to do a detailed plan for the next 18 months to 2 years if you are limited statutorily to only providing a budget for the coming fiscal year?

Dr. ACHESON. What I committed to provide was a detailed implementation plan in terms of timelines and short- and long-term goals and I said I would work within the Administration to the best of my ability to provide maximum information on the resources required to achieve those goals. I cannot promise that.

Ms. DEGETTE. Well, the problem we have is, if it is going to take a 5-year plan to fully implement the food safety regulations in this country, then we need to know how much it is going to cost and what we are going to need to do to do it. If in 6 to 8 weeks we receive more of this exhibit 10 or this other plan with sort of hortatory goals, that is not going to help us in feeling like we are developing legislation that is going to protect our constituents. You can see our frustration, Dr. Acheson.

Dr. ACHESON. I understand. You want to know how much is it going to cost to implement——

Ms. DEGETTE. We want to know. We are not asking for a budget. What we are asking for is cost estimates, and we believe that is in your statutory authority, and furthermore, we don't see how we can really do legislation. We don't see how the FDA can implement a plan if it doesn't have cost estimates that go out over the life of the plan.

Dr. ACHESON. I understand your frustration. Will you allow me to explore that and see what I can provide?

Ms. DEGETTE. Absolutely. When can you get back to us with an answer? Because part of my other frustration with FDA, although not with you personally, is that over the years I have asked for reams of information from the FDA on many, many topics and never received a response. So I know you won't be that way, so when are you going to respond on that?

Dr. ACHESON. I will. Until I explore the ramifications, I am loathe to commit to how long it will take but I will begin. I just don't know.

Ms. DEGETTE. Are you willing to meet with the chairman and ranking member of the Subcommittee next week to discuss this?

Dr. ACHESON. I would be very willing to do that.

Ms. DEGETTE. Thank you very much.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you.

Dr. Acheson, if I may, if you take a look at the frustration of what we are trying to ask you, if you go to page 5 of your plan, the Food Protection Plan, item 2, it states the following: "Use enhanced modeling capability, scientific data and technical expertise to evaluate and prioritize the relative risk of specific food and animal agents that may be harmful." That is a very admirable goal but there is no spreadsheet. It doesn't show how you intend to do this; how do you intend to accomplish this or what is the expected cost? So where would we find that information? I mean, this is a bunch of laudatory goals but it doesn't say how you are going to do it. What do you expect to do? How are you going to achieve that goal of prioritizing the relative risk? What is the biggest risk we have in food right now? What is the biggest risk to this country's health in food? I am not talking about tomatoes. What is the biggest risk?

Dr. ACHESON. Probably meat and poultry.

Mr. STUPAK. Meat and poultry, so that would be USDA. Give me one that is under your jurisdiction. What is the greatest risk under FDA jurisdiction?

Dr. ACHESON. Fresh produce.

Mr. STUPAK. Fresh produce, like spinach. How many outbreaks have we had of that? We have had——

Dr. ACHESON. Two.

Mr. STUPAK. Man, the last 10 years I think there have been eight——

Dr. ACHESON. No, two with spinach. There has been eight or nine with other leafy greens.

Mr. STUPAK. No, Salinas Valley, there has been at least 20 in 10 years.

Dr. ACHESON. Excuse me. I think you are confusing spinach with other leafy greens like lettuce, romaine lettuce.

Mr. STUPAK. Right.

Dr. ACHESON. Two spinach outbreaks, and you are correct; there has been seven or eight other leafy green outbreaks like lettuce and the like.

Mr. STUPAK. In the Salinas Valley?

Dr. ACHESON. Yes.

Mr. STUPAK. So wouldn't one of your priorities on the risk, if you are taking a look at Salinas Valley, which is the salad bowl of America and you have had 20 outbreaks of leafy greens in 10 years. Wouldn't that be a priority to try to crack down on that and get an epidemiology study to determine what is going on? Wouldn't that be a priority?

Dr. ACHESON. Absolutely. It is a priority, and that is why there was a leafy green initiative started, which is still underway.

Mr. STUPAK. Right, and we have this Tomato Safety Initiative that has been going on for a year, so why is it the FDA is having a difficult time determining the source of the current salmonella tomato outbreak?

Dr. ACHESON. There are two answers to that question. One is related to the complexities of a trace-back, particularly when it is linked to something like tomatoes where not every tomato has a code on it. The second part to your question is, how does that tie in with the tomato initiative that is currently underway in Florida

and in Virginia? That is essentially a collaborative effort to understand what is going on at the grower level, at the farms, that could help prevent future outbreaks.

Mr. STUPAK. But you can't determine that unless you know where the tomatoes are coming from.

Dr. ACHESON. Well——

Mr. STUPAK. If the tomatoes are coming from Mexico, as some people suspect, then you have to know what the growing process is in Mexico and what the water they are using, what is the handling, what is the processing, what is the shipping. Would you not?

Dr. ACHESON. I beg to differ.

Mr. STUPAK. Really?

Dr. ACHESON. Yes. Preventative controls to prevent salmonella getting on a tomato are going to work in Florida just as well as they are going to work in Mexico. The key thing is, what is the science behind the correct preventative control and then you apply it in Florida and you apply it in Mexico.

Mr. STUPAK. Absolutely, if Mexico is doing the same as we do in Florida or Virginia or wherever we are growing tomatoes, right?

Dr. ACHESON. You know, there are not a million different ways to grow tomatoes.

Mr. STUPAK. Oh, I agree, but if your water isn't clean in Mexico, I don't care the way you grow it, you are probably going to have salmonella poisoning in the tomatoes, right?

Dr. ACHESON. Having a water supply that is not heavily contaminated with salmonella is going to be important but that is true wherever you are growing them.

Mr. STUPAK. Let me ask you this. The Food Protection Plan and what you have laid out here, how would that specifically have prevented the salmonella outbreak in tomatoes? If this was implemented, how would this have prevented it?

Dr. ACHESON. If that is fully implemented, number 1, you would have done more research to understand the preventative controls and what actually works. To your point, is it the water supply that you have really got to control? What is the science behind that? What is the risk associated with water versus frogs that happen to be living in the field, so you would get to that point. And through the legislative proposals, you would have required the preventative controls to be put in place at the various points.

Mr. STUPAK. OK, legislative proposals. Why haven't you submitted any legislative proposals then to help us because you need legislators, us, to implement your plan? So why haven't you submitted any legislative proposals to us?

Dr. ACHESON. There is a fair degree of detail in terms of what those would look like in our plan and we have certainly met multiple times with staff on the Hill to discuss specifics around these and are now providing and want to provide more technical assistance and other discussions based on the language that has already been put out by a number of Congressmen.

Mr. STUPAK. Tell me one Congressman who has a legislative proposal to implement this.

Dr. ACHESON. Senator Durbin.

Mr. STUPAK. OK. That is the other body. We can't talk about them. I am talking about in the House.

Dr. ACHESON. There are many aspects in your bill that address——

Mr. STUPAK. But see, we are the committee that has sort of been looking at this and if we don't know what those legislative proposals are; how is anyone else going to know? I would think if you are going to do legislative proposals to implement a food safety plan, you at least start with the Energy and Commerce Committee, who has jurisdiction over it.

Dr. ACHESON. We have had many conversations with the Energy and Commerce Committee and I look forward to having more about the specifics of this, but the draft language that your committee came up with essentially used much of the proposals and thinking that were in the plan.

Mr. STUPAK. So you support Mr. Dingell's bill, the Globalization Food and Drug Act of 2008?

Dr. ACHESON. There are many aspects in that which are synchronized with——

Mr. STUPAK. Would you please put in writing what you would agree with and not agree with in the globalization bill of Mr. Dingell so we have some idea where you agree and you don't agree so we can work it out? Because we have nothing like that yet.

Dr. ACHESON. We are certainly committed to providing the appropriate technical assistance along those lines, yes.

Mr. STUPAK. You indicated when we were talking about Mexico, we were talking about the tomatoes, but you also indicated in your statement the FDA Beyond Our Borders and you specifically mentioned China. When we had our hearings on heparin, the agreement with China really didn't help us any. When they tried to go into certain plants, they were not allowed to look for heparin. When they wanted to take a look at the labs, they were not allowed to. So how do these agreements, if the FDA inspectors cannot really get into the nitty-gritty to make the determination if the water is clean that is used to grow tomatoes, if it is not working in China, what is going to be different to make sure it is going to work in Mexico or China, whether it is food or drugs?

Dr. ACHESON. With regard to the agreement in China, on the food side, that is, with AQSIQ, the regulatory body in China that controls exports, the process that we are undergoing there is that they have a registration and certification system in place. The question we have is, what comprises that? Does it meet our standards? That is the first question, at least on paper. Second question, when we go out and audit that process, which the intent is to do that sometime later in 2008, early 2009, are they actually doing what they say they are doing. Then the third part is assuming that they are, there needs to be an ongoing audit of the process, and if we start to receive certified product based on that process, we have got to do checks in the United States, and to your point, if we find that it doesn't meet those standards, then clearly the agreement is not being met.

Mr. STUPAK. Well, to my point then, if you don't find that they are meeting the standards, if we take a look at drugs alone and there are many more hectares growing food for export to the United States than there are plants producing drugs in China and you are inspecting them, FDA is inspecting them every 30 to 40

years, that is not going to be very efficient. Now, I know you need more people, but would you commit to supporting the COOL, the country-of-origin labeling, so we can help understand where some of this food comes from so if you do have the outbreak like you do with tomatoes, if they came from China or from Mexico, which might narrow your focus on the salmonella in tomatoes, would it not? So would you commit to supporting the COOL program?

Dr. ACHESON. Well, to answer the first part of your question, this is not all about having an FDA inspector going and visiting every foreign food manufacturing facility in China. This is about leveraging through the Chinese government, and if our voluntary certification program moves forward, through third-party voluntary inspections.

Mr. STUPAK. The leveraging hasn't worked; that we saw with heparin. We had this agreement. We were supposed to go into the plants when we wanted to go into certain plants, and Dr. Woodcock and Dr. Brown, they said they were denied access to plants and the labs to make sure, to see if that detail that we were supposed to do that and that the Chinese were following to certify these labs and the process. It was denied, so——

Dr. ACHESON. If access is denied and there is a problem, then clearly the agreement isn't operating in the way the agreement was agreed, so that is a different issue.

Mr. STUPAK. What about COOL? Do you support that, country-of-origin labeling? Will you implement it?

Dr. ACHESON. Country-of-origin labeling is under the jurisdiction of USDA.

Mr. STUPAK. But also you have responsibility for 80 percent of the food, most of our food, especially the fruits and vegetables and tomatoes that we are talking about come underneath your jurisdiction when they come from other countries, especially this time of the year, in the winter, so——

Dr. ACHESON. Country-of-origin labeling is no guarantee of the safety or lack thereof of a food.

Mr. STUPAK. I agree, but it——

Dr. ACHESON. It is a piece of information for consumers.

Mr. STUPAK. And it would also narrow your focus in trying to find out where this tomato outbreak is. If we knew those tomatoes were coming from Mexico because they were marked because they don't have a bar code, as you said. But at least if they were marked, we could at least narrow our focus; could we not?

Dr. ACHESON. Probably not, in fact, in practicality for tomatoes, simply because most people when they consume a tomato just know they have consumed a tomato. They don't know where it came from. And by the time somebody——

Mr. STUPAK. You think consumers don't know where food comes from if it is labeled?

Dr. ACHESON. Well, let me ask you a question, if I may?

Mr. STUPAK. Sure.

Dr. ACHESON. If you have eaten a tomato in the last week, do you know where it came from?

Mr. STUPAK. No, because you won't implement country-of-origin labeling. If you had country-of-origin labeling, I would know where the tomato came from and you could focus your resources on Mex-

ico, if that is where we believe the same is coming from, as opposed to New Mexico and Texas and the other States that you are sort of spinning the wheels on.

Ms. DEGETTE. Will the chairman yield? Or if we had traceability?

Mr. STUPAK. Right.

Dr. ACHESON. I would support that, absolutely. I think traceability is a far more powerful tool than country-of-origin labeling in terms of food safety.

Mr. STUPAK. So you don't support country-of-origin labeling?

Dr. ACHESON. I don't go either way on it. My point is that it is not a food safety tool. It is an information for consumers tool.

Mr. STUPAK. I agree, but it would help narrow your focus when you are doing investigations; would it not?

Dr. ACHESON. It certainly wouldn't hurt.

Mr. STUPAK. If you had the address—when I did criminal investigations, if I had addresses, it would certainly help me out when I did mine. Let me ask you one more.

Dr. ACHESON. Traceability would help you a whole lot more. That is what the address is giving you. It is giving you the traceability.

Mr. STUPAK. That is right. Let me ask you one more question. The Office of Regulatory Affairs manages the majority of the FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. Shouldn't that be more consolidated underneath your position as Associate Director of Food Safety?

Dr. ACHESON. The way that the Commissioner has chosen to set up my position is to give me the mandate of integration and coordination across the Agency. This is essentially the structure that he has established. I achieve that through providing essentially the leadership and the vision with ORA and CFSAN and CVM and the National Center for Toxicological Research and others working on implementing the Food Protection Plan. As you well know, the current structure is set up that way and that is the way that the Commissioner has decided to do it.

Mr. STUPAK. All right. Our committee staff was at the Port of Baltimore to learn about the FDA's entry reviewers inspect food imports using the IT platform called Oasis. As you know, current methods are often labor-intensive, are not interoperable with other existing databases and provide almost no risk analysis to inbound food commodities. So under the Food Protection Plan, how will the system change and when can we expect results?

Dr. ACHESON. There are many components to answer your question. First of all, you need to be addressing what is the level of risk associated with certain foods, and it is not just the food product, the food hazard combination. It is where does that food come from, what do we know about the foreign manufacturer, many components that feed into this. The model that we have developed to begin to address this is Predict. Predict is run through a pilot program in the Port of Los Angeles looking at seafood. The evaluation of that program looked like it was successful. So the question is, how do we expand that, where do we go, and part of the Food Protection Plan includes the expansion of Predict. Some of the new

monies in the 2009 budget will go toward doing that. Are you going to ask a question?

Mr. STUPAK. When will Predict then be validated if that is the new model? When will that be validated? It has been going on for some time for Los Angeles. I mean, in order to expand it other places, you have to validate its accuracy and—

Dr. ACHESON. Yes.

Mr. STUPAK. So when will that be done?

Dr. ACHESON. The components of Predict are currently going out for peer review from FDA to see whether through peer review there is a sense that this works. We believe that we are now at a point where we need to do two or three things on Predict. One is to expand it on seafood to some other ports, see if it is applicable to other places. The second is to rank the food items under a series of priorities in terms of what is the next food that we would want to load into Predict and then to begin the process of risk ranking that food, because one of the powers of Predict is; it doesn't just give you a yes-no answer. It gives you levels of risk depending on a variety of factors. And then the third component is to look at what is the IT interoperability, applying Predict across the whole system. Those three things will begin all in parallel, and the peer review process that is underway will help tweak, if necessary, the scientific approach and the data handling approach to make the system better.

Mr. STUPAK. I appreciate your patience.

Next to Mr. Shimkus for questions, please.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I think they are going to call votes around 2:00. You will be spared from too much more harassment. I have three quick questions. They really do follow up on Predict. I am hopeful, and I think a lot of us are hopeful this will be rolled out to a larger venue. You made a statement already—some of my question was dealing with that and also if new monies come in, some would be directed—I think you have kind of mentioned that would happen.

Dr. ACHESON. Yes.

Mr. SHIMKUS. Can you—can the FDA provide a copy of the contract with New Mexico State University that pertains to Predict? Is that doable?

Dr. ACHESON. Can we provide you with the contract?

Mr. SHIMKUS. Yes, a copy of the contract.

Dr. ACHESON. I can certainly see if we can provide you with that, yes.

Mr. SHIMKUS. Good. I want to now jump to China real quick and these agreements that we have, not just with China but other countries. What insights are we gaining in our negotiations with other countries and in particular with China? Is there—in our negotiations with them, I think one of our concerns is the inspection and quarantine, address preservation of evidence, and access to personnel beyond just faster access to production facilities. Can you talk about that?

Dr. ACHESON. Yes, this isn't all about faster access to production facilities. It is about gaining a level of confidence in their registration and certification process. When they say that a shipment of shrimp is certified to be safe and meets FDA standards, we have

to be sure that that is true. That means getting an understanding of their systems, how do they inspect, not only the processing facility but the farm where these shrimp are grown, the control over use of inappropriate antibiotics——

Mr. SHIMKUS. Right, and that keys into the whole heparin debate that we were talking about because the ability of the Chinese government to go back to the hog confinement facility obviously is questionable, in fact, did not happen, and so these negotiations I think we are going to be—and how you all conduct those in the whole chain is going to be very, very important.

Dr. ACHESON. I agree. We are at the point of laying out what the expectation is. There is an audit built into this. This is where we go and say—when you say that you are checking up on not only the processor but also the farm where these shrimp are grown, are they doing that and to what level and——

Mr. SHIMKUS. That is the accessibility part, though.

Dr. ACHESON. Yes, and——

Mr. SHIMKUS. We have to have someone to be able, if there is a question mark, to be able to have those folks onsite that will get quick access to these facilities.

Dr. ACHESON. Yes, it is a matter of gaining confidence in their system, and we have to do that by understanding the system and physically getting over there and looking at it and watching what they are doing and then continuing the audit process.

Mr. SHIMKUS. Part of this whole FDA reform debate and legislation will be how do we fund, how do we bring more resources to you so we can effectively have the arrangement so that we have the people in these facilities, and there are a lot of us—what I want is, I want the people who want to provide, who want to sell into our market to help pay for us to make sure that those goods that people are trying to get access to our market is funding for your ability to make sure that they are safe. That is why it is timely. That is why this Oversight and Investigation Subcommittee is great because it really sets the building blocks for legislative response.

The last time I want to tie in with this debate is using science. We had one of our hearings, we talked about irradiation, and of leafy greens. In fact, I double-dog dared the chairman to eat a leafy green that was irradiated. We found it was tasty. He wouldn't eat the mushroom. But there is also gene splicing and other technologies that we will need your help to push forward as we—to hopefully overcome this concern. We would rather be proactive versus reactive. When we are reactive, then it is going to be costly, both in money, in human suffering and frustration, and these tomato folks, there is going to be a lot of people that are going to take a big loss and they are not going to be culpable or responsible, and so can you just talk briefly about technology real quick.

Dr. ACHESON. Technology is critical. Utilizing modern technology, that is part of the Food Protection Plan. That is a high-level vision. And it gets down to detection technology: what can you develop in terms of handheld rapid detection technology. What is the prevention technology that works. I mean, you mentioned irradiation. Is that a reasonable approach that you could take that is actually economically effective and protects public health? You talked about ge-

netic tools. Are there some components there that could help us? I think part of what we are going to use this new money for is to build up the scientific cadre within the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine, and that will help address some of those questions, figuring out what is the new technology. We don't have to develop all of that ourselves but what we have got to do is make the connectivity with academia and others and industry who have that technology and say well, that is interesting, we could apply that in a preventative mechanism for an FDA-regulated product. That only happens if you have enough people to get out there and have that dialogue, so it is all built in to that. I couldn't agree more that modern technology is key here.

Mr. SHIMKUS. And that will help us as we talk about what is the plan, what are the costs and that is that long-range debate and the milestones. That ties into the whole thing, and I am done, Mr. Chairman. I yield back.

Mr. STUPAK. Thank you.

Ms. DeGette for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Acheson, I want to talk to you for a few minutes about the tomato situation. Has the FDA been able to trace the location of the original contamination of the tomatoes?

Dr. ACHESON. Not yet.

Ms. DEGETTE. And what is the process currently for trying to trace the source?

Dr. ACHESON. I would like to first of all correct a mis-comment earlier in terms of this trace-back that has been going on since mid-April. It hasn't. The first case from CDC was reported on April 16. It wasn't until May 31 that the link with tomatoes was officially made by CDC and the State and the local officials and FDA began its trace-back, so that was 12 days ago.

Ms. DEGETTE. So what you are saying is that the first case of salmonella was reported in April but the CDC didn't know what was causing the salmonella?

Dr. ACHESON. What I am saying is, is that the first case, yes, was April 16. Now, you have to remember that you are talking here not just about CDC, you are talking here about the State and local public health infrastructure.

Ms. DEGETTE. Right. I understand that, but what you are saying is the first cases of salmonella were reported in mid-April?

Dr. ACHESON. Yes.

Ms. DEGETTE. But the cause of the salmonella was not pinpointed until late May?

Dr. ACHESON. May 31.

Ms. DEGETTE. OK. And that is because—and I know how these public health issues are. They have these cases of salmonella, it took them a while to link that it was from tomatoes, right?

Dr. ACHESON. That is right.

Ms. DEGETTE. So what you are saying is, the trace-back efforts started May 31?

Dr. ACHESON. Right.

Ms. DEGETTE. So what is that process?

Dr. ACHESON. OK. That process is when you know that you have got a patient who has consumed a tomato, you want to then find

out where did you buy it and when did you buy it. That will take you to the local supermarket. You then say to the supermarket, where do you get your tomatoes from in this time frame when the patient got sick, and it may be from two or three suppliers. You go back to each one of those suppliers and say where did you get your tomatoes from, and it may be from two or three distributors and the legs expand as you go out and you are chasing every one down.

Ms. DEGETTE. Right.

Dr. ACHESON. One of the legs that we are doing right now, beginning with a single case, it has led down five different sets of distribution, of which there is anything from two to nine different distributors or suppliers. The other complexity with tomatoes specifically is when a crate of tomatoes arrives at a distributing facility, they may handpick them because somebody says I only want small, unripe ones; somebody says I only want large, ripe ones.

Ms. DEGETTE. Right.

Dr. ACHESON. So they are pulling them out and mixing them up, and that has to be figured out. We have to get the invoices to show that it is tracking back. We have—as you know, we have excluded many areas of the country that either were not harvesting at the time——

Ms. DEGETTE. They weren't harvesting?

Dr. ACHESON. They weren't harvesting or they were harvesting and where they were distributing was not where we were seeing illness so somebody who is distributing to the State it is grown in and the neighboring State, you see illness in 17 States, it is not them.

Ms. DEGETTE. But it is sort of an inexact science the way we do traceability right now for produce and a lot of other food items too.

Dr. ACHESON. It is actually very exact but it is very cumbersome. It needs to be exact to be legally binding.

Ms. DEGETTE. Well, we had some hearings on the spinach issue and it took them a long time to trace that and they were never 100 percent sure what the source of the contaminated spinach was. They thought they isolated it to a farm in California but they could never be 100 percent sure. I was actually encouraged when I heard you tell Mr. Stupak that you support trace-back provisions. First of all, we have the technology right now to do traceability for produce, correct?

Dr. ACHESON. There is a lot of technology that is out there. It is not necessarily interoperable at this point.

Ms. DEGETTE. And Dole, for example, is using trace-back process, correct?

Dr. ACHESON. I don't know.

Ms. DEGETTE. If we could get interoperability with trace-back systems, that would expedite the traceability dramatically, correct?

Dr. ACHESON. Interoperability is critical, yes.

Ms. DEGETTE. But if we had interoperability, it would——

Dr. ACHESON. It would help.

Ms. DEGETTE [continuing]. Greatly increase the response because it would be a lot more easy to pinpoint where that produce came from once you realized that the outbreak was caused by that produce, correct?

Dr. ACHESON. Assuming that the produce we are talking about had some marker on it that allowed you to——

Ms. DEGETTE. Well, right now when you go to the store, and I am amazed, frankly, when I go to the grocery store, everything you buy has now a little label on it. A tomato has a little sticky label on it. Each banana has a sticky label on it. So you can do that, correct?

Dr. ACHESON. Yes, and often the labels have the country of origin on them, just as a point.

Ms. DEGETTE. Well, right now I am focusing on traceability.

Dr. ACHESON. I apologize.

Ms. DEGETTE. And has the FDA investigated what it would take to make the traceability systems interoperable?

Dr. ACHESON. We are actively doing that right now. We have met with a number of trade associations who are using traceability systems and they are a little different, and we are trying to right now understand what is the universe of traceability systems to begin to understand what might an interoperable system look like.

Ms. DEGETTE. And what is your time frame for making those assessments?

Dr. ACHESON. Well, I think clearly this tomato outbreak has accelerated those. There is no question.

Ms. DEGETTE. So are you thinking again the 6- to 8-week time period, 3 to 6 months, a year?

Dr. ACHESON. For what? For an understanding of what an interoperable system——

Ms. DEGETTE. For an understanding of what we would need to do nationally to implement a traceability system.

Dr. ACHESON. I sincerely hope we would be there within a year, if not sooner.

Ms. DEGETTE. OK. I am wondering if you have someone over at the FDA who is an expert in traceability that we might meet with as we develop our food safety legislation.

Dr. ACHESON. We have many people who do this.

Ms. DEGETTE. If you wouldn't mind having those people get in touch with my staff, I would say next week also, that would be extremely helpful.

Dr. ACHESON. Sure.

Ms. DEGETTE. I have one last question, if I can find it. I don't know if you are familiar with the letter that Senator Specter sent to Secretary Leavitt on June 10, 2008, about his concern about the budget amendment for the FDA for food safety. Are you familiar with that letter?

Dr. ACHESON. I am familiar with some of the press around it. I haven't seen the letter itself.

Ms. DEGETTE. Well, in the letter—and I will have someone give you a copy of it—Senator Specter says, "The submission of your budget amendment at this time undermines the work that we have been doing to obtain these additional dollars on an expedited basis. The facts are that if these funds are not provided in the supplemental, no additional dollars will be available until March or April of 2009 at the earliest. Supporting additional dollars in fiscal year 2009 sends a signal that there is no urgency in providing these funds." It is in the third paragraph of that letter. I would ask you

if the department supports the providing of the funds in the supplemental appropriations bill so we can begin to get some funding for these food safety issues right now rather than waiting for an entire another year by going through the regular budget process?

Dr. ACHESON. My understanding is that there is an active discussion between Congress and the White House right now, and that essentially all I know about that component is that it is under active discussion.

Ms. DEGETTE. Well, let me ask you this. Would the Agency support—well, let me just strike that and ask you, if we could begin to provide the money to fund the Food Safety Plan right now, would that enable the Agency to start expediting some of the planning and some of the implementation that we all agree needs to happen right away?

Dr. ACHESON. The sooner we get the money, the sooner we will be able to move and the faster we will be able to go.

Ms. DEGETTE. Thank you very much.

Mr. STUPAK. Let me ask just to wrap things up; the traceability now, are you saying that you support Ms. DeGette's idea of traceability or will the Administration support it?

Dr. ACHESON. I am saying that I am supporting the importance of traceability.

Mr. STUPAK. So it is possible what happened with the United Fresh Produce Association and Produce Marketing Association when they worked with the FDA to establish safety standards, could get swatted down as one farther up the totem pole, right?

Dr. ACHESON. Let me just back up a little bit. I haven't read Ms. DeGette's bill for a little while and I don't remember the specifics in it, but what I can tell you is that traceability is critical in terms of response, and whether the Administration may ultimately take what Ms. DeGette's draft language is, I couldn't say. But the concept of traceability certainly is important.

Mr. STUPAK. Well, you said all day today your hands have been tied with OMB as far as budget money. Testimony earlier was that the federally-mandated risk base that allow for commodity-specific regulation that the fresh produce association and the FDA started to swat it down by Secretary of HHS; so traceability, that I think we all agree would be helpful. It could get swatted down as it went farther up the chain, right?

Dr. ACHESON. I can't predict what farther up the chain may do to anything. All I can say is, is that from my role as associate commissioner for foods, traceability is important and I would advocate for it.

Mr. STUPAK. You would advocate for it. Well, let me ask you this. So you advocate. Since we have had outbreaks of salmonella, E. coli, botulism over the past 12 months and in our last hearing on heparin, Dr. Woodcock agreed that subpoena power would be helpful. As food czar, will you also agree that subpoena power would be helpful to address the food-related outbreaks?

Dr. ACHESON. Subpoena power for what?

Mr. STUPAK. For records. Take ConAgra, the salmonella and peanut, we are still waiting for those records, and you have no subpoena power, FDA has no subpoena power to get those records. Would you support subpoena power to get records of the producers?

Dr. ACHESON. Well, through the Bioterrorism Act, we do have the authority to require records through section 414. If somebody has got—and we have done that a number of times in relation to foodborne outbreaks where——

Mr. STUPAK. Well, will you use it then to get the records from ConAgra for peanut butter?

Dr. ACHESON. I don't think we have used it for that.

Mr. STUPAK. But will you?

Dr. ACHESON. You are talking about old records.

Mr. STUPAK. We are talking about past records.

Dr. ACHESON. Yes. Records that are linked to a current ongoing situation, we use section 414 of the Bioterrorism Act and have used that to get records.

Mr. STUPAK. So do you support subpoena power or not?

Dr. ACHESON. I would have to get back to you on that to try to understand more specifically subpoena power, whether it is additive to what we already have or whether we would need it.

Mr. STUPAK. How about mandatory recall? Would you support mandatory recall?

Dr. ACHESON. Yes, that is in the Food Protection Plan.

Mr. STUPAK. OK. And last but not least, we talked about Mr. Dingell's legislation, the Food and Drug Administration Globalization Act of 2008. Will you get back, make a commitment to get back with us with specific technical assistance on the Dingell legislation?

Dr. ACHESON. I certainly will promise to get back to you and probably the most constructive way is to have a direct dialogue over that.

Mr. STUPAK. OK, but that does that mean you are going to provide the technical assistance? The Dingell draft has been around for some time and we have got nothing from the FDA. We have asked for it.

Dr. ACHESON. I will—yes, the FDA will provide technical assistance.

Mr. STUPAK. When? This year, next year?

Dr. ACHESON. This year.

Mr. STUPAK. How about next week?

Dr. ACHESON. That may be a bit quick.

Mr. STUPAK. All right. Six days then. I am not going up any further.

Dr. ACHESON. Six days.

Mr. STUPAK. All right.

Dr. ACHESON. I will do my best.

Mr. STUPAK. I will look for it in 6 days. Any questions?

I want to thank you, Dr. Acheson, for your testimony and thank you for your time. That concludes all of our questioning. I want to thank all the witnesses for coming here today and for your testimony. I ask for unanimous consent that the hearing record remain open for 30 days for additional questions for the record. Without objection, the record will remain open. I ask unanimous consent that the contents of our document binder be entered into the record. Without objection, the documents will be entered into the record.

That concludes our hearing. Without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 2:14 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. JOE BARTON

Thank you Chairman Stupak and Ranking Member Shimkus, for holding this hearing today to examine FDA's food protection plan.

We are again reminded about how important food safety is with this week's salmonella outbreak in raw tomatoes. Each year in the U.S. there are 76 million cases of food poisoning and 5,000 deaths, according to the Centers for Disease Control. What can we do to reduce the number of outbreaks?

First, we can't forget that in America, it isn't the government that feeds the people. That system mostly collapsed along with the Berlin Wall. The government does have a role, though, and I think our first job is to examine policies that help promote innovation among the industries that produce the food we eat. For example, this subcommittee has already received testimony on the increased safety levels that can be achieved with more food irradiation. According to Dr. Michael Osterholm of the University of Minnesota, if 50% of meat and poultry were irradiated, 900,000 fewer people would get sick and 300 fewer would die.

Irradiation isn't the only food safety technology available, however. There are new gene-splicing technologies that go beyond irradiation and could kill bacterial toxins before these microorganisms could grow within the plant cells. Unfortunately, the Luddites who insist on scaring consumers about the value of science and technology are hard at work, too, and I realize that winning broad acceptance of these new techniques is going to be a slow and difficult business.

Second, we must bring FDA into the 21st century on matters of food safety. Today we will examine the FDA's Food Protection Plan. We should look closely at the details and keep on top of this agency to make sure it can make the sustained effort necessary to implement its proposed reforms.

This subcommittee's work has helped the Agency and Administration respond to our findings—and the Administration really has responded. Just 2 days ago, Health and Human Services Secretary Michael Leavitt announced an amendment to the FY 2009 FDA budget request that adds $275 million for food and drug safety. I think the President and Secretary Leavitt got it right, and I am in favor of this additional funding because I think it will go a long way to allowing FDA to correct the deficiencies that this subcommittee's good work has highlighted over the past year.

This is serious money, for a serious purpose. After eight oversight hearings and one legislative hearing on food safety, it's time for us to join the Administration and start acting. We don't have much time because as everybody in this room knows, the legislative window for this Congress is closing. Oversight functions can't stop, but the legislating needs to start in earnest.

I have made clear throughout these Oversight hearings that I support working with the Majority to craft effective legislation to authorize resources and reform this agency. We seem to agree on a lot of the same things, and I'm convinced that we have a real chance to create effective, bipartisan legislation that will help make people's food safer.

That brings me to my third point—bipartisanship. I've spent nearly a quarter of a century on this committee, and what I've learned tells me that major pieces of FDA legislation pass through this committee most easily and most effectively when we figure out how to work together. There just should not be any light between Republicans and Democrats on this issue, but the Majority's a latest sweeping food and drug safety draft bill was written and made public with no input from the Republican side.

I'm happy to report, however, that our staffs have been regularly meeting to overcome a poor start. I appreciate your efforts, Chairman Stupak. I hope we can see more bipartisan interaction on the legislation, especially now that the Administration has given us something to work with.

# # #

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June 11, 2008

The Honorable David Obey
Chairman, Committee on Appropriations
United States House of Representatives
H-218 The U.S. Capitol
Washington, D.C. 20515

The Honorable Jerry Lewis
Ranking Member, Committee on Appropriations
United States House of Representatives
1016 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Obey and Ranking Member Lewis:

Thank you for your continued leadership in providing the funding necessary to strengthen the U.S. Food and Drug Administration (FDA) over the last year. With all the critical issues related to ensuring the safety of our food and drug supply the FDA is currently facing, we need to continue to build on the gains we have made recently.

Through our Committee's oversight activities, it has become clear to us—as we are sure it has to you—the FDA does not have sufficient resources to fulfill its mission. Nowhere is this more clear than in the area of food and drug imports—FDA has immediate resource needs in order to fulfill its statutory responsibilities.

If domestic spending provisions are ultimately included in the FY 2008 Emergency Supplemental Appropriations bill, we strongly encourage you to incorporate the $275 million for the Food and Drug Administration that was included in the Senate bill. FDA Commissioner Andrew von Eschenbach is supportive of this amount, and has described it as necessary for FDA to modernize its systems and strengthen its capacity at a time when its responsibilities far outstrip its resources.

We recognize the challenges in prioritizing appropriations requests; however, the immediate need for increased funding for the FDA is critical to ensure that FDA can perform its

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core missions in ensuring a safe food and drug supply. To ensure these funds are used in a responsible way, we suggest that the funding be specifically provided for the priority needs Dr. von Eschenbach has identified.

Thank you for your consideration and support for this critical cause. If you have questions or need additional information, please do not hesitate to contact us, or have your staff contact Ryan Long at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member
Committee on Energy and Commerce

Nathan Deal
Ranking Member
Subcommittee on Health

John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

Fred Upton
Ranking Member
Subcommittee on Energy and Air Quality

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U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. von Eschenbach:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations have had a longstanding interest in the management and operations of the FDA Office of Criminal Investigations (OCI).

When it was administratively created in 1991, OCI started with about 130 criminal investigators. OCI now has about 190 criminal investigators, which is almost a 50% increase. The OCI budget has grown substantially as well: it was $21.2 million in Fiscal Year 2000 (FY2000) and $36.3 million for FY2006—a 71% increase in spending in only six years. However, the number of arrests and convictions has been just the opposite: 421 arrests and 353 convictions in FY2000; only 341 arrests and 279 convictions for FY2006. Doing the math, this means that the cost per conviction has more than doubled from $51,000 in FY2000 to $130,000 in FY2006.

At a time when we are contemplating how to ensure that FDA has sufficient resources to carry out its core missions of ensuring food, drug and device safety, we question whether continued funding and staffing of OCI at current and projected levels is the best use of scarce federal dollars. Further, as a policy matter, we question whether keeping investigations as a separate entity may have a detrimental impact on FDA's ability to effectively carry out its inspection activities.

In order to assist us in examining whether these resource trends and priorities make sense in light of the 21st century challenges facing FDA, we are seeking further information about OCI:

1. The budget request and the budget justification for OCI covering FY 2009.

2. Detailed expenses and accounting for FY2007, including the following breakdown with associated source of funding:

   a. Salary, overtime, bonuses, awards, and pay grade (e.g., GS-10) for each individual in OCI. Please identify the number of OCI agents working with law enforcement task forces, the names of these task forces, and the salary/overtime/bonus/award expenses for these agents.

   b. Number of hours OCI agents logged against each particular case, and number of hours and/or cost amounts for categories (e.g., counterfeit drugs, tampering) of cases worked.

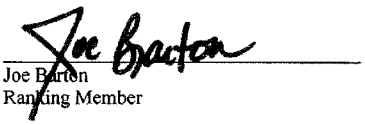
   c. Amounts paid from Central Funds for OCI leased office space.

   d. An accounting of all other administrative expenses, sufficiently detailed to identify the particular activity for which disbursement was made. At a minimum, this should include expenditures related to field office inspections, training, firearms, non-salary personnel costs, and seizure and storage costs.

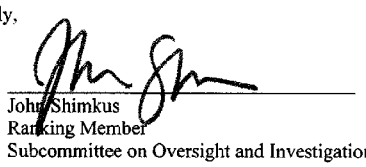
3. For FY2007, if OCI's claimed forfeitures include disgorgements, the amount generated from disgorgements. In addition, the amount of money OCI has recovered for OCI's budget from sharing in fines or forfeitures in cases, the amounts from each case and the name of the case, and where the asset forfeitures went.

Please provide responses to the following by June 6, 2008. If you have any questions, please contact Mr. Alan Slobodin of the Minority Committee staff at (202) 225-3641.

Sincerely,



Joe Barton
Ranking Member



John Shimkus
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Chairman
The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

Meat Recall List (2007-Present)

Company	Date	Product	Quantity	Cause
Pap's Lousiana Cuisine	Jan. 3	hog head cheese	290 lbs.	Listeria
Gold Star Sausage Co.	Jan. 5	sausage	15,514 lbs.	Listeria
Sigma Foods, Inc.	Jan. 9	cooked ham	19,488 lbs.	Mislabeled (poultry omitted)
Agriprocessors, Inc.	Jan. 23	frankfurters	2,700 lbs.	Underprocessing
Water Lilies Food, Inc.	Jan. 25	pork dumplings, won-ton products	77,730 lbs.	Undeclared allergens (egg white)
Garden Leaf Foods	Jan. 25	chicken pasta salad	1,591 lbs.	Listeria
Hill Meat Co.	Jan. 26	smoked ham	1,080 lbs.	Underprocessing
Natural State Meat Co.	Jan. 29	ground beef	4,240 lbs.	E. coli
Morgan Foods	Feb. 3	chicken noodle soup	6,317 lbs.	Undeclared allergen (milk)
The Wornick Company	Feb. 5	pasta entrees for toddlers	7,848 lbs.	Undeclared allergen (cheese)
ConAgra	Feb. 12	pasta & meatball meals	402,623 lbs.	Underprocessing
Carolina Culinary Foods	Feb. 18	chicken breast strips	52,650 lbs.	Listeria
First Quality Sausage	Feb. 27	semi-boneless ham steak	930 lbs.	Listeria
Tyson Fresh Meats	Mar. 2	ground beef	16,743 lbs.	E. coli
Hempler Foods, Inc.	Mar. 9	summer sausage	5,084 lbs.	Undeclared allergen (hydrolyzed sodium caseinate)
Petrapport	Mar. 23	pig ear dog treat	unknown	Salmonella
Kraft Foods Groups	Mar. 27	bacon	1,800 lbs.	Insufficient cooling
Earle of Sausage	Apr. 13	sausage	330 lbs.	Staphylococcus aureus
Patrick Cudahy, Inc.	Apr. 18	soppressata (salami) products	5,625 lbs.	Undeclared allergen (wheat)
Richwood Meat Company	Apr. 20	frozen ground beef	107,943 lbs.	E. coli
HFX, Inc.	Apr. 20	beef	259,230 lbs.	E. coli
Diestel Turkey Ranch	May. 1	ready-to-eat turkey	6,907 lbs.	Listeria
PM Beef Holdings, LLC	May. 10	beef trim w/ ground beef	117,500 lbs.	E. coli
Davis Creek Meats and Seafood	May. 11	beef	129,000 lbs.	E. coli
Kayem Foods, Inc.	May. 18	raw chicken sausage products	35,580 lbs.	Undeclared allergen (wheat)
United Food Group, LLC	Jun. 3	ground beef	5.7 million lbs.	E. coli
Really Cool Food Company	Jun. 5	chicken	140 lbs.	Listeria
Tyson Fresh Meats	Jun. 8	ground beef	40,440 lbs.	E. coli
Washington Beef	Jun. 15	beef	86,286 lbs.	Unsanitary conditions
State of Tennessee Cook Chill	Jun. 29	ready-to-eat chicken	2,768 lbs.	Listeria
Agriprocessors, Inc.	Jul. 6	frozen beef and chicken products	35,860 lbs.	Undeclared allergen (egg albumen)
Castleberry's Food Co.	Jul. 18	canned meat	721,389 lbs.	Botulism
Abbott's Meat, Inc.	Jul. 21	ground beef	26,669 lbs.	E. coli

Custom Pack, Inc.	Jul. 25	ground beef, buffalo	5,920 lbs.	E. coli
Ian's Natural Foods	Aug. 14	frozen turkey products	12,894 lbs.	Undeclared allergen (non-fat milk)
Frank Wardynski & Sons, Inc.	Aug. 16	sausage product	17,000 lbs.	Undeclared sulfites
Interstate Meat Distributors, Inc.	Aug. 31	ground beef	41,300 lbs.	E. coli
Fairbank Farms (reconstruction corp.)	Sept. 5	ground beef	884 lbs.	E. coli
Topps Meat Company LLC	Sept. 25	frozen ground beef	21.7 million lbs.	E. coli
Impero Foods and Meats, Inc.	Sept. 29	ground beef	65 lbs.	E. coli
Cargill Meat Solutions Corporation	Oct. 6	frozen ground beef	845,000 lbs.	E. coli
Aliki Foods, Inc.	Oct. 9	chicken and pasta	70,400 lbs.	Listeria
ConAgra	Oct. 11	frozen pot pie	all	Salmonella
J & B Meats Corporation	Oct. 13	frozen ground beef	173,554 lbs.	E. coli
Arko Veal Company	Oct. 13	ground beef	1,900 lbs.	E. coli
Blue Ribbon Meats	Oct. 24	frozen ground beef	8,200 lbs.	E. coli
Del-Mar Provision Co.	Oct. 27	ground beef	50 lbs.	E. coli
General Mills Operations	Nov. 1	frozen pizza with pepperoni	3.3 million lbs.	E. coli
Annex Foods	Nov. 1	cooked beef and chicken products	4,374 lbs.	Adulterated
Cargill Meat Solutions Corporation	Nov. 3	ground beef	1,084,384 lbs.	E. coli
Circle Foods, LLC	Nov. 8	frozen beef tamales	3,750 lbs.	metal
Double B Foods, Inc.	Nov. 15	frozen sausage rolls	98,000 lbs.	Listeria
American Foods Group, LLC	Nov. 24	ground beef	95,927 lbs.	E. coli
Custom Culinary, Inc.	Dec. 6	beef and chicken base products	990 lbs.	Undeclared allergen (milk, soy)
Specialty Foods Group, Inc.	Dec. 10	Braunschweiger liver sausage products	98,772 lbs.	Undeclared allergen (non-fat dry milk)
Snapps Ferry Packing	Dec. 17	hamburger patties, bulk ground beef	102 lbs.	E. coli
Maramont Corporation	Dec. 20	beef patty	88 lbs.	Listeria
Texas American Food Service Corp.	Dec. 27	ground beef	recalled yet, only	E. coli
Mark's Quality Meats Inc.	Jan. 5	steak cuts, ground beef products	13,150 lbs.	E. coli
Rochester Meat Co.	Jan. 12	ground beef products	188,000 lbs.	E. coli
Perdue Farms, Inc.	Jan. 26	boneless, skinless chicken breast	24,710 lbs.	Undeclared allergen (milk)
Chef's Requested Foods, Inc.	Feb. 1	bacon wrapped beef tenderloin	8,910 lbs.	Undeclared allergen (milk, soy)
Hallmark/Westland Meat Packing Co.	Feb. 17	raw, frozen beef products	143,383,823 lbs.	Unfit for consumption
Meijer Distribution Center	Mar. 2	frozen chicken entrees	2,184 lbs.	Listeria
Costco Wholesale	Mar. 3	frozen chicken entrees	10,368 lbs.	Listeria
Inovata Foods	Mar. 4	frozen chicken entrees	3,780 lbs.	Listeria
Gourmet Boutique L.L.C.	Mar. 4	meat and poultry products	6,970 lbs.	Listeria
Cagle's Inc.	Mar. 14	fresh, frozen poultry giblets; fresh carcasses with inserted giblets	943,000 lbs.	Adulterated due to improper disposition
Koch Foods	Mar. 29	frozen chicken breast products	1,420 lbs.	Mislabeled

Elkhorn Valley Packing LLC	Apr. 4	frozen cattle heads	406,000 lbs.	Tonsils not completely removed
Gourmet Boutique LLC	May 3	fresh, frozen meat and poultry products	286,320 lbs.	Listeria
Palama Holdings, LLC	May 8	ground beef products	68,670 lbs.	E. coli
Fairbank Reconstruction Corp.	May 12	ground beef products	22,481 lbs.	contained plastic
JSM Meat Holdings Co., Inc.	May 16	beef products		E. coli
Sofia Chicharones, Inc.*	May 19	pork crackling products	1,100 lbs.	Salmonella
Tyson Fresh Meats*	May 21	ground beef products	808 lbs.	E. coli
Cecina Los Amigos	May 21	pork blood sausages	290 lbs.	Listeria
Dutch's Meat, Inc.	Jun. 8	ground beef products	13,275 lbs.	E. coli
Gourmet Foods, Inc.	Jun. 9	ready-to-eat chicken products	130 lbs.	Listeria

*health alert only
*no recall because no longer available

Vegetable Recall List (2007-Present)			
Company	**Date**	**Product**	**Cause**
Whole Foods Market	Jan. 31	365 Everyday Value Kalamata Olive Tapenade	glass fragments
Dole Foods	Feb. 16	cantaloupes	Salmonella
Americas Kitchen	Feb. 22	Green Bean Casserole	Listeria
Castle Produce	Feb. 23	cantaloupes	Salmonella
Simply Fresh Fruit, Inc.	Mar. 1	Fresh Cut Fruit trays	Salmonella
Cibo Specialty Foods	Mar. 6	olives	Botulism
Strong America Ltd.	Mar. 7	Dried Potato	undeclared sulfites
Flora Foods	Mar. 8	Cerignola Olives	Botulism
Charlie Brown di Rutigliano & Figli S.r.l.	Mar. 27	olives	Botulism
McCall Farms	May. 18	Margaret Holmes Seasoned Turnip Greens	Diesel fuel
Gills Onions Inc.	Jun. 19	diced yellow onions	Listeria
Robert's American Gourmet	Jun. 28	Veggie Booty	Salmonella
Robert's American Gourmet	Jul. 2	Super Veggie Tings	Salmonella
Lakeside Foods, Inc.	Aug. 1	French Style Green Beans	Botulism
Los Angeles Salad Co.	Aug. 22	Genuine Sweet Baby Carrots	Shigella
Metz Fresh	Aug. 28	spinach	Salmonella
Dole Foods	Sept. 17	Dole Hearts Delight Salad	E. coli
Strong America Ltd.	Sept. 26	Goldensmell brand Dried Fungus	undeclared sulfites
Top Line Specialty Produce	Dec. 19	Fresh Italian Basil	Salmonella
New Era Canning Co.	Dec. 21	canned cut green beans	Botulism
Strong America Ltd.	Dec. 23	Dried Potato	undeclared sulfites
New Era Canning Co.	Jan. 8	Mexican style chili beans, green beans, dark red kidney beans	inadequately cooked (could have Botulism)
New Era Canning Co.	Jan. 18	canned green beans, garbanzo beans	Botulism
Inter-American Products	Jan. 21	Deli Chef Tri-Bean Salad	Botulism
New Era Canning Co.	Feb. 7	all large cans of vegetable products	Botulism
Lion Pavilion LTD.	Feb. 15	Grassplot brand Dried Pachyrhizus	undeclared sulfites
Walker's Food Products Co.	Feb. 28	Four Bean Salad	Botulism
Agropecuaria Montelibano	Mar. 22	cantaloupes	Salmonella
Charlie's Produce	Mar. 22	cantaloupes	Salmonella
Central American Produce, Inc.	Mar. 24	cantaloupes	Salmonella
T.M. Kovacevich International, Inc.	Mar. 25	cantaloupes	Salmonella
Tropifresh Inc.	Mar. 26	cantaloupes	Salmonella
Simply Fresh Fruit, Inc.	Mar. 27	fresh cut fruit products containing cantaloupe	Salmonella

Chiquita Brands International, Inc.	Mar. 27	cantaloupes	Salmonella
Bounty Fresh, LLC	Mar. 27	cantaloupes	Salmonella
Dole Fresh Fruit Company	Mar. 28	cantaloupes	Salmonella
Spokane Produce, Inc.	Mar. 28	cantaloupes	Salmonella
JARD Marketing	Mar. 28	fresh cut fruit products containing cantaloupe	Salmonella
Fresh Express Foods Corporation, Inc.	Mar. 28	cut cubed processed cantaloupe	Salmonella
Taylor Fresh Foods	Apr. 3	fresh cut fruit products containing cantaloupe	Salmonella
Chang Farms	Apr. 19	Soy Sprouts	Listeria

Seafood Recall List (2007-Present)					
Company	Date	Food	Quantity	Cause	Origin
Royal International Trading, Inc.	Jan. 30	Atlantic herring		Uneviscerated (may cause botulism)	
Bayview Seafood	Feb. 26	oysters		norovirus	
Rose Bay Oyster Co.	Feb. 28	oysters		norovirus	
Southeast Asian Foods	Mar. 27	fish paste, fish ball, fish cake		Undeclared liquid egg white	
Ikea	May. 14	marinated herring		Glass fragments	Sweden
Hong Chang Corporation	May. 23	monkfish		Tetrodotoxin	China
Nissin Foods Co., Inc.	Jul. 20	shrimp-flavored noodles		Undeclared cod and lobster	
Krasniy Oktyabr Inc.	Aug. 7	Herring of the Special Ambassador "7 Uzlov"		Botulism	
Everlasting Distributors, Inc	Aug. 13	Blue Ocean Smoked Mackerel		Botulism	Philippines
Acme Smoked Fish Corporation	Aug. 14	Smoked Salmon	246 lbs.	Listeria	Chile farm
Ocean King Enterprises Inc.	Aug. 16	Ready-to-Eat Seafood Dips		Listeria	
Everlasting Distributors, Inc	Aug. 29	Blue Ocean Smoked Indian Sardine Tamban		Botulism	
Jensen's Old Fashioned Smokehouse Inc.	Sept. 7	Jensen's Seattle Style Wild Smoked Salmon Spread Lemon Dill and Onion, PCC brand Smoked Salmon Spread all-natural	936 tubs	Listeria	Alaska, Washington
Bell's Fishery	Oct. 25	Bell's Whitefish Pate		Undeclared egg, soy, milk	
House of Thaller	Oct. 29	Smoked Salmon Dip	529 lbs.	Listeria	United States
Quality Plus Products, Inc.	Nov. 29	Jackson's Quality Plus Smoked Wild Salmon Spread		Undeclared egg	
Royal Seafood Baza, Inc	Dec. 19	dried roach fish		Botulism	Latvia
Seoul Shik Poom Inc.	Jan. 23	Yellow Croaker		Botulism	
Choyce Products	Feb. 9	frozen Yellowfin Tuna	5,452 lbs.	Salmonella	
Summit Import Corporation	Feb. 12	Sum Cheong Lung brand Dried Fish		Uneviscerated (may cause botulism)	
Slade Gorton and Co.	Mar. 14	cooked, ready-to-eat, frozen langostinos		Listeria	
Grand Supercenter, Inc.	Apr. 1	HC Fresh, Frozen Salted Croaker		Botulism	South Korea

LFI Enterprises Inc.*	May 15	cream cheese, seafood		HACCP violations	
Lifeway Foods, Inc.*	May 15	cream cheese, seafood		HACCP violations	
Hope Food Supply, Inc.*	May 16	dried smoked catfish steak, smoked seafood products		HACCP violations	

*closure, not recall

Other Recalls (2007-Present)			
Company	Date	Product	Cause
Ho's Trading Inc.	Jan. 2	Home Special Health Soup Recipe (dry mix)	undeclared sulfites
El Norteno Distributors	Jan. 12	brown corn cookies	undeclared eggs
Tastefully Simple	Jan. 18	Dried Tomato and Garlic Pesto Mix	undeclared sulfites
Lesley Elizabeth, Inc.	Jan. 22	products containing sun dried tomatoes	undeclared sulfites
Elegant Gourmet Inc.	Jan. 22	Elegant Sweets Chocolate Cream Truffles	undeclared milk
E.D. Smith & Sons, LP	Jan. 25	Wegman's Fat Free Garden French Dressing	undeclared milk
Fine Land Corporation	Jan. 25	Ying Feng Foodstuffs brand Melon Candy	undeclared sulfites
Vitalabs, Inc.	Jan. 29	Egg Protein Powder	undeclared dairy content
United States Bakery	Jan. 30	Betsy Ross Brand Chocolate Donuts, Old Fashioned Donuts	undeclared milk
QFL, Inc.	Jan. 31	Major Egg products	undeclared dairy content
Unilever	Feb.1	Knorr Chicken flavor Bouillon Cubes	undeclared cod fish
McKee Foods	Feb. 5	Little Debbie Nutty Bars	metal fragments
Ho's Trading Inc.	Feb. 5	Fortune Star Brand Dried Lily Bulb	undeclared sulfites
The Grainless Baker	Feb. 5	gluten and casein free sandwich bread	undeclared milk
Peanut Processors, Inc.	Feb. 6	peanut paste	metal fragments
Vintage Food Corp.	Feb. 12	Elmas Brand Apricots	undeclared sulfites
ConAgra	Feb. 14	Peter Pan peanut butter, Great Value peanut butter	Salmonella
Vita Specialty Foods, Inc.	Feb. 16	various sauces	undeclared milk
Earth's Best	Feb. 16	Organic 2 Apple Peach Barley Wholesome Breakfast baby food	botulism
American Italian Pasta Co.	Feb. 20	Giant Eagle brand Egg Free Pasta Ribbons	undeclared eggs
Daiei Trading-Chicago-Co.	Feb. 22	Bean Cracker (Itomo Mame Mix)	undeclared peanuts
Denise Distribution Corp.	Mar. 1	Denise brand Dyno Mix	undeclared sulfites
Stump Acres Dairy	Mar. 2	raw milk	Salmonella
Jermuk	Mar. 7	Jermuk brand Mineral Water	arsenic
Frito-Lay	Mar. 9	Fritos Original Corn Chips	undeclared milk, wheat
Continental Mills	Mar. 9	GFS Buttermilk Pancake Mix	undeclared eggs
Safeway Inc.	Mar. 9	Safeway brand breads	metal fragments
WinCo Foods	Mar. 9	Cascade Pride breads	metal fragments
Gretchen's Shoebox Express	Mar. 15	Tuna and Garden Salad Mixer	undeclared soybeans
Ben & Jerry's	Mar. 16	Country Peach Cobbler Ice Cream	undeclared wheat

DBC Foods	Mar. 16	Coburn's, Cash Wise, and Midwest Pride potato salad	Listeria
Frango Cheggs	Mar. 23	Frango Cheggs Chocolate and Chocolate-Covered Egg-Shaped Candies	undeclared eggs, milk
Harry London Candies, Inc.	Mar. 23	Harry London Chocolate Fudge, Peanut Butter Egg Candies	undeclared eggs, corn starch, dextrose, Red#40, Yellow #6, Blue #2.
Guida's Milk & Ice Cream	Mar. 23	Guida Label Lowfat Chocolate Milk	contains food grade sanitizer
Healthy Corner Foods Inc.	Mar. 29	chicken and turkey sandwiches, salads, salad sandwiches	undeclared milk
Acapulco Bakery	Mar. 29	Lorenzo brand Conchas de Sabor Vainilla, Cuernitos de Canela, Hojaldras, Croissant and Sweet Mexican Bread	undeclared milk
Greenleaf	Apr. 2	Lemon Bars	undeclared milk
86th Meat	Apr. 3	Energy Club brand Healthy California Mix	undeclared sulfites
ChemNutra	Apr. 3	wheat gluten	melamine
Energy Club, Inc.	Apr. 4	Energy Club brand Healthy California Mix	undeclared sulfites
Harry & David Operations Corp.	Apr. 6	Dark Chocolate Clusters The Ultimate Walnut Cherry Caramel Indulgence	undeclared peanuts, cashews
Harry & David Operations Corp.	Apr. 13	boxes of candies	undeclared nuts
Fisher's Dairy	Apr. 13	raw milk	Listeria
Wilton Industries	Apr. 20	Wilton Premium Dark Cocoa Candy Melts, Dark Cocoa Candy Melts, Dark Cocoa Mint Flavored Candy Melts	undeclared milk
Galliker Dairy Co.	May 2	Galliker's Acidophilus Plus Reduced Milk	contains under-processed milk
Galliker Dairy Co.	May 3	Galliker's Healthy Chekd Calcium Enriched Fat Free Milk	over-fortified with Vitamin A
Aulcorp Food Marketers Inc.	May 4	Archer Farms Four Cheese Risotto	Salmonella
Mayfield Dairy Farms	May 8	Mayfield Turtle Tracks ice cream	undeclared peanuts
Gurley's Foods, Inc.	May 8	Golden Recipe Cranberry Trial Mix	undeclared sulfites
Misty Meadow Farm	May 10	raw milk	Listeria
Interstate Brands Corp.	May 10	Hostess Mini Pound Cake	mislabeling, contains walnuts
Adelines, Inc.	May 15	Adeline's Steak and Cheese, Adelines Steak, Egg and Cheese, Adelines Bacon, and Adelines Bacon, Egg and Cheese Sandwiches	undeclared milk
Whole Foods Market	May 22	365 Organic Everyday Value Sesame Tahini	Salmonella
R.A.B. Food Group, LLC	May 24	sparkling grape juices	additional pressure in bottle

nSpired Natural Foods	May 25	MaraNatha Sesame Tahini	Salmonella
Abbott	May 25	Similac Special Care Ready-to-Feed Premature Infant Formula with Iron	insufficient iron
Murray International Trading Company, Inc.	May 29	Lucky Eight Brand Dried Lily Bulb	undeclared sulfites
Domega International Ltd.	May 30	King Chief brand Dried Lily Flowers	undeclared sulfites
Green Acres Jersey Farm	Jun. 1	raw milk	Listeria
Toby's Family Foods	Jun. 6	Toby's Lite Sour Crème, Toby's Toasted Sesame Dressing	Salmonella
Tristar Food Wholesale	Jun. 6	Ferrari Chocolate	undeclared peanuts
WholeSoy & Co.	Jun. 7	blueberry yogurt	undeclared dairy content
A. L. Bazzini Company, Inc.	Jun. 11	Dried Turkish Jumbo Apricots	undeclared sulfites
WholeSoy & Co.	Jun. 12	blueberry, mixed fruit yogurt	undeclared dairy content
Back to Nature Foods Co.	Jun. 13	Back to Nature Sesame Ginger Rice Thins Crackers	undeclared milk
Piney Ridge Farm	Jun. 14	raw milk	Listeria
Artisan Confections Co.	Jul. 6	Scharffen Berger Kumasi Sambirano 68 percent Cacao Pure Dark Chocolate bars	undeclared milk
Karlin Food Products, Inc.	Jul. 10	Market Basket Complete Pancake & Waffle Mix	undeclared milk
Prosperity Resources International Inc.	Jul. 10	Sun Kee Brand Dried Sweet Potato	undeclared sulfites
Gerber Products Co.	Jul. 13	Gerber Organic Rice, Organic Oatmeal Cereals	chocking risk
Dul-Mex Guadalajara Inc.	Jul. 20	De La Rosa Pulparindo Candy	lead
Sara Lee Food & Beverage	Jul. 26	whole wheat bread products	metal fragments
Modern Trading, Inc.	Jul. 29	ginger	aldicarb sulfoxide
Whole Foods Market	Jul. 31	365 Organic Everyday Value Swiss Dark Chocolate Bars	undeclared almonds
CFS Operating Ltd.	Aug. 7	Cloud's Tuna Salad Sandwiches and Egg Salad Sandwiches	Listeria
IFS, Inc.	Aug. 10	sandwiches	Listeria
American Pie, LLC	Aug. 25	Marie Callender Turtle Pies	shipped prior to test results
Bella Cucina	Aug. 27	Death by Chocolate cookies	undeclared walnuts
Stirrings, LLC	Aug. 30	Rimmer Brand Mojito Cocktail Garnish	Salmonella
Organic Pastures Dairy Co.	Sept. 7	Grade A raw cream	Listeria
Strong America Ltd.	Sept. 10	Chinese Wolfberry	undeclared sulfites
Harry & David Operations Corp.	Sept. 12	Harry and David Hearthside Soups, Southwestern Chicken Chili Mix	undeclared milk

MCP	Sept. 18	Queso Cincho de Guerrero	Salmonella
Quong Hop & Co.	Sept. 19	Quong Hop and Soy Deli brand tofu	Listeria
MOM Enterprises, Inc.	Sept. 20	Baby's Bliss Gripe Water	cryptosporidium
Inter-American Products, Inc.	Sept. 20	Private Selection Classic Churned Light Chocolate Chip Cookie Dough Ice Cream	undeclared eggs
Sabanero, Inc.	Sept. 28	frying and grating cheese	Staphylococcus aureus
Kraft Foods	Oct. 3	Baker's Premium White Chocolate Baking Squares	Salmonella
Campbell Soup Co.	Oct. 4	Campbell's Chunky Baked Potato Soup with Cheddar & Bacon Bits	plastic fragments
Winn-Dixie Stores, Inc.	Oct. 5	Prestige Chocolate Ice Cream	undeclared almonds
Wegman's Food Markets, Inc.	Oct. 5	Wegmans Food You Feel Good About Country Wheat Rolls	undeclared milk
Vintage Chocolates Inc.	Oct. 10	soy milk chocolate	undeclared milk
Dairy State Foods	Oct. 12	Minnie's Bake Shop Chocolate Chunk Cookies	undeclared macadamia nuts
Quesos Mexico LLC	Oct. 12	Queseria Mexico, Queso Fresco, Fresh White Cheese	Listeria
Lochmead Dairy	Oct. 15	Lochmead Farms Country Fresh Chocolate Premium Ice Cream	undeclared almonds
Shain's of Maine Ice Cream	Oct. 17	Kahlua Brownie Ice cream, Double Fudge Brownie Ice cream	undeclared eggs
A&M Cookie Co. Canada	Oct. 25	President's Choice Chocolate Chunk Brownie Cookies	undeclared milk
The Dutch Kettle	Oct. 30	Hickory BBQ Sauce	undeclared fish protein
The Kroger Co.	Nov. 8	Kroger brand Light Caesar Salad Dressing	mislabeling
Del Rey Tortilleria, Inc.	Nov. 12	flour tortillas	microbial contamination
Coffee Masters, Inc.	Nov. 13	Chipper With Coffee Biscotti	undeclared proteins
Blue Planet Foods Inc.	Nov. 19	Heartland brand Graham Pie Crusts	undeclared milk, almonds, coconuts
Charlemagne Chocolatiers	Nov. 20	dark chocolate organic bars	undeclared milk
Le Gourmet Connection	Nov. 21	Jack Cheese	Listeria
Sweetwater Valley Farms, Inc.	Nov. 21	Southern Cheddar Jack Volunteer Special Cheese	Listeria
Harry & David Operations Corp.	Nov. 21	Milk & Dark Chocolate, White Chocolate Macadamia, Peanut Butter, Milk Chocolate, Macadamia Nut tubs	undeclared nuts
Stop & Shop Supermarket Co.	Nov. 21	Stop & Shop cookie trays	undeclared artificial colors

Sweetwater Valley Farms, Inc.	Nov. 28	Tennessee Aged Southern Mild and Sharp Cheddar Cheese	Listeria
Heuvelton Community Irrevocable Trust d/b/a Heritage Cheese	Nov. 30	Heritage Cheese Ranch Peppercorn Cheese Curd	undeclared eggs
Prosperity Resources International Inc.	Dec. 4	Golden Flower Brand Dried Lily Bulb	undeclared sulfites
Soma Beverage	Dec. 4	Metromint flavor water	Bacillus cereus
Wegman's Food Markets, Inc.	Dec. 7	Wegmans Wreath Kuchen	undeclared pecans
Trader Joe's Co.	Dec. 7	Trader Joe's Pinjur	glass fragments
Harry & David Operations Corp.	Dec. 7	Oatmeal Chocolate Chip, Chocolate Peanut Butter, Cranberry Vanilla Chip cookie mixes	undeclared sulfites, coconut, milk, peanuts
Frito-Lay	Dec. 10	Lay's Classic Potato Chips	undeclared milk
Back to Nature Foods Co.	Dec. 10	Sesame Ginger Rice Thins Crackers	undeclared milk
Prosperity Resources International Inc.	Dec. 11	Sun Kee Brand Ching Po Leung (Soup Mix)	undeclared sulfites
Domega International Ltd.	Dec. 12	King Chief brand Dried Kudzu	undeclared sulfites
Kadouri International Foods Inc.	Dec. 12	King brand Dried Turkish Apricots	undeclared sulfites
Cedarline Natural Foods	Dec. 12	Cedarlane Low Fat Bean Rice & Cheese style Burritos	undeclared casein
Wegman's Food Markets, Inc.	Dec. 12	Wegmans Bouillabaisse Seafood Sauce	undeclared wheat
Whole Foods Market	Dec. 14	365 Organic Everyday Value Swiss Milk Chocolate Bars with Rice Crisps	undeclared nuts
Weis Markets	Dec. 31	Fruit Miniatures, Mini-Fruit Diamonds	undeclared walnuts
Fine Land Corporation	Jan. 3	SNGNE brand Fruit Flavour Chews	undeclared milk
Raja Foods LLC	Jan. 16	Swad brand Abil, Gulal, Kanku, Kum Kum, Lagan Samagri Kit, Pooja Samagri Kit	high lead levels
Harry & David Operations Corp.	Jan. 22	Harry & David Giant Cashews	undeclared nuts
Dreyer's Grand Ice Cream	Jan. 22	Dreyer's Slow Churned Light Caramel Delight and Light Butter Pecan ice cream	undeclared pecans
Prosperity Resources International Inc.	Jan. 23	Wu Hua Cha Instant Tea Beverage	undeclared sulfites
Domega International Ltd.	Jan. 25	Zebra brand sweetened lotus root seed, sweetened coconut	undeclared sulfites
Shiloh Farms	Jan. 28	Shiloh Farms Organic Unhulled Sesame Seeds	Salmonella
Olivier Olive Oil Products, Inc.	Jan. 31	Olivier brand Parmesan & Asiago Dip with Garlic & Basil	botulism

Wang Globalnet	Jan. 31	Lotte Margaret Brand Korean Cracker	undeclared eggs
Cibo Naturals	Feb. 1	Classic Basil Pesto	undeclared pine nuts
Summit Import Corp.	Feb. 1	Oriental Mascot Brand Sweetened Sliced Coconut	undeclared sulfites
Domega International Ltd.	Feb. 4	Korica brand Dried Plum	undeclared sulfites
International Foodsource LLC	Feb. 6	Sun Dried Apricots	undeclared sulfites
Onion Crock of Michigan	Feb. 6	Old Fashion Potato, Minestrone Soups	undeclared soy, wheat
Nick and Katie's, Inc.	Feb. 7	Crab Stuffed Mushrooms, Crayfish, Stuffed Portabella Mushroom, Stuffed Bell Pepper, Stuffed Crab, Mediterranean Stuffed Artichoke, Stuffed Italian Artichoke, Artichoke Balls	undeclared milk, soy, wheat
International Foodsource LLC	Feb. 7	Sun Ripened Apricots	undeclared sulfites
Annie's Naturals	Feb. 11	Shiitake & Sesame Vinaigrette	mislabeling, contains soy sauce
Rocky Mountain Popcorn Co.	Feb. 11	Low Fat Caramel Popcorn	undeclared tree nuts
New BCN Trading, Inc.	Feb. 11	Asian Boy brand Sweet Ginger	undeclared sulfites
See's Candies, Inc.	Feb. 12	Semi Sweet Chocolate Chips	undeclared milk
Sherwood Brands LLC	Feb. 14	Pokémon branded Valentine Cards and Pops	metal fragments
Wang Globalnet	Feb. 14	Lotte Margaret Brand Korean Cracker	undeclared egg, peanuts, milk
Nutri-Foods, Inc.	Feb. 15	Organic Sesame Seeds Natural (Unhulled)	Salmonella
Pierre's Ice Cream Co.	Feb. 20	Pierre's Homestyle Dutch Chocolate Ice Cream	undeclared peanut butter
Mayfield Dairy Farms	Feb. 21	Mayfield Vanilla Classic Ice Cream	undeclared pecans
Quaker Oats Co.	Mar. 4	Aunt Jemima Pancake & Waffle Mix	Salmonella
Alaz Food Corp.	Mar. 6	Delta brand Golden Raisins	undeclared sulfites
Publix Super Markets	Mar. 14	Apple, Pineapple and Pumpkin Empanadas	undeclared milk
Tiffany Food Corp.	Mar. 14	Preserved Rose Plum	undeclared sulfites
Food For Life Baking Co.	Mar. 18	Spelt Bread	contains spelt grain
Williams Foods, Inc.	Mar. 18	Bass Pro Shops Uncle Buck's Light 'n Krispy Original, Light 'n Krispy Hot & Spicy Fish Batter Mix	undeclared milk
Acme Markets	Mar. 18	cinnamon rolls with icing	undeclared milk
Stonyfield Farm	Mar. 28	Stonyfield Organic Fat Free Blueberry Yogurt	plastic, glass fragments
Bay Valley Foods	Mar. 31	America's Choice Classic Caesar Dressing	undeclared fish, soy, wheat
Mrs. Baird's Bakeries	Apr. 1	buns	undeclared milk
Harry & David Operations Corp.	Apr. 4	Harry and David Chocolate Covered Select Blend Espresso Beans	undeclared milk
Malt-O-Meal	Apr. 5	unsweetened Puffed Rice, unsweetened Puffed Wheat Cereals	Salmonella
Piney Ridge Farm	Apr. 7	raw milk	Listeria

Inter-American Products, Inc.	Apr. 7	Private Selection Light Churned Mint Chocolate Chip Ice Cream	undeclared egg, soy, wheat
North Aire Market	Apr. 8	Chicken Dumpling Soup Mix	undeclared almonds
Cracker Barrel Old Country Store, Inc.	Apr. 9	chocolate-covered peanuts, almonds	mislabeling
Fine Land Corporation	Apr. 11	Ying Feng Foodstuffs brand Dried Bulbus Lily	undeclared sulfites
Grand Carnival LLC	Apr. 16	S'morestick Kits	undeclared milk
Pulmuone Wildwood, Inc.	Apr. 16	Leek and Oriental Noodle Fried Dumplings	undeclared eggs
Chaca Chaca Chacatrozo	Apr. 17	candy	lead
KFC Corp.	Apr. 18	Double Chocolate Chip Cakes	unlabeled
WhiteWave Foods Co.	Apr. 23	Silk Soymilk Chocolate Flavor	undeclared milk protein
Little Bay Baking Co.	May 2	corn bread and muffin mix	undeclared soy
Cedar Crest Specialties Inc.	May 2	Lezza Blue Raspberry Water Ice	undeclared milk protein
Cedar Crest Specialties Inc.	May 6	Lezza Blue Raspberry Italian Ice	undeclared milk protein
Blount Fine Foods	May 6	All Natural New England Clam Chowder	undeclared shrimp
Sweetwater Valley Farms, Inc.	May 15	Tennessee Aged Black Pepper Cheese	Listeria
Supreme Cuts LLC	May 27	Off the Cob Fresh Kernel Corn	Listeria
Orval Kent Foods	May 28	Amish Macaroni Salad	E. coli
Fresca Italia, Inc.	May 30	Burrata	Listeria
	Jun. 3	raw red tomatoes* (excluding cherry, grape, those with attached vines, & home grown)	Salmonella
Kraft Foods	Jun. 5	Post LiveActive Mixed Berry Crunch Cereal	undeclared tree nuts

washingtonpost.com

Rotten Tomatoes

Advertisement

Congress should give agencies the power to protect the nation's food supply.

Thursday, June 12, 2008; A22

WHEN HIGH levels of E. coli bacteria turned spinach into a mealtime menace in 2006, we agreed with calls to give the Food and Drug Administration the power to issue mandatory recalls of tainted produce. We also supported the smart idea to require the FDA and other agencies with responsibility over food safety to institute a tracing system so that the next outbreak of tainted food could be contained in days, not weeks. Well, the next outbreak is upon us. And neither good idea has been implemented.

The latest outbreak involves the rare Saintpaul strain of salmonella bacteria in Roma, red plum and red round tomatoes. Don't worry about homegrown, cherry and grape tomatoes or those attached to the vine. The FDA says they are safe. What should make us all worry is the disturbing timeline. Since mid-April, 167 people in 17 states, including Virginia, have been infected with *Salmonella saintpaul*. According to the Centers for Disease Control and Prevention, as of Monday, "At least 23 people were hospitalized. No deaths have been reported." A search for the source of the outbreak has been underway since last month after Texas and New Mexico reported cases. The CDC issued its first warning to consumers on June 5. Stores and restaurants across the country have been pulling tomatoes from their shelves and menus voluntarily since the weekend. Relying on the consciences of folks worried about the bottom line or their corporate reputations is not ideal.

Nestled within the Food Safety Act of 2007 under consideration in the House is a provision sponsored by Rep. Diana DeGette (D-Colo.) that would give the Agriculture Department and the FDA the power to issue a mandatory recall of contaminated food. This is more than reasonable, since the federal government can and did recall lead-tainted toys imported from China last year. Besides, the hammer of potential government action would be a powerful incentive for growers and packers to conform to safety standards.

What's missing from the act is another provision pushed by Ms. DeGette that would require that food producers track their products from "farm to fork." Rep. John D. Dingell (D-Mich.), chairman of the House Energy and Commerce Committee, who is shepherding the act through the House, should include the tracking provision as part of the package -- and then get the legislation passed. This and the power to recall are two tools that would make it easier to protect the nation's food supply and find the source of tainted meat and vegetables the moment an outbreak occurs -- not months and many victims later.

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Ahead of the Bell: FDA food safety program

Democrats expected to leverage salmonella outbreak in calling for more food safety oversight

June 12, 2008: 06:07 AM EST

NEW YORK (Associated Press) - House Democrats on Thursday are expected to use worries over salmonella-infected tomatoes to bolster their calls for tougher food safety measures.

A House Energy and Commerce subcommittee will scrutinize the Food and Drug Administration's food safety efforts. The hearing comes as agency scientists scramble to identify the source of tainted tomatoes that have sickened nearly 170 people in 17 states.

McDonald's Corp., Wal-Mart Stores, Kroger Co. and other grocery and restaurant chains have pulled tomatoes from their stores in recent days as a safety precaution.

Bart Stupak, chairman of the House subcommittee on oversight and investigation, is expected to press FDA officials on the progress they've made toward implementing stronger food safety measures.

The Bush administration in November laid out a plan for requiring government safety seals on imported foods. But experts from the Government Accountability Office and FDA's outside advisory board are expected to tell lawmakers those plans have not been adequately funded.

Democrats on the Energy and Commerce Committee have introduced their own import safety proposal that would charge companies user fees to help pay for more safety inspections.

Prior to the hearing, lawmakers are expected to vote on whether to subpoena records from nine private laboratories that help test food imports for the FDA.

The committee last month requested documents from the labs after learning they sometimes throw out negative test results at the request of food importers. The labs will then retest the food until they get a positive result, according to lawmakers.

Michigan Democrats Stupak and John Dingell, who chairs the House Energy and Commerce Committee, are among FDA's toughest critics in Congress. They have sent three letters to FDA Commissioner Andrew von Eschenbach this year critical of the agency's food safety policies. The committee also has launched about a half-dozen investigations into FDA's oversight of the drug industry. ■

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THE WALL STREET JOURNAL. ONLINE

June 12, 2008

Food-Safety Measures Faulted

Report Questions Funding, Structure Provided for FDA

By JANE ZHANG
June 12, 2008; Page A4

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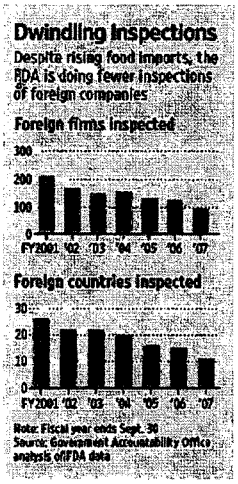
WASHINGTON -- Amid a salmonella outbreak linked to tomatoes, a congressional report criticized the Bush administration for failing to identify the steps and funding needed to protect the nation's food supply.

The Food and Drug Administration hasn't given details on how or when it will put into practice a food-safety plan it first laid out in November, or how much it will cost, according to the Government Accountability Office, Congress's investigations arm.



The report comes as the FDA is under fire for the latest outbreak, this one involving a rare, virulent strain of salmonella linked to fresh tomatoes. Federal officials said Wednesday that 167 people in 17 states have become ill after eating fresh tomatoes. Authorities are investigating whether a death in Texas is related to the outbreak, said Ian Williams, chief of the OutbreakNet team at the federal Centers for Disease Control and Prevention.

The salmonella outbreak follows a slew of food recalls in recent years, including lettuce, peanut butter to pet food.

The GAO report said the FDA had promised a progress report by April on steps it had taken to carry out its plan to keep the food supply safe. But the agency recently told the GAO that its parent, the Department of Health and Human Services, hasn't approved the report.

As a result, "neither Congress nor the public can gauge the plan's progress or assess its likelihood of success in achieving its intended results," Lisa Shames, GAO director of natural resources and environment, said in testimony prepared for a Thursday hearing of the House Energy and Commerce Committee's investigations panel.

Among other things, the plan would make it easier for the FDA to obtain company records that can help trace food contamination, and to force food recalls.

Many lawmakers would like to give the FDA more money and authority, but some say they are puzzled that the Bush administration hasn't sent clear legislative language on what it needs. HHS Secretary Mike Leavitt said Monday that the administration would request an additional $275 million in next year's budget for food safety.

[1] THE FOOD CRISIS

• **See more coverage[2] of the sharp rise in food prices world-wide.**

That drew an angry response Wednesday from Sen. Arlen Specter, the Pennsylvania Republican who was one of Capitol Hill's biggest proponents for getting the FDA an emergency boost of $275 million. Mr. Specter accused the administration of trying to "sabotage" the agency's chances of getting that money any time soon, saying that Mr. Leavitt's approach would "defer it to next March or April."

The FDA declined to comment on Mr. Specter's letter.

On the House side, Rep. John Dingell (D., Mich.), who heads the Energy and Commerce Committee, said the FDA's food-safety plan "will become just a paper exercise if there are no details or money to back it up."

An FDA spokeswoman declined to comment and said the agency will respond to the GAO statement at the hearing.

The FDA has been scrambling to find the source of the salmonella outbreak, David Acheson, FDA's associate commissioner for foods, told reporters Wednesday. Dr. Acheson said the steps the FDA has taken so far to implement the food-safety plan haven't helped track the source.

Unlike bagged salads, which have production codes printed on packages, tomatoes mostly come to retailers, supermarkets and consumers in bulk. To track where the tainted tomatoes were grown, the FDA is relying on record-keeping in the supply chain. That can be spotty and confusing, partly because tomatoes are easily perishable and many merchants have more than one supplier.

"We are getting very close" to identifying the source, but it is "time consuming and complicated," Dr. Acheson said.

The FDA, constrained by resources, hasn't kept pace with the rising number of imported and domestic food products, the GAO said. Dr. Acheson said the agency's food-safety plan would change its focus from crisis management to prevention, and that the salmonella outbreak showed the need to pursue the change "with maximum vigor."

--Jared Favole and Alicia Mundy contributed to this article.

Write to Jane Zhang at Jane.Zhang@wsj.com[3]

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Bloomberg.com

Food Safety Plan by U.S. FDA Lacks Cost Estimate, Deadlines

By Justin Blum

June 12 (Bloomberg) -- The U.S. Food and Drug Administration has failed to provide costs or deadlines for a plan to improve food safety even as tainted tomatoes have sickened Americans, according to a report to Congress.

The agency oversees the safety of about 80 percent of the nation's food supply, including $417 billion in domestic products and $49 billion in imports annually, according to a report by the Government Accountability Office.

The FDA said in a November plan it would improve the way it polices the food industry by collecting data it needs to focus on the riskiest products. Prospects for the plan can't be judged unless the agency explains how it would be carried out, said **Lisa Shames**, director of natural resources and environment for the GAO, in testimony to be given at a House hearing today.

``As food-borne illness outbreaks continue, FDA is missing valuable opportunities to reassure Congress and the public that it is doing all it can to protect the nation's food supply," Shames said in her testimony.

The FDA said yesterday it hasn't been able to identify the source of tomatoes that health officials say are the likely cause of 167 reported **cases** of salmonella in 17 states since mid-April. Lawmakers criticized the FDA's handling of food and drug safety when consumers became ill after eating tainted spinach in 2006, peanut butter in 2007 and using contaminated lots of the blood-thinner heparin this year.

$90 Million in Costs

The FDA plans to spend about $90 million during fiscal years 2008 and 2009 to put in place several aspects of the food safety plan, including identifying risks, according to the GAO, the investigative arm of Congress.

The total cost to follow through with the plan isn't clear, Shames said.

``We continue to have concerns about FDA's lack of specificity on the necessary resources and strategies to fully implement the plan," Shames said.

The FDA plans to respond to the GAO assessment during today's hearing held by the oversight subcommittee of the **Energy and Commerce Committee**, agency spokeswoman **Julie Zawisza** said yesterday in an e-mail.

``The Food Protection Plan will become just a paper exercise if there are no details or money to back it up," said Representative **John Dingell**, a Democrat from Michigan who is chairman of the Energy and Commerce Committee, in an e-mailed statement yesterday. ``I'm curious whether this was just a public relations stunt in response to the repeated recalls and illnesses relating to FDA's inadequacies."

If the agency were to inspect each of more than 65,500 domestic firms regulated by the agency one

time, the cost would be about $524 million, according to the GAO. Inspecting 189,000 facilities overseas would cost about $3.16 billion.

`Need Underscored'

``These figures underscore the need for FDA to focus safety inspections based on risk," Shames said.

Inspections have declined as the number of producers has increased, according to the GAO.

From 2001 to 2007, the number of domestic firms regulated by the FDA increased from 51,000 to more than 65,500 while the number of inspections declined from 14,721 to 14,566, according to the GAO. The FDA conducted 96 overseas inspections last fiscal year, compared with 211 in 2001.

Providing costs for the FDA's food-safety plan is important because some tasks, such as opening offices in China, will require long-term funding, Shames said.

The FDA hasn't adopted recommendations made by the GAO in the past to improve food safety, Shames said. As of May, the agency had adopted seven of 34 food safety recommendations made by the GAO since 2004.

`Shifting Burden'

The agency hasn't established agreements with other countries to ``shift some of the FDA's oversight burden to foreign governments," as the GAO recommended in 2004, according to Shames.

New reports of contaminated tomatoes were still coming in, said Ian Williams of the Atlanta-based Centers for Disease Control and Prevention, on a conference call with reporters yesterday. Salmonella bacteria can cause fever diarrhea, abdominal pain and vomiting, according to the **FDA**.

To contact the reporter on this story: **Justin Blum** in Washington at **jblum4@bloomberg.net**.

Last Updated: June 12, 2008 00:00 EDT

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FDA Budget Figures and Estimates Related to Food Safety

- FDA has approx $619.6 million for current food protection activities (FY 2008 enacted)
- President's initial FY09 budget provides $51 million total new budgetary authority
- Approx $42 million of the $51 million is for food safety efforts ($30 million operational support, $12 million salary adjustments)
- Cost to implement *Food Protection Plan* and implementation details such as implementation of key milestones is UNKNOWN

Source: http://www.fda.gov/oc/factsheets/budget2009.html & Protecting America's Food Supply: An Investment in the FDA Food Protection Plan

Science Board Subcommittee Recommendations Related to Food Safety

- $375 million total new budgetary authority for FDA (for ALL programs)
- $128 million for FY 2009 for food safety efforts
- $75 million for IT system enhancements for FY 2009 (which are essential for food protection efforts)

Source: Science Board Letter to Chairman Dingell, et al, February 25, 2008.

Commissioner von Eschenbach Requested an Additional $275 Million for FY 2008 in the Following Areas:

- $125 million for food protection
- $100 million for safer drugs, devices, and biologics
- $50 million for modernizing science and workforce

Source: Letter from the Commissioner to Senator Arlen Specter, May 5, 2008

June 9, 2008 Request to Amend FDA's FYO9 Budget by Adding the following to the Original Request

- $125 million "Protecting America's Food Supply."
- $100 million "Safer Drugs, Devices and Biologics."
- $50 million "Modernizing FDA Science and Workforce."

Source: HHS News Press Release June 9, 2008

WSJ.com THE WALL STREET JOURNAL. ONLINE

Sen. Specter Says FDA Can't Even Ask for Money Properly

Posted By Theo Francis On June 11, 2008 @ 3:00 pm In Congress, Drugs, FDA | 8 Comments

Now that the FDA has gotten around to asking for $275 million more from Congress for inspections, the agency got another tongue-lashing from frequent critic Sen. Arlen Specter, who chastised HHS Secretary Michael Leavitt for compounding months of foot-dragging with a dollop of spin.

If you're just tuning in, Democrats and some Republicans have been slamming the FDA for failing to adequately police the U.S. food and drug supplies — think tainted heparin, implicated in the deaths of more than 80 people, and salmonella, which most recently is spreading on tomatoes.

Wouldn't a little more money help the FDA cause, the folks on Capitol Hill kept asking? At hearings in May, FDA Commissioner Andrew von Eschenbach wouldn't directly acknowledge that the agency could use more cash than President Bush requested — apparently hindered by an Administration rule forbidding public disagreement with his budget; a subsequent letter danced around the issue.

So, the HHS and FDA have asked for the cash. But the way they did it would put FDA on tap to receive the emergency funds in March or April of next year. Specter (R-Penn.) wants it done a lot sooner, WSJ.com reports. "The grave problem with that is that the FDA has become a joke," Specter told a Judiciary Committee hearing today.

Then there's the way the FDA has presented its about-face. Lately, von Eschenbach and Leavitt have sounded like they're the ones champing at the bit for more money while Congress dilly-dallies. "I would like to once again strongly urge Congress to act quickly to enhance the safety of food and medical products," Leavitt told reporters in a conference call Monday night.

That really set off Specter, who wrote by hand at the bottom of a letter to Levitt: "I am really surprised by your comment quoted in The NY Times today urging Congress to act quickly when the Administration is drastically hindering NECESSARY immediate relief by delaying the funding for 8 or 9 months. The FDA NEEDS this money now to save lives." (You can read the letter by clicking on the PDF icon on the right.)

Article printed from Health Blog: **http://blogs.wsj.com/health**

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June 10, 2008

Honorable Michael Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary ~~Leavitt~~ Mike

I reviewed the $275 million budget amendment for the Food and Drug Administration that the Office of Management and Budget submitted last evening. While I applaud the effort to provide additional dollars for protecting the food supply, assuring safer drugs and modernizing FDA buildings and facilities, I do not understand the timing of this request.

As you are aware, at my urging, an additional $275 million was included in the Senate version of the FY'08 supplemental appropriations bill. This amount was determined after I wrote to Dr. Andrew von Eschenbach requesting that he "submit to me his professional judgment concerning what resources FDA needs to protect the public's health." Currently, negotiations are underway to reduce the domestic portion of the supplemental bill. The FDA funding is among the items being discussed for elimination.

The submission of your budget amendment at this time undermines the work that we have been doing to obtain these additional dollars on an expedited basis. The facts are that if these funds are not provided in this supplemental, no additional dollars will be available until March or April of 2009 – at the earliest. Supporting additional dollars in FY'09 sends a signal that there is no urgency in providing these funds.

The 81 deaths due to contaminated heparin and the one suspected death in the ongoing salmonella outbreak show that we cannot wait nine months to give the FDA the resources needed to protect the public.

I ask that you support our efforts in providing the additional funds for the FDA in the supplemental appropriations bill. Anything less is risking the lives of Americans.

My best,

I am really surprised by your comment quoted in the NY Times today urging Congress to act quickly when the Administration is drastically hindering necessary immediate relief by delaying the funding for 8 or 9 months. FDA needs this money now to save lives.

Sincerely,

Arlen Specter
Ranking Member
Subcommittee on Labor, Health and Human Services and Education Appropriations

AS/blp

#	Description	Date
1	Trust for America's Health Issue Brief, "Fixing Food Safety: Protecting America's Food Supply From Farm-to-Fork."	April 2008
2	GAO Testimony before the Subcommittee on Oversight and Investigations, "Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, But Capacity to Carry Them Out Is Critical" (GAO-08-435T).	01/29/2008
3	Interagency Working Group on Import Safety Report to the President, "Action Plan for Import Safety."	November 2007
4	FDA Food Protection Plan.	November 2007
5	Letter to Dr. Gail Cassell, Chair of FDA Science Board Subcommittee on Science and Technology, from Chairman Dingell, et al.	02/04/2008
6	Gail Cassell's (on behalf of FDA Science Board Committee) response to Chairman Dingell, et al.	02/25/2008
7	Letter to FDA Commissioner von Eschenbach from Senator Arlen Spector (with attachments).	05/05/2008
8	Summary of FDA's FY 2009 Budget	
9	Food Protection Operations Plan (source: FDA)	
10	Food Protection Operations Plan (larger font document)	
11	Protecting America's Food Supply: An Investment in the FDA Food Protection Plan (source: FDA).	
12	Implementing FDA's Food Protection Plan	
13	Status of Information Technology	June 2008
14	HHS News release, "Administration Proposes Additional Funding for FDA to Improve Food and Medical Product Safety."	June 9, 2008
15	Nationally Available Import Databases	

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APRIL 2008

PREVENTING EPIDEMICS. PROTECTING PEOPLE.

Fixing Food Safety:

PROTECTING AMERICA'S FOOD SUPPLY FROM FARM-TO-FORK

Approximately 76 million Americans – one in four – are sickened by foodborne disease each year. Of these, an estimated 325,000 are hospitalized and 5,000 die.[1] Medical costs and lost productivity due to foodborne illnesses are estimated to cost $44 billion annually.[2, 3] Major outbreaks can also contribute to significant economic losses in the agriculture and food retail industries.

Experts estimate that most foodborne illnesses could be prevented if the right measures were taken to improve the U.S. food safety system.

> "FOODBORNE ILLNESSES ARE DEFINED AS DISEASES, USUALLY EITHER INFECTIOUS OR TOXIC IN NATURE, CAUSED BY AGENTS THAT ENTER THE BODY THROUGH THE INGESTION OF FOOD. EVERY PERSON IS AT RISK OF FOODBORNE ILLNESS.[4]"
>
> – World Health Organization

A 2007 public opinion poll conducted by the Trust for America's Health (TFAH) found that 67 percent of Americans are worried about food safety.[5] In fact, concerns about food safety and food contamination rank higher than Americans' concerns about pandemic flu, biological or chemical terror attack, and natural disasters, like Hurricane Katrina.[6]

The recent *E. coli* contamination of spinach and lettuce, concerns about the safety of farm-raised fish from China, and alarming reports of cattle slaughter practices have heightened anxieties about the vulnerability of the nation's food supply.

Studies from the National Academy of Sciences (NAS), the Institute of Medicine (IOM), the U.S. Government Accountability Office (GAO), and the FDA Science Board, which serves as an advisory committee to the U.S. Food and Drug Administration (FDA), have all raised serious concerns about the system that is responsible for keeping the country's food safe.[7, 8, 9]

The U.S. food safety system has not been fundamentally modernized since its incep-

tion over 100 years ago. Current food safety polices are largely based on early twentieth century laws written to deal with concerns that rarely pose significant threats today because of changes in farming and processing practices and technologies.[10]

These outdated concerns receive the bulk of the national resources devoted to food safety, and emerging threats are often only addressed on a piecemeal basis in the aftermath of a crisis. The result is a fractionalized system focusing on antiquated threats, instead of a strategic approach to protecting the nation's food supply through state-of-the-art technologies, practices, and policies.

Obsolete laws, misallocation of resources, and inconsistencies among major food safety agencies underlie watchdog groups' calls for a "fundamental re-examination of the federal food safety system."[11] In fact, a 2007 GAO report concluded that the federal oversight of food safety is now one of the government's "high risk" programs.

This report provides an overview of the current problems in U.S. food safety and recommended solutions. Fixing food safety in the U.S. will require a collaborative effort by food producers, processors, distributors, retailers, and consumers, combined with strong leadership from the federal, state, and local government.

Sections of this report include:

I. Top Concerns with the Government's Food Safety System;

II. An Overview of Foodborne Disease Threats; and

III. Recommendations

I. Top Concerns With the Government's Food Safety System

While most of the food Americans eat each day is safe, according to experts, the chance for getting seriously ill needs to be improved. In fact, one in four Americans will experience food borne illness on an annual basis.

Recent outbreaks combined with vulnerabilities identified by the leading experts, including reports from the GAO, NAS, IOM, and FDA's Science Board serve as a wake up call for policymakers that problem in the U.S. food safety system must be addressed now before they become worse.

The "food safety system" includes the government and the food industry. The food industry produces, processes, distributes, and sells food, while the government serves a regulatory function.

THE GOVERNMENT'S GOALS IN THE FOOD SAFETY SYSTEM ARE TO:

- Reduce foodborne disease in the U.S.;
- Maintain public confidence in food safety and the food supply; and
- Exert international leadership on food safety.

Most food producers and food companies take safety issues very seriously. Historically, much of the innovation for improving food safety has come from within the food industry. However, food producers, processors, and retailers operate in markets and allocate their resources in response to market pressures and incentives.

Government regulatory agencies exist to balance the public interest with market forces, taking responsibility for ensuring that safety comes first. The role of government is to set standards on behalf of the public and hold companies accountable for meeting the standards.

Food safety requires strong public-private partnerships. For regulation to be effective, it must realistically address current industry practices and structures. This includes keeping pace with advances and changes in the industry.

Currently, however, there are a number of **obstacles** that impair the ability of the government to carry out these functions effectively. Key problems that experts have identified include:

- **Inadequate Federal Leadership, Coordination, and Resources;**
- **Outdated Laws and Policies; and**
- **Limited Federal, State, and Local Coordination.**

Today's U.S. laws and policies do not meet the need for a food safety system that protects the nation's food supply from farm-to-fork.

A **comprehensive system** would use strategic inspection practices and state-of-the-art surveillance to prevent disease outbreaks and harmful contaminants in meat, poultry, seafood, produce, and processed foods that could lead to human illness.

A modern, successful food safety strategy must:

- Make prevention of food safety problems the central focus of the system;
- Update priorities so resources are devoted to the areas of highest hazard and risk;
- Develop uniform best practices and standards;
- Invest in research to continually update practices and standards to keep pace with changes in the food supply and the industry; and
- Shift from the current outdated inspection practices that focus on end products and limited inspections at processing plants to instead strategically inspect foods throughout the food production and processing processes via "control points."

Inadequate Federal Leadership, Coordination and Resources

According to the 2007 GAO report, "the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety."[32]

The 4 agencies with the largest roles include the **U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), Environmental Protection Agency's (EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS)**, and **U.S. Centers for Disease Control and Prevention's (CDC) Food Safety Office**.

The other agencies involved include:[33]

- FDA's Center for Veterinary Medicine;
- Department of Commerce's National Marine Fisheries Service (NMFS);
- Department of Treasury's Customs Service;
- National Institutes of Health (NIH);
- USDA's Animal and Plant Health Inspection Service (APHIS);
- USDA's U.S. Codex Office;
- USDA's Agricultural Marketing Service (AMS);
- USDA's Agricultural Research Service (ARS);
- USDA's Cooperative State Research, Education, and Extension Service (CSREES);
- USDA's Economic Research Service (ERS); and
- USDA's Grain Inspection, Packers and Stockyard Administration (GIPSA).

None of the agencies has ultimate authority or responsibility, so accountability for the total system is limited. No one person in the

federal government has the oversight and accountability for carrying out comprehensive, preventive strategies for reducing foodborne illness.

The nation lacks an integrated, holistic approach to ensuring food safety. The government's ability to play an effective role in preventing foodborne illness is severely undermined by this fragmentation of food safety responsibilities among many agencies, each of which operates more or less independently with often differing regulatory approaches. No agency has statutory authority or a practical mandate to forge an integrated strategy that puts research, regulatory, and educational tools of government to work in a coherent way to minimize risks.

In addition, according to GAO, limited funds restrict the capabilities of food safety agencies. The current funds are often not strategically used to focus on the greatest threats, because they are supporting the outdated legacy systems and practices.[14]

SEGMENTED RESPONSIBILITIES: LEAD AGENCIES

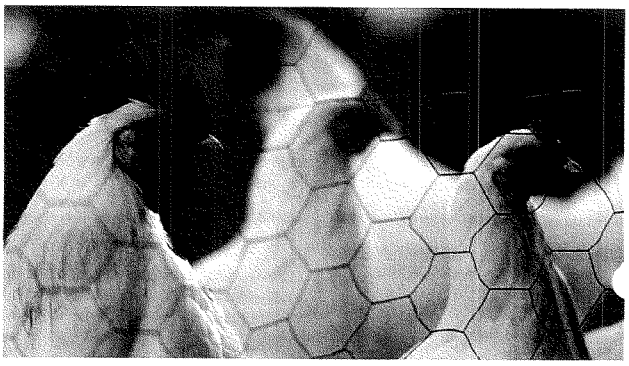
FDA's CFSAN: FDA has responsibility for overseeing the safety of all domestic and imported food with the exceptions of:

- Meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of USDA's FSIS.[15]

USDA's FSIS: The mission of FSIS is to serve as "the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."[16]

CDC's Office of Food Safety: Surveillance and identification of foodborne illness outbreaks are among the Food Safety Office's primary responsibilities. "The role of the Foodborne Disease Outbreak Response and Surveillance Team (ORST) is to conduct national surveillance on foodborne infections and outbreaks of foodborne illness and to assist in the investigation of foodborne disease outbreaks that take place in the United States or affect its population."[17]

EPA's OPPTS: The Office of Prevention, Pesticides and Toxic Substances (OPPTS) is charged with protecting public health and the environment from potential risk of pesticides and toxic chemicals. The agency "regulates the use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply."[18]



Resource Shortages

> "THE PRESIDENT'S [FY 2009] BUDGET BARELY GIVES FDA ENOUGH FUNDS TO OPERATE AT LAST YEAR'S LEVEL, AND DOES LITTLE TO MAKE UP FOR THE STEADY LOSS OF STAFFING THAT THE AGENCY HAS ENDURED FOR THE PAST DECADE. INDEED, THIS OVERSTRETCHED AGENCY HAS LOST 1,000 STAFFERS OVER THE PAST 10 YEARS IN THEIR FOOD, DRUG AND MEDICAL DEVICE SAFETY PROGRAMS."[19]
>
> -- Mark McClellan, former FDA Commissioner

A series of reports have highlighted the problems resulting from chronic underfunding of U.S. food safety efforts, particularly those run by FDA.

A 2008 report by the FDA Science Board's Subcommittee on Science and Technology found that continual underfunding of FDA has resulted in:

A plethora of inadequacies that threaten our society – including but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function.[20]

In the past three years alone, CFSAN has lost 20 percent of its science staff and 600 inspectors.

The Subcommittee's report urged Congress to increase FDA's food safety base by $755 million over 5 years, which includes $350 million to strengthen imports and $100 million to strengthen FDA oversight of nutritional supplements, animal feed, and cosmetics.

In addition to allocating more federal dollars to food safety, some food safety experts have called on Congress to authorize FDA to collect food manufacturer and producer registration fees and import fees. These fees would provide a steady base of revenue for food safety initiatives.[21]

Misaligned Priorities and Resources

	FDA's Food Safety Programs	USDA's Food & Agriculture Safety Programs
Scope of Responsibility	Experts estimate that 85 percent of known foodborne illness outbreaks are associated with FDA-regulated food products.	Experts estimate less than 15 percent of known foodborne illness outbreaks are associated with USDA-regulated food products
Funding for Food Safety Activities	▲ Fiscal year (FY) 2007: $563 million[22] ▲ FY 2008: $619 million ▲ Proposed FY 2009: $661 million	▲ FY 2007: $1.02 billion[23] ▲ FY 2008: $1.07 billion ▲ Proposed FY 2009: $1.09 billion
Number of Field Staff or Inspectors	1,700	7,600

Note: The increases in funding for FDA food safety programs over the past 3 years have barely kept up with inflation, which means that these programs have had no capacity to address the increasing challenges in food safety.

IMPORTED FOOD

According to USDA's Economic Research Service, approximately 15 percent of the nation's food supply is imported.[24] However, the country relies more heavily on imports for certain types of foods. For instance, 60 percent of the fresh fruits and vegetables consumed in the U.S. are imported, as is 75 percent of the seafood Americans consume.[25]

Currently, FDA and the U.S. Customs Border and Protection enter data on all U.S. food imports into a database system that electronically screens paperwork on shipments to determine whether their contents might pose a risk to the public's health. Imported goods that trigger concern can be physically inspected, but due to limited resources, FDA only inspects approximately one percent of shipments.

In addition, of the thousands of foreign food manufacturing facilities that export food to the U.S., FDA only conducts approximately 100 inspections a year. The current paradigm for protecting foreign foods places the responsibility for catching problems onto FDA through infrequent and inadequate inspections, instead of setting up a more strategic regulatory system where FDA sets standards for food processors that they can then hold industry accountable for meeting those standards.

The majority of U.S. food imports go straight to Americans' plates without any domestic processing and related FDA oversight. Given that FDA "often has very limited information regarding conditions under which most food is produced in foreign countries," this may mean that these foods pose a higher-risk to the consumer. [26]

In light of growing concerns regarding the safety of imported goods, the Bush Administration released its ***Import Safety Action Plan*** in November 2007. The Plan is integrated with the FDA's ***Food Protection Plan***, also released in November. The Food Protection Plan discusses the need to build safety into the entire food supply chain -- including imported foods. The Plan directs FDA to "work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards."[27]

The Plan, however, fails to call for accountability on the part of the food importers to ensure that preventive action is taking place in the country of origin. According to Michael Taylor, former FDA Deputy Commissioner for Policy, "FDA will never have enough resources to police and ensure the safety of imports without harnessing the expertise and efforts of the private sector and making a U.S.-based entity legally accountable for ensuring prevention is 'built-in' for imports, just as it should be for domestically produced food."[28]

Until food importers are legally accountable for assuring that foreign growers, producers and processors are shipping goods to the U.S. that meet U.S. food safety standards, it is unlikely that the quality and safety of U.S. food imports will improve.

FOOD DEFENSE

Agroterrorism is the "deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining stability."[29]

The deliberate contamination of our nation's food supply is a serious threat that could have a quick, widespread impact. In January 2004, the Bush Administration responded to this very real threat with *Homeland Security Presidential Directive/ HSPD- 9*, "Defense of United States Agriculture and Food."[30] This directive calls for a coordinated national approach to countering threats to the food supply. HSPD-9 directed U.S. agencies to protect the food supply by:

- Identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements;
- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing screening procedures for domestic and imported products; and
- Enhancing response and recovery procedures.[31]

The directive tasked the U.S. Department of Homeland Security (DHS) with leading national food defense efforts, while working in coordination with USDA, U.S. Department of Health and Human Services (HHS), and EPA.

Despite increased responsibility and concern, FDA has not received additional funding to support food-related anti-terrorism activities, and USDA has only received an additional $150 million.

One tool used by FDA and FSIS is *CARVER + Shock*, a computer program that assesses the vulnerabilities within a food supply system and infrastructure to an attack.[32] Interested parties work with food safety officials on a voluntary basis to identify weaknesses in their systems. Once these vulnerabilities are identified, food growers, producers and manufacturers can "focus resources on protecting the most susceptible points in their system."[33] Food safety officials, however, currently have no means to ensure that farmers and manufacturers implement measures to protect the food supply.

In fact, the November 2007 FDA *Food Protection Plan* stated that additional legislative authority is needed to give FDA the power to "implement measures solely intended to protect against the intentional adulteration of food by terrorists or criminals."[34]

RECENT THREATS, EXISTING VULNERABILITIES

Contaminated Wheat Gluten

Americans witnessed the real danger of deliberate food contamination in early 2007, when thousands of cats and dogs were sickened and died after ingesting pet food that had been contaminated with **melamine**, a nitrogen-rich chemical used to make plastic and sometimes as a fertilizer.[35] Although U.S. officials did not call this contamination malicious or agroterrorist in nature, some experts believe it was done for economic gain by exporters who substituted wheat gluten with melamine.[36] A U.S. federal grand jury recently indicted 2 Chinese businessmen and their firms, along with a U.S. company and its president and chief executive officer, for their roles in a scheme to import products purported to be wheat gluten into the U.S. that were contaminated with melamine.[37]

Botulism

Botulism is a "paralytic illness caused by a nerve toxin that is produced by the bacterium *Clostridium botulinum*."[38]

Although botulism is a naturally occurring toxin, there are serious concerns that it could be used as a weapon. A July 2005 issue of the *Proceedings of the National Academy of Sciences* outlined a relatively easy and potentially devastating method using botulism to kill thousands of people and disrupt the U.S. economy. The study, conducted by Stanford Graduate School of Business Professor Lawrence M. Wein, determined that "a mere 4 grams of botulinum toxin dropped into a milk production facility could cause serious illness and even death for 400,000 people in the United States."[39]

The report recommended that FDA make current volunteer safety guidelines mandatory, "such as requiring that milk tanks and trucks be locked and that 2 people be present when milk is transferred from one stage of the supply chain to the next. Before releasing milk into silos, milk-tank truck drivers should be required to employ a new 15-minute test that can detect the 4 types of toxins associated with human botulism."[40]

Outdated Laws and Policies

A number of problems are created by the current food safety laws being out of date. Resources and attention are being spent on food safety issues that are no longer significant threats to our food supply, but these practices are required under current law and policies. The current statutes require wasting resources on antiquated activities. And, whil most food safety resources are going to support outdated problems, new problems are not receiving adequate attention or funds.

OUTDATED PRACTICES AT FSIS, REQUIRED BY LAW

FSIS spends most of its resources inspecting every beef and pork carcass in ways not too different from practices used 100 years ago, based on the agency's mandate from Congress. Current laws, in effect since 1906, require carcass-by-carcass and daily inspections of meat and poultry to check for animal diseases, although the health of animals coming to slaughter has greatly improved in modern times due to changes in agricultural practices and technologies.

While the agency focuses virtually all of its resources and efforts on slaughter and processing plants, it lacks many modern tools necessary to improve public health protection, such as clear legal authority to set binding standards and practices for reducing pathogen contamination in raw products; it lacks any legal authority to act on the farm, where some of the most significant meat and poultry safety hazards originate; and it is given few resources to oversee what happens to the safety of products after they leave inspected plants, such as during transport, storage and commercial handling at retail.

For example, FSIS spends approximately $1 billion to regulate meat, poultry, and processed egg products, even though many of these regulation practices are considered obsolete. In fact, about 3,000 of the 7,600 USDA inspectors (and a commensurate share of the $1 billion spent on USDA inspections) are currently devoted to a poultry slaughter inspection practice that has been considered obsolete for more than 20 years. The practice involves 2 seconds of visual inspection for every one of the 8 billion chickens produced annually in the U.S. Modern agricultural practices make the need for this type of inspection obsolete, while no inspection practice has been developed to address the current health threat from poultry products -- bacteria that cause disease, including Salmonella.

FDA'S CFSAN NO MATCH FOR MODERN THREATS

Current statutes that provide the foundation for FDA's food safety functions date back to 1906 and 1938. Unlike USDA's inspection mandates, FDA's law sets forth a system that is largely reactive to problems prevalent in an early twentieth century agricultural and food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur, rather than prevent them.

These laws permit FDA to inspect processing plants and warehouses and remove harmful or potentially harmful food from the market through court enforcement action and to block imports if it detects potential problems. FDA's functional powers and effectiveness are limited, however, because:

- Congress has not provided the agency with a modern, public health mandate to prevent foodborne illness;
- Congress has not updated the agency's legal tools to meet the challenges of a high-tech, globalized food supply; and
- Congress has not provided the funding stream FDA needs to carry out research, standard setting, and inspection at a level commensurate with today's food safety challenge.

> *"The near unanimity about the agency's weaknesses -- among Congressional Democrats and Republicans, industry and consumer groups, and authoritative independent analysts -- is striking. But hand wringing is not enough. The FDA desperately needs an infusion of money and talent."*[1]
>
> -- New York Times Editorial

PIECEMEAL MODERNIZATION: THE EXAMPLE OF HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

Despite the statutory and resource constraints under which they operate, FSIS and FDA have made efforts to modernize their food safety programs. The most prominent example of this is the institution of Hazard Analysis and Critical Control Points (HACCP) as a regulatory standard for some sectors of the food system.

HACCP is a food industry-developed, science-based approach that focuses on identifying and minimizing hazards throughout the production and processing system, rather than relying solely on the traditional techniques of food inspection, which focus on end-product testing and are largely reactive rather than preventive. HACCP controls are designed, validated and implemented to prevent or minimize potential hazards, and these controls are continuously verified and monitored by the food processor and subject to inspection by regulatory agency.

The HACCP system can be adapted to fit the different production and processing procedures of different types of foods. FDA requires HACCP for seafood (1995) and juice (2001), while FSIS requires it for meat and poultry (1996).[42]

EXAMPLES OF THE NEED FOR MODERNIZING AND INTEGRATING THE FOOD SAFETY SYSTEM

- *E. coli O157:H7* originates in the gut of cattle and other mammals but, with manure as its vehicle, spreads throughout the food supply, contaminating meat, fresh produce, juice, and other foods. FSIS is responsible for inspecting meat and poultry plants but is not empowered to deal directly and preventively with the problem on the farm. FDA regulates produce but has ambiguous legal authority and no clear mandate to set safety standards for animal producers and growers of fruits and vegetables. CDC works with state and local health departments to investigate outbreaks but cannot act preventively.
- FDA regulates frozen pizza. However, if the pizza is topped with 2 percent or more of cooked meat or poultry, then FSIS is the regulatory agency. Inspections at pizza production facilities follow 2 sets of guidelines, one issued from FDA and one from USDA.[43] And, FSIS inspects plants making pepperoni pizza every day, after it has already inspected the manufacture of the pepperoni on a daily basis and the slaughter of every animal used to make the pepperoni, while FDA inspects cheese pizza plants on average once every 10 years.[44]
- A decade ago, concerns about produce safety became prominent, as federal, state, and local health officials began seeing more frequent produce-related outbreaks. FDA responded by issuing in collaboration with USDA a guidance document outlining general principles for minimizing microbial food safety hazards in fresh fruits and vegetables.

  This included guidance on "good agricultural practices" for managing manure, irrigation water, worker hygiene and other safety-related practices on the farm, as well as sanitation during processing and transportation. Experts considered these recommended principles sound but limited. In many cases, the guidance lacked the specificity required to make them actionable, in part because not enough research has been done to establish credible and effective criteria or performance standards for implementing the broad principles. While many producers and processors likely made good faith efforts to comply with FDA's guidance, it has failed to drive widespread change.

HOW IS THE SAFETY OF OUR FOOD MONITORED FOR DISEASE OUTBREAKS?

The systems used to monitor the safety of the nation's food supply is a patchwork of various government agencies at the federal, state, and local level working largely independently, with limited coordination, alongside food safety practitioners from the private sector, public interest groups, and academia -- all of whom collect and use food safety information for a wide variety of purposes.

This group of diverse actors includes, but is not limited to:

- FDA, CDC, USDA, and EPA at the federal level;
- Departments of health, agriculture and the environment and public health laboratories across the 50 states;
- Over 3,000 local health departments and retail inspection agencies;
- Millions of agricultural producers; hundreds of thousands of food processors, retailers and restaurants; and dozens of associations representing various segments of the food and agriculture industry;
- A wide range of government and university-based food safety researchers; and
- An active community of consumer representatives and organized victims of foodborne illness.

The fragmented nature of the current food safety surveillance system complicates efforts by food safety regulators to share data in a timely and efficient manner. These challenges include, but are not limited to:

- The analysis of data on a variety of subjects, ranging from foodborne illness disease rates to the cost of preventive action.
- Data collection that is spread across various disciplines including public health epidemiology, medical research, microbiology, risk analysis, and economics.
- Multiple actors in this complex food safety surveillance system that are only loosely affiliated with one another and are not accountable to any one oversight body or agency.
- A surveillance system that is designed to respond to foodborne illness outbreaks, rather than gather the data that would help government and industry design effective prevention strategies.
- Institutional issues that impede data sharing among government agencies and private sector. For example, government agencies face legal restrictions on data sharing. In the event that legal restrictions do not hinder data sharing, agencies may be reluctant to share data they consider to be their own. For the private sector there are competitive business reasons for firms to withhold food safety information, while university-based researchers may collect a lot of data but only publish bits and pieces of their results.

There are no easy solutions to these barriers. However, initial steps to address these issues include a recognition that a problem exists and buy-in from key leaders at relevant agencies to do something about this problem. Once there is support from the leadership at the government agencies, the next steps include legislative action to: 1) mandate coordinated data collection among government agencies, and 2) improve the collection of and accessibility to data in a timely and efficient manner. At the same time, action should be taken by leading food safety officials to build a network-of-networks among all actors in the food safety system, including private sector and academia.

Inadequate Federal, State, and Local Collaboration

The current decentralized governmental food safety system means state and local governments have jurisdiction for food safety issues in their communities beyond those that are directly regulated and monitored by federal agencies.

In lieu of official required national standards, 2 voluntary efforts have been developed to try to create more uniform standards and practices as well as enhancing the efficiency and effectiveness of the nation's food safety system: **FDA's Food Code** and a **Voluntary National Retail Food Regulatory Program**.

FDA's Food Code is intended to serve as a model "that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes)."[6] The Food Code does not attempt to regulate food processors or growers.

The Food Code is updated periodically to provide the most current food safety provisions to state and local agencies. FDA gets feedback from many organizations on its code, including the Conference for Food Protection, a group of state and federal officials, industry representatives, consumer groups, and academic officials that meets every 2 years to recommend Code changes. The Conference seeks to balance the interests of industry with those of food safety officials and consumer groups. Despite this, food safety advocates have criticized FDA for relying too heavily on industry at the expense of consumer groups.

Many states revise and update their own codes after FDA publishes a new version of the Food Code, although this is done on a voluntary basis. The most recent version of the Food Code was issued in 2005 and the next version is due out in 2009.

All but four states have adopted codes patterned after the 1993, 1995, 1997, 1999, 2001 or 2005 versions of the Food Code. The four states that have not adopted any version of the Food Code – California, Kentucky, Maryland, and North Carolina – are taking steps towards adopting the voluntary standards.

STATUS OF STATE FOOD CODE ADOPTIONS

State	2005	2001	1999	1997	1995	1993
Alabama		✓				
Alaska	✓					
Arizona			✓			
Arkansas		✓				
California						
Colorado		✓				
Connecticut			✓	✓		
Delaware			✓			
District of Columbia			✓			
Florida		✓				
Georgia		✓				
Hawaii				✓		
Idaho		✓				
Illinois					✓	
Indiana		✓				
Iowa				✓		
Kansas			✓			
Kentucky						
Louisiana			✓			
Maine			✓			
Maryland						
Massachusetts			✓			
Michigan			✓			
Minnesota					✓	
Mississippi	✓					
Missouri			✓			
Montana			✓			
Nebraska		✓				
Nevada						✓
New Hampshire		✓				
New Jersey		✓				
New Mexico			✓			
New York			✓			
North Carolina						
North Dakota		✓				
Ohio		✓				
Oklahoma		✓				
Oregon			✓			
Pennsylvania		✓				
Rhode Island						✓
South Carolina						✓
South Dakota					✓	
Tennessee			✓			
Texas		✓				
Utah			✓	✓		
Vermont		✓				
Virginia			✓			
Washington		✓				
West Virginia			✓			
Wisconsin	✓	✓				
Wyoming	✓					

Source: FDA's Center for Food Safety and Applied Nutrition[46]

The FDA, in collaboration with federal, state, and local regulatory agencies, industry, trade associations, academic, and consumers, has also established a **Voluntary National Retail Food Regulatory Program**. The program's goal is to reduce or eliminate the occurrence of illnesses and deaths from food produced or handled at the retail level.[47]

The program seeks to provide state and local food regulatory officials with science based measures of performance that will lead to more effective and uniform regulation of the food industry.

Participation in the program is voluntary. To be part of the program, the jurisdiction must carry out an initial self-assessment of its retail food safety program within 12 months of enrollment in the program, conduct self-assessments every 36 months after that, and submit to verification audits by outside parties.

Status of States Enrolled in Voluntary National Retail Regulatory Program

State	State Agency Enrolled	Self-Assessment Completed	Achieved at least 1 of 9 Standards Based on Self-Assessment	Achievement Verified by External Evaluator
Alabama	✓	✓		
Alaska	✓	✓	✓	✓
Arizona*	✓			
Arkansas	✓	✓	✓	
California	✓	✓	✓	
Colorado	✓	✓		
Connecticut	✓	✓	✓	
Delaware	✓			
District of Columbia	✓			
Florida	✓	✓	✓	✓
Georgia	✓	✓	✓	✓
Hawaii	✓	✓	✓	
Idaho	✓	✓	✓	✓
Illinois	✓	✓	✓	
Indiana				
Iowa	✓	✓	✓	✓
Kansas	✓	✓	✓	✓
Kentucky				
Louisiana				
Maine				
Maryland	✓	✓	✓	
Massachusetts	✓	✓	✓	✓
Michigan	✓	✓	✓	✓
Minnesota	✓	✓	✓	
Mississippi	✓	✓	✓	
Missouri	✓	✓	✓	✓
Montana	✓	✓	✓	
Nebraska	✓	✓	✓	
Nevada	✓	✓	✓	
New Hampshire				
New Jersey	✓			
New Mexico	✓	✓	✓	
New York				
North Carolina	✓	✓	✓	✓
North Dakota				
Ohio	✓	✓	✓	
Oklahoma	✓	✓	✓	
Oregon	✓	✓	✓	✓
Pennsylvania	✓	✓	✓	
Rhode Island	✓	✓	✓	
South Carolina				
South Dakota	✓			
Tennessee	✓			
Texas	✓	✓	✓	✓
Utah	✓			
Vermont				
Virginia	✓			
Washington				
West Virginia	✓			
Wisconsin	✓	✓	✓	
Wyoming	✓	✓	✓	

Source: FDA's Center for Food Safety and Applied Nutrition.[49] *Note: *No state-wide agency is enrolled in the program. However, 11 of 15 counties in Arizona are enrolled. Of the 11 counties, 5 have had their achievements verified by an outside auditor.*

STANDARDS FOR THE VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM

1. Regulatory Foundation
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Foodborne Illness and Food Security Preparedness and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

II. An Overview of Foodborne Disease Threats

AGRICULTURE INDUSTRY AND FOOD SAFETY

- Agriculture today is primarily based on a large-scale agribusiness model. As consolidation (shifting away from the single-family farm) has taken place, certain livestock or crops are increasingly centralized in specific regions and even certain farms. For example in 1990, 74 percent of all wet corn (a popular livestock feed) was milled by the top 4 processing firms in only 15 facilities.[49] Five million head of cattle were fattened by the top 30 feedlots in 1998.[50] And 83 percent of all beef in the U.S. was processed by the largest 5 beef packers in 32 plants.[51] This centralization can facilitate the spread of disease because there is significant contact between livestock or crops, which can lead to a single infected animal or contaminated product causing widespread damage.
- As specialized centers of activity have developed throughout the nation, livestock rearing has changed from a localized process to a geographically dispersed effort. An animal is most likely born on a breeding farm, at which point it is shuttled to a different farm for fattening, and then transported again for slaughter and processing. The carcass may even be sent to another state for disposal.[52] In addition, animals are frequently shown or displayed at regional shows or auctions. This mingling of animals from various regions of the country, as well as the widespread distribution networks of the industry, can accelerate the spread of disease.
- Many countries have adopted sophisticated systems of animal identification and tracking that are important to identify and isolate sources and spread of diseases in an animal population. However, the U.S. is dramatically behind in this effort, promoting a voluntary system that is decades behind some of our trading partners, and provides inadequate protection to the nation's farmers and consumers.

FDA'S MAJOR CONCERNS RELATED TO FOOD PROCESSING, PACKAGING, TRANSPORTATION, AND PREPARATION[53]

- Biological pathogens (e.g., bacteria, viruses, parasites)
- Naturally occurring toxins (e.g., mycotoxins, ciguatera toxin, paralytic shellfish poison)
- Dietary supplements (e.g., ephedra)
- Pesticide residues
- Toxic metals (e.g., lead, mercury)
- Decomposition and filth (e.g., insect fragments)
- Food allergens (e.g., eggs, peanuts, wheat, milk)
- Nutrient concerns (e.g., vitamin D overdose, pediatric iron toxicity)
- Dietary components (e.g., fat, cholesterol)
- Radionuclides
- TSE-type diseases (e.g., chronic wasting disease in deer)
- Product tampering

HIGH MERCURY LEVELS IN SEAFOOD

Although mercury occurs naturally in the environment, it is also released into the air through industrial pollution. The mercury then falls from the air and can accumulate in streams and oceans, becoming methylmercury. Fish absorb the methylmercury as they feed in these waters and over time it builds up in them. Some fish, particularly larger fish such as swordfish and king mackerel, are more susceptible to high levels of methylmercury based on what they eat.[54]

According to EPA it has been demonstrated that high levels of methylmercury in the bloodstream of unborn babies and young children may harm the developing nervous system, making the child less able to think and learn.[55] More recent studies have suggested a link between mercury and poor health outcomes in adults, including increased risk of cardiovascular disease and neurological symptoms.[56]

In 2004, FDA and EPA warned women who might become pregnant and children to limit their consumption of canned and fresh tuna to 6 ounces a week due to high mercury levels. In fact, a recent analysis by *The New York Times* and the Environmental and Occupational Health Sciences Institute in New Jersey found levels of mercury in tuna sushi far higher than the amount typically found in canned tuna.[57]

Although FDA officials have not commented on these findings, the agency has said it is reviewing its seafood mercury warnings.

EXAMPLES OF POTENTIAL DISEASE THREATS

E. coli 0157:H7

In the late summer and early fall of 2006, nearly 200 people became sick and at least 3 died due to *E. coli* contamination in spinach. It is possible that even more illnesses or deaths were related to the outbreak as "officials believe that for every *E. coli* case reported, 20 go unreported."[58] Illnesses associated with *E. coli* often also go undiagnosed.[59, 60]

> "*Escherichia coli O157:H7 (E. coli)* is a leading cause of foodborne illness."[61] *E. coli* is most contracted through "eating undercooked, contaminated ground beef... (or) eating contaminated bean sprouts or fresh leafy vegetables such as lettuce and spinach. Person-to-person contact in families and child care centers is also a known mode of transmission."[62]

The deaths and illnesses from the spinach have led to a renewed call for increased regulation. FDA does not inspect produce on a similar scale as USDA's inspection of beef, and it has fewer inspectors and more facilities to inspect than it did in 2003.[63] Additionally, "more outbreaks of the disease are now traced to produce than to meat, poultry, fish, eggs, and milk combined."[64]

In August 2006, just prior to the outbreaks, FDA launched a Lettuce Safety Initiative to respond to recurring outbreaks of *E. coli* in lettuce.[65] The initiative focused first on California regions, where a large portion of past outbreaks have occurred (including the most recent spinach outbreak), and concentrates on the following objectives:

- Assessing industry approaches and actions.
- Early detection and rapid response.
- Observing and identifying practices that might lead to contamination.
- Consideration of regulatory action.[66]

> *"In the last 20 years, the incidence of produce-related food-borne illness has increased 2½ to 3 times."*[67]
>
> — Richard H. Linton, director of the Center for Food Safety Engineering at Purdue University

Hepatitis A

In January 2008, a produce handler at a grocery store in Buffalo, New York was diagnosed with hepatitis A. As a precaution, county health officials issued a warning to anyone who may have purchased and consumed certain kinds of produce from the store in the prior 3-week period. Health officials set up free clinics to distribute hepatitis A vaccine and immune globulin (IG) shots. More than 8,300 people were vaccinated over a 5-day period at a cost of some $500,000.

Hepatitis A is a viral infection that causes inflammation of the liver and can result in short-term illness.[68] Transmission occurs by the fecal-oral route, either by direct contact with an infected person or by ingestion of contaminated food or water. Although foodborne or waterborne hepatitis A outbreaks are relatively uncommon in the United States, food handlers with hepatitis A are frequently identified.[69]

The majority of foodborne hepatitis A outbreaks are associated with infected food handlers working in grocery stores and restaurants, such as the case in Buffalo. A single infected individual can transmit hepatitis A to dozens, if not hundreds of persons.[70]

Hepatitis A outbreaks have also been associated with fresh produce that was contaminated sometime during growing, harvesting or processing. In 2003, more than 500 individuals in 6 states were infected by eating contaminated green onions. Three individuals died as a result.[71] Hepatitis A contaminated shellfish have also been the source of outbreaks, although the last reported U.S. outbreak occurred in 1988.[72]

Hepatitis A is the only common vaccine-preventable foodborne disease in the U.S., although only children under the age of 2 are routinely vaccinated.[73] Instead of widespread vaccination, scientists believe reducing foodborne transmission of hepatitis A can be achieved by improving sanitary conditions in food production and encouraging routine proper food-handler hygiene.

Listeria

Listeria monocytogenes (LM), a harmful bacterium, causes some 2,500 illnesses and 500 deaths in the U.S. each year.[74] LM, which can be present in soil and water, has been found in a variety of raw foods, such as uncooked meats and vegetables. Processed foods can also become contaminated with LM, particularly deli meats and unpasteurized cheeses.

Listeriosis is a serious infection caused by eating food contaminated with the bacterium *Listeria monocytogenes*. Symptoms include fever, muscle aches, nausea, and diarrhea. Infected pregnant women can pass the illness on to the fetus which can result in miscarriage or stillbirth, premature delivery or infection of the newborn.[75]

Voluntary recalls of food products contaminated with LM, or suspected to be contaminated with LM, are frequent. On March 3, 2008 Costco Wholesale recalled 10,000 pounds of frozen chicken entrees produced in Washington State and distributed across the Pacific Northwest.[76] A day earlier, a Michigan firm recalled some 2,000 pounds of frozen chicken entrees that were possibly contaminated with LM, while in November 2007, a Texas producer recalled some 98,000 pounds of frozen sausage roll products thought to be contaminated with LM.[77]

Although healthy people rarely contract listeriosis, pregnant women, newborns, the elderly and persons with compromised immune systems are at highest risk of infection. The medical community recommends that those people at risk avoid high risk foods such as deli meats, pates and other processed meats, and unpasteurized cheese, and practice good hygiene when cooking -- washing hands after handling meat or poultry; keeping raw meat and poultry away from foods that won't be cooked; cleaning all cooking utensils in hot soapy water.

Salmonella

In February 2007, FDA issued a nationwide advisory warning consumers to avoid certain brands of peanut butter due to risk of contamination with *Salmonella Tennessee*, a subtype of the *Salmonella* bacteria, after 290 people in 39 states were sickened from the contaminated food.[78] Although 46 people were hospitalized as a result, there were no deaths associated with the contamination.

> *Salmonella* live in the intestinal tracts of humans and other animals, including birds, and the germ is usually passed to humans by eating foods contaminated with animal feces.[79] Most people infected with Salmonella develop diarrhea, fever and stomach cramps 12 to 72 hours after infection.[80]

Each year, some 40,000 cases of *Salmonella* infection are reported in the U.S., although scientists believe the actual number of infections is much higher as mild cases often go unreported. Children, the elderly and the immuno-compromised are the most likely to have severe infections. CDC estimates that some 600 persons die from acute *Salmonella* infection each year.

As with many foodborne illnesses, good hygiene and safe kitchen practices can do a lot to prevent illness. For example, proper cooking of meat, poultry and eggs can significantly reduce the risks associated with those foods.

Mad Cow Disease

In March 2006, the USDA announced that a cow in Alabama tested positive for bovine spongiform encephalopathy (BSE), better known as mad cow disease. The Alabama cow was the third such case in the U.S., with the first case occurring in Washington state in December 2003.[81, 82]

> *Mad cow* is a fatal illness that strikes the central nervous system of cattle. Humans can contract a related illness called variant Creutzfeldt Jakob disease (vCJD) by eating infected beef.

Also in 2003, a single cow in Canada was diagnosed with mad cow disease, leading many nations (including the U.S.) to place a ban on Canadian cattle and beef imports. Economic losses due to the import bans have been massive, with estimates ranging from $1.6 to $3.2 billion.[83,84]

If a significant outbreak of mad cow disease occurred in the U.S., the USDA estimates that there would be a loss of $15 billion, resulting from a 24 percent decline in domestic beef sales and an 80 percent decline in beef and live cattle exports.[85] Slaughter and disposal costs of at-risk cattle could add up to an additional $12 billion.[86] Experts point out that generally concerns about mad cow are related to animal health rather than human health in the U.S.

ADULTERATED FOOD

A large number of food advisories and recalls are due to adulterated food, which runs the gamut from food that is improperly inspected to food that is contaminated with a foreign substance.[87,88]

Prevention and stringent controls at the manufacturer level are the keys to reducing the number of incidents of adulteration.

Under FDA's food safety statute, food is considered "adulterated" if:[89,90,91]

- It bears or contains any poisonous or deleterious substance that may render it injurious to health;
- It bears or contains any added poisonous or deleterious substance other than pesticide residue, food additive, color additive, or new animal drug (which are covered by separate provisions) that is unsafe;
- Its container is composed in whole or in part of any poisonous or deleterious substance that may render the contents injurious to health;
- It bears or contains a pesticide chemical residue that is unsafe (EPA establishes tolerance for pesticide residues in food, which is enforced by the FDA).
- It is, or it bears or contains, an unsafe food additive;
- It is, or it bears or contains, an unsafe new animal drug;
- It is, or it bears or contains, an unsafe color additive;
- It consists, in whole or in part, of any filthy, putrid, or decomposed substance or is otherwise unfit for food;
- It has been prepared, packed or held under unsanitary conditions (insect, rodent, or bird infestation) whereby it may have become contaminated with filth or rendered injurious to health;
- It has been irradiated and the irradiation processing was not done in conformity with a regulation permitting irradiation of the food (with exceptions approved by FDA including refrigerated or frozen uncooked meat, fresh or frozen uncooked poultry, and seeds for sprouting);
- It contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended in labeling;
- A valuable constituent has been omitted in whole or in part or replaced with another substance; damage or inferiority has been concealed in any manner; or a substance has been added to increase the product's bulk or weight, reduce its quality or strength, or make it appear of greater value than it is; or
- It is offered for import into the U.S. and is a food that has previously been refused admission, unless the person reoffering the food establishes that is in compliance with U.S. law.

CDC'S LIST OF MAJOR CAUSES OF FOODBORNE ILLNESS: BACTERIAL, PARASITIC, VIRAL, AND NON-INFECTIOUS[7]

Amebiasis (*Entamoeba histolytica Infection*) [parasitic]
Anisakiasis (Anisakis Infection) [parasitic]
Ascariasis (Intestinal Roundworm Infection) [parasitic]
Botulism (*Clostridium botulinum* toxicity) [bacterial]
Brainerd Diarrhea [bacterial]
Brucellosis (*Brucella* Infection) [bacterial]
Campylobacteriosis (Campylobacter Infection) [bacterial]
Cholera (Vibrio cholerae Infection) [bacterial]
Cryptosporidiosis (*Cryptosporidium* Infection) [parasitic]
Cyclosporiasis (*Cyclospora* Infection) [parasitic]
Cysticercosis (Neurocysticercosis) [parasitic]
Diphyllobothriasis (*Diphyllobothrium* infection) [parasitic]
Enterohemorrhagic *Escherichia coli* [bacterial]
Enterotoxogenic *Escherichia coli* (ETEC) [bacterial]
Escherichia coli O157:H7 [bacterial]
Giardiasis (*Giardia* Infection) [parasitic]
Helicobacter pylori [bacterial]
Hepatitis A [viral]
Listeriosis (*Listeria* Infection) [bacterial]
Marine Toxins [non-infectious]
Norovirus [viral]
Rotavirus [viral]
Salmonella Enteritidis [bacterial]
Salmonellosis (*Salmonella* Infection) [bacterial]
Shigellosis (*Shigella* Infection) [bacterial]
Toxoplasmosis (*Toxoplasma* Infection) [parasitic]
Trichinellosis/Trichinosis (Trichinella Infection) [parasitic]
Typhoid Fever (Salmonella Typhi Infection) [bacterial]
Vibrio parahaemolyticus [bacterial]
Vibrio vulnificus [bacterial]
Viral Gastroenteritis [viral]
Yersiniosis (*Yersinia enterocolitica* Infection) [bacterial]

III. Recommendations

Modernizing the food safety system could significantly decrease the number of foodborne illnesses in the U.S. each year and help restore public confidence in the system and in the safety of food.

Action must be taken to realign U.S. food safety policies with current priorities and threats.

The nation should focus on building a modern food safety system that emphasizes:

- **Farm-to-Fork Disease Prevention Practices:** Food safety priorities must shift from a system focused on outdated, limited end-product and processing plant inspections to a system where the emphasis is on preventing outbreaks and illnesses throughout the entire food production process and supply chain.
  - Preventive strategies, such as the Hazard Analysis and Critical Control Points (HACCP) process, should be at the center of food safety practices. Outdated practices, like those called for in the current the FSIS inspection mandate, should be repealed.
  - Uniform performance standards and best practices should be defined and adopted, and should be enforceable, including detention and recall authority, records access, establishment registration, and civil penalty authority.
  - Food safety education programs for commercial food handlers and consumers are essential components of preventing disease.
- **The Ability to Keep Pace with Modern Threats:** Threats to the food supply change as industry practices and farming and processing technologies change. Government strategies for protecting and inspecting the food supply must be able to adapt quickly to these changes.
  - Ongoing research is needed to identify emerging threats and up-to-date ways to contain them.
  - Government food safety officials and food companies must be able to kee track of information about disease outbreaks in humans, plants, and animals and results of food inspections so they can quickly detect and contain problems.
- **Monitoring Foreign Imports and International Practices:** Food safety agencies must have clear statutory authority and receive resources necessary to educate overseas regulators and food producers about U.S. food safety standards, require that food importers demonstrate these standards are being met, and permit U.S. regulators to inspect foreign establishments as well as food at the port of entry. Food safety agencies should also be given the authority and funding to participate in international negotiations and discussions, such as with the Codex Alimentarius Commission and the World Trade Organization. Trade agencies often take the lead in these discussions, but often lac the food safety mission, expertise, and cred ibility to effectively represent U.S. interests.

To accomplish these goals:

- **Start by Strengthening FDA and Aligning Resources with the Highest-Risk Threats:** Funding for FDA's food program must grow substantially, at least doubling in real terms over the next 5 years, and statutory mandates should be updated to strengthen the agency's abilities to carry out preventive efforts and oversee food imports. FDA is responsible for overseeing the biggest threats to the country's food safety, but the agency lacks the resources and the mandates needed to carry out its programs and adequately protect the nation from foodborne disease threats. Government funding should be realigned so that it can be strategically allocated to food safety research, regulation, and education to maximize reduction in foodborne disea Resources for inspections should be dis tributed and used in the manner most likely to contribute to disease reduction.

- **As a Second Step, Strategically Realign and Elevate Food Safety Functions at HHS:** As immediate measures are taken to strengthen current food safety functions at FDA, steps should also be taken to realign and elevate organizationally all of the food regulatory functions at HHS. Currently, FDA's senior management focus is split between regulating medical products (drugs and devices) and food, with its food functions typically taking the backseat in terms of resources and management attention. FDA's food functions should be brought together under unified leadership, with a single official, reporting to the Secretary, focusing full time on, and being responsible and accountable for, providing food safety leadership nationally and internationally and effectively implementing a modern, prevention-oriented food safety system. Efforts should also be made to better align the surveillance functions at CDC with other federal food safety efforts and with state and local efforts in a way that provides more timely and responsive reporting to allow public health officials throughout the country to better detect and control outbreaks.

- **Set a Long-Term Goal to Integrate Federal Food Safety Agencies:** While the immediate focus is on fixing FDA, in order to strategically address food safety concerns, make good use of federal resources, and have stronger national and international leadership, the goal over time should be to consolidate and align all federal food safety functions into a single agency to increase effectiveness, responsibility, and accountability. This agency could then address the food supply as a whole and set priorities accordingly. It should oversee regulation and inspection, but also must also have research and surveillance functions as part of its mandate. It should also be required to report on accomplishments, progress, and problems.

  - The realigned agency should include: FSIS; the food regulatory functions of FDA, including CFSAN, the Center for Veterinary Medicine, and the food portion of FDA's field resource; and the food safety aspects of the EPA's pesticide program.

  - The placement of CDC's foodborne disease surveillance program should be reviewed. It must be able to function in a way that not only monitors foodborne disease outbreaks and helps investigate preventive strategies but also provides accountability to gauge how well U.S. food safety systems are working.

In addition to changes at the federal level, measures must be taken to better integrate and coordinate policies and practices among levels of government, including:

- **Creating Uniform Standards and Practices Across Federal-State-Local Levels:** While the states play a critical food safety role, particularly at the retail level, the federal-state relationship is not well defined or financed. States should be encouraged and incentivized to adopt and comply with the uniform standards and practices of the FDA's Food Code and the National Retail Food Regulatory Program.

FDA'S FOOD PROTECTION PLAN[93]

In November 2007, HHS unveiled its plans to strengthen and update the U.S. food safety system.

In order to make many of the necessary changes, the plan stresses the need to **realign roles and responsibilities** within the agency and for **legislative action**.

- For instance, FDA is seeking legislative changes that will allow the agency to require food facilities to renew their FDA registrations every 2 years, which the agency argues will allow for superior prevention.
- Also, among other recommended changes, FDA is urging Congress to empower the agency to issue mandatory recalls of contaminated products when voluntary recalls fall short.

The Food Protection Plan was developed in conjunction with the broader U.S. Import Safety Action Plan that focuses on how the U.S. can improve the safety of all imported products.

The Food Protection Plan focuses FDA's efforts on 3 critical areas: prevention; intervention; and response. According to FDA Commissioner Andrew von Eschenbach, while the FDA will maintain and improve its response capacity, "the primary goal is to prevent contaminated food from ever reaching the consumer."[94]

Prevention

FDA will boost efforts to prevent food from becoming contaminated via a 3-pronged approach of: 1) promoting increased corporate responsibility to prevent foodborne illnesses; 2) identifying food vulnerabilities and assessing risks; and 3) expanding the understanding and use of proven mitigation strategies.

Intervention

FDA will intervene at critical points in the food supply chain from production to consumption. Inspections will be based on risk assessments and enhanced risk-based surveillance.

Response

FDA intends to improve both the agency's immediate response to a foodborne illness outbreak, and its risk communication with the U.S. public, industry and other interested parties.

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FEDERAL OVERSIGHT OF FOOD SAFETY

FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical

Statement of Lisa Shames, Director
Natural Resources and Environment

GAO-08-435T

January 29, 2008

GAO
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Highlights

Highlights of GAO-08-435T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

FEDERAL OVERSIGHT OF FOOD SAFETY

FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical

Why GAO Did This Study

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food highlight the risks posed by the accidental contamination of FDA-regulated food products. Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. In response to these challenges, in November 2007, FDA and others released plans that discuss the oversight of food safety. FDA's *Food Protection Plan* sets a framework for food safety oversight. In addition, FDA's Science Board released *FDA Science and Mission at Risk*, which concluded that FDA does not have the capacity to ensure the safety of the nation's food supply.

This testimony focuses on (1) federal oversight of food safety as a high-risk area that needs a governmentwide reexamination, (2) FDA's opportunities to better leverage its resources, (3) FDA's *Food Protection Plan*, and (4) tools that can help agencies to address management challenges. To address these issues, GAO interviewed FDA officials; evaluated the *Food Protection Plan* using a GAO guide for assessing agencies' performance plans; and reviewed pertinent statutes and reports. GAO also analyzed data on FDA inspections and resources.

To view the full product, including the scope and methodology, click on GAO-08-435T. For more information, contact Lisa Shames at (202) 512-3841 or ShamesL@gao.gov.

What GAO Found

FDA is one of 15 agencies that collectively administer at least 30 laws related to food safety. This fragmentation is the key reason GAO added the federal oversight of food safety to its High-Risk Series in January 2007 and called for a governmentwide reexamination of the food safety system. We have reported on problems with this system—including inconsistent oversight, ineffective coordination, and inefficient use of resources.

FDA has opportunities to better leverage its resources. Efficient use of resources is particularly important at FDA because we found that its food safety workload has increased in the past decade, while its food safety staff and funding have not kept pace. GAO has recommended that FDA establish equivalence agreements with other countries to shift some oversight responsibility to foreign governments, explore the potential for certifying third party inspections, and consider accrediting private laboratories to inspect seafood, among other actions. We also reported that FDA and the U.S. Department of Agriculture (USDA) conduct similar inspections at 1,451 facilities that produce foods regulated by both agencies. To reduce overlaps, we recommended that, if cost-effective, FDA enter into an agreement to commission USDA inspectors at such facilities. FDA incorporated some of these recommendations in its *Food Protection Plan*.

FDA's *Food Protection Plan* also proposes some positive first steps intended to enhance its oversight of food safety. Specifically, FDA requests authority to order food safety recalls and issue additional preventive controls for high-risk foods, both of which GAO has previously recommended. However, more specific information about its strategies and the resources FDA needs to implement the plan would facilitate congressional oversight. FDA officials acknowledge that implementing the *Food Protection Plan* will require additional resources. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, including a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. In light of these challenges, GAO has identified through other work some tools that can help agencies improve their performance over time. For example, a Chief Operating Officer/Chief Management Officer can help an agency address longstanding management problems that are undermining its ability to accomplish its mission and achieve results. In addition, a well-designed commission can produce specific practical recommendations that Congress can enact. Critical success factors that can help ensure a commission's success include a statutory basis with adequate authority, a clear purpose and timeframe, leadership support, an open process, a balanced membership, accountability, and resources.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the resources the Food and Drug Administration (FDA) uses to meet one of its key regulatory responsibilities, the oversight of food safety. FDA is responsible for ensuring the safety of roughly 80 percent of the U.S. food supply, including $417 billion worth of domestic food and $49 billion in imported food annually. Contaminated food can harm human health, have severe economic consequences, and undermine consumer confidence in the government's ability to ensure the safety of the U.S. food supply. The recent outbreaks of *E. coli* in spinach, *Salmonella* in peanut butter, and contamination in pet food, highlight the risks posed by the accidental contamination of FDA-regulated food products. For example, according to FDA, the recent California spinach *E. coli* outbreak resulted in 205 confirmed illnesses and 3 deaths, and industry representatives estimate that economic losses ranged from $37 million to $74 million.

Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. According to FDA, shifting demographics mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illnesses. The risk of severe and life-threatening symptoms from infections caused by foodborne pathogens is higher for older adults, young children, pregnant women, and immune compromised individuals. According to FDA, these groups make up about 20 to 25 percent of the U.S. population. In addition, we are increasingly eating foods that are consumed raw or with minimal processing and often associated with foodborne illness. For example, according to the U.S. Department of Agriculture (USDA), leafy greens such as spinach, are the category of produce most likely to be associated with an outbreak, and the average consumer ate 2.4 pounds of fresh spinach in 2005—a 180 percent increase over 1992.

In response to these increasing challenges, FDA and other agencies recently released plans that discuss the oversight of food safety. In November 2007, FDA released its *Food Protection Plan*, which sets forth FDA's framework for overseeing the safety of food.[1] Concurrently, a twelve-agency working group presented to the President its *Action Plan*

[1]Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C., 2007).

for Import Safety,[2] which contains, among other things, recommendations for improving the safety of food imports entering the United States. Both plans spell out numerous actions FDA plans to take to enhance food safety, including writing new food protection guidelines for industry and helping foreign countries improve their regulatory systems. The plans also request new legislative authorities. One requested legislative authority is for enhanced access to a food company's records during food safety emergencies. Subsequently, FDA's Science Board, an advisory board to the agency, released a report titled, *FDA Science and Mission at Risk*.[3] This report, which is the focus of today's hearing, concluded that FDA is not positioned to meet current or emerging regulatory needs, and stated that FDA does not have the capacity, such as staffing and technology, to ensure the safety of the nation's food supply. In addition, the report found that FDA's ability to provide its basic food system inspection, enforcement, and rulemaking functions is severely eroded, as is its ability to respond to outbreaks of foodborne illnesses in a timely manner and to develop and keep pace with the science needed to prevent food safety problems. The report stated that the system cannot be fixed using available resources, and its primary food safety recommendation was that FDA needs additional resources to fulfill its regulatory mandate.

I will focus on four key points: (1) federal oversight of food safety is a high-risk area that needs a governmentwide reexamination, (2) FDA has opportunities to better leverage its resources, (3) FDA's *Food Protection Plan* proposes some positive first steps but additional information on the plan's strategies and resources can facilitate congressional oversight, and (4) tools such as a commission or chief operating officer can help agencies to address management challenges. This testimony is based on new and previously issued work. Today, GAO is also testifying on another FDA regulatory responsibility—inspections of medical device manufacturers.[4] These and other recent testimonies on food and drug safety offer observations on FDA's management capacity.

[2]Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C., 2007).

[3]FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Washington, D.C., November 2007).

[4]GAO, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, GAO-08-428T (Washington, D.C.: Jan. 29, 2008).

To assess FDA's *Food Protection Plan*, we interviewed FDA officials; reviewed pertinent statutes and reports; and evaluated the plan using a GAO guide for assessing agencies' performance plans. To analyze data on FDA inspections, we examined data from FDA and determined that they were sufficiently reliable for our analyses. We also reviewed funding data from the Science Board and analyzed the data in real terms. To provide updated information on our previously issued reports, we gathered information on the status of our recommendations. We conducted our work in January 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Federal Oversight of Food Safety Is a High-Risk Area that Needs a Governmentwide Reexamination

While part of today's hearing focuses specifically on FDA's responsibilities for the oversight of food safety, it is important to note that FDA is one of 15 federal agencies that collectively administer at least 30 laws related to food safety. This fragmentation is a key reason we designated federal oversight of food safety as a high-risk area. Two agencies have primary responsibility—FDA is responsible for the safety of virtually all foods except for meat, poultry, and processed egg products, which are the responsibility of USDA. In addition, among other agencies, the National Marine Fisheries Service (NMFS) in the Department of Commerce conducts voluntary, fee-for-service inspections of seafood safety and quality; the Environmental Protection Agency (EPA) regulates the use of pesticides and maximum allowable residue levels on food commodities and animal feed; and the Department of Homeland Security is responsible for coordinating agencies' food security activities. This federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises.

In January 2007, we added the federal oversight of food safety to our High-Risk Series,[5] which 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. Over the past 30 years, we have reported on issues—for

[5]GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: Jan. 31, 2007).

example, the need to transform the federal oversight framework to reduce risks to public health as well as the economy—that suggest that the federal oversight of food safety could be designated as a high-risk area. The fragmented nature of the federal food oversight system calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illnesses, and focus on promoting the safety and integrity of the nation's food supply.

While we have reported on problems with the federal food safety system—including inconsistent oversight, ineffective coordination, and inefficient use of resources—most noteworthy for today's hearing is that federal expenditures for the oversight of food safety have not been commensurate with the volume of foods regulated by the agencies or consumed by the public. We have reported that four agencies—USDA, FDA, EPA, and NMFS—spent a total of $1.7 billion on food safety-related activities in fiscal year 2003.[6] USDA and FDA were responsible for nearly 90 percent of those federal expenditures. However, 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 even though USDA is responsible for regulating only about 20 percent of the food supply. In contrast, FDA accounted for only 24 percent of expenditures even though it is responsible for regulating about 80 percent of the food supply.

Others have called for fundamental changes to the federal food safety system overall. In 1998, the National Academy of Sciences concluded that the system is not well equipped to meet emerging challenges.[7] In response to the Academy's report, the President established a Council on Food Safety which released a Food Safety Strategic Plan in January 2001. The plan recognized the need for a comprehensive food safety statute and concluded, "the current organizational structure makes it more difficult to achieve future improvements in efficiency, efficacy, and allocation of resources based on risk."

While many of the recommendations we made have been acted upon, a fundamental reexamination of the federal food safety system is warranted.

[6]GAO, *Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Related Activities*, GAO-05-549T (Washington, D.C.: May 17, 2005).

[7]Institute of Medicine, *Ensuring Safe Food from Production to Consumption* (Washington, D.C., 1998).

Taken as a whole, our work indicates that Congress and the executive branch can and should create the environment needed to look across the activities of individual programs within specific agencies, including FDA, and toward the goals that the federal government is trying to achieve. To that end, we have recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational food safety structures.[8] We have also recommended that the executive branch reconvene the President's Council on Food Safety to facilitate interagency coordination on food safety regulation and programs. According to documents on the council's Web site, the current administration has not reconvened the council.

These actions can begin to address the fragmentation in the federal oversight of food safety. Going forward, to build a sustained focus on the safety and integrity of the nation's food supply, Congress and the executive branch can integrate various expectations for food safety with congressional oversight and through agencies' strategic planning processes, including FDA's. We have previously reported that the development of a governmentwide performance plan that is mission-based, is results-oriented, and provides a cross-agency perspective offers a framework to help ensure agencies' goals are complementary and mutually reinforcing. Further, with pressing fiscal challenges, this plan can help decision makers balance trade-offs and compare performance when resource allocation and restructuring decisions are made.

FDA Has Opportunities to Better Leverage its Resources

In response to the nation's fiscal challenges, agencies may have to explore new approaches to achieve their missions, and we have identified options for FDA to better leverage its resources. Efficient use of resources is particularly important at FDA because, while its food safety workload has increased in the past decade, resources have not kept pace. FDA has proposed actions toward implementing some of these options.

Our analysis of FDA data shows that while FDA received increased funding for new bioterrorism-related responsibilities in 2003, subsequent staffing levels and funding have not kept pace with the agency's growing

[8]GAO, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T (Washington, D.C.: Oct. 10, 2001).

responsibilities. Specifically, the number of FDA-regulated domestic food establishments increased more than 10 percent from fiscal years 2003 to 2007—from about 58,260 in 2003 to about 65,520 in 2007. Additionally, FDA notes that there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports, and recently reported that the number of food import entry lines has tripled in the past ten years.[9] Meanwhile, staffing for FDA's Center for Food Safety and Applied Nutrition (CFSAN) has decreased. According to the Science Board, the number of staff years for CFSAN operations at headquarters dropped about 14 percent, from 950 in fiscal year 2003 to 812 in fiscal year 2006. During that same time period, field-based staff responsible for carrying out inspection and enforcement activities for CFSAN-regulated products dropped by 255 staff years, or about 11.5 percent—from 2,217 in fiscal year 2003 to 1,962 in fiscal year 2006. In addition, while CFSAN-related funding at headquarters and in the field increased from $407 million in fiscal year 2003 to $439 million in fiscal year 2006, this represents a decrease in real terms from about $457 million to about $451 million during that period. One consequence is that foreign inspections have declined: GAO analysis of FDA data shows that inspections of foreign food firms, which number almost 190,000, decreased from 211 in fiscal year 2001 to fewer than 100 in fiscal year 2007. The Science Board considered the funding issues to be more acute for CFSAN than for other FDA programs: unlike the FDA programs responsible for drugs, biologics, and medical devices, which charge manufacturers hundreds of millions of dollars in user fees each year, CFSAN is not authorized to charge user fees for its services.

Recent GAO work has identified opportunities for FDA to better leverage its resources. Specifically, in 2004 we reviewed FDA's imported seafood safety program and identified several options that FDA could consider to augment its resources and enhance its current program.[10] We found that FDA's seafood safety program had shown some progress from a 2001 review. For example, FDA increased its laboratory testing of seafood products at ports of entry from less than 1.0 percent in fiscal year 1999 to about 1.2 percent in fiscal year 2002. We also recommended several

[9]According to FDA, an entry line is each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

[10]GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, GAO-04-246 (Washington, D.C.: Jan. 30, 2004).

options for enhancing FDA's oversight of seafood while leveraging outside resources. Some of these options are presented in FDA's *Food Protection Plan*. We recommended that FDA:

- *Make it a priority to establish equivalence agreements with other countries.* Subject to its jurisdiction, FDA could certify that countries exporting food products to the United States have equivalent food safety systems before food products from those countries can enter the United States. Such agreements would shift some of FDA's oversight burden to foreign governments. While FDA has not yet established equivalence agreements with any foreign countries, the *Food Protection Plan* requests that Congress allow the agency to enter into agreements with exporting countries to certify that foreign producers' shipments of designated high-risk products comply with FDA standards.

- *Explore the potential for certifying third-party inspectors.* FDA could consider developing a program that uses certified third-party inspectors to conduct inspections on its behalf, both at foreign processing firms and domestic importers of seafood. FDA's *Food Protection Plan* requests authority from Congress to accredit third parties to conduct voluntary inspections for foods, and FDA officials told us that they envision using third-party inspectors to inspect foreign facilities, where FDA conducts few inspections. If FDA receives this authority, it can take lessons from its own implementation of third-party inspection programs for medical device manufacturing establishments. As we are reporting in a separate statement today, few inspections of these establishments have been conducted through FDA's two accredited third-party inspection programs.

- *Consider accrediting private laboratories to test seafood.* Currently, FDA does not accredit or use any private laboratories to collect or analyze seafood samples. However, for some seafood violations, it allows seafood firms to use private laboratories to provide evidence that imported seafood previously detained because of safety concerns is now safe and can be removed from the detention list at the port of entry. We recommended that FDA consider accrediting private laboratories because it could leverage outside resources while providing FDA greater assurance about the quality of the laboratories importers use to demonstrate that their products are safe. FDA has not formally changed its policies or practices, but the *Action Plan for Import Safety* notes that FDA intends to issue guidance by mid-2008 on sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA on food safety.

- *Develop a memorandum of understanding with the National Oceanic and Atmospheric Administration (NOAA) to use NOAA's Seafood Inspection Program resources to complete inspections on FDA's behalf.* NOAA officials said that they could provide various services to augment FDA's regulatory program for imported seafood, including inspection, training, and product sampling services. FDA has been working on a program to refer certain export-related work to NOAA, and it is in discussions with NOAA about commissioning its inspectors, but to date, nothing is finalized or operational.

We have not reviewed these actions to determine whether they adequately address our recommendations.

We separately reported on overlaps we identified in the federal oversight of food safety, such as overlapping inspection and training activities that exist among the agencies conducting food safety functions.[11] Such overlaps mean that federal agencies are spending resources on similar activities, which may waste scarce resources and limit effectiveness. Specifically, we found that FDA food safety activities may overlap with, if not duplicate, the efforts of other agencies, including USDA and NMFS. FDA could take practical steps to reduce overlap and duplication and thereby free resources for more effective oversight of food safety, but FDA has made little progress since our report. For example:

- *Domestic inspections.* In fiscal year 2003, FDA and USDA spent most of their food safety resources—about $900 million—on inspection and enforcement activities. A portion of these activities included overlapping and even duplicative inspections of 1,451 domestic food-processing facilities that produce foods regulated by both agencies. Under authority granted by the Bioterrorism Act of 2002,[12] FDA could authorize USDA to inspect these facilities on its behalf, but FDA has not yet reached an agreement with USDA to do this. We recommended that, if cost effective, FDA enter into an agreement to commission USDA inspectors at jointly regulated facilities. FDA told us that they are working with USDA to consider which products might be covered by each agency under such an agreement.

[11]GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO-05-213 (Washington, D.C.: Mar. 30, 2005).

[12]Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594.

- *Import inspections.* FDA and USDA both inspect shipments of imported food at ports of entry and also visit foreign countries that export food to the United States. We found that both FDA and USDA maintain inspectors at 18 U.S. ports of entry to inspect imported food. In fiscal year 2003, FDA spent more than $115 million on imported food inspections, and USDA spent almost $16 million. The two agencies do not share inspection resources at these ports. Although USDA maintains a daily presence at these facilities, the FDA-regulated products may remain at the facilities for some time awaiting FDA inspection. Further, FDA conducted inspections in 6 of the 34 countries that USDA evaluated in 2004 to determine whether their food safety systems for ensuring the safety of meat and poultry are equivalent to that of the United States. We recommended that FDA consider the findings of USDA's foreign country equivalence agreements when determining which countries to visit. In their response to our recommendation, the agency noted that they will consider USDA's foreign country evaluations when making such determinations.

- *Inspectors' training.* FDA and USDA spend resources to provide similar training to food inspection personnel. FDA spent about $1.6 million and USDA spent $7.8 million in fiscal year 2003. We found that, to a considerable extent, food inspection training addresses the same subjects, such as plant sanitation and good manufacturing practices. While other agencies have consolidated training activities that have a common purpose and similar content, FDA and USDA have not. We recommended that USDA and FDA consider joint training programs, but to date, FDA has told us that they have identified no training needs common to both agencies.

FDA's *Food Protection Plan* Proposes Some Positive First Steps, but Additional Information on the Plan's Strategies and Resources would Facilitate Congressional Oversight

FDA's *Food Protection Plan* proposes several positive first steps that are intended to enhance food safety oversight, including requesting several authorities recommended by GAO, but more specific information about its strategies and the resources needed to implement the plan would facilitate congressional oversight. Positively, FDA's *Food Protection Plan* aims to shift the agency's focus to prevention of foodborne illness instead of intervention after contamination and resulting illnesses occur—an important shift given that experts consider prevention to be a core element of an effective food safety system. FDA says that its key prevention steps are promoting corporate responsibility, identifying food vulnerabilities, assessing risks, and expanding its understanding and use of effective mitigation measures.

In addition to the actions we discuss earlier to address resource constraints, FDA's *Food Protection Plan* requests other authorities to

enhance oversight of food safety that begin to respond to prior GAO recommendations. Specifically, the plan requests authority for FDA to:

- *Order food recalls.* The *Food Protection Plan* requests the authority to order a recall when FDA has reason to believe that food is adulterated and presents a threat of serious adverse health consequences or death, to be imposed only if a company refuses or unduly delays conducting a voluntary recall. Currently, food recalls are largely voluntary—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. 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. These agencies have the authority to require a company to notify the agency when the company has distributed a potentially unsafe product, order a recall, establish recall requirements, and impose monetary penalties if a company does not cooperate. In a report and testimony before this subcommittee,[13] we 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. While FDA's *Food Protection Plan* requests mandatory recall authority, this request could also include recall authorities held by other agencies, including establishing recall requirements and imposing penalties for noncompliance. FDA officials noted that while recall requirements and penalties for noncompliance were not explicitly stated in the *Food Protection Plan*, they are encompassed in the request. Further, the plan does not propose a definition of "undue delay" by a company, another critical element of recall authority given that timing is essential in reacting to outbreaks, and delays can cost lives.

- *Issue additional preventive controls for high-risk foods.* FDA is requesting explicit authority from Congress to issue regulations requiring

[13]GAO, *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 *Federal Oversight of Food Safety: High Risk Designation Can Bring Attention to Limitations in the Federal Government's Food Recall Programs*, GAO-07-785T (Washington, D.C.: Apr. 24, 2007).

foods that have been associated with repeated instances of serious health problems or death to be prepared, packed, and held under a system of preventive food safety controls. According to FDA, this would clarify the agency's ability to require industries to implement preventive Hazard Analysis and Critical Control Point (HACCP) systems, which it currently requires for companies that process seafood and juice. HACCP systems are designed to improve food safety by having industry identify and control hazards in products before they enter the market. FDA officials told us that they are asking for explicit authority to put measures in place for other high-risk foods, such as leafy greens. Officials told us that this request, if granted, would allow the agency to focus its preventive efforts on foods that present the highest risk for contamination, consistent with the agency's risk-based focus. However, others have expressed concern that requiring a history of repeated outbreaks before issuing preventive controls would not allow FDA to proactively establish regulations for foods before they cause additional illnesses.

While FDA officials have acknowledged that implementing the *Food Protection Plan* will require additional resources, FDA has not provided specific information on the resources it anticipates the agency will need to implement this plan. For example, the *Food Protection Plan* proposes to develop food protection guidelines for industry; however FDA's Science Board reported that modernizing safety standards for fresh produce and other raw foods and developing and implementing inspection programs could cost $210 million. Additionally, the *Food Protection Plan* proposes to enhance FDA's information technology systems related to both domestic and imported foods which the Science Board report suggests could cost hundreds of millions of dollars. FDA officials have declined to provide specific information on how much additional funding it believes will be necessary to implement the *Food Protection Plan*, saying that finalizing the amounts will take place during the budget process. Similarly, the *Food Protection Plan* does not discuss the strategies it needs in the upcoming years to implement this plan. FDA officials told us that they have internal plans for implementing the *Food Protection Plan* that detail timelines, staff actions, and specific deliverables. While FDA officials told us they do not intend to make these plans public, they do plan to keep the public informed of their progress. Without a clear description of resources and strategies, it will be difficult for Congress to assess the likelihood of the plan's success in achieving its intended results.

Tools that Agencies Can Use to Address Management Challenges

The Science Board cites numerous management challenges that have contributed to FDA's inability to fulfill its mission, such as a lack of a coherent structure and vision, insufficient capacity in risk assessment, and inadequate human capital recruitment and retention. The Science Board also noted that public confidence in FDA's abilities has diminished. In light of these challenges, we have identified through other work some tools that can help agencies improve their performance, which may also be relevant to FDA.

For example, we reported on the use of a Chief Operating Officer (COO)/Chief Management Officer (CMO) as one way to address longstanding management problems that are undermining agencies' abilities to accomplish their missions and achieve results.[14] Agencies with such challenges, including FDA, could benefit from a senior leader serving as a COO/CMO who can elevate, integrate, and institutionalize responsibility for key management functions. While GAO has long advocated the need for a COO/CMO position at the Department of Defense and the Department of Homeland Security, a relatively stable or small organization could use the existing deputy or related position to carry out the role. In addition to GAO, a number of other organizations have supported the need for the creation of COO/CMO positions in federal agencies. McKinsey & Company recommended that a COO be established in many federal agencies as the means to help those agencies successfully achieve transformation.[15] In addition, a working group within the National Academy of Public Administration (NAPA) recommended creating COO positions in federal agencies to oversee the full range of management functions, including procurement, finance, information technology, and human capital.[16]

Another tool that can help federal agencies address their management challenges is a well-designed commission that can produce specific practical recommendations that Congress can enact. For example,

[14]See for example, GAO, *A Call for Stewardship: Enhancing the Federal Government's Ability to Address Key Fiscal and Other 21st Century Challenges*, GAO-08-93SP (Washington D.C.: November 2007) and *Organizational Transformation: Implementing Chief Operating Officer/Chief Management Officer Positions in Federal Agencies*, GAO-08-34 (Washington, D.C.: Nov. 1, 2007).

[15]McKinsey & Company, *How Can American Government Meet its Productivity Challenge?* (July 2006).

[16]NAPA, *Moving from Scorecard to Strategic Partner: Improving Financial Management in the Federal Government* (October 2006).

Congress created the National Commission on Restructuring the Internal Revenue Service (IRS) in 1995 to review current practices at IRS and report on requirements for improvement. Congress subsequently passed the IRS Restructuring and Reform Act of 1998, which was influenced by the Commission's report, and reorganized the structure and management of IRS, revised the mission of IRS, and mandated numerous other detailed changes.[17] Based on our recent analysis of several commissions, there are several critical success factors that can be applied to ensure a commission's success including:[18]

- *A statutory basis with adequate authority.* When provided with a clear mandate and adequate authority, a commission can comprehensively access and analyze information related to a given policy issue and thereby provide more informed policy options for the President and Congress to consider.

- *A clear purpose and timeframe.* A commission should have a clear purpose for its objectives and activities to help guide the members in carrying out their responsibilities. In addition, a fixed agenda and timeframe can help keep a commission focused and on track. However, a commission should have a broad enough scope to help ensure it has the authority to address all the issues necessary in order to come up with a comprehensive and integrated solution without encountering any constraints in the process as to what it can or cannot consider.

- *Key leadership support.* Institutional leadership, commitment, and support from the President and Congress are necessary to help a commission succeed.

- *An open and transparent process.* By having an open and transparent process, such as public hearings, a commission can help build consensus among the public for its goals by gaining their input and support.

- *A balanced and capable membership.* Balanced and capable membership can help lessen political influences and build consensus among the commission members when carrying out its purpose. Specifically, a commission should involve current or former Members of Congress as well as experts and professionals on the topic. Current or former elected

[17]Pub. L. No. 105-206 (July 22, 1998).

[18]GAO, *Long-Term Fiscal Challenge: Comments on the Bipartisan Task Force for Responsible Fiscal Action Act,* GAO-08-238T (Washington, D.C.: Oct. 31, 2007).

officials can ensure viability of a commission's legislative proposals due to their experience.

- *Accountability.* Clear accountability for a commission can help foster specific, useful outputs that could help inform the public and provide specific policy options and, hopefully, recommendations for Congress and the President.

- *Resources.* The success of the commission is dependent on having the adequate resources to carry out its purpose and any potential recommendations.

Generally, one concern regarding commissions may be whether or not there is sufficient buy-in from key stakeholders on the purpose of the commission along with a commitment to act on any resulting recommendations. Any recommendations by a commission in a final report are generally advisory in nature and may not automatically result in any public policy changes. Congressional action through subsequent legislation with Presidential support may be necessary for the commission's recommendations to be implemented and for any changes to occur.

Food safety concerns not only continue but will likely become more urgent in view of changing demographics and consumption patterns. Clearly, FDA plays a critical role in the federal oversight of food safety because of the breadth of its responsibilities. Thus its ability to carry out those responsibilities is necessary to help ensure the safety of the nation's food supply in the most efficient, effective, accountable, and sustainable way. Nevertheless, in light of the federal government's long-term fiscal challenges, agencies, including FDA, need to seek out opportunities to better leverage their resources. FDA's *Food Protection Plan* is a step in the right direction and proposes to implement many of the recommendations made by GAO. However, additional information on the strategies and resources needed to implement the plan can help Congress assess the likelihood of its success. Further, concerns over FDA's management challenges, such as those identified by the Science Board could hinder the implementation of the plan. Tools such as commissions and positions like a COO/CMO can help agencies address management challenges and make needed progress to achieve their missions. Continued congressional oversight, including today's hearing, and additional legislative action are key to achieving that progress and to promoting the safety and integrity of the nation's food supply.

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

Contact and Staff Acknowledgments

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. For further information about this testimony, please contact Lisa Shames, Director, Natural Resources and Environment at (202) 512-3841 or shamesl@gao.gov. Key contributors to this statement were Candace Carpenter, Bart Fischer, José Alfredo Gómez, and Alison O'Neill.

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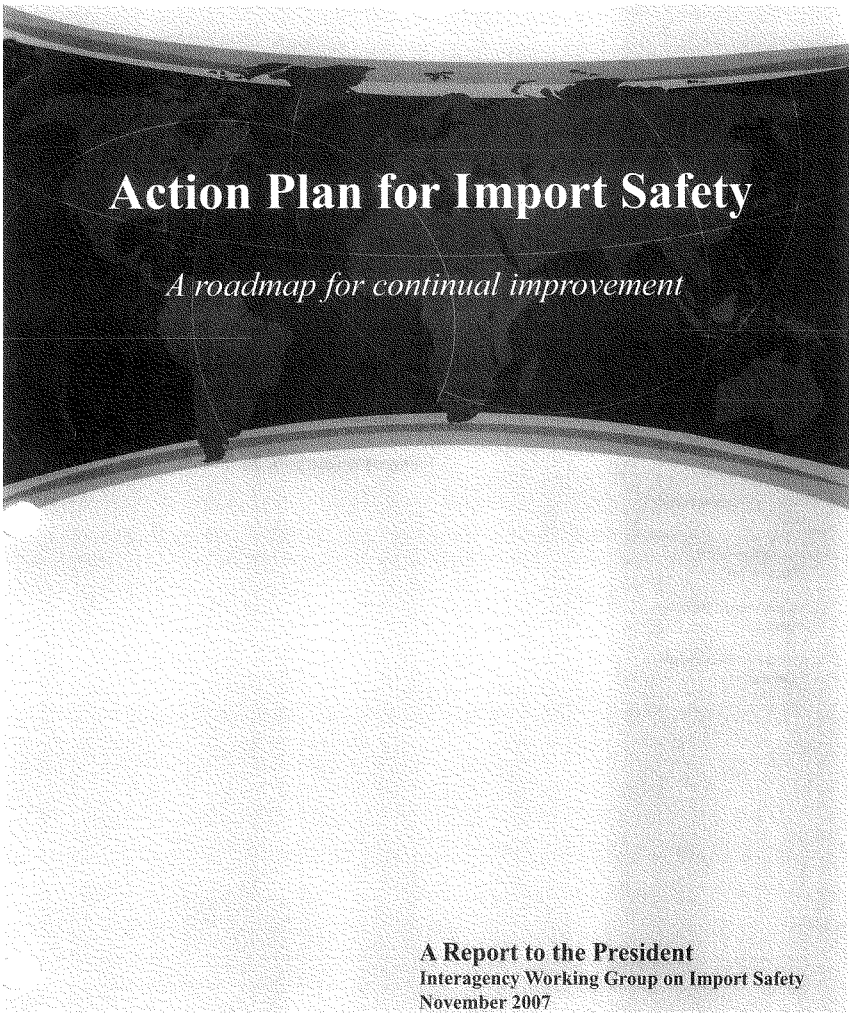

Action Plan for Import Safety
A roadmap for continual improvement
A Report to the President
Interagency Working Group on Import Safety
November 2007

Interagency Working Group on Import Safety:

Department of Health and Human Services

Department of State

Department of Treasury

Department of Justice

Department of Agriculture

Department of Commerce

Department of Transportation

Department of Homeland Security

Office of Management and Budget

United States Trade Representative

Environmental Protection Agency

Consumer Product Safety Commission

We will continually improve the safety of imported products in a manner that expands global trade and protects the health and safety of every American.

President George W. Bush

November 6, 2007

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The Interagency Working Group on Import Safety is pleased to submit this *Action Plan for Import Safety: A roadmap for continual improvement.* In it, we detail a roadmap with short- and long-term recommendations and action steps.

This Action Plan represents the culmination of thousands of hours of research and analysis, as well as public comment received from hundreds of stakeholders. The Action Plan takes the form of 14 broad recommendations and 50 specific action steps based on *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety* and the *Immediate Actions Memorandum* presented to you on September 10, 2007.

In the last two months, significant progress has been made on the Immediate Action Items listed in my memorandum to you accompanying the Strategic Framework. The Office of Management and Budget has actively engaged the departments, and all agencies are on track to accelerate their participation in the Automated Commercial Environment / International Trade Data System. In addition, the State Department has led a vigorous international outreach effort to communicate our import safety priorities with our trade partners around the world. The Office of the United States Trade Representative has moved forward with the departments and agencies to explore existing import safety-related agreements with foreign governments and to coordinate future agreements to benefit the United States and not merely individual agencies.

A variety of actions and plans are already underway to improve import safety. Today, the Food and Drug Administration is releasing a new Food Protection Plan. In September, the Consumer Product Safety Commission signed a renewed agreement with the People's Republic of China focused on the safety of toys, fireworks, cigarette lighters and other targeted products. These steps, and other recent actions and current plans, have jump-started our efforts to continually improve the safety of products imported to the United States.

Each recommendation in this Action Plan falls under the organizing principles of prevention, intervention and response and expands upon the building blocks identified in the Strategic Framework. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

The information collected and analyzed for this Action Plan reaffirms the essential and integrated import-safety roles of the public and private-sector. Our recommendations pertain to all parties involved in the import life cycle, from production in the foreign country through U.S. ports-of-entry to final consumption or use by American

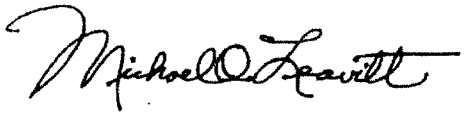
consumers. The public and private-sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

This Action Plan provides a roadmap that ensures the benefits of the global economy and improves the safety of imported products. Progress will require that we work collaboratively, partner with the importing community and state and local governments, and reach out to foreign producers, exporters and governments. By doing so, all involved will be more prosperous and will continue to benefit from an abundant and safe marketplace.

We recommend that Working Group designees meet within 30 days to assess progress in implementation of this Action Plan, and to discuss how best to collaborate with the private-sector to continue effective implementation.

On behalf of the members of the Interagency Working Group on Import Safety, we thank you for the opportunity to serve this great country.

Respectfully,



Michael O. Leavitt
Secretary, Health and Human Services and
Chair, Interagency Working Group on Import Safety

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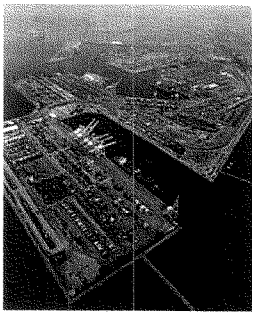
Action Plan for Import Safety:
A roadmap for continual improvement

Introduction

On September 10, 2007, the Interagency Working Group on Import Safety[1] (Working Group) presented an *Action Plan for Import Safety: A roadmap for continual improvement* (Strategic Framework) and Immediate Actions[2] for continual improvement in import safety.[3] The Strategic Framework provides the foundation for this Action Plan for Import Safety. Together, the Strategic Framework, Immediate Actions and this Action Plan fulfill the requirements of Executive Order 13439, which established an Interagency Working Group on Import Safety and was signed by President Bush on July 18, 2007.

A careful examination of import safety has been motivated by the recent challenges presented by an increasingly global economy, in which U.S. consumers are purchasing approximately $2 trillion worth of products that are imported by over 800,000 importers through over 300 ports-of-entry.

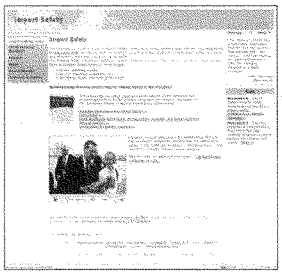
In developing the Strategic Framework, Immediate Actions and Action Plan, the Working Group engaged in a campaign to solicit comments and recommendations from the public. Since the release of the Framework, the Working Group has received information and comments from hundreds of stakeholders. Health and Human Services Secretary Leavitt and other Cabinet members traveled throughout the United States and other countries to discuss import-safety issues. They met with federal, state and local officials, producers, importers, distributors and retailers. In addition, they held roundtable discussions and media events to engage the public and importing community[4] in the activities of the Working Group.



The Working Group also met with Members of Congress and representatives of foreign governments to solicit comments and recommendations. The Working Group issued a Federal Register notice requesting written comment and announcing a public meeting, which was held in Washington, D.C., on October 1, 2007. Representatives from the 12 Cabinet departments and agencies comprising the Working Group listened to comments and recommendations from the importing community and the public on import safety. Officials from each member department met with

1 The Working Group includes the Secretaries of the Department of Health and Human Services, the Department of State, the Department of the Treasury, the Attorney General, the Secretaries of the Department of Agriculture, the Department of Commerce, the Department of Transportation and the Department of Homeland Security, the Director of the Office of Management and Budget, the United States Trade Representative; the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food and Drug Administration, Customs and Border Protection and the Food Safety and Inspection Service were active participants on the Working Group as well.
2 See Appendix B for the September 10, 2007 correspondence to the President that included these Immediate Actions.
3 See *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety.*
4 The term "importing community" is used broadly throughout this document to include all domestic entities in the supply chain.

scores of their private-sector constituencies to discuss import-safety issues. Texas A&M University convened a Conference on Import Safety Science and Technology on October 18, 2007. Additionally, the Working Group created an import-safety Web site, and utilized novel approaches such as webinars to provide information and to solicit comments and views from the importing community and the public.



The oral comments from the public meeting and the written comments submitted, as well as the input received by the member departments from the public, provided significant input that was used in the development of the recommendations in this Action Plan.

The seminal finding of the Framework was that, to adapt to a rapidly growing and changing global economy, the U.S. government must develop new import-safety strategies that expand and emphasize a cost-effective, risk-based approach. Such an approach identifies risks at the points they are most likely to occur, and then targets the response to minimize the likelihood that unsafe products reach U.S. consumers.

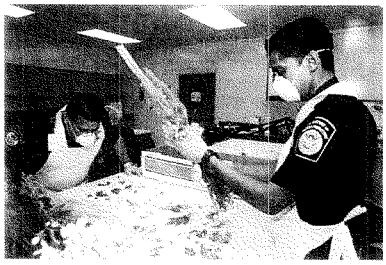
This Action Plan presents broad recommendations and specific short- and long-term action steps under the organizing principles of prevention, intervention and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. The Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Implementation of this Action Plan will require expanded legal authorities, improved collaboration and capacity building with our trading partners, improved collaboration with state and local governments and the private sector, increased information gathering and the discovery and application of new science. Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities.

The Working Group recommends that representatives of the member departments and agencies meet within 30 days to assess progress in implementation of the Action Plan and to discuss possible mechanisms for collaboration with the private sector to continue the effective implementation of this Action Plan.

Background

This Action Plan builds on the earlier companion report: *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*. That report concluded that the United States must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused "video" model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important points.



This Action Plan follows the organizing principles identified in the Strategic Framework – prevention, intervention, and response – and draws on six building blocks:

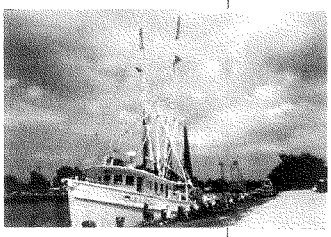
1. Advance a Common Vision;
2. Increase Accountability, Enforcement and Deterrence;
3. Focus on Risks Over the Life Cycle of an Imported Product;
4. Build Interoperable Systems;
5. Foster a Culture of Collaboration; and
6. Promote Technological Innovation and New Science.

Public comments on the Strategic Framework show widespread acceptance and support of the organizing principles and building blocks.

The following is a brief summary of the Strategic Framework that forms the foundation of this Action Plan. Readers familiar with the Framework are encouraged to proceed to the Recommendations section.

Summary of the Strategic Framework

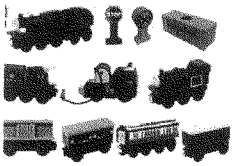
The Strategic Framework advocates a strategy that shifts the primary emphasis for import safety from intervention to a risk-based prevention with verification model. It recommends that the public and private sectors work together to identify risks and consider new approaches for addressing these risks. The vision of the Strategic Framework is to improve continuously the safety of imported products.



Three organizing principles form the keystones of the Strategic Framework and the recommendations included within this Action Plan:

1. **Prevention** – *Prevent harm in the first place.*
   The U.S. government must work with the private sector and foreign governments to adopt an approach to import safety that builds safety into manufacturing and distribution processes. This effort will reduce the risks to consumers from otherwise dangerous imported products.

2. **Intervention** – *Intervene when risks are identified.*
   Federal, state, local and foreign governments, along with foreign producers and the importing community, must adopt more effective techniques for identifying potential product hazards. When problems are discovered, government officials must act swiftly, and in a coordinated manner, to seize, destroy or otherwise prevent dangerous goods from advancing beyond the point-of-entry. For foreign countries, taking steps to ensure the safety of products exported to the United States will benefit them by facilitating trade.



3. **Response** – *Respond rapidly after harm has occurred.*
   In the event that an unsafe import makes its way into domestic commerce, swift actions must be taken to limit potential exposure and harm to the American public.

Within each of these organizing principles are the cross-cutting building blocks identified in the Strategic Framework that departments and agencies should use to guide their programs.

Action Plan for Import Safety:
A roadmap for continual improvement

Building Block 1: Advance a Common Vision

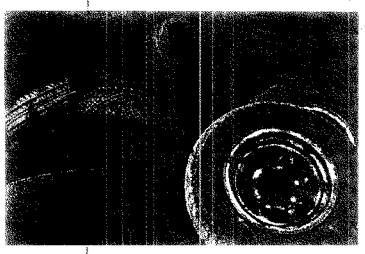
There should be a shared vision and shared goals across the federal government for promoting import safety. Relevant policies and procedures should be reviewed and, where appropriate, revised to ensure that all federal departments and agencies are working together with shared objectives. Revised measures should encourage public and private parties involved in the import life cycle to adopt this common vision.

Building Block 2: Increase Accountability, Enforcement and Deterrence

While it is important to remember that industry has a financial interest to sell safe products to its consumers, all actors involved in the production, distribution and sale of imports must be held accountable for meeting their obligations to ensure that imported products meet safety standards[5] in the United States. The federal government will continue to work with industry to foster compliance with these standards, but is also prepared to use appropriate criminal and civil enforcement tools to hold companies and individuals accountable and to protect consumers.

Building Block 3: Focus on Risks Over the Life Cycle of an Imported Product

In addition to identifying unsafe products at the border, the new approach must focus on the most important safety considerations affecting imported goods throughout their import life cycle – from overseas production to U.S. ports-of-entry, through final consumption or use in the United States. A key element is developing the ability to identify and manage risk at critical points along the import life cycle. Rather than the primary line of defense, intervention at the border must become one part of a network of interconnected measures that protect the American public and facilitate the entry of safe imports that comply with U.S. statutes and regulations.



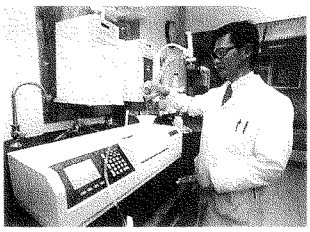
The federal government should move to a more risk-based, cost-effective approach to identify and mitigate risks posed by imported products. Principles of hazard analysis and risk management have long been applied in manufacturing as a method of minimizing risks and maximizing quality in production processes. These principles enable the targeting of resources to areas of greatest risk.

---

5 "Safety standards" may have a different meaning in different contexts. In this case, we are using the term in a broad sense to refer to recognized standards in the United States that ensure products, including chemical substances and pesticides, are safe for people and animals. By "recognized standards" we are referring to those standards for which compliance is required by United States law or regulation, or for which compliance is voluntary but, if met, is considered by the federal agency with jurisdiction as sufficient to meet federal requirements. These standards can be national or international.

Building Block 4: Build Interoperable Systems

The federal government needs to finalize implementation of interoperable data systems already under development that facilitate the exchange of relevant product information among parties within the import supply chain to ensure import safety. The International Trade Data System (ITDS) initiative is a key component to improve system interoperability. The ITDS initiative will create a single-window environment for the collection of information and will improve and enhance information sharing among government departments and agencies and the import community.

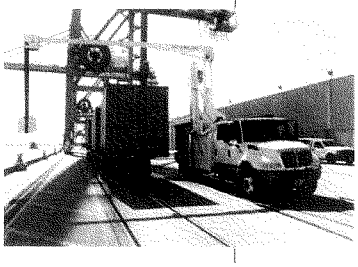


Building Block 5: Foster a Culture of Collaboration

The federal government must develop a culture of collaboration that will permeate relationships among federal departments and agencies and their external stakeholders. All parties (federal, state, and local governments, foreign governments, foreign producers, foreign exporters and the importing community) involved in the import life cycle need to work together to prevent unsafe products from entering the United States and to take swift and effective action if such products do enter domestic commerce. This collaboration must build on international multilateral and bilateral agreements to ensure the safety of products imported into the United States without creating unjustified trade barriers. As some unsafe products result from violations of patents and trademarks, the federal government will also work to increase coordination with U.S. industry to enforce intellectual property rights (IPR) and prevent the entry of counterfeit and potentially unsafe products into supply and distribution chains. This will require a new era of collaboration, as the federal government works to identify better ways to engage all parties in the import life cycle.

Building Block 6: Promote Technological Innovation and New Science

A more effective and efficient import-safety system will depend on the development and application of new science and technology. Implementation of innovative technologies will afford the opportunity to screen larger volumes of imported products at points-of-entry. These screening procedures will help evaluate and target high-risk commodities, increasing analytical efficiency and the number of imported products tested. Research into the causes of risk, such as the conditions that lead to contamination of foods with certain pathogens, can help government and industry identify vulnerable points in the import life cycle for specific products.



These building blocks and the organizing principles provide the foundation for the recommendations that follow.

Import Safety Strategic Framework
Vision
Our aspiration
Continuously improve the safety of imported products
Strategy
How we achieve our vision
Shift focus from intervention to prevention
(over the entire import life cycle)
Organizing principles
How we organize our strategy
Prevention
Intervention
Response
Building Blocks
Steps necessary to achieve our vision
Advance a Common Vision
Focus on Risks Over the Import Life Cycle
Increase Accountability, Enforcement, & Deterrence
Build Interoperable Systems
Foster a Culture of Collaboration
Promote Technological Innovation & New Science

Sample Summary of Actions and Current Plans to Protect American Consumers

As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. Here is a sample of significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan. A more complete list is shown in Appendix C: Recent Actions and Current Plans to Protect American Consumers.

Safety Standards

- **Food Protection Plan.** The Food and Drug Administration (FDA) has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. A number of other plants are scheduled to be inspected.
- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong, and has plans to put inspectors in other countries that export large volumes of seafood to the United States.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks, Electrical Products.** Meetings held in September 2007 between the Consumer Products Safety Commission (CPSC) and its counterpart, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China, resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products – children's toys, fireworks, cigarette lighters, and electrical products.
- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.
- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food, and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.
- **Motor Vehicle Safety Agreement with China.** On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.
- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, the United States Department of Agriculture (USDA) and FDA conducted a seven-week training program for Chinese inspection officials. The Food Safety and Inspection Service (FSIS) also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.

Response

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked "United States: Refused Entry." Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.

Recommendations

The current import-safety system in the United States has served the public well for many years and is among the most effective in the world. In this system, the public and private sectors work collaboratively to collect and evaluate pertinent information for all commercial cargo before it reaches the United States. Under U.S. law, cargo that does not meet federal government requirements, including those relating to safety, is not allowed to enter domestic commerce. In a similar fashion, cargo that does not meet the expectations, contractual requirements or safety standards of the private sector jeopardizes trading relationships and compromises business. These legal requirements and market-based measures work together to protect the American public.

> **We live in a world that is risky. We will not be able to eliminate all risks, but we also need to manage those risks in a way that is smart and efficient.**
>
> **Dr. Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of Homeland Security**

The recommendations included in this Action Plan build upon the current import-safety system and activities already being undertaken by the public and private sectors by focusing on cost-effective, risk-based approaches across the entire import life cycle. The Working Group presents 14 broad recommendations and 50 action steps, each with a lead entity and time frame. The recommendations include short- and long-term action steps that should commence immediately.[6]

The recommendations are categorized in this Action Plan based on the organizing principles outlined in the Strategic Framework – prevention, intervention and response. Together, the organizing principles, recommendations and action steps create an import-safety roadmap to promote continual improvements in import safety.

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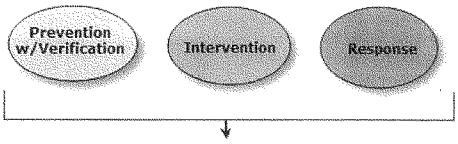
6 "Short term" refers to those action steps that can be completed within the next 12 months; "Long term" refers to those action steps that will take longer to complete.

Import Safety Roadmap

Organizing Principles



Recommendations

1. Create new and strengthen existing safety standards
2. Verify compliance of foreign producers with U.S. safety standards and U.S. security standards through certification
3. Promote Good Importer Practices
4. Strengthen penalties and take strong enforcement actions to ensure accountability
5. Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities
6. Harmonize federal government procedures and requirements for processing import shipments
7. Complete single-window interface for the intra-agency, interagency, and private sector exchange of import data
8. Create interactive import-safety information network
9. Expand laboratory capacity and develop rapid testing methods for swift identification of hazards
10. Strengthen protection of intellectual property rights (IPR) to enhance consumer safety
11. Maximize the effectiveness of product recalls
12. Maximize federal-state collaboration
13. Expedite consumer notification of product recalls
14. Expand use of electronic track-and-trace technologies

Sample Action Steps

- Establish 3rd party certification
- Make available information about certified firms and importers who only use certified firms
- Increase the dollar amount of bonds
- Expand asset-forfeiture remedies
- Raise the Consumer Product Safety Act (CPSA) statutory civil penalty cap
- Develop capability to exchange information electronically among the federal departments and agencies and with the importing community
- Establish field presence at key foreign ports
- Enhance field laboratory capacity
- Develop best practices for track-and-trace technologies

Footnote: The roadmap includes 50 short- and long-term actions steps. The steps here are a subset of the larger total and illustrative of the recommended actions.

Points of Clarification

Before presenting the recommendations and action steps, several clarifications are helpful:

- **Shared interest** – The information collected and analyzed for this Action Plan reaffirms the key and integrated import-safety roles of public- and private-sector actors. Both have a shared interest in the safety of imported products and both must continue working together to protect the American consumer. The import-safety chain stretches from the point of foreign origin, both of materials and finished product, to domestic consumption or use. All entities involved in the import life cycle – foreign producers (growers and manufacturers), governments, distributors, exporters, U.S. importers, distributors, manufacturers and retailers, testing and certification bodies and regulatory authorities at the federal, state and local levels – must work together to prevent unsafe products from entering the United States. The appropriate entities in the supply chain must also take swift and effective action when harmful products do enter domestic commerce.

> **We believe that the responsibility for safety has to be firmly attached to each link in the supply chain.**
>
> **Donald Mayes, Consumers Union**

- **Private-sector interest and mechanisms** – The private sector not only has a significant interest in ensuring safety, but also has a wide array of mechanisms to support federal objectives. Likewise, the federal government can learn and benefit from the experience of the private sector. Although the action steps in this Action Plan pertain primarily to the federal government, the Action Plan recognizes the importance of private-sector mechanisms and experience and lays a foundation for ongoing, substantive public-private collaboration.

> **It makes sense to focus our limited resources on those shipments that pose the greatest risk.**
>
> **Josh Green, Panjiva**

- **Consumer interest** – The Action Plan recognizes that consumers have a vital interest in the safety of imported products and anticipates active consumer engagement in the implementation of the recommendations and action steps.

- **Risk-based strategies** – This Action Plan is built on the concept that focusing on risk is the most effective way to address safety over the broad spectrum of products imported by the United States. Some areas and products need more attention than others because of the potential risks they could present and because of differences in the product and the production environment. These differences include process controls, the history of compliance, the intended use of the product, the inherent risks of the product and other factors demonstrated by science and experience to be valid predictors of

risk to the public. The federal government must continue to make choices about where it focuses its resources, and basing those choices on risk means that better and more logical decisions will be made with more effective results. Therefore, there is no one-size-fits-all solution. The recommendations and action steps in this Action Plan reflect this cost-effective, risk-based approach.

- **Accountability** – The Strategic Framework stresses that import safety can be advanced through shared efforts and shared responsibility throughout the entire import life cycle, from foreign governments, producers, distributors and exporters to U.S. importers, producers, distributors and retailers, as well as the federal and state governments. Any private entity that seeks to benefit from access to the U.S. market has the same responsibility domestic producers have to ensure their products meet all applicable U.S. safety standards. For example, producers of drugs and medical devices are expected to meet the standards set by the FDA. Steps to create incentives for foreign firms to ensure this outcome are an important part of the Action Plan. In addition, the U.S. importing community, either as a link in the U.S. distribution chain or as the seller to the ultimate consumer, must share the commitment to ensure that products brought into the United States are manufactured in accordance with U.S. safety standards.

  All entities involved in the import life cycle are responsible for ensuring the safety of the products they produce, distribute, export, import or sell. The specific responsibilities of each entity depend on the activities in which they engage. For example, producers are responsible for making products that comply with U.S. safety standards. Importers are responsible for bringing products that meet U.S. safety standards into this country in a manner that does not compromise the safety and, where appropriate, efficacy of the product.

Facilitate Trade but Target High-Risk Imports
The recommendations in this Action Plan are designed to promote import safety while avoiding restrictions on the flow of international trade. Some recommendations provide incentives to foreign producers, suppliers, and importers that will expedite the entry of products that meet U.S. standards. Others lead to greater information about these entities. These incentives and the collection of better information will enhance the capacity of the federal government to focus on those products that may present a risk to consumers in the United States. By improving the management of risk, we can facilitate the trade of safe products and devote more personnel and resources to high-risk products and products of unknown risk.

- **Resources** – To implement the Action Plan to its fullest extent will require resources. Federal departments and agencies will coordinate, plan effectively and meet these goals by submitting additional funding needs through the normal budget process.

- **Common mission, varying statutory roles** – While the entire federal government is responsible for advancing import safety, each department and agency operates within a unique statutory framework. The recommended actions do not apply uniformly to all federal entities. Instead

they are tailored to product risk and the relevant statutory frameworks serve as tools to improve the safety of imported products on an ongoing basis. Where appropriate, the action steps identify affected departments and agencies.

- **Complementary Findings** – The recommendations and action steps outlined in this Action Plan take into consideration the wide array of other planned or ongoing actions by the federal government and other entities to improve the safety of imported products. The findings of this Action Plan are additive and complement other meaningful changes and programs. Appendix C includes a summary description of recent activities and current plans that expand upon and complement this Action Plan.

The United States import safety system must be a comprehensive, risk-based, preventative approach in which food manufacturers build food safety into their products. Indeed, the changing import environment for our increasingly global food supply demands a new approach to import safety.

John D. Floros, Ph.D.
Institute of Food Technologists

Implementation

Effective implementation will require the concerted effort of all participants in the import life cycle, creating an expanded culture of collaboration. The federal government must lead by example to build each of these recommendations into agency priorities and budgets. To aid in this process and ensure accountability, each action step has a designated lead agency or agencies.

Prevention with Verification

This Action Plan recommends using market-based and regulatory incentives and deterrents to encourage foreign entities to build safety into products destined for the American market and to encourage domestic entities to ensure that the products they import meet safety standards in the United States. This approach holds all participants in the import life cycle, both foreign and domestic, accountable for ensuring the safety of imported products by using a cost-effective, risk-based strategy. It includes:

- Creation of mandatory and voluntary third-party certification programs for foreign producers that are based on product risk to verify compliance with U.S. safety standards,
- Development of good importer practices, and
- Use of strong penalties against bad actors.

Based on their risk, many products may not warrant the establishment of a mandatory or voluntary certification program. The federal government will also work with its trading partners to promote, where needed, the development of the regulatory capacity and legal systems necessary to ensure the safety of the products they export to the United States.

Safety and Security
Since the United States government bases its decisions about whether or not a product may enter the country on both safety and security considerations, certification programs referenced in the action steps would assess compliance with both safety and security standards. In today's world, certification for import safety and certification for import security need to be closely coordinated. Consideration should be given to merging these two certification processes into one program.

The following recommendations, action steps, lead entities and time frames present a detailed roadmap for further action.

Safety Standards

Recommendation 1 – Create New and Strengthen Existing Safety Standards

An organizing principle of the Strategic Framework is the concept of prevention with verification. This concept is predicated on a philosophy of building assurances of safety into production processes and establishing appropriate supply-chain controls, rather than relying solely on physical inspection and testing of products at ports-of-entry to identify and mitigate safety hazards. Prevention with verification embraces the incorporation of science-based safety standards into production and distribution systems, combined with compliance assessments to ensure these standards are being met.

Industry best practices have long reflected a commitment to the use of risk-based preventive controls as an effective mechanism for assuring product safety. The federal departments and agencies with jurisdiction over imported products should work with industry, standards development organizations and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk. Federal departments and agencies should also increase their participation in international standards-setting organizations to encourage the development of international standards that reflect, to the extent possible, the same level

of protection maintained in the United States. When adopting or developing safety standards, the federal department or agency with jurisdiction should consider the best available science, industry best practices and standards set by credible national and international standards development organizations.

1.1 *Extend the mandatory manufacturer/importer certification requirement under section 14 of the Consumer Product Safety Act to all statutes administered by Consumer Product Safety Commission.* All mandatory safety standards promulgated by the CPSC under the CPSA require a manufacturer's or importer's certification of conformity to those standards. The other key statutes administered by the CPSC do not contain similar certification provisions for mandatory safety standards. In the CPSC's experience, requiring the certification of conformity improves supplier compliance with mandatory standards. The requirement simplifies and strengthens enforcement at ports because products that are not accompanied by a declaration of conformity must be refused entry. Also, because it is unlawful to issue a false declaration, firms can not easily circumvent the requirement. As a benefit to inspecting officials, the process of checking for a certificate is not burdensome and does not require any additional government testing or evaluation. Extending the existing conformity requirement under the CPSA to other statutes administered by the CPSC would enhance the Commission's ability to ensure product safety.
Lead: CPSC
Time Frame: Short Term

Apply the Same Safety Standards to Domestic and Foreign Made Products
A product sold to American consumers should be safe regardless of whether it is made in the United States or abroad. These recommendations are aimed at ensuring that foreign producers, exporters and distributors, as well as importers, are held accountable for compliance with the same product safety standards as producers and distributors in the United States. Consistent with international trade rules and longstanding United States practice, any new safety rules will be transparent, will be based on available scientific and technical information and will not discriminate unfairly against imported products over domestic products.

1.2 *Clarify the Food and Drug Administration's (FDA) authority to require preventive controls for certain foods.* This action step would strengthen FDA's ability to require, by regulation, preventive control measures to address risks that might occur for domestic and foreign produced foods associated with repeated serious adverse health consequences or death from unintentional contamination. FDA would take into consideration industry best practices, such as Hazard Analysis and Critical Control Points (HACCP) requirements.
Lead: HHS / FDA
Time Frame: Short Term

1.3 *Provide the FDA with authority to require measures to prevent the intentional contamination of domestic and foreign foods.* The FDA would use this authority to issue regulations to require companies to implement practical food defense measures at specific points in the food supply chain where the potential for intentional adulteration resulting in serious adverse health consequences or death to humans or animals is the greatest. This authority would apply to food in bulk or batch form, prior to being packaged.
Lead: HHS / FDA
Time Frame: Short Term

1.4 *Examine food-safety control systems of other countries to determine whether improvements can be made to the operation of FDA's food regulatory program.* The examination would provide FDA with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention and response activities.
Lead: HHS / FDA
Time Frame: Long Term

1.5 *Expand the use of public-private sector standards programs.* Standards programs established and administered by the private sector with input from government can provide a generally accepted forum for developing safety standards. Organizations such as the International Organization for Standardization and U.S.-based international standards developers accredited by the American National Standards Institute devise standards that the federal government may subsequently recognize. Greater use of these venues can accelerate the development of needed safety standards. They should be pursued, as appropriate, as long as the standards developed are based on sound scientific information and utilized domestically.
Lead: Department of Commerce
Time Frame: Long Term

Certification

Recommendation 2 – Verify Compliance of Foreign Producers with United States Safety and Security Standards Through Certification

Import certification can augment federal department and agency resources, facilitate trade by expediting the entry of products from certified firms, and assist the importing community in implementing effective Good Importer Practices. As appropriate, certification would include periodic on-site inspections and random testing. Certification would need to be renewed periodically at intervals that could vary based on product risk, such as with greater frequency for high-risk goods. This Action Plan contemplates the use of both mandatory and voluntary certification.

> The federal departments and agencies with jurisdiction over imported products should work with regulated industry and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk.

The Action Plan recommends tailoring import certifications to both the product's level of risk and its intended use. Currently, federal departments and agencies use import certifications in a variety of contexts. For example, as a condition for export of meat, poultry and egg products to the United States, the Food Safety and Inspection Service (FSIS) certifies foreign countries that, in turn, certify producers that meet U.S. requirements. Such certification ensures that the products comply with U.S. requirements. While requiring import certifications for all goods is not necessary, in certain circumstances (e.g., high-risk products), this extra step may be warranted. Therefore, the Action Plan recommends mandatory certification for select high-risk products.

The Action Plan also recommends expanded use of voluntary import certifications for other products. To encourage and assist foreign producers to meet U.S. standards, the federal government should establish voluntary certification programs as appropriate. Voluntary certification programs may provide importers with important compliance information and help them ensure that the products they import meet U.S. standards. If widely used, these programs will also assist the federal government in properly targeting inspection resources to those products of greatest risk. For this reason, we propose incentives to motivate voluntary participation. For example, products made by certified firms would generally receive expedited processing at U.S. ports-of-entry. Furthermore, the federal government will ensure that information about certified firms and importers of record is easily accessible to the public.

Manufacturers will demonstrate compliance with national standards when there is value in it for them, such as recognition at the border by customs, preference by distributors and retailers, and selection by consumers.

Stan Hazan, NSF International

Mandatory Certification

Mandatory certification may be necessary to ensure that imported products are safe in certain circumstances. This would involve safety considerations, including risks associated with the product itself or its place of origin. Generally, in such cases, the only other option available is to deny the entry of these products into the United States. In requiring that such products be certified, or produced by a certified firm in order to be imported, a mechanism would be provided that allows trade to continue flowing while also enhancing safety.

2.1 *Provide the FDA with the authority to require a certification or other assurance that a product under its jurisdiction complies with FDA requirements.*
Certification would be mandated based on risk and generally would apply to products coming from a particular country, region, or producer where safety cannot be adequately ensured for these products in the absence of such assurance. This would allow the FDA to redirect its resources to other products. Such import certification programs would be used for designated products imported from countries with which FDA has an agreement to establish a certification program that provides sufficient safety to meet HHS/FDA standards. FDA would accept certifications from either relevant government agencies or accredited third parties.
Lead: HHS/FDA
Time Frame: Short Term

Voluntary Certification

For foreign producers, the ability to participate in voluntary certification programs could allow products from firms that comply with U.S. safety and security standards to enter the United States more quickly. This would facilitate trade, while allowing federal departments and agencies to focus their resources on products from non-certified firms or for which information suggests there may be safety or security concerns. This would allow federal

departments and agencies to more effectively target their resources. It may not be necessary to establish certification programs for low-risk products.

2.2 *Develop voluntary certification programs based on risk for foreign producers of certain products who export to the United States.* The federal government will work with the importing community and other members of the public to develop voluntary certification programs, as appropriate, based on risk. As part of this effort, the federal government should take into consideration, incorporate or expand upon existing trusted trader partnership programs including CBP's Importer Self Assessment Program (ISA) and programs that relate to security.[7]
Leads: CPSC, HHS / FDA, DHS / CBP
Time Frame: Long Term

In September 2007, the U.S. Toy Industry of America (TIA) announced plans to implement new compliance systems to bolster the safety of toys sold in the United States. The initiative, created in consultation with the American National Standards Institute and the Consumer Product Safety Commission, includes the development of standardized testing procedures and laboratory certification criteria.

2.3 *Provide FDA with legislative authority to accredit independent third parties to evaluate compliance with FDA requirements.* To implement the previous action step (2.2), FDA will accredit third party organizations, or recognize an entity that accredits third parties. Third party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would use information from these accredited third party organizations in its admissibility decision-making.
Leads: HHS / FDA
Time Frame: Short Term

2.4 *Create incentives for foreign firms to participate in voluntary certification programs and for importers to purchase only from certified firms.* The federal government should establish these incentives, which could include expedited entry, expedited processing of samples for laboratory testing, and access to CBP's account manager program. Utilizing expedited entry, federal departments and agencies with jurisdiction typically would be much less likely to physically examine or otherwise delay products made by certified firms unless the product is examined for auditing purposes, there is information suggesting this product violated U.S. law, is considered high-risk for safety or security reasons, or the importer of record did not provide correct or complete information

The United States is unique to the world in many ways, including the fact that it relies heavily on the private sector for voluntary standards development, as well as product safety testing and certification services.

August W. Schaefer
Underwriters Laboratories Inc.

7 ISA is a voluntary program for importers who agree to monitor their own compliance in exchange for benefits from CBP. Its primary objective is to maintain a high level of compliance with United States entry requirements through a cooperative partnership and information exchange between the importing community and CBP.

required by U.S. law. Should samples be taken for testing from a product made by a certified firm, the agency with jurisdiction could expedite processing of those samples. Under CBP's account manager program, the importer of record is assigned a contact person who can answer questions and facilitate the resolution of problems should they arise. The federal government will also consider setting less stringent bonding requirements as an incentive to import products from certified firms.
Leads: DHS / CBP, HHS / FDA, CPSC
Time Frame: Long Term

There are many private sector and government organizations that presently certify products and producers as meeting established national or international standards or accredit certifying bodies. The presence of such certifying or accrediting organizations serves as a ready resource to implement new voluntary certification programs.

2.5 Develop a plan to ensure that information regarding certified firms and importers of record is easily accessible. This will help importers to more easily determine whether or not a foreign firm is certified, and help distributors and retailers to identify importers of record who only handle goods from certified firms. It will also help insurers use this information for determining risk when underwriting importers of record, and help consumers determine whether or not a foreign-made product sold under its own label comes from a certified firm.
Leads: DHS / CBP, HHS / FDA
Time Frame: Long Term

Good Importer Practices

Recommendation 3 – Promote Good Importer Practices.

Although some members of the importing community have established and met their own best practices, the importing community does not have available Good Importer Practices focused on ensuring product safety throughout the supply chain. Developing such practices can assist the entire importing community in taking appropriate steps to ensure the safety of the products they bring into the United States.

We owe it not only to our consumers, but, of course, our farmers, ranchers and producers as well. And we must work with our trading partners to share best practices and agree on common standards of science-based approaches for food safety.

Chuck Conner
Acting Secretary of Agriculture

To encourage the importing community to take appropriate steps to ensure the products they bring into this country meet U.S. standards, the federal government will work with the importing community to develop Good Importer Practices. These practices should be developed as guidelines, be risk-based and provide concrete guidance to the importing community for evaluating imported products. This evaluation would be based on due diligence and preventive controls principles. These practices will provide a set of factors that can be used by the importing community to evaluate foreign suppliers and products.

Based on this evaluation, the importing community will have greater confidence that the products they import will be in compliance with U.S. laws and regulations. For example, for products with known risks, a key precaution

the importing community could take to ensure safety consistent with Good Importer Practices is to purchase, distribute and sell products made by certified producers. As part of this collaboration, the federal government and the importing community should consider whether and how to foster the development of voluntary third-party programs to certify importers as meeting Good Importer Practices.

3.1 *Develop Good Importer Practices.* The federal government should work with the importing community and other members of the public to develop Good Importer Practices and issue guidance with respect to particular product categories. The focus of these practices will be to ensure that imported products meet U.S. safety standards, as well as to promote effective supply-chain management. Development of these practices would help the importing community take appropriate steps to ensure the safety of the products they bring into the United States.
Leads: USDA, CPSC, HHS / FDA, DHS / CBP, Department of Commerce (DOC)
Time Frame: Long Term

3.2 *Partner with the importing community to foster the creation of voluntary certification programs for importers.* These programs would be private-sector based and would serve to verify compliance with Good Importer Practices. The federal government would evaluate these programs to determine whether they should be accredited by the federal government and whether certification should be required for importing certain high-risk products.
Leads: CPSC, HHS / FDA, DHS / CBP, DOC
Time Frame: Long Term

Penalties

Recommendation 4 – Strengthen Penalties and Take Strong Enforcement Actions to Ensure Accountability.

To hold both foreign and domestic entities accountable and discourage them from producing, distributing, exporting, importing and selling unsafe products, the federal government will take steps to strengthen penalties against entities that violate U.S. laws. Effective penalties can serve as a deterrent against violating U.S. requirements and will improve compliance with U.S. safety standards and laws.

Rigorous enforcement of U.S. import-safety laws promotes deterrence. Assessing civil and criminal penalties against bad actors creates the proper incentives for all parties across the import life cycle to behave lawfully and responsibly and to build safety into their products to prevent harm to consumers. For enforcement to be an effective tool in the promotion of import safety, however, civil penalties must amount to more than a business expense

and, for the worst offenders, criminal penalties should apply. Where penalties are weak or lacking, enforcement measures must be strengthened to reflect a meaningful expectation of accountability.

Bonds serve as a guarantee of payment for specific types of penalties levied against the importer. Minimum bond amounts have not changed since 1991 and do not reflect the likelihood that a product may not meet U.S. importing or safety requirements. Compliance with U.S. safety requirements can be encouraged by raising the minimum bond amounts and increasing CBP's authority to consider the risk presented by a product in calculating bond amounts.

As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task ... by reducing the number of needles to find, and by reducing the size of the haystack in which to find them.

Scott Faber,
Grocery Manufacturers Association/
Food Products Association

4.1 *Amend the Federal Food, Drug, and Cosmetics Act (FDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA) and the Consumer Product Safety Act (CPSA) to include asset-forfeiture remedies for criminal offenses.* This proposal would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used by bad actors to aid in the importing, exporting, transporting, selling, receiving, acquiring or purchasing of products in violation of the FDCA, FMIA, PPIA, EPIA or CPSA, as well as the proceeds from the criminal offense. Such penalties would apply only to those actors who knowingly and willfully violate the act, and the court of record would make the ultimate determination of relief. This action would be wholly administered by the Department of Justice (DOJ) consistent with current practice under many statutes.[8]
Lead: DOJ
Time Frame: Short Term

4.2 *Raise the statutory civil penalty cap under the CPSA.* Currently, the penalty cap stands at $1.8 million for any related series of violations under the CPSA. Raising this amount to $10 million would serve as a deterrent to unlawful conduct and provide the CPSC with leverage to negotiate penalties against violators. In assessing penalties, the CPSC should consider whether a company is a repeat offender.
Lead: CPSC
Time Frame: Short Term

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8 For example, Congress limited all criminal forfeiture and the civil forfeiture of real property for drug offenses to felony violations of the Controlled Substances Act (see 21 U.S.C 853 (a) and 881 (a) (7)). So, too, could Congress limit forfeiture sanctions to the statutory provisions that require a knowing and willful violation.

4.3 *Strengthen CBP's mitigation guidelines and increase the maximum penalties against importers who repeatedly import products that violate U.S. law.* CBP needs to impose maximum penalties against such parties to provide effective deterrence.
Lead: DHS / CBP
Time Frame: Short Term

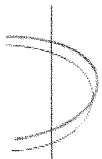
4.4 *Increase the dollar amount of bonds that importers of record must provide to reflect inflationary increases and risk.* Without an adequate bond, CBP is unable to issue and collect penalties for bad actors in the amount allowable by law.
Lead: DHS / CBP
Time Frame: Short Term

4.5 *Authorize FDA to refuse admission of imported products if access--including access to all applicable records, equipment, finished and unfinished materials, containers and labeling--to any factory, warehouse or establishment in which a product for export to the United States is manufactured, processed, packed or held is unduly delayed, limited or denied.* An important tool for the federal government to verify whether a firm complies with U.S. safety standards is to conduct a routine inspection and to review relevant production and distribution records. Domestic firms have an incentive to work with federal departments and agencies with such inspection authority because efforts to delay, limit or deny such an inspection may lead to an enforcement action. However, foreign firms can often deny U.S. officials access to their facilities without any adverse consequence. Having the authority to prevent entry of products from firms that fail to provide FDA access will enable FDA to protect consumers by keeping potentially unsafe products from entering U.S. markets. This authority also will provide a strong incentive for foreign firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms.
Lead: HHS / FDA
Time Frame: Short Term

Enforcement plays an important role, not just in remedying past harms, but by providing proper incentives and deterrents, which, in turn, help to prevent harm to consumers in the first place.

John O'Quinn, Deputy Associate Attorney General, Department of Justice

4.6 *Provide authority for the destruction of medical products refused admission into the United States.* The federal government has had limited success in stopping unsafe medical products for personal use from entering the United States because of the statutory requirements that must be met before those products are destroyed. Expedited destruction of these products would address this limitation but would only apply to refused shipments that are valued below a certain threshold or which pose a certain level of risk to humans or animals. This is intended to address problems, such as personal shipments of drugs being re-imported after they have been denied entry.
Lead: HHS / FDA
Time Frame: Short Term



4.7 *Remove the notice requirement for violations of the CPSA.* Under its enabling statute, the CPSC must first provide the offending party with notice of its violation prior to prosecution by the DOJ. Although the notice requirement is designed to ensure that a violating firm was aware of its offense prior to prosecution, the standards for prosecution are such that the DOJ must prove knowledge and intent on the part of the offender. Thus, the notice requirement in the CPSA is unnecessary.
Leads: DOJ, CPSC
Time Frame: Short Term

Foreign Collaboration and Capacity Building

Recommendation 5 – Make Product Safety An Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities.

In the global economy, import safety begins abroad. While many of our trade partners have active and effective programs, some lack an adequate regulatory regime or legal system, both of which are conducive to maintaining and enforcing adequate product safety standards. U.S. investment in capacity building can benefit developing nations by helping them strengthen their economies, enhance their legal systems and public health infrastructure and ultimately facilitate commerce.

While many federal departments and agencies offer capacity-building support to foreign countries, and many U.S. assistance programs provide training in the rule of law and government oversight of products standards and testing, the United States needs to reinforce the importance of product safety as a priority in our broader diplomatic relationships.

For example, in order to develop foreign regulatory capacity building and accountability, the United States needs to advance import safety when negotiating cooperative arrangements with other countries. Further, the United States needs to build effective coalitions with our trading partners and encourage them to become more involved in identifying solutions to product safety challenges.

In addition to building the regulatory capacity of foreign governments, it is vital that the United States share information with foreign counterparts who have active and effective regulatory programs. There is currently information in the hands of foreign governments — such as foreign inspection results, best practices, adverse event reports and data on recalls and outbreaks — that could be useful to U.S. regulatory agencies to better screen products arriving at the border. For example, FDA has begun an active information-sharing program with many of its foreign counterparts to obtain information about

product approval, inspection, testing and safety for FDA-regulated food, medical products and cosmetics.

5.1 *Direct the federal government to make product safety a guiding principle in negotiating future cooperative arrangements with foreign government entities.* To foster effective relationships with foreign government counterparts and demonstrate the importance of product safety in international trade, the United States should make product safety an important component of cooperative arrangements.
Lead: Executive Office of the President (EOP)
Time Frame: Short Term

5.2 *Expand and administratively streamline, as appropriate, government inspections in foreign countries and improve collaborative investigation and enforcement activities when negotiating cooperative arrangements with foreign governments.* Streamlining bureaucratic processes, such as the visa process for government inspectors, can result in more-timely and less-costly authorized foreign inspections. In addition, as appropriate, federal departments and agencies should provide foreign countries with training and technical assistance regarding U.S. standards and conformity assessment practices.
Lead: Department of State
Time Frame: Long Term

The more data that can be captured early in the supply chain process, the better. If U.S.-based importers, retailers and government agencies can identify product safety problems in the manufacturing or transportation stages before a product reaches the U.S. market, the public will be safer, and enforcement and recall costs will be significantly reduced.

Donald P. Bliss
National Infrastructure Institute

5.3 *Review existing overseas programs that target rule of law, regulatory capacity-building and trade capacity-building, to determine how to improve product safety standards and conduct.* This would encourage departments and agencies with relevant programs to include product safety standards and compliance, where appropriate, in their capacity-building efforts. Existing foreign assistance efforts related to strengthening the rule of law, regulatory capacity-building and trade capacity-building may currently seek to improve product safety standards and compliance. However, there has been no coordinated policy review of these efforts to help policy makers understand if the level of effort is appropriate and effective and to ensure consistency in U.S. policy.
Lead: Department of State
Time Frame: Long Term

Strengthen the Capacities of Our Trading Partners
One way to ensure compliance with United States safety standards, if warranted, is to increase the capacity of our trading partners to adopt strong safety standards and regulations and to develop a legal system that is capable of enforcing those standards.

5.4 *Improve U.S. liaison to foreign countries.* For example, establish FDA field presence at key foreign ports of embarkation and a CPSC liaison to certain countries.
Leads: HHS / FDA, CPSC
Time Frame: Long Term

5.5 *Develop strategic information-sharing arrangements with key foreign government counterparts.* Through greater information-sharing, such as data on recalls, the federal government can leverage the inspection and regulatory expertise and experience of foreign regulatory authorities to facilitate admissibility determinations, provide advance notice of problems, and enhance enforcement capabilities.
Leads: HHS / FDA, USDA, CPSC, EPA
Time Frame: Long Term

We're working with foreign governments, informing them of our environmental requirements and helping them to strengthen their capacity to comply with U.S. standards.

Stephen L. Johnson
Administrator, Environmental Protection Agency

Intervention

The second organizing principle—Intervention—recognizes the need to intervene when risks to product safety are identified. These recommendations address the importance of focusing intervention activities throughout the life cycle of imported products, rather than just at the time the goods arrive at the U.S. border. To accomplish this, the federal government will need to put in place automated systems and foster a culture that optimizes both government and private-sector knowledge. The incompatible systems that comprise the current approach must be replaced with interoperable systems that provide all regulatory departments and agencies, as well as the importing community, with the most complete information possible while protecting confidential information. This will allow federal agencies, either prior to shipment, at the port-of-arrival, or at the port-of-entry, to effectively target shipments that may represent a risk if allowed entry into the United States. This would maximize the use of federal resources and facilitate legitimate trade, as well as assist the importing community in meeting its responsibility to ensure unsafe products do not enter the United States.

Common Mission

Recommendation 6 – Harmonize Federal Government Procedures and Requirements for Processing Import Shipments.

Border officials inspect and clear cargo before it enters the United States in accordance with relevant federal laws and regulations. New risk information can complicate efforts to conduct inspections of entering shipments consistent with the applicable admissibility requirements. Better coordination among federal regulatory departments and agencies; cross-training; commissioning of federal personnel in the application of import entry requirements; and the establishment of common inspection, testing and enforcement protocols are needed, in some cases, to ensure that only products that comply with relevant regulations and standards enter domestic commerce, and that federal efforts to achieve this goal are effective and efficient.

> **We're committed at the Food and Drug Administration to continuing to foster the collaboration among other federal agencies and with the states to fully implement the shift to a prevention, intervention and response strategy.**
>
> **Andrew C. von Eschenbach, M.D.**
> **Commissioner, Food and Drug Administration**

6.1 Develop uniform interdepartmental procedures, where appropriate, for clearing and controlling shipments at ports-of-entry. These procedures would be used by all federal departments and agencies, where appropriate, and would help streamline the entry process as well as facilitate the exchange of information and intelligence, processing of samples and interagency coordination so that federal resources are used more efficiently and effectively in assuring product safety. As part of this action, federal departments and agencies with border regulatory responsibilities

should develop and deliver cross-training, where necessary, to keep the agencies updated on current U.S. import requirements.
Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA
Time Frame: Short Term

6.2 *Develop a strategic plan for rapid response to import-safety incidents.* To implement an effective rapid response requires coordination among all the involved parties. This plan would identify the roles and responsibilities of the federal departments and agencies; include a communication plan with state and local governments, private industry, foreign governments, the media and others; and include a business resumption model, as applicable.
Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA
Time Frame: Short Term

6.3 *Co-locate border officials from multiple agencies, when feasible, to enhance targeting and risk-management decisions on import safety.* Border officials can work together more effectively when stationed at the same location. The federal government has co-located border officials in limited locations in the past, including CBP's National Targeting Center (NTC),[9] resulting in improved coordination and more effective operations.
Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC
Time Frame: Long Term

6.4 *Exercise commissioning and cross-designation authority to leverage federal resources to prevent unsafe products from reaching consumers in the United States.* Under this model, participating agencies would agree that one agency would act under the authority of the other to carry out select activities, such as audits and lab processing, dependent on capacity constraints. Commissioning is particularly helpful when one agency has staff at a location where the other does not.
Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC
Time Frame: Long Term

Interoperability

Recommendation 7 – Complete a Single-Window Interface for the Intra-agency, Interagency and Private Sector Exchange of Import Data.

In Fiscal Year 2006, 31.3 million entries were filed with CBP for import shipments. Today, interactions between the government and importing community frequently involve time-consuming, resource-intensive paper reporting. The Automated Commercial Environment (ACE), which is currently

9 The NTC is a CBP facility where federal officials are co-located to enable better risk-assessment and targeting of imported cargo.

being developed, will provide an automated "single-window" system for processing the entry of import shipments.[10] Information about imported commodities will be collected for all federal departments and agencies involved in the importing of goods. Through ACE, the importing community, CBP and other federal departments and agencies will exchange real-time data about products, compliance and revenue for each import transaction. The federal government would therefore base a decision to clear or reject an import shipment for entry into the United States upon an immediate information exchange. This would facilitate cargo movements as well as more effective risk determinations and enforcement actions.

The Safety and Accountability for Every (SAFE) Port Act of 2006 makes implementation of the single-window concept a mandatory requirement for federal departments and agencies with import and export responsibilities.[11] Agencies that license, permit, or certify the importation of products into the United States must establish an electronic interface with CBP's ACE system as part of the International Trade Data System (ITDS) initiative. ITDS is developing a Standard Data Set (SDS) of data elements to be used in reporting international trade transactions, which will facilitate exchanging data among all parties involved with an import transaction including regulatory and enforcement agencies.

The success of the Food Safety and Inspection Service and other agencies has been the result of the extensive import information that's available electronically in both ITDS and ACE on imports and importers ... It is a tremendously powerful tool to give you the information you need in order to be able to assess the risk.

Samuel Banks,
Sandler & Travis Trade Advisory Services

7.1 *Require federal departments and agencies by the end of 2009 to have the capability to exchange commercial data and, to the extent allowable by law, communicate electronically with the importing community and other departments and agencies through ACE / ITDS.* ACE / ITDS will permit integration of import data collected by federal departments and agencies to facilitate decision-making on the safety of imports. As part of this action step, departments and agencies, in partnership with the importing community, should develop a coding system for imported products and participants in the import life cycle, as well as draft any regulations necessary for implementation. The coding system will provide greater specificity than currently provided under the Harmonized Tariff Schedule (HTS) and will, thus, help identify products more quickly and accurately. The necessary regulations will be issued by the participating departments and agencies with jurisdiction.
Lead: DHS / CBP and Treasury as executive agents
Time Frame: Long Term

ACE / ITDS Data
In 2006, FSIS gained access to data from CBP's ACE. Since then, detection of illegally-entered meat and poultry products has increased 60-fold. These products have either been destroyed or returned to FSIS for import re-inspection. In all, FSIS has prevented over 3.5 million pounds of illegal meat and poultry products from entering United States commerce.

10 The Immediate Actions Memorandum (September 10, 2007) required that the implementation of ITDS be accelerated. (See Appendix B)
11 The Act permits the Office of Management and Budget (OMB) to exempt certain agencies.

7.2 *Develop, as appropriate, within the Automated Targeting System (ATS), risk-based screening technologies to target high-risk products in a more effective way and facilitate the entry of low-risk products.* Such technologies would use information available through ATS to facilitate risk determinations by federal department and agency officials, thereby expediting the entry of safe and secure products and allowing departments and agencies to better target their resources on high-risk products.
Lead: DHS / CBP
Time Frame: Long Term

We are finding that the ACE system data are allowing us more efficient collection and analysis of records of incoming consumer products and helping us identify likely shipments of violative products before they can be introduced into the stream of commerce.

Nancy A. Nord
Acting Chairman, U.S. Consumer Product Safety Commission

7.3 *Develop an implementation plan for the integration of the Standard Establishment Data Service (SEDS) module into ACE/ ITDS.* SEDS would create a centralized service to provide accurate information on the import supply chain. It would provide unique standard identifiers for establishments (to facilitate verification of involvement) and capture a minimal set of establishment violation data from import transactions at the central source.
Leads: DHS / CBP, USDA, HHS / FDA, EPA, Commerce
Time Frame: Long Term

Information Gathering

Recommendation 8 – Create an Interactive Import-Safety Information Network.

Receipt of advance safety and security data regarding the product, the country of export, the manufacturer, the carrier and the importer prior to export of merchandise allows for a preliminary analysis of import-safety. Analysis of the data is critical to making risk-based determinations on actions to be taken by border officials prior to loading shipments in the exporting country and while they are in transit to the United States. In many cases, making these decisions for further review and examination prior to arrival of the shipment can facilitate the clearance of legitimate trade at the time of arrival in the United States.

For example, the Trade Act of 2002 requires carriers to provide limited data elements prior to loading shipments for export to the United States. The Trade Act provisions apply to all modes of transportation. The 2006 SAFE Port Act allows CBP to collect additional information that is reasonable for security purposes prior to the loading of maritime cargo destined for export to the United States.

8.1 *Expand upon existing public-private relationships to seek and share the importing community's recommendations and best practices with other federal departments and agencies for import safety and security purposes, and provide training in accessing this information.* The importing community has a great deal of information about the product life-cycle that would assist the

federal government in its enforcement and compliance actions. Use of this data could allow federal departments and agencies to make early determinations of import risk based on data already being collected.
Lead: DHS / CBP
Time Frame: Short Term

8.2 *Identify whether additional information is necessary to enhance import safety as allowed for under the SAFE Port Act.* After gaining experience with information gathered under the SAFE Port Act, the federal government, working with the importing community, may conclude that access to additional security information is necessary to make admissibility determinations based on risk.
Lead: DHS / CBP
Time Frame: Long Term

8.3 *Seek legislation that would provide CBP authority to extend reporting requirements for maritime shipments under the SAFE Port Act to all modes of transportation.* This would allow CBP to require both importers and carriers to submit additional information pertaining to cargo before the cargo is brought into the United States. The information would improve the ability of CBP to identify and target high-risk shipments in order to prevent smuggling and ensure cargo safety and security. CBP would exercise this authority through notice and comment rulemaking.
Lead: DHS / CBP
Time Frame: Short Term

8.4 *Develop a private-sector import-safety interactive information exchange process.* The Department of Homeland Security (DHS) would work with the importing community to address a means for the private sector to report critical import-safety information in a timely manner at one virtual location through existing information-sharing systems. DHS would also use this means to share information with the private sector.
Lead: DHS
Time Frame: Short Term

New Science

Recommendation 9 – Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards.

Advancement in the discovery, development and application of science and technology to detect problems in imported products more rapidly is essential for effective intervention strategies. Through research to develop more and better detection tools and to improve the reliability of existing tools, the federal government and the private sector can detect contaminants and defects more quickly and accurately. These tools could include real-time diagnostic instruments and methodologies that allow for rapid, on-site analysis of a

particular product, especially those that are high-risk. For example, technology that would allow rapid detection of a contaminant could be expanded to cover food types such as produce and dairy products, reducing analysis time from days to minutes and improving the accuracy of test results. New tools would also be developed to identify additional pathogens. Increasing the speed at which federal departments and agencies can detect problems will allow those departments and agencies to take more rapid action, including expediting import entry review decisions and providing critical health information to the public when a problem is identified with a product in commerce.

Laboratory capacity is critical to rapid response to product emergencies. For example, the Food Emergency Response Network (FERN) is a nationwide network made up of more than 130 federal, state and local public health laboratories that support emergency-response activities related to food defense and food safety. FERN also provides training to member laboratories to use new testing methods and provides funding of selected state laboratories through cooperative agreements.

Support from the Scientific Community
During the recent event involving melamine contamination of imported gluten-vegetable protein, the National Center for Food Protection and Defense (NCFPD) provided subject matter expertise and real-time data analysis to assist federal agencies in responding. NCFPD also developed a case study including lessons learned and key unknowns, conducted a rapid assessment of imported food risks, and initiated a joint research project on imported food vulnerabilities and solutions with FDA and FSIS.

Another example is the Electronic Laboratory Exchange Network (eLEXNET). eLEXNET is a seamless, integrated, secure network that allows multiple federal, state and local government agencies engaged in food safety activities to compare, communicate and coordinate findings in laboratory analyses by using information technology tools. The system enables U.S. health officials to assess risks, analyze trends and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enhances the effectiveness of federal-state collaboration.

Ongoing efforts to enhance import safety will benefit from current and future contributions from the academic community. In addition to the obvious role of educating and training the next generation of professionals and experts, academia is an important resource for innovating new solutions for import safety. For example, subject matter experts from the academic community provided advice, incident monitoring, event assessment and the capturing of lessons learned during several recent food and agriculture sector incidents, such as the contamination of pet food with melamine and the recent foot-and-mouth disease outbreak in the United Kingdom.

Because freedom from risk cannot be ensured nor can safety be inspected into products, we agree that the private sector has a leading role in strengthening the safety of imports by building safety into food products.

John D. Floros, Ph.D.
Institute of Food Technologists

Basic research in new technologies, strategies and tools is a natural contribution to import safety from the academic community. Several academic centers are assisting in developing food and agriculture disease and product contamination monitoring tools as well as training tools and programs. The efforts of the academic community in developing new approaches for risk communication and supply chain resiliency can be most effectively tested and further refined via engagement with government. Multiple federal and state agencies, as well as the private sector, already partner with and support research in the academic community.

9.1 *Enhance field laboratory capacity for testing and work collaboratively with the public and private sectors to develop analytical tools for enhanced rapid screening of larger volumes of import samples.* This will allow the federal government to detect risks and take actions to remove problem products from commerce more quickly and effectively.
Leads: DHS / CBP, USDA / FSIS, HHS / FDA, CPSC
Time Frame: Long Term

9.2 *Increase the capacity and capability of FERN laboratories by developing and validating methods to increase the number of chemical, radiological and microbial threat agents that can be rapidly detected in food as well as broadening the reach of the methods to allow foreign laboratories to provide information.* Ensuring adequate capacity and capability of FERN provides a strong surge capacity that is independent of FDA, USDA and EPA laboratory operations.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term

9.3 *Develop rapid test methods for pathogens and other contaminants to ensure that test results are quickly available at ports-of-entry for determining whether or not a product should be admitted into the United States.*
Leads: HHS / FDA, USDA
Time Frame: Long Term

9.4 *Increase the quantity and quality of data submitted by participating laboratories to eLEXNET.* FDA would create an automatic data exchange, which would increase the quantity of samples and/or analytes (the components of laboratory tests) a laboratory is able to submit, increase the frequency and timeliness of data submission and ensure a better degree of data integrity as compared to manual data entry. This action would enhance the effectiveness of federal and state laboratory-testing capabilities to protect American consumers.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term

Intellectual Property Protection

Recommendation 10 – Strengthen Protection of Intellectual Property Rights (IPR) to Enhance Consumer Safety.

Strong IPR enforcement is essential to the protection of public health and safety. Counterfeit trademarked goods purporting to be made and marketed by someone other than the owner of the mark not only pose a threat to public safety, but undermine confidence in the quality of brand name products. These illegal activities also result in billions of dollars of lost revenue, investment, future sales and growth opportunities and harm legitimate businesses and workers who play pivotal roles in creating, manufacturing, distributing and selling genuine and safe products. The public and private sectors must work in concert to identify infringing and potentially unsafe goods and prevent them from entering the domestic marketplace.

If a container is packed with counterfeit goods, there is surely a higher likelihood than average that the goods in that container are dangerous in some way.

David Spooner
Assistant Secretary for Import Administration
Department of Commerce

Patents protect the design, formulae and content of a wide variety of manufactured products, consumer goods and pharmaceuticals. Trademarks protect the brand name of known and trusted companies so that consumers can be sure they are getting the same quality product that they expect to obtain under that mark. When patents are infringed, consumers suffer because infringers create disincentives to the invention of new products and processes. Patent infringement may be accompanied by counterfeiting and trademark infringement. When look-alike knock-off and counterfeit products violate trademarks, consumers cannot be certain of the quality or origin of the knock-off product. In addition, because infringing products are often substandard in quality, they can harm consumers in myriad ways and pose serious health and safety risks. For example, a counterfeit drug may have too little, too much or no active ingredient or contain a toxic contaminant, possibly putting consumers at risk for serious adverse events or worsened health from ineffective treatment of their underlying medical condition.

10.1 *Focus the work of the interagency Strategy Targeting Organized Piracy (STOP) and the United States government-private sector Coalition against Counterfeiting and Piracy Initiative on import-safety issues.* STOP focuses on empowering American innovators to protect better their rights at home and abroad, increasing efforts to seize counterfeit goods at U.S. borders, pursuing criminal enterprises involved in piracy and counterfeiting, working closely and creatively with U.S. industry and aggressively engaging trading partners to join U.S. efforts.

The Coalition Against Counterfeiting and Piracy encourages close cooperation between the public and private sectors to effectively secure supply chains and protect consumers and rights holders.
Lead: Department of Commerce
Time Frame: Short Term

10.2 *Expand information-sharing about counterfeit and other goods that infringe IPR among relevant U.S. departments and agencies to identify and target products, manufacturers and distributors with potential safety violations.* The International Intellectual Property Enforcement Coordinator, housed at the Department of Commerce, is responsible for disseminating information and coordinating actions on IPR among federal departments and agencies, primarily Commerce, DOJ, USTR, DHS and State. With a new emphasis on ensuring import safety, the Coordinator should extend its outreach and coordination activities to include agencies responsible for import-safety inspections, such as FDA, CPSC and USDA. In addition, with the anticipated increase in private entity certifiers for U.S. safety requirements, it is essential to enhance interagency IPR coordination to include these inspecting agencies.
Lead: Department of Commerce
Time Frame: Short Term

Safety and Intellectual Property
It is critical that the federal government continue to work with trading partners to improve the protection and enforcement of intellectual property rights because counterfeit products can pose significant safety risks.

10.3 *Encourage companies that have registered trademarks with the U.S. Patent and Trademark Office (USPTO) to record their registrations with CBP.* Industries must record their trademarks with CBP to enable CBP to identify, seize and destroy infringing and potentially unsafe goods.
Lead: Department of Commerce
Time Frame: Short Term

The end goal must be to create the necessary mechanisms that will allow risk assessment and risk management professionals to actively engage with manufacturers and importers in assessing and reducing risks along their supply chains.

SuiMing (Tomi) Hong
AmeriSci Group

Response

In the event that an unsafe import does make its way into the domestic stream of commerce and may or does injure consumers or animals, swift actions must be taken to limit potential exposure and harm.

Recall

Recommendation 11 – Maximize the Effectiveness of Product Recalls.

The recall process is the principal tool in the arsenal of response mechanisms to protect consumers from exposure to hazardous products whether the products are domestic or imported. Generally, the manufacturer, distributor, importer or retailer initiates a product recall with the cooperation of the appropriate government agency (e.g., FDA for most foods and CPSC for consumer goods).

11.1 *Amend the CPSA to make it unlawful for any manufacturer, distributor or retailer to sell a recalled product knowingly and willfully after the date of public announcement of the recall.* Under the CPSA, it is currently legal for such entities to sell a recalled product (other than a product that fails to comply with a mandatory standard or ban) even after the public announcement of the recall. Amending the CPSA will create proper incentives for retailers and distributors to halt sales of recalled products as quickly as possible.
Lead: CPSC
Time Frame: Short Term

11.2 *Authorize follow-up recall authority for CPSC.* If, after public notice of a voluntary recall, it later comes to the attention of the Commission that products subject to the voluntary recall remain widely available on the market, this provision would allow the agency to act quickly to issue an identical follow-up recall notice without having to consult again with the subject firm. This authority would be particularly helpful in instances of high-volume recalls in which one announcement may prove inadequate to inform the public.
Lead: CPSC
Time Frame: Short Term

11.3 *Authorize CPSC to require all recalling firms to provide the name and address of companies that supplied or received the recalled product.* Although maintaining thorough and accurate information about product suppliers, manufacturers and distributors is widely viewed as an industry best practice, not all firms maintain such information. Others do not disclose it to the Commission in the event of a recall. With proper authority, the CPSC could require every recalling entity to provide the agency with detailed contact information for all relevant parties across the life cycle

of the recalled product. Granting the CPSC authority to compel such information in times of recall creates an incentive for firms to adopt strong record-keeping practices as a matter of standard business operations.
Lead: CPSC
Time Frame: Short Term

11.4 *Authorize FDA to issue a mandatory recall of food products when voluntary recalls are not effective.* Currently, FDA lacks the authority to require the recall of food, including food it reasonably believes is adulterated and presents a threat of serious adverse health consequences or death. Although market incentives have made the voluntary recall system generally effective, providing mandatory recall authority to FDA when the voluntary system is not successful would ensure that the agency has the ability to compel action in those instances when firms have refused or unduly delayed a voluntary recall of food. The authority would provide for appropriate due process rights for any firm subject to a recall order.
Lead: HHS / FDA
Time Frame: Short term

Federal-State Rapid Response

Recommendation 12 – Maximize Federal-State Collaboration.

The roles of and the resources used by the federal government and the states in import safety are complementary. States possess legislative authority and resources to respond to unsafe imported products within their jurisdiction. The federal government can take steps to interdict unsafe imported goods at ports-of-entry. Should an unsafe product enter domestic commerce, federal departments and agencies often work with state authorities to track it down, seize it, notify the public if it has already been purchased by consumers and impose appropriate penalties on domestic entities who violate U.S. law. Also, both the federal government and states may have access to information relevant to protecting consumers that the other does not possess. For example, federal departments and agencies may have relevant information about the foreign source of the imported product and about the importer. This information can help state officials track down an unsafe imported product within their jurisdiction. On the other hand, state officials may identify an unsafe imported product during transport or at the point-of-sale, if the product does get into the country, and can tip off federal officials to prevent future shipments from entering domestic commerce.

To achieve comprehensive coordination, state and local governments also have a vital role and must be fully integrated into overall national efforts.

Hallock Northcott, American Association of Exporters and Importers

Several federal departments and agencies already collaborate closely with state authorities to protect consumers. For example, FDA has contracts and cooperative agreements with state governments to share information, conduct joint inspections and collaborate on laboratory analyses. Greater mutual leveraging of state and federal resources can further enhance consumer protection.

12.1 *Consider cooperative agreements between the federal inspection agencies and their state counterparts for greater information-sharing.* Such cooperative agreements would not infringe on the statutory authorities of federal or state regulators and would encourage a coordinated effort that would result in a more rapid and effective response. Establishing clear procedures and points-of-contact for information sharing and joint enforcement efforts can further enhance the effectiveness of federal-state actions to limit exposure and potential harm to consumers if an unsafe imported product makes it into domestic commerce.
Leads: HHS / FDA, USDA, CPSC, EPA
Time Frame: Long Term

12.2 *Review admissibility policies to improve the use of evidence and laboratory results from state investigations of imported products.* Currently, there are limitations on the use of state-developed evidence in federal court cases due to the gathering, analysis and retention of such evidence by non-federal government entities. Being able to use this evidence would make it easier for federal departments and agencies to take enforcement actions against bad actors.
Leads: DOJ, HHS / FDA, USDA, CPSC
Time Frame: Short Term

Technology

Technological advancements can help industry, as well as federal and state governments, more effectively respond to safety incidents involving imports.

Recommendation 13 – Expedite Consumer Notification of Product Recalls.

After a manufacturer has recalled an imported product because of safety concerns, it is essential for consumers to receive notification of the recall as quickly as possible. While government and industry work largely in cooperation to enact product recalls, the emergence of new technologies may permit an even more rapid and efficient response.

13.1 *Develop best practices for the use of technologies to expedite consumer notification of recalls.* With advances in product-tracking technologies, such as integrated circuit cards (Smart Cards) and Radio Frequency Identification (RFID), retailers are increasingly capable of learning and anticipating their customers' preferences, both as individuals and

cohorts. Information collected at the point-of-sale, provided voluntarily by consumers in exchange for product discounts and other benefits, has significant potential in the realm of product safety. For example, consumers who voluntarily share their personal contact information with a retailer (email address, telephone number, etc.) also can agree to receive instant recall notification from the seller regarding any of the products they recently purchased at that store. To the extent that the private sector can leverage the use of Smart Cards, RFID and other technologies to expedite consumer notification of emerging or existing product hazards while adequately protecting consumer privacy, the government should support such efforts.
Leads: USDA, HHS / FDA, CPSC
Time Frame: Long Term

Track-and-Trace

Recommendation 14 – Expand the Use of Electronic Track-and-Trace Technologies.

To be effective, tracking requirements must apply at all points along the production continuum, from point of origin to retail sale, and consumers should be given clear information to use to identify recalled products in their home.

Caroline Smith DeWaal, Center for Science in the Public Interest

Traceability is the capacity to identify and track a product or group of products along the import life cycle, including at all points throughout the sourcing, manufacturing and distribution chain. The ability to identify the product source and points of distribution across the import life cycle is of prime importance for the protection of consumers, particularly in the event of a product recall. If unsafe imports are discovered, effective traceability mechanisms can facilitate timely product recovery and reduce the opportunity for harm to occur. Additionally, the capacity to connect the dots and link import life cycle information back to the point of origin enables both government and private-sector actors to provide consumers with targeted and accurate information concerning implicated products. Traceability is also an effective preventive tool in that post-recall information and feedback can be processed to identify and address weaknesses across the import life cycle.

14.1 Work with foreign and domestic industry to encourage the development of best practices for the use of electronic track-and-trace technologies.
Leads: USDA, HHS / FDA, CPSC, DOT
Time Frame: Long Term

Conclusion

This Action Plan creates a roadmap for short-term and long-term improvements in the safety of imported products. The Working Group sets forth 14 recommendations and 50 action steps that are based on the organizing principles and building blocks identified in the Strategic Framework released on September 10, 2007. In addition, at the same time as the release of the Strategic Framework, the Working Group outlined Immediate Actions to be taken by federal departments and agencies to effect meaningful change. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Key action steps, which provide the pathway for implementing these recommendations, have each been assigned to lead entities that will be responsible for implementing this Action Plan.

Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities. Additionally, it will require expanded authorities, greater coordination among federal departments and agencies, improved accountability for industry, increased foreign capacity building, greater information-sharing, partnerships with the private sector and the application of new science, to name just some of the activities the federal government must place priority on in coming years. Implementation will also require a collaborative approach by all participants in the import safety life cycle. By doing so, American consumers will be able to continue to enjoy the benefits of the global economy with confidence.

The recommendations in this Action Plan create a path for the United States to complete the shift from an intervention approach to a prevention with verification, risk-based approach that builds safety into the products that reach U.S. consumers. This shift in emphasis can occur by following these recommendations:

1. **Safety Standards:** Create new and strengthen existing safety standards.
2. **Certification:** Verify compliance of foreign producers with U.S. safety and security standards through certification.
3. **Good Importer Practices:** Promote Good Importer Practices.
4. **Penalties:** Strengthen penalties and take strong enforcement actions to ensure accountability.
5. **Foreign Collaboration and Capacity Building:** Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities.
6. **Common Mission:** Harmonize federal government procedures and requirements for processing import shipments.
7. **Interoperability:** Complete a single-window interface for the intra-agency, interagency and private-sector exchange of import data.
8. **Information Gathering:** Create an interactive import-safety information network.
9. **New Science:** Expand laboratory capacity and develop rapid test methods for swift identification of hazards.
10. **Intellectual Property Protection:** Strengthen protection of intellectual property rights (IPR) to enhance consumer safety.
11. **Recall:** Maximize the effectiveness of product recalls.
12. **Federal-State Rapid Response:** Maximize federal-state collaboration.
13. **Technology:** Expedite consumer notification of product recalls.
14. **Track-and-Trace:** Expand the use of electronic track-and-trace technologies.

Appendix A: Executive Order

Executive Order: Establishing An Interagency Working Group on Import Safety

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to ensure that the executive branch takes all appropriate steps to promote the safety of imported products, it is hereby ordered as follows:

Section 1. Establishment of Interagency Working Group on Import Safety. The Secretary of Health and Human Services shall establish within the Department of Health and Human Services for administrative purposes only an Interagency Working Group on Import Safety (Working Group).

Sec. 2. Membership and Operation of Working Group.

(a) The Working Group shall consist exclusively of the following members, or their designees who shall be officers of the U.S. appointed by the President or members of the Senior Executive Service:

(i) the Secretary of Health and Human Services, who shall serve as Chair;
(ii) the Secretary of State;
(iii) the Secretary of the Treasury;
(iv) the Attorney General;
(v) the Secretary of Agriculture;
(vi) the Secretary of Commerce;
(vii) the Secretary of Transportation;
(viii) the Secretary of Homeland Security;
(ix) the Director of the Office of Management and Budget;
(x) the United States Trade Representative;
(xi) the Administrator of the Environmental Protection Agency;
(xii) the Chairman of the Consumer Product Safety Commission; and
(xiii) other officers or full-time or permanent part-time employees of the United States, as determined by the Chair, with the concurrence of the head of the department or agency concerned.

(b) The Chair shall convene and preside at meetings of the Working Group, determine its agenda, and direct its work. The Chair may establish and direct subgroups of the Working Group, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Working Group. The Chair shall designate an officer or employee of the Department of Health and Human Services to serve as the Executive Secretary of the Working Group. The Executive Secretary shall head any staff assigned to the Working Group and any subgroups thereof, and such staff shall consist exclusively of full-time or permanent part-time Federal employees.

Sec. 3. Mission of Working Group. The mission of the Working Group shall be to identify actions and appropriate steps that can be pursued, within

existing resources, to promote the safety of imported products, including the following:
(a) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including reviewing existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector regarding their inspection and certification of exported goods and factories producing exported goods and considering whether additional initiatives should be undertaken with respect to exporting countries or companies;

(b) identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products, including identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying origin of products, and safeguarding the supply chain; and

(c) surveying authorities and practices of Federal, State, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.

Sec. 4. Administration of Working Group. The Chair shall, to the extent permitted by law, provide administrative support and funding for the Working Group.

Sec. 5. Recommendations of Working Group. The Working Group shall provide recommendations to the President, through the Assistant to the President for Economic Policy, on the matters set forth in section 3 within 60 days of the date of this order, unless the Chair determines that an extension is necessary. The Working Group may take other actions it considers appropriate to promote the safety of imported products

Sec. 6. Termination of Working Group. Following consultation with the Assistant to the President for Economic Policy, the Chair shall terminate the Working Group upon the completion of its duties.

Sec. 7. General Provisions.
(a) Nothing in this order shall be construed to impair or otherwise affect (i) authority granted by law to a department, agency, or the head thereof, or (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.
(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(c) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH
THE WHITE HOUSE,
July 18, 2007.

Appendix B : Immediate Actions Memorandum
September 10, 2007

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 10, 2007

The President
The White House
Washington, D.C. 20500

Re: Interagency Working Group on Import Safety

Dear Mr. President:

On behalf of the Interagency Working Group on Import Safety and in accordance with Executive Order 13439, I am pleased to submit this report, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety.*

Accompanying this report is a listing of *Immediate Actions* that the Working Group recommends that the Federal government implement without delay to protect American consumers. These recommendations will be followed by an Action Plan in mid-November 2007, which will set out a roadmap with short- and long-term recommendations for improving import safety.

I want you to know of my appreciation for the assistance of all of your designees in this process. Their contributions have been exceptional.

As a Working Group, we provide the Strategic Framework and Immediate Actions with a belief that these changes will make the most effective use of our resources and provide the greatest protection to American consumers over the long term.

Thank you for the opportunity to serve.

Sincerely,

Michael O. Leavitt
Secretary, Department of Health and Human Services

Listing of Immediate Actions

1. **Improve collaboration and information sharing with the private sector to improve the safety of imports.**

   A wide range of products that could potentially threaten the health and safety of U.S. consumers are imported every day. Due to the vast volume of imported products, it is impossible to ensure safety simply by increasing government inspections. Rather, engagement with the importing community must be enhanced to gain insights from the owners and operators of the commercial import infrastructure through which all imported products reach American consumers, and to share best practices among this community.

   To conduct this outreach and improve collaboration with the importing community, the agencies should expand on existing public-private relationships, such as COAC (Commercial Operations Advisory Committee), TSN (Trade Support Network), F&ASCC (Food and Agriculture Sector Coordinating Council), ITACs and ATACs (Industrial Trade and Agricultural Trade Advisory Committees), and other groups, to seek and share the importing community's recommendations and best practices with the objective of enhancing import safety and promoting comprehensive supply chain verification.

   Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

2. **Interoperability Acceleration – Instruct Executive Agencies to Complete Their Identification of Technical, Business and Legal Requirements for Operating Within the Automated Commercial Environment/International Trade Data System.**

   The Security and Accountability for Every ("SAFE") Port Act of 2006 requires all Federal agencies that license, permit, or certify imported products to participate in the International Trade Data System (ITDS), a "single-window" system for reporting imports and exports electronically. ITDS will operate as a feature of U.S. Customs and Border Protection's (CBP) trade data processing system called the Automated Commercial Environment (ACE), which is currently under development. Functional capabilities within ACE are being implemented in stages, with full operability expected in 2009. Currently, 34 Federal agencies, referred to as Participating Government Agencies (PGAs), are at varying stages in integrating into ITDS.

   In order to accelerate implementation of ITDS, the Office of Management and Budget should issue a directive to PGAs requiring that within 60 days of the directive they establish or refine their Implementation Plan setting deadlines for developing, reviewing and finalizing conceptual operating plans (Concept of Operations),

memoranda of understanding for the ITDS interface, and a set of technical and business requirements for identifying any program and system modifications needed to support the interface. This would include considerations for the budget process. OMB should give special priority to import safety agencies for this task in the budget process

Further, in order to accelerate implementation of ITDS, the Office of Management and Budget should direct that CBP, within 60 days, establish or refine its Implementation Plan setting deadlines to:

- Include information currently reported by importers and carriers to CBP in the ACE Data Warehouse, where it can be accessed by other agencies.
- Advise other agencies with an import safety mission how they can take full advantage of current ITDS capabilities and deepen their engagement in ITDS development
- Implement World Customs Organization Data Model messages (new international international standard for customs reporting), which could provide a platform for electronic reporting of health and safety information in advance of the current ITDS production schedule.

In addition, all PGAs are instructed to:

- Within their fiscal year 2009 budget submissions, identify the budgetary resources needed to support the ACE/ITDS interface. Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

  Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

Participating Government Agencies (PGAs)

- AMS - Agricultural Marketing Service (Agriculture)*
- APHIS - Animal and Plant Health Inspection Service (Agriculture)*
- ATF - Bureau of Alcohol, Tobacco, Firearms and Explosives (Justice)*
- BIS – Bureau of Industry and Security (Commerce)
- BLS - Bureau of Labor Statistics (Labor)
- BTS - Bureau of Transportation Statistics (Transportation)
- CDC- Center for Disease Control (Health and Human Services)*
- Census – U.S. Census Bureau (Commerce)
- CPSC – Consumer Product Safety Commission*
- DEA – Drug Enforcement Administration (Justice)*
- EPA - Environmental Protection Agency*
- FAA - Federal Aviation Administration (Transportation)*
- FAS – Foreign Agricultural Services (Agriculture)
- FCC - Federal Communications Commission*
- FDA - Food and Drug Administration (Health and Human Services)*

- FMC - Federal Maritime Commission
- FMCSA - Federal Motor Carrier Safety Administration (Transportation)*
- FSIS - Food Safety and Inspection Service (Agriculture)*
- FTZB - Foreign Trade Zones Board (Commerce)
- FWS - Fish and Wildlife Service (Interior)*
- GIPSA – Grain Inspection, Packers and Stockyards Administration (Agriculture)
- IA - International Trade Administration–Import Administration
- (Commerce)
- IRS - Internal Revenue Service (Treasury)
- ITC – International Trade Commission
- MARAD - Maritime Administration (Transportation)
- NHTSA – National Highway Traffic Safety Administration (Transportation)*
- NMFS – National Oceanic Atmospheric Administration / National Marine Fisheries Service, Office for Law Enforcement (Commerce)*
- NRC - Nuclear Regulatory Commission*
- OFAC - Office of Foreign Assets Control (Treasury)
- OFE – Office of Fossil Energy (Energy)
- OFM - Office of Foreign Missions (State)
- State – Logistics Management (State)
- TTB - Alcohol and Tobacco Tax and Trade Bureau (Treasury)*
- USACE - Army Corps of Engineers (Defense)

*Agencies designated by the Board of ITDS as import safety agencies due to their roles in licensing, certifying, and permitting import shipments.

3. **Global Collaboration – Instruct agencies to develop and increase international cooperation and collaboration.**

The Department of State (State) has contacted host governments in 39 countries that are top exporters of food and consumer products to the United States to seek information on how various countries handle import safety issues. In the coming weeks, State, the Office of the United States Trade Representative (USTR), and other interested agencies will analyze the responses to these inquiries and meet to determine appropriate next steps.

As part of these next steps, State and USTR should coordinate with other Working Group members to determine whether appropriate international and regional organizations could be helpful in hosting international conferences or other actions to promote product safety, in order to generate high-level global attention to a worldwide problem. Such events could provide a forum to exchange information on effective product safety practices, identify opportunities for regulatory capacity building, and promote science-based regulation, consistent with U.S. law and our international obligations

Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

4. **Agreements with Foreign Governments – Instruct agencies to catalog on-going and planned import safety-related agreements (bilateral and multilateral) with foreign governments. In addition, require agencies to meet within 45 days and then on a regular basis to discuss negotiations underway or that are anticipated and share lessons learned.**

Various U.S. government agencies work with foreign governments to conclude and implement bilateral and multilateral agreements to improve import safety. In many cases, the agency that has expertise in a particular facet of import safety takes the lead in the negotiations. The resulting agreements, however, may affect the jurisdiction, operations, and resources of other agencies. Therefore, coordination among all the relevant agencies is necessary to ensure that all such agreements are as effective as possible and can be fully implemented.

Currently, coordination procedures vary depending on the nature of the agreement. Despite the various existing means for coordination, interagency work on import safety negotiations with foreign governments can be improved. In particular, efforts should be made to increase interagency awareness of agencies' ongoing and planned discussions with foreign governments regarding import safety agreements. In addition, the current coordination processes should be modified to provide a forum for agencies to share successful strategies and approaches with other agencies that could benefit from their experiences. Earlier and improved coordination will help ensure that agreements fully benefit from relevant agencies' experiences, avoid duplicative or counterproductive efforts, and generally improve the negotiating position of the U.S. government.

To this end, as an immediate action, agencies should be required to catalog ongoing and planned discussions with foreign governments regarding import safety. Until the Action Plan is issued, the Department of Commerce should host regular advisory meetings for these agencies to share information about their efforts, experiences and concerns. This process is not a review and would in no way supplant or delay the TPSC and C-175 processes, or any other on-going relevant inter-agency process. International cooperation regarding law enforcement or other similar activities would not be subject to these meetings.

Appendix C: Recent Actions and Current Plans to Protect American Consumers

As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. They have met with foreign governments, foreign manufacturers and others in the exporting country's private sector, as well as with producers, importers, retailers, trade associations, consumer groups and others in the U.S. importing community.

Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. This appendix summarizes significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan.

The actions are structured according to the organizing principles from the Strategic Framework and the recommendations included in this Action Plan.

Prevention with Verification

Safety Standards

- **Food Protection Plan.** FDA has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **NOAA Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. There are a number of other plants in the queue to be inspected.

- **Improved Compliance with Toxic Substance Control Standards.** EPA's Office of Prevention, Pesticides and Toxic Substances has been developing a Toxic Substance Control Act (TSCA) "Section 13 Import Compliance Checklist" as a compliance assistance tool to help chemical importers and government inspectors better understand import certification requirements. When finalized, the Checklist will be posted on various Web sites and disseminated in other ways.

- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong and has plans to put inspectors in other countries that export large volumes of seafood to the United States.

- **New Zealand Meat Certification.** USDA's Food Safety and Inspection Service (FSIS) began reprogramming its import inspection data system to enable an electronic data transfer of certifications for meat export shipments from New Zealand. This will constitute verification that importers have presented New Zealand import shipments for FSIS inspection as required by law. Full electronic certificate exchange capability is expected to be operational by the end of 2007 and will be extended to include Australia and Canada during 2008.

- **Accreditation of Private Labs.** FDA will issue guidance by mid-2008 that would set standards for the sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved. Increased confidence in the sampling techniques and methodologies used by accredited laboratories and in the data they submit may allow FDA to base decisions on abbreviated laboratory packages from accredited laboratories, expedite review of the information in those packages and facilitate admissibility decisions.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks and Electrical Products.** Meetings held in September 2007 between CPSC and its counterpart, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of the People's Republic of China resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products—children's toys, fireworks, cigarette lighters and electrical products.

- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.

- **Motor Vehicle Safety Agreement with China.** On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor

vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.

- **Tire Safety Standards Talks with China.** From September 11 through September 18, NHTSA staff with expertise in NHTSA's tire standards and enforcement process attended the Chinese International Tire Exposition in Shanghai and met with China's technical experts on tire issues in Hangzhou. At both locations, NHTSA representatives made detailed presentations on the agency's standards and enforcement process. The presentations were well received by the many representatives of the Chinese tire industry who participated in these sessions. NHTSA's delegation also obtained information that will be useful in designing strategies to help deter and detect the shipment of noncompliant or defective tires from China to this country.

- **Seafood Inspection Agreement with China.** NOAA's National Marine Fisheries Service (NMFS) has begun discussions with China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on an MOU to improve information transfer and to increase the traceability of products. The MOU would establish a notification system whereby each party would alert the other in the event that a problem is detected with seafood being imported from China. Drafts have been exchanged and a final agreement is anticipated in early 2008.

- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, USDA and FDA conducted a seven-week training program for Chinese inspection officials. FSIS also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.

- **United States-Europe Consumer Protection Talks.** On October 14, 2007, the Trans-Atlantic Consumer Dialogue was held at the State Department. Topics included the review of the respective regulatory impact assessment guidelines on trade and investment and their application, reduction in barriers on trade in chemicals, controlling hazardous toy and consumer product imports, recognition of Supplier's Declaration of Conformity for electrical equipment and other topics of concern in the ongoing trans-Atlantic dialogue.

- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.

- **Product Safety in Standards Dialogues**. The Department of Commerce is engaging in standards dialogues with key trade partners like Brazil, the European Commission and India. Product safety issues were discussed with India on October 25 and with the European Union on October 29. These dialogues encourage information exchange on policies, procedures and processes to ensure the safety of imported products.

- **International Food Safety Standards Work in Codex Alimentarius.** The Department of Commerce, State, EPA, USDA, FDA and USTR are actively engaged in international food safety standards development work in Codex Alimentarius. Codex already has a significant inventory of standards and guidelines that address food hygiene, food labeling, food import and export certification and inspection systems, contaminants in food and other areas. The United States is considering what gaps exist in food safety standards that Codex might address through new work activities.

- **China Joint Commission on Commerce and Trade (JCCT) Pharmaceutical Task Force.** The JCCT provides ongoing workshops to the Chinese government on anti-counterfeiting and manufacturing best practices for pharmaceuticals. Accomplishments have included direct input into the China State Food and Drug Administration's update of its drug registration review process.

- **China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force.** The Department of Commerce and FDA provide ongoing training to the Chinese government on the use of quality systems to ensure the safety of manufactured products, including conducting product recalls for medical devices.

- **Pharmaceutical anti-counterfeiting activity under the United States-India High Technology Cooperation Group's Biotechnology & Life Sciences Working Group.** This group organizes activities to fight the counterfeiting of pharmaceuticals and addresses the regulation of active pharmaceutical ingredients

to prevent the production of counterfeit medicines. In August 2007, this group discussed with Indian government officials the need to cooperate with the international community in stopping the production and export of counterfeit pharmaceuticals and the need to regulate active pharmaceutical ingredients.

- **APEC Anti-Counterfeit and Regulatory Harmonization Seminars on Medical Devices.** DOC and FDA are organizing a series of capacity-building seminars for Asia and Latin America focused on stopping the spread of counterfeit health products and promoting regulatory harmonization for medical devices. The first anti-counterfeit seminar will take place in Singapore in January 2008; the first regulatory harmonization seminar will take place in Kuala Lumpur in March 2008. Subsequent seminars will take place throughout 2008 and early 2009 in Asia and Latin America. Participants will include pharmaceutical and medical device regulators, custom and law enforcement officials, health professionals and industry representatives.

- **Motor Vehicle Safety Seminars with Chinese Companies.** In late 2007 or early 2008, NHTSA plans to send senior officials to China to meet with the relevant government departments and agencies, trade associations and companies to discuss how NHTSA's standards and enforcement process apply to exports intended for sale in the United States. NHTSA intends to reach those companies already engaged in exporting motor vehicle equipment and those that have announced plans to export motor vehicles to the United States in the next two years. NHTSA will also look for opportunities to enter into more detailed agreements with the Chinese government on cooperative methods to help ensure that imports are compliant with NHTSA standards.

- **Cooperative Agreement with China on Environmental Requirements.** In April 2007, EPA met with China's AQSIQ and other groups and agreed to draft an EPA-AQSIQ MOU to exchange information on environmental requirements and cooperate to help ensure compliance.

- **Cooperation on Enforcement of Environmental Laws in North America.** An understanding was recently reached among EPA, Canadian and Mexican environmental law enforcement officials to share information about noncompliant imports entering the borders of any of the countries.

- **North American Development of Enforcement Training to Ensure Legal Imports.** In September 2007, representatives from environmental agencies of the United States, Canada and Mexico, reviewed an electronic training module on ozone-depleting substances. At the same time, the officials approved the creation of a similar module for hazardous waste.

- **Outreach on Import Safety through Diplomatic Channels.** The State Department's Bureaus of Economic, Energy and Business Affairs and International Information Programs developed an outreach plan to reach foreign audiences on import safety. To date, import safety articles have already been published in international newspapers; more are expected over the near term. In August 2007, the Department of State sent cables to all overseas posts to provide them with information about import safety and the role of the Interagency Working Group on Import Safety for discussion with governments and the private sector.

- **Negotiation and Capacity Building through Trade Channels.** An integral part of U.S. free trade agreements are commitments to address sanitary and phytosanitary (SPS) [12] issues. In the past year, USTR concluded free trade agreements with Peru, Colombia, Panama and Korea, each of which includes a specific SPS chapter that has as a principal objective the protection of human and animal health. In particular, the SPS chapters provide for the establishment of a standing committee of the parties to enhance cooperation and consultation on SPS matters and improve understanding of each other's SPS requirements. These agreements also provide for capacity building and technical assistance in SPS activities.

- **Anti-Counterfeiting Trade Agreement.** On October 23, 2007, USTR announced that the United States and some of its key trading partners will seek to negotiate an Anti-Counterfeiting Trade Agreement. Anti-counterfeiting efforts will help to improve the safety of imported products.

- **International Dialogues.** The Department of State, Department of Commerce, USDA, USTR, HHS and other federal departments and agencies are encouraging the inclusion of import safety in regional and international dialogues.

  - Import safety will be discussed at the United States-European Union High Level Regulatory Cooperation Forum in November and may also be taken up by the Transatlantic Economic Council, which is also meeting in November.

12 An SPS measure is generally any measure applied to protect human, animal or plang life ot health from risks arising from pests, diseases or adulterands or contaminants in food feed.

- At the Asia-Pacific Economic Cooperation (APEC) Summit in September, leaders agreed "to develop initiatives in the coming year that effectively address problems related to import safety in ways that do not hinder trade." There are a number of specific project proposals underway, including one by China to promote information sharing to improve "food safety systems" and another to address Hazard Analysis and Critical Control Points (HACCP).
- USDA has indicated it will fund food safety related workshops for APEC. The primary goal of these workshops would be to raise awareness of, engagement in and compliance with international food safety standards-setting bodies, such as Codex Alimentarius, World Organization for Animal Health (OIE) and the International Plant Protection Convention.
- The Association of Southeast Asian Nations (ASEAN) has endorsed creating a Coordinating Committee on Consumer Protection at its August meeting and is in communication with officials at the CPSC, USDA, FDA and the Federal Trade Commission.

Intervention

Common Mission

- **Enhanced Interagency Cooperation on Animal and Plant Inspections.** USDA's FSIS and USDA's Animal and Plant Health Inspection Service (APHIS) continued monthly conference calls to discuss key import and export issues of concern and to resolve technical problems between the agencies. Recently, participation was expanded to include representatives from the Food and Drug Administration and U.S. Customs and Border Protection.

- **Enhanced Cooperation on Egg Product Safety.** USDA agencies (FSIS, AMS and APHIS) coordinated potential product code systems in use by FDA and the Global Safety Initiative that might further identify USDA-regulated animal, egg and plant products in ITDS/ACE. The agencies currently responsible for regulating the import of eggs and egg products—FDA, APHIS, FSIS, CBP and AMS—are currently identifying product codes to provide clarity in classifying imported products under the Harmonized Tariff Codes.

- **Cooperation on Counterfeits.** DOC's International Trade Administration (ITA) Office of Intellectual Property Rights is

collaborating with CPSC to create a Counterfeit Alert System that would refer reports of counterfeits received by CPSC's hotline to DOC's Stop Fakes hotline.

Interoperability

- **Public Health Information System.** On September 27, the Food Safety and Inspection Service (FSIS) awarded a contract for development of a new corporate data warehouse called the Public Health Information System, which will support a user interface for imports and exports. FSIS will develop, test and launch the system. This includes establishing an electronic connection with CBP's ACE/ITDS system and importers for processing imported meat, poultry and egg product shipments.

- **USDA Harmonization with Trade Data System.** USDA's Agricultural Marketing Service (AMS) and APHIS made important progress in establishing an interface with ACE/ITDS. AMS completed import-related business processes, drafted a Concept of Operations and Memorandum of Understanding with CBP and engaged a contractor to identify areas where its connection with ACE/ITDS can be optimized. APHIS submitted its Concept of Operations and Memorandum of Understanding to CPB on October 10. USDA's Grain Inspection, Packers and Stockyards Administration began the ITDS process with CBP on October 30, 2007.

- **EPA Harmonization with Trade Data System.** Building on previous work with CBP and other relevant federal agencies on the development of the single window import-export data system, EPA has accelerated steps in order to become interoperable with ACE/ITDS. EPA is developing business processes and requirements to exchange data between six EPA programs and ACE/ITDS. EPA identified the Chief Information Officer as the executive level representative; assigned EPA's internal Exchange Network Subcommittee as the governance body; established a project management/implementation team structure; is preparing a project implementation plan for submission to OMB on November 12, 2007 and is revising a concept of operations document for submission to CBP in December 2007. EPA is leveraging the Central Data Exchange and Exchange Network technology which the Agency currently uses to exchange data with all 50 states and seven Indian Tribes.

Response

Vigorous Enforcement of Safety Statutes

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked "United States: Refused Entry." Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.

- **Criminal Prosecution of Counterfeit Drug and Illegal Substance Offenders.** FDA, CBP and DOJ are continuing vigorous enforcement of statutes banning trade in counterfeit and illegal products. For example, DOJ recently prosecuted an Ohio man charged in online pharmacy conspiracy for selling counterfeit drugs (Viagra, Cyalis, Levitra) shipped from such countries as Pakistan, India and Great Britain. The agencies also collaborated in an international law enforcement operation targeting the underground manufacture of anabolic steroids. The operations have led to 124 arrests nationwide to date and the dismantling of approximately 100 illegal sites that aided in the manufacture and distribution of anabolic steroids, prescription medicines, counterfeit drugs and chemical precursors originating from approximately 30 rogue laboratories in China.

Appendix D: List of Acronyms and Abbreviations

Acronyms

ACE	Automated Commercial Environment
AMS	Agricultural Marketing Service
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ASEAN	Association of Southeast Asian Nations
ASISA	Aviation Safety Information Sharing and Analysis
ATS	Automated Targeting System
COAC	Commercial Operations Advisory Committee
CBP	Customs and Border Protection
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
C-TPAT	Customs Trade Partnership Against Terrorism
DHS	Department of Homeland Security
DOC	Department of Commerce
DOJ	Department of Justice
DOT	Department of Transportation
eLEXNET	Electronic Laboratory Exchange Network
EOP	Executive Office of the President
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug and Cosmetics Act
FERN	Food Emergency Response Network
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
GIDEP	Government Industry Data Exchange Program
GSI	Global Safety Initiative
HACCP	Hazard Analysis and Critical Control Points
HHS	Department of Health and Human Services
HTS	Harmonized Tariff Schedule
ICAO	International Civil Aviation Organization
IIP	International Information Programs
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
IPR	Intellectual Property Rights
ITA	International Trade Administration
ITDS	International Trade Data System
MOU	Memorandum of Understanding
NHTSA	National Highway Traffic Safety Administration
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NTC	National Targeting Center

OASIS	Operational and Administrative System for Import Support
OMB	Office of Management and Budget
PHMSA	Pipeline and Hazardous Materials Safety Administration
PPIA	Poultry Products Inspection Act
RFID	Radio Frequency Identification
SAFE Port	Safety and Accountability for Every Port Act
SCC	Food and Agriculture Sector Coordinating Council
SDS	Standard Data Set
SEDS	Standard Establishment Data Service
SFDA	China State Food and Drug Administration
SIP	Seafood Inspection Program
SPP	Security and Prosperity Partnership
State	Department of State
STOP	Strategy Targeting Organized Piracy
TACD	Trans-Atlantic Consumer Dialogue
TIA	U.S. Toy Industry of America
Treasury	Department of Treasury
TSCA	Toxic Substance Control Act
USDA	Department of Agriculture
USPTO	U.S. Patent and Trademark Office
USTR	U.S. Trade Representative
Working Group	Interagency Working Group on Import Safety

Appendix E: Working Group Designees and Staff

Interagency Working Group on Import Safety Designees

Secretary Michael O. Leavitt, Department of Health and Human Services, Chair of the Interagency Working Group

Al Hubbard, Assistant to the President for Economic Policy and Director, National Economic Council

Dan Price, Deputy National Security Advisor for Economic Affairs

Andrew C. von Eschenbach, Commissioner, Food and Drug Administration, Department of Health and Human Services

Dan Sullivan, Assistant Secretary for Economic, Energy and Business Affairs, Department of State

Alan Holmer, Special Envoy for China and the Strategic Economic Dialogue, Department of Treasury

John O'Quinn, Deputy Associate Attorney General, Department of Justice

Richard Raymond, Under Secretary for Food Safety, Department of Agriculture

David Spooner, Assistant Secretary for Import Administration, Department of Commerce

Jeff Shane, Under Secretary for Policy, Department of Transportation

Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of Homeland Security

Robert Shea, Associate Director for Management, Office of Management and Budget

Warren Maruyama, General Counsel, U.S. Trade Representative

Jim Gulliford, Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency

Quin Dodd, Chief of Staff, Consumer Product Safety Commission

Interagency Working Group on Import Safety Staff

Jerry Regier, Executive Secretary for the Working Group, Department of Health and Human Services

Jeff Shuren, Food and Drug Administration

Cathy Sauceda, Department of Homeland Security

John Menard, Department of State

Bob Tuverson, Department of Agriculture

Karen Stuck, Department of Agriculture

Stephen Claeys, Department of Commerce

Bernard Carreau, Department of Commerce

Randy Pate, Department of Health and Human Services

Rob Raffety, Consumer Product Safety Commission

Celesia Gouhari, Department of Health and Human Services

Natalie Gochnour, Department of Health and Human Services

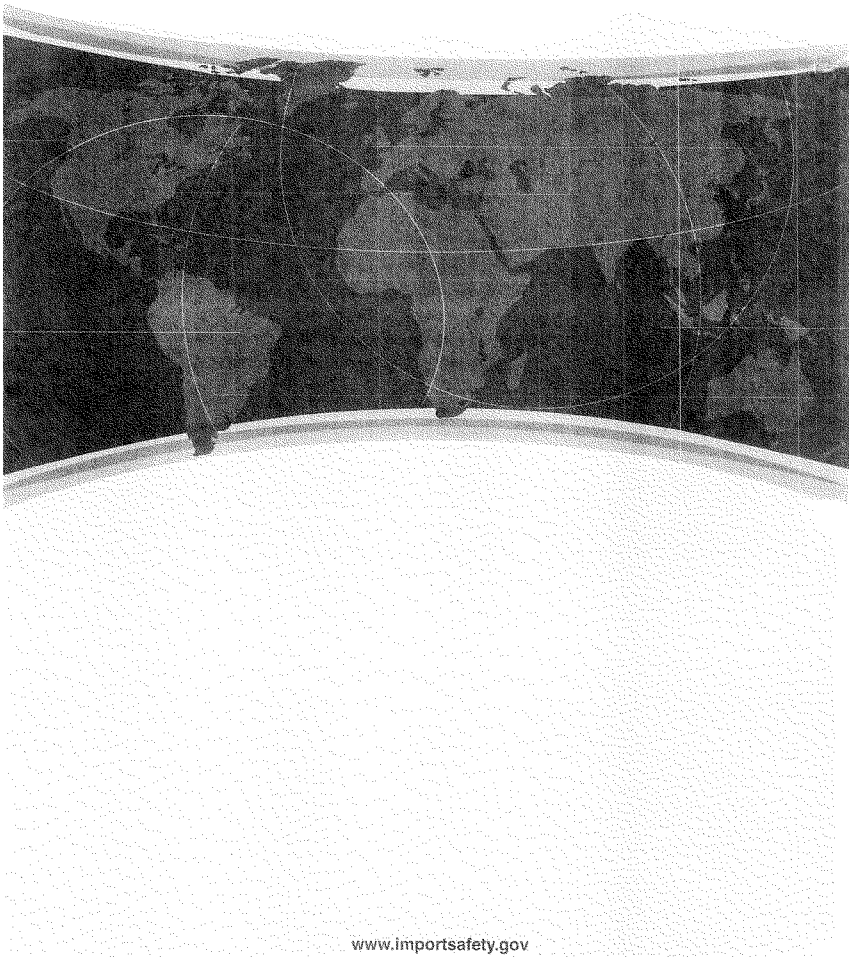
Erik Mettler, Food and Drug Administration

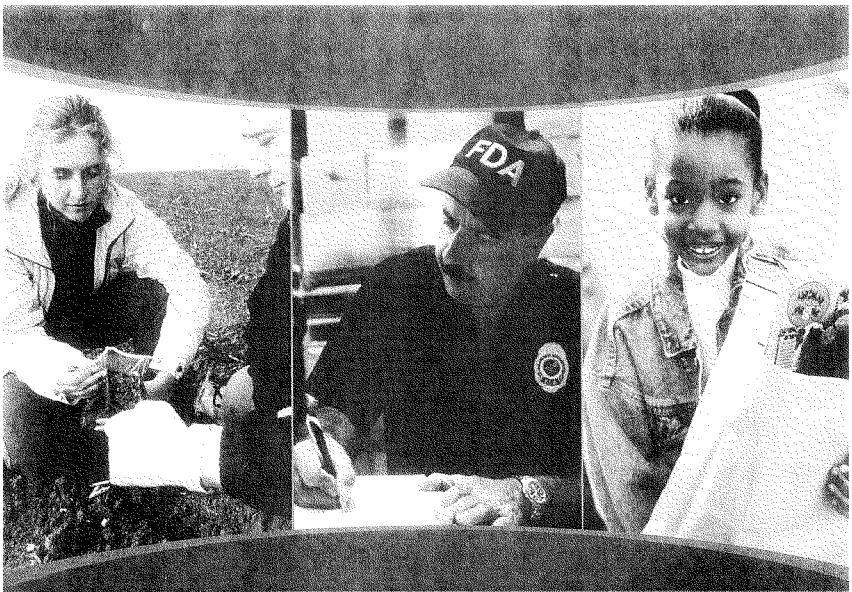
John Herrmann, Executive Office of the President

John Cobau, Executive Office of the President

No import-safety system can succeed without collaboration from everyone involved. We share a common interest in import safety and this Action Plan will guide our collective actions moving forward.

Secretary Michael O. Leavitt
Chair, Interagency Working Group on Import Safety


www.importsafety.gov



Department of Health and Human Services
U.S. Food and Drug Administration

Food Protection Plan

An integrated strategy for protecting the nation's food supply

NOVEMBER 2007

PREVENTION · INTERVENTION · RESPONSE

"Americans enjoy unprecedented choice and convenience in filling the cupboard today, but we also face new challenges to ensuring that our food is safe. This Food Protection Plan will implement a strategy of prevention, intervention and response to build safety into every step of the food supply chain."

Michael O. Leavitt

Secretary of Health and Human Services
U.S. Department of Health and Human Services

Cover Photos

An investigator from the FDA's San Francisco District (left) working with an investigator from the California Department of Health Services, collecting soil samples as part of an investigation into an *E. coli* outbreak in spinach.

Black Star/Steve Yeater for FDA

A senior import specialist in FDA's New York District, reconciling importers' invoices with shipping labels and collecting samples at a food warehouse.

Black Star/Michael Falco for FDA

Today's consumers have come to expect increased levels of convenience and choice, both of which contribute to the need for a global food supply.

Getty Images

A MESSAGE FROM THE COMMISSIONER

As a physician and the Commissioner of Food and Drugs, protecting America's food supply is extremely important to me.

American consumers have one of the safest food supplies in the world, but the world is changing and we know it can be safer. New food sources, advances in production and distribution methods, and the growing volume of imports due to consumer demand call for a new approach to protecting our food from unintentional or deliberate contamination. The U.S. Food and Drug Administration (FDA) must keep pace with these changes so that the safety of the nation's food supply remains second to none.

In the past few years, FDA has introduced several initiatives that address microbial and other food safety hazards with domestic or imported produce and that guide industry practices in the safe production of fresh-cut fruits and vegetables. FDA has also worked hard to raise awareness about food defense issues and preparedness. These are just a few things we are doing to improve food safety and food defense.

Recent nationwide recalls remind us how devastating foodborne illness can be. In the past year, contaminated peanut butter led to illnesses in more than 300 people and at least 50 hospitalizations. Contaminated spinach resulted in 206 illnesses, three deaths, and more than 100 people hospitalized. Reports of kidney failure and deaths in cats and dogs prompted a recall of more than 100 brands of pet food.

For every one of these emergencies, the FDA responded immediately to minimize harm. FDA investigators traced each problem's source and worked without delay to remove the affected products from market shelves. FDA staff continue to work diligently to protect our food supply, by containing outbreaks and preventing further illnesses.

With this FDA Food Protection Plan we are going even further. It is a forward-oriented concept that uses science and modern information technology to identify potential hazards ahead of time. By *preventing* most harm before it can occur, enhancing our intervention methods at key points in the food production system, and strengthening our ability to respond immediately when problems are identified, FDA can provide a food protection framework that keeps the American food supply safe.

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

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FDA is implementing a Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products. The Plan is integrated with the Administration's Import Safety Action Plan. The Food Protection Plan operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Strategy Provides Three Elements of Protection

PREVENT Foodborne Contamination

- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

INTERVENE at Critical Points in the Food Supply Chain

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" that Indicate Contamination

RESPOND Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. This Plan identifies the administrative actions we are proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

Additional Protections that Involve Legislative Changes to FDA's Authority

PREVENT Foodborne Contamination

- Allow FDA to Require Preventive Controls to Prevent Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain
- Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods
- Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

box continued on page 4 ...

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INTERVENE at Critical Points in the Food Supply Chain

- Authorize FDA to Accredit Highly Qualified Third Parties for Voluntary Food Inspections
- Require New Reinspection Fee From Facilities That Fail to Meet current Good Manufacturing Practices (cGMPs)
- Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products
- Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products
- Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

RESPOND Rapidly to Minimize Harm

- Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective
- Give FDA Enhanced Access to Food Records During Emergencies

FDA plans to enhance its information technology (IT) capabilities to fully support the implementation of the FDA Food Protection Plan.

For More Information

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To download a copy of this report, go to *http://www.fda.gov/oc/initiatives/advance/food/plan.html* or for the PDF version go to *http://www.fda.gov/oc/initiatives/advance/food/plan.pdf*

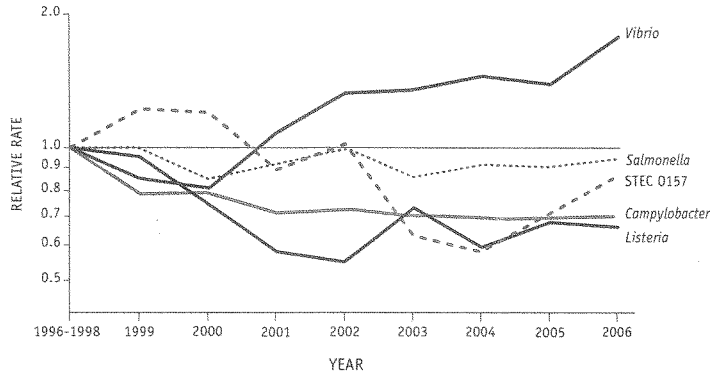
For more in-depth information on the many programs FDA has underway to protect the nation's food supply, go to the Food Protection main page at *http://www.fda.gov/oc/initiatives/advance/food.html*

II. INTRODUCTION

Every day across the country, people eat out, buy groceries, and cook meals for their families. Americans expect that all their food will be safe, and FDA plays a critical role in making sure this is true. FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for meat, poultry, and processed egg products, which are regulated by the U.S. Department of Agriculture (USDA).

In May 2007, Secretary of Health and Human Services Michael O. Leavitt and Commissioner of Food and Drugs Andrew C. von Eschenbach, M.D., charged FDA with developing a compre-

Relative rates compared with 1996-1998 baseline period of laboratory-diagnosed cases of infection with *Campylobacter*, STEC O157, *Listeria*, *Salmonella* and *Vibrio*, by year.



Under its FoodNet program (*www.cdc.gov/foodnet*), the Centers for Disease Control and Prevention (CDC) monitors foodborne microorganisms that cause illness and tracks trends. This graph shows the progress that has been made in reducing foodborne infections. Other than recent increases in *Vibrio*- and Shiga toxin-producing *Escherichia coli* (STEC) O157-related illness, the incidence of illnesses associated with these foodborne microorganisms has mostly remained steady or gone down since the late 1990s, although further progress is needed. Note that the graph represents all illnesses associated with the five types of bacteria, not just that from contaminated food. The graph also represents illnesses from foods not regulated by FDA.

Source: Centers for Disease Control and Prevention

hensive and integrated FDA Food Protection Plan to keep the nation's food supply safe from both unintentional and deliberate contamination. Driven by science and modern information technology, the Plan aims to identify potential hazards and counter them before they can do harm. A cornerstone of this forward-thinking effort is an increased focus on prevention.

The Plan builds in safety measures to address risks throughout a product's life cycle, from the time a food is produced to the time it is distributed and consumed. The Plan focuses FDA's efforts on preventing problems first, and then uses risk-based interventions to ensure preventive approaches are effective. The Plan also calls for a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

- The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures with industry and other stakeholders, FDA can best address critical weaknesses.

- The *intervention* element focuses on risk-based inspections, sampling, and surveillance at high risk points in the food supply chain. These interventions must verify that the preventive measures are in fact being implemented, and done so correctly.

- The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. It also includes the idea of better communication with other federal,

state, and local government agencies and industry during and after emergencies. Whether contamination is unintentional or deliberate, there is a need to respond quickly and to communicate clearly with consumers and other stakeholders. The communication should emphasize identifying products of concern as well as assuring the public of what is safe to consume.

FDA is committed to strengthening the nation's food protection system through implementation of the FDA Food Protection Plan. The Plan's strategic and partnered activities are driven by science and incorporate the use of 21st-century technologies.

Scope of the Food Protection Plan

1. Applies to food for people and animals
2. Addresses domestic and imported products
3. Encompasses food safety (unintentional contamination) and food defense (deliberate contamination)

FDA Regulates Roughly 80 Percent of the U.S. Food Supply

- FDA regulates $417 billion worth of domestic food and $49 billion in imported food[1] annually.
- FDA has oversight of more than 136,000 registered domestic food facilities (including more than 44,000 U.S. food manufacturers and processors and approximately 113,000 U.S. food warehouses, including storage tanks and grain elevators).[2]
- FDA or state and local authorities regulate more than 2 million farms, roughly 935,000 restaurants and institutional food service establishments, and 114,000 supermarkets, grocery stores, and other food outlets.[3] FDA provides guidance, model codes, and other technical assistance to state and local partners.
- Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

1 Based on FDA value-of-shipment information, 2003.
2 Facilities that are engaged in more than one type of activity (e.g., manufacturing and warehousing) are counted in both categories; thus, the sum of the individual numbers of type of facilities exceeds the number of total registered facilities.
3 Data from U.S. Department of Agriculture, National Restaurant Association, and U.S. Census Bureau.

III. CHANGES AND CHALLENGES

Current trends in the food industry promise better nutrition and wider choices for consumers. At the same time, multiple factors pose challenges. These include changing food production technology, patterns of human demographics and behavior, business practices, new threats, and communication issues.

Trends in Demographics and Consumption

Changes in demographics and consumption have increased consumers' susceptibility to foodborne illness. For example, by 2015, it is estimated that 20 percent of the population will be 60 or older. Older Americans are among those at highest risk for foodborne illness.

Also, the practice of a family buying a head of lettuce and preparing a salad at home is not as common. Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

Increasingly, consumers want the convenience of opening up a bag of salad that's already prepared, and immediately serving it.

It used to be that when a single head of lettuce was contaminated, the resulting illness affected one family. Now, contaminated heads of lettuce may be processed with thousands of other heads of lettuce and placed into bags of convenience salad that many consumers can buy. These bags of salad end up in thousands of homes, potentially resulting in hundreds of illnesses.

The shifting demographics have increased the numbers of susceptible consumers, and the convenience factors have meant that small problems can lead to large outbreaks–both indications of the need to make changes to ensure a continued high level of food protection.

Shifting Demographics

Our population demographics are changing. Shifting demographics means that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness.

- In 2007, 20-25 percent of the population is in a high-risk category (young, older, pregnant, immune-compromised). These Americans face a risk of serious illness or death from foodborne illness*.
- In 1980, 15 percent of the population was 60 or older. By 2025, the number will be 25 percent.
- Four percent of the population is immune-compromised (transplant patients, people who are HIV positive, people receiving chemotherapy or other immunosuppressive treatments, people with chronic diseases).

** For example in a joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) report on Listeria monocytogenes (LM) microbiological risk assessment, it was estimated that transplant patients had a 2,584 increased probability of becoming ill from LM, compared with a healthy adult less than 65 years old. The same report indicated that AIDS patients had an 865-fold increase and an otherwise healthy adult over the age of 65 had a 7.5-fold increase [ftp://ftp.fao.org/docrep/fao/007/y5394e/y5394e00.pdf].*

Convenience Trends

Americans are consuming more convenience foods. Foods prepared outside the home may be subject to cross-contamination from other foods, as well as contamination from food workers.

- Ready-to-eat foods (bagged salad, cut fruit) and prepared foods (including hot bars with main and side dishes, as well as salad bars) and frozen dishes that can be cooked quickly are increasing in popularity.
- Cooking in the home is decreasing—people are eating out and bringing prepared foods home.
- Spending on foodservice items, such as supermarket deli foods, accounts for about half of all U.S. food spending.

Consumption Patterns

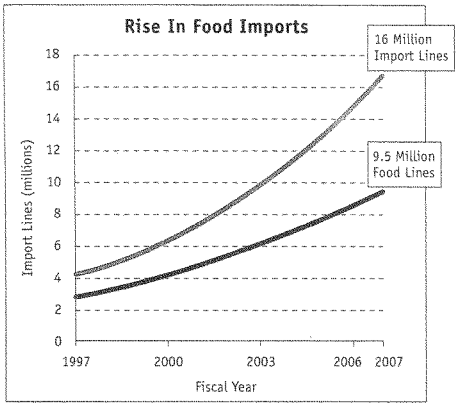
A greater variety of foods are eaten year round. Also, foods that are consumed raw or with minimal processing are often associated with foodborne illness.

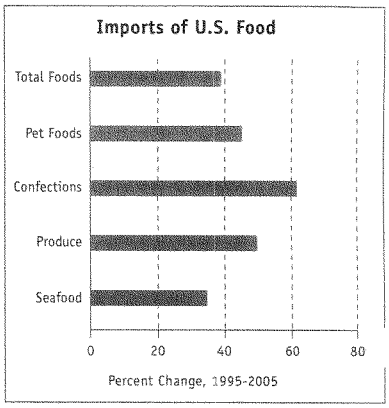
- Consumers are encouraged to make healthier food choices and increase consumption of fruits and vegetables (5-9 servings/day), including fresh produce.
- U.S. per capita consumption of fresh fruit and vegetables increased 36 percent from 1981 to 2000.
- A typical grocery store carried 173 produce items in 1987 and now carries 558 produce items.
- Produce items that were once considered seasonal are available on a year-round basis.
- Increased consumption of exotic foods whose safety hazards are not well understood.

Sources: U.S. Census Bureau and USDA Economic Research Service

Global Food Supply

There have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/territories with products coming into over 300 U.S. ports. In the last decade, the number of food entry lines[1] has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the U.S. are imported, which fills the gap when U.S. domestic production is inadequate or out of season (e.g., bananas, tropical fruits, etc.). Imports of seafood rose from less than 50 percent of U.S. seafood consumption in 1980 to more than 75 percent today.





The type of imported foods is changing. In the past, the bulk of FDA-regulated imports consisted of unprocessed food ingredients with subsequent processing of those ingredients covered by FDA domestic regulatory oversight. Today, foods that are inherently more likely to pose risks, such as ready-to-eat food products, fresh produce and seafood, account for an increasing proportion of imported foods.

This is not to suggest that food imported into the United States, as a whole, poses a greater food safety risk than domestically produced food. But increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports. Currently, data on 100 percent of the shipments are submitted through the electronic systems of the U.S. Customs and Border Protection (CBP) and FDA. The data are screened electronically to determine whether the food appears to present a significant risk to public health. Some foods are then inspected physically based on perceived risk. Food products of greater concern are physically inspected more frequently.

Currently, FDA often has very limited information regarding conditions under which most food is produced in foreign countries. While many foreign countries have well-developed regulatory systems to ensure food safety, other countries have systems that are less well-developed and that may not be able to ensure food safety to the same degree.

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1 An entry line means each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately.

Growth in Foreign Manufacturers Exporting Low-Acid Canned Foods		
	1973	**2004**
Domestic LACF/AF Firms	742	1,300
Foreign LACF/AF Firms	34	6,700

One example of how the source of food has changed is in the import of canned or sealed fruits, vegetables, fish, and other products (collectively known as low-acid canned food/acidified food or LACF/AF). As the table shows, the number of domestic firms nearly doubled between 1973 and 2004. By contrast, there was close to a 200-fold increase in the number of foreign firms manufacturing these products for importation into the United States during the same period.

New Threats

New Foodborne Pathogens

Symptoms of foodborne illness range from mild stomach discomfort to life-threatening neurologic, liver, and kidney syndromes. In 1999, the CDC estimated that there were around 76 million cases per year of illness from foodborne agents, with 325,000 hospitalizations and 5,000 deaths in the United States each year. These data do not identify exactly how many are spread via foods (as opposed to person-to person contact or by some other means) nor do they indicate how the food became contaminated. However, we know that the most severe cases tend to occur in people who are very young, very old, or who have compromised immune systems.

Foodborne illnesses are caused by more than 200 different foodborne pathogens (agents that can cause illness) of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals. The variety of agents associated with foodborne illness has steadily grown over the last few decades, and there is every probability that this list will continue to increase.

One example of a newer foodborne pathogen is *Enterobacter sakazakii*, which can cause serious illness such as sepsis (blood infection) and meningitis (inflammation of the membrane surrounding the brain and spinal cord). In 2002, FDA, working with CDC, discovered and subsequently alerted health care professionals to clusters of *E. sakazakii* infections reported in a variety of locations among hospitalized newborns, particularly premature or other immuno-compromised infants who were fed powdered infant formulas.

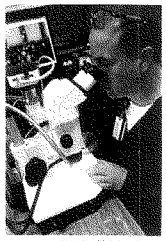
The emergence of new foodborne pathogens requires updated technologies that can detect the presence of new agents in a variety of foods. Addressing these emerging hazards requires cooperation among industry, academia, and government to share information and establish testing protocols.

Pathogens Newly Associated with Foodborne Illness Since the Mid-1970's	
• *Campylobacter jejuni*	• *Campylobacter fetus*
• *Cryptosporidium parvum*	• *Cyclospora cayetanesis*
• Shiga toxin-producing *E. coli*	• *Listeria monocytogenes*
• Noroviruses	• *Salmonella* Enteritidis
• *Salmonella* Typhimurium DT104	• *Vibrio vulnificus*
• *Vibrio cholerae* O139	• *Yersinia enterocolitica*
• *Vibrio parahaemolyticus*	• *Enterobacter sakazakii*

Intentional Contamination
We must also consider food as a potential vehicle for intentional contamination. Such intentional contamination of food could result in human or animal illnesses and deaths, as well as economic losses.

The stark possibilities are suggested by the recent incident in which vegetable protein products, which were represented as wheat gluten and rice protein concentrate, were contaminated with melamine and melamine analogues. Though not considered an act of terrorism, the incident appeared to be a deliberate act for economic gain. It resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products, state quarantine or voluntary holds on livestock that consumed suspect animal feed, and concern regarding the possible associated human health risks.

FDA has no reason to believe any physical harm was intended, but the melamine event indicates the danger of attempts to deliberately compromise the U.S. food system.



Black Star/Chris Cone for FDA

A scientist at FDA's Forensic Chemistry Center examines wheat gluten for possible melamine contamination.

Communication

Effective communication requires active collection and use of incoming information and timely communication to external groups. FDA uses the information it receives to make appropriate decisions about food safety. FDA also shares information and advice with consumers, news media, industry, and state, local, and foreign agencies. Providing information that is timely, useful, and easy to understand is critical.

FDA, states, and industry receive food safety information in various ways. Signals of potential problems come in the form of consumer complaints, inspection data, positive test results, adverse event reports, and other reports of illness. FDA is committed to improving information flow to improve detection and response to signs of trouble.

FDA collects data from several sources. Data from the testing of food, inspections, and reports of illnesses are collected in federal and state systems. Data from foodborne illness and pathogen identification are entered into systems maintained by the CDC, the lead federal agency for conducting disease surveillance and outbreak investigations. Data from imports are entered into specific import systems. Currently, states conduct 10,000 inspections under contract to FDA and another 40,000 inspections under state law. These inspections include the collection of 300,000 food samples each year.

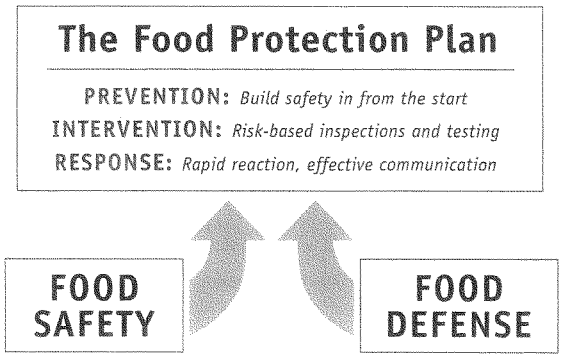
Enabling FDA's information systems to communicate more effectively with internal and external data sources is essential. This will increase productivity of FDA staff and streamline response times during food emergencies. The overall success of the Plan depends on improving the integration and analysis of the vast amount of information collected.

Just as consumers and businesses have important roles to play in providing information to FDA, the FDA plans to improve communication with stakeholders during food emergencies. In the 2007 outbreak involving chili sauce contaminated with *Clostridium botulinum*, the recalled product remained on the shelves of small retailers weeks after the recall announcement. Improving outreach to all segments of the food industry will ensure that harmful products are removed from the market quickly.

IV. AN OVERVIEW OF THE APPROACH

Core Elements

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA—an increased emphasis on prevention.



Greater attention to prevention requires closer interaction with growers, manufacturers, distributors, retailers, food service providers, and importers.

Recent outbreaks linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today. The FDA will work with the private sector to build on the actions of the food industry to ensure product safety. Building safety into products is described in one word: ***prevention.***

This shift to an increased emphasis on prevention is at the core of FDA's Food Protection Plan, and will be evident immediately as the FDA begins an industry-wide effort to focus attention on prevention, from general best practices for all foods to the possibility of additional measures for high-risk foods. ***Prevention*** needs to be augmented by targeted ***intervention*** that focuses inspection and testing on the areas of greatest risk. This will reduce the likelihood that contaminated products will reach consumers. However, even the best system in the world cannot prevent all incidents of foodborne illness. Along with prevention and intervention, faster and more focused ***response*** is needed once a problem is detected.

Prevention *– Build safety in from the start.*
FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, and importers. These partners have the ability to implement preventive approaches and to require them of their suppliers. FDA will continue to work with industry, state, local, and foreign governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, FDA will also work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards.

Intervention *– Verify prevention and intervene when risks are identified.*
FDA, along with other federal agencies and state, local, and foreign governments, must undertake interventions in a coordinated and risk-based manner. Interventions, in the form of targeted inspections and testing, verify that preventive controls are working and that resources are being applied to the areas of greatest concern—either when the product is at the manufacturing facility, on its way to stores, or at a port of entry. Successful intervention will also require enhanced risk analysis, along with new detection technology to allow for faster analysis of samples. A successful and fully integrated food protection system will identify signals that indicate the need for intervention. Such signals may be a positive test for a harmful contaminant following an inspection, an industry report, a consumer complaint, or a full blown outbreak.

***Response** – Respond rapidly and appropriately.*
Working with its food safety partners, FDA will improve its response system to more rapidly react when signals indicate either potential or actual harm to consumers. As part of an improved response system, the FDA will develop faster and more comprehensive ways to communicate with consumers and others during a food-related emergency.

Cross-Cutting Principles

Four important cross-cutting principles will allow a comprehensive food protection approach along the entire production chain.

Principles of the Food Protection Plan
1. Focus on risks over a product's life cycle from production to consumption.
2. Target resources to achieve maximum risk reduction.
3. Address both unintentional and deliberate contamination.
4. Use science and modern technology systems.

1. Focus on risks over a product's life cycle from production to consumption.

Comprehensive food protection requires considering the safety and defense risks associated with foods through their whole life cycle whether domestically produced or imported. Consideration must be given to areas that are potentially vulnerable to both unintentional and intentional contamination such as the point at which food is grown or produced, every processing or manufacturing step, points involved in distribution, transport, and warehousing, as well as all the points at the retail level through distribution to consumers. It is also important to consider the role that consumers play in safeguarding food once it is in their homes.

Consideration of the risks throughout a product's life cycle is a significant shift in the Agency's approach not only for domestic products but for imported foods too. A focus on prevention at the point of manufacture based on risk will provide data to strengthen risk-based inspections domestically, at the border, and overseas. In particular, FDA plans to work with foreign governments and federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements. Risk-based targeted inspections at the border will serve as a second layer of protection, rather than the principal one.

2. Target resources to achieve maximum risk reduction.

A comprehensive risk-based approach must consider the many variables that define risk. Such variables include:

- the possibility that consuming a particular food will result in a foodborne illness due to contamination of the product, which depends on such factors as the number of microbes present or the level of a chemical or toxin present, the susceptibility of the person to the contaminating agent, and whether the food was properly handled and cooked;
- the severity of that illness, should it occur;
- the point in the production cycle where contamination is most likely to occur; and
- the likelihood of contamination and steps taken during the production cycle to reduce the possibility of contamination

Foodborne illnesses range from distressing, but tolerable, symptoms to critical and life-threatening health problems. Illness due to *E. coli* O157:H7 can lead to kidney failure. Exposure to botulinum toxin can cause paralysis. Other, less severe illnesses may cause diarrhea and vomiting.

Some foods, such as those grown in the ground, may have little or no processing before they arrive in consumers' homes. Other foods are cooked to high temperatures (e.g., canned goods). Examining all aspects of the product life cycle helps define the areas of greatest risk. Implementation of the Plan will involve acquiring the data to best address risk, or, where the data is unavailable, working with appropriate partners to determine those risks.

3. Address both unintentional and deliberate contamination.

Food safety, which traditionally refers to unintentional contamination, has been a cornerstone of public health for many years. The idea that someone may use food as a vehicle to deliberately cause harm is a risk that must be addressed. There is a heightened awareness of terrorism as a real possibility that could cause a major public health crisis. To this end, FDA has devoted significant efforts over the last six years to address food defense—defending the food supply against deliberate attack.

Whether dealing with intentional or unintentional contamination, the same regulatory experts, resources, and industry partners are involved. The best way to handle food safety and food defense is to develop approaches that appropriately address both. Although there are differences in how these events are addressed, there are also many overlaps and parallels between the two. For example, the concepts of prevention, intervention, and response apply equally to both.

Those at highest risk for serious foodborne illness include young children, older adults, pregnant women, and people with weakened immune systems.

4. Use science and modern technology systems.

A successful plan for food protection is based on science. FDA's Food Protection Plan emphasizes the need to know the science underpinning how and where food becomes contaminated and the associated risks. The Plan also highlights the use of science to determine optimal interventions to reduce the likelihood of contamination. If contamination does occur, then the priority is to minimize the likelihood that it will cause significant harm. For example, successful intervention relies in large part on the science of epidemiology to understand which foods pose risks and the science of modern detection methods to identify harmful agents quickly.

The Food Protection Plan also highlights the need to further integrate information systems. Too often, sophisticated data systems lack the ability to share information. A priority in the Plan involves creating interoperable data systems, along with making current systems more interoperable, to allow for the exchange of product information along the whole life cycle. The goal is to make the most of important data from all relevant systems, and to obtain easier access to critical information.

V. THE INTEGRATED PLAN

The Food Protection Plan is based on three integrated elements of protection:

1. ***Preventing*** foodborne illnesses in the first place;
2. ***Intervening*** with risk-based FDA actions at critical points in the food supply chain; and
3. ***Responding*** rapidly when contaminated food or feed is detected.

Implementation of the elements will begin immediately, be phased in over time, and be integrated with the Administration's Import Safety Action Plan. All of the elements build on existing partnerships and direct resources to the areas of greatest risk.

But the FDA cannot take some key actions without new legislative authority. We summarize below in each element the new authorities needed to fully implement the Plan and strengthen

our ability to protect Americans. We look forward to working productively with Congress to ensure understanding of the design of and need for these authorities.

CORE ELEMENT #1: PREVENTION

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's Plan implements three key prevention steps, which will move forward concurrently. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

The Plan's Key Prevention Steps
1. Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses 2. Identify Food Vulnerabilities and Assess Risks 3. Expand the Understanding and Use of Effective Mitigation Measures

USDA

The Food Protection Plan builds on partnerships and directs resources to the areas of greatest risk.

FDA designed its Plan for the full life cycle of food—from production to consumption whether it be domestic or imported. The prevention elements of the Plan emphasize the importance for FDA and corporations to work collaboratively to prevent food problems from occurring.

This will be accomplished through a comprehensive review of food supply vulnerabilities. FDA will work with industry and other stakeholders to develop effective tools and science to head off outbreaks of foodborne illness caused by unintentional and intentional factors.

Some examples of enhanced corporate responsibility might include:
- evaluating safety and security vulnerabilities and possible impacts
- when appropriate, implementing preventive measures—both required and voluntary—to ensure that food is produced safely and securely
- developing a contingency plan to aid in a response in the event of contamination

1.1 Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses

Strengthen FDA Actions

- Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply.
- Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines.
- Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility.
- Issue in Spring 2008, a final regulation requiring measures to prevent *salmonella* in shell eggs and resulting illnesses.
- Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source.
- Provide foreign countries with technical assistance so that they can enhance their regulatory systems.
- Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk.
- Focus foreign inspections on high-risk firms and products.
- Improve FDA's presence overseas.

CORE ELEMENT #1. PREVENTION continued

Additional Legislative Authority Needed

Allow FDA to Require Preventive Controls Against Intentional Adulteration by Terrorists or Criminals at Points of High Vulnerability in the Food Chain

The FDA requests authority to require entities in the food supply chain to implement measures solely intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on tanker trucks transporting food. The specific points would be determined using vulnerability assessments such as CARVER+Shock[1], and the authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations will be developed, taking into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk. FDA also proposes that firms be extended an affirmative defense in civil litigation if they comply with these controls.

Authorize FDA to Issue Additional Preventive Controls for High-Risk Foods

The FDA requests explicit authority to issue regulations requiring specific types of foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination) be prepared, packed, and held under a system of preventive food safety controls. Such authority would strengthen the FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from high-risk foods.

Require Food Facilities to Renew Their FDA Registrations Every Two Years, and Allow FDA to Modify the Registration Categories

FDA requests statutory changes that would require facilities to register every two years and authorize the FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

[1]The CARVER+Shock model, explained in detail at http://www.cfsan.fda.gov/~dms/vltcarv.html, stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability, plus Shock. It is available as a software tool to evaluate the potential vulnerabilities of farm-to-table supply chains of various food commodities, as well as individual facilities or processes.

Why These Actions Are Important and What They Will Accomplish

Those with the biggest stake in food safety, after the consumers who eat the food, are the people and companies who grow, process, and sell food. Their livelihood depends entirely on the confidence of their customers. A poor reputation for proper food handling can drive a company to bankruptcy. Promoting increased corporate responsibility is key in shifting FDA's food protection effort to a proactive rather than a reactive one. The FDA will seek partnerships with industry to enhance consumer confidence. FDA will continue to work with industry in a) developing food protection plans that address safety and defense vulnerabilities, b) implementing prevention steps, and c) developing contingency plans to improve response to an outbreak of foodborne illness.

The FDA will primarily focus on promoting the use of risk-based, preventive systems that companies can apply at all levels of food production and processing, when appropriate. Voluntary approaches may be as basic as good manufacturing practices to ensure proper equipment sanitation and employee safety training. Potentially high-hazard food categories may require additional control measures. FDA will work with industry, consumer, and federal, state, local, and international partners to help model and promote preventive controls based on best industry practices.

FDA plans to acquire additional data to develop a better understanding of foreign country practices for food and feed. This may include the examination of best practices around the food safety control systems of other countries as well as increased understanding of the difficulties faced in implementing food protection measures. FDA will also seek to share U.S. food safety and defense best practices with foreign governments and provide technical assistance, when possible, to those countries exporting food products to the U.S. so they can enhance their regulatory systems. As part of its review of foreign systems and products, the Agency will analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk. This approach will also focus foreign inspections on high-risk firms. In the near term, a special emphasis will be placed on firms located in countries where imports into the United States have been refused repeatedly and import violations have threatened the health of U.S. consumers.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Build safety and defense into the full food product life cycle–from production to consumption.
- Support work with industry, and state, local, and foreign governments to understand industry best practices and identify how and where preventive controls would work best.
- Promote the adoption of voluntary preventive controls throughout the food supply chain.
- Enhance relationships with trading partners and improve FDA's presence abroad.

1.2 Identify Food Vulnerabilities and Assess Risks

Strengthen FDA Actions
- Work with the food industry, consumer groups, and federal, state, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities.
- Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful.
- Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
- Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish
These FDA actions provide important tools to facilitate increased corporate responsibility to prevent food contamination. These actions also address the need for additional information to better understand food safety and defense vulnerabilities and possible impacts. FDA will continue its work in this area and further engage industry and other outside groups to identify and target the greatest risks.

FDA actions will include gathering data for risk assessments and to conduct risk evaluations of commodity-agent combinations and relative risk ranking of commodities. A comprehensive, risk-based approach allows the FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with CDC, FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated.

Once established and emerging risks have been identified, assessed, and ranked, we can more effectively allocate our available resources to manage these risks as addressed below.

FDA's current and planned actions would:
- Strengthen the FDA's risk assessment capabilities and capacity to provide risk evaluations efficiently and rapidly.
- Advance collaborative work with CDC, USDA, and other federal, state and local agencies to understand attribution data on the food commodities that cause foodborne illnesses.

1.3 Expand the Understanding and Use of Effective Mitigation Measures

Strengthen FDA Actions
- Focusing on higher-risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination.
- Research, evaluate, and develop new methods to detect food contaminants.
- Encourage outside development of new contamination detection and prevention technologies.
- Develop Web sites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish
Building on risk assessments, FDA will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information in turn will inform FDA's efforts above to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher-risk foods, FDA—working with other agencies—will undertake basic research and leverage relationships with outside organizations. The FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

FDA's current and planned actions would:
- Initiate risk-driven research about sources, spread and prevention of contamination.
- Develop new mitigation tools and implement appropriate risk management strategies.

CORE ELEMENT #2: INTERVENTION

Because no plan will prevent 100 percent of food contamination, we must have targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. These interventions must also identify contaminated food that either unintentionally or intentionally circumvent our prevention plan. The Plan includes three key intervention steps.

The Plan's Key Intervention Steps
1. Focus Inspections and Sampling Based on Risk 2. Enhance Risk-Based Surveillance 3. Improve the Detection of Food System "Signals" that Indicate Contamination

These steps emphasize targeted interventions at the point of manufacture and during distribution. They allow FDA to safeguard domestic products while increasing protection against importation of unsafe food.

Using robust risk-based analysis, FDA will conduct high-priority inspections that rely on statistical sampling and advanced risk detection tools. The FDA will verify industry busi-

ness practices across the food chain to ensure that effective preventive measures are in place. Gathering and analyzing test results, adverse event reports, consumer complaints, and other information will help the FDA track emerging food protection problems.

2.1 Focus Inspections and Sampling Based on Risk

Strengthen FDA Actions

- Focus food and feed safety inspections and sampling based on risk.
- Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample.
- Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspection strategies.
- Collaborate with foreign authorities to reduce potential risk of imported food.

Additional Legislative Authority Needed

Authorize FDA to Accredit Highly Qualified Third Parties for Food Inspections

The universe of domestic and foreign food establishments subject to FDA inspection is immense and continuing to grow faster than the FDA's inspection resources. Even with the most sophisticated detection tools and laboratory capabilities, the FDA's inspection resources are finite. Therefore, legislation to authorize the FDA to accredit independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements would allow FDA to allocate inspection resources more effectively.

To establish such an accreditation program for voluntary food inspections, FDA would undertake a public process to determine best practices and solicit industry input in the design of the program. An FDA accreditation program would require FDA to accredit third-party organizations, or recognize an entity that accredits third parties. Third-party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would also:

- *Audit the work of these organizations to ensure that FDA requirements were consistently assessed;*
- *Review their inspection reports; and*
- *Provide ongoing training criteria to ensure they maintain their skills and knowledge, especially as technology and requirements change over time.*

FDA would use information from these accredited third-party organizations in its decision making but not be bound by such information in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by the FDA when setting inspection and surveillance priorities.

Require New Reinspection Fee From Facilities That Fail to Meet Current Good Manufacturing Practices (cGMPs)

As part of the 2008 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet cGMPs or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Why These Actions Are Important and What They Will Accomplish

Effective FDA intervention means getting product risk information quickly to FDA investigators who oversee the regulated products, including a high volume of import entries. This information will allow the FDA to make better-informed decisions about what products

should be examined more closely and tested. It also signals when to initiate further action such as additional surveillance or an enforcement action.

FDA will look to leverage the resources of outside parties to accomplish more in-depth review of food products. By improving product knowledge and communication with all of our partners, including foreign authorities and the import community, we also can identify lower-risk products requiring less FDA scrutiny at U.S. facilities and at the border. This would enable the FDA to shift more resources to evaluating more closely products that are more risky, less well known, or from unknown manufacturers.

Modern detection tools and methods are critical for effective inspections and sampling. Better detection tools will allow FDA and other partners involved in food testing to more quickly and accurately detect contaminants. Because of its relevant expertise and experience, the FDA has unique capabilities to develop these tools.

Such tools could include real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample or entry, especially those that are considered high-risk. For example, rapid contamination detection technology could be expanded to cover new agents and new food types, such as produce and dairy products. This type of technology could reduce analysis time from days to minutes. Increasing the speed at which the FDA can detect problems will allow FDA to expedite import entry review decisions or provide critical health information to the public when a problem is identified.

In addition to modernizing detection tools using information technology, the FDA must modernize inspectional strategies. This means increasing the probability that investigators will observe and identify potential problems.

FDA's current and planned actions, along with the proposed legislative changes, would result in:

- Focused risk-based inspections and sampling across the food chain.
- Development of rapid detection and testing tools.
- Increased involvement of federal, state, local, and foreign governments, in coordination with other food safety partners.
- Greater product knowledge and oversight through the accreditation of independent third parties.
- Modernized inspectional strategies.

2.2 Enhance Risk-based Surveillance

Strengthen FDA Actions

- Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule in 2008 as part of Bioterrorism Act implementation.
- Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms.
- Use advanced screening technology at the border.
- Improve data quality and handling capacity for food imports.
- Enhance information sharing agreements with key foreign countries.

Additional Legislative Authority Needed

Authorize FDA to Require Electronic Import Certificates for Shipments of Designated High-Risk Products

For food imports, the burden falls primarily on FDA to inspect and detect contamination at the U.S. border. With the explosion in import volume, this burden has become a serious challenge. The FDA should have

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the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority for that authority (or an FDA-recognized third-party inspector) to certify each shipment or class of shipments for compliance with FDA's standards prior to shipment. FDA would apply this requirement for imported products that have been shown to pose a threat to public health for U.S. consumers and thus would be unlike other imports where there is no such showing of risk. Such import certificate programs would be used for designated products imported from countries with whom FDA has concluded an agreement on a certification program that provides a level of safety sufficient to meet HHS/FDA standards. FDA would implement the government-to-government agreement by requiring importers to provide certificates from either relevant government agencies or accredited third parties.

While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. Shipments that fail to meet requirements would be refused entry.

For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria the foreign authority or third party uses in certifying products are sufficient to ensure compliance with FDA food safety standards. The FDA will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration transshipment of products as a way to avoid certification.

FDA would use non-discriminatory science and risk-based criteria to determine the focus of this proposed authority and would use the authority only to the extent necessary to protect human or animal life or health.

Require New Food and Animal Feed Export Certification Fee to Improve the Ability of U.S. Firms to Export Their Products

As part of the 2008 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA's enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by the FDA for export certificates for drugs and devices.

Provide Parity Between Domestic and Imported Foods if FDA Inspection Access is Delayed, Limited, or Denied

While FDA currently has the authority to obtain a warrant or initiate criminal proceedings if it is denied access to inspect facilities here in the U.S., its ability, under the Federal Food, Drug & Cosmetic Act, to enforce the inspection provisions for overseas sites is very limited. In particular, the FDA cannot refuse admission of food, even if its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable the FDA to keep possibly unsafe food from entering U.S. markets. This authority provides strong motivation for firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms. The authority would include several procedural safeguards, including an informal hearing if food is refused admission into the United States, such as is available for food that may be refused entry for other reasons.

Sampling the highest priority imports, especially those posing a significant public health threat, is critical ...

Why These Actions Are Important and What They Will Accomplish

FDA must prevent products that pose food safety and food defense threats from entering the United States. A targeted, risk-based approach to foreign product regulation is essential. Sampling the highest priority imports, especially those posing a significant public health threat, is critical and dependent on data related to the practices in the foreign facility. The activity will enhance FDA's import programs and focus these programs on the life cycle of the imported product, through such means as enhanced use of information-sharing agreements with key foreign countries.

In addition, FDA will continue to look for enhanced ways to use risk-based screening technology to identify products that pose health risks at the border. For example, a screening technology prototype is currently being tested on imported seafood products in Los Angeles. If demonstrated successful, this technology could be extended to other imported products

and ports, thus enhancing the FDA's ability to quickly screen products at the border.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Better focus on the imported products' total life cycle.
- Improve data systems to monitor foreign-produced food products.

2.3 Improve the Detection of Food System "Signals" that Indicate Contamination

Strengthen FDA Actions

- Deploy new rapid screening tools and methods to identify pathogens and other contaminants.
- Improve FDA's adverse event and consumer complaint reporting systems, including capturing complaints made to food manufacturers and distributors.
- Work to create a *Reportable Food Registry* for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]. Under FDAAA, industry is expected to report such situations to the FDA within 24 hours.
- Work to create an *Early Warning Surveillance and Notification System* to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls (as defined in the 2007 Food and Drug Administration Amendments Act or FDAAA).

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

FDA can better detect and more quickly identify risk "signals" in the food supply chain via two key approaches: 1) deploying new rapid screening tools and methods to identify pathogens and other contaminants; and 2) enhancing its ability to "map" or trace adverse events back to their causes (whether reported to FDA or the food manufacturer or distributor) by improving its adverse event and consumer complaint reporting systems. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA will develop a centralized database for veterinarians that captures data on food safety incidents and the causes of food-related illness. The FDA will populate the database with key information from the veterinary community, veterinary hospitals, and other private U.S. sources.

FDA's current and planned actions would identify:
- signals that may indicate a problem with food from routine testing, consumer complaints, industry reporting and documented illnesses.

CORE ELEMENT #3: RESPONSE

During the past year, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. Whether contamination is unintentional or deliberate, there is a need to respond faster and communicate more effectively with consumers and other partners.

The following key response steps will increase FDA's ability to quickly identify food safety problems, better coordinate a rapid emergency response among FDA, state and local government response teams as appropriate, and improve communications to the public, industry and other partners. This will better protect public health, help reduce the economic hardship affected industries face, and most importantly, maintain consumer confidence in the U.S. food supply following an incident.

The Plan's Key Response Steps

1. Improve Immediate Response
2. Improve Risk Communications to the Public, Industry and Other Stakeholders

3.1 Improve Immediate Response

Strengthen FDA Actions

- Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System.
- Work with stakeholders to develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.
- Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions.
- Work with CDC and other selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

Additional Legislative Authority Needed

Empower FDA to Issue a Mandatory Recall of Food Products When Voluntary Recalls Are Not Effective

Although FDA has the authority to seize adulterated or misbranded food, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while the FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct a recall. In such situations FDA needs the ability to require a firm to conduct a recall to ensure the prompt and complete removal of food from distribution channels. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

Provide FDA Enhanced Access to Food Records During Emergencies

During food-related emergencies, the FDA needs more complete and streamlined access to records necessary to identify the source of foodborne illness and take needed action. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

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

The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

Why These Actions Are Important and What They Will Accomplish

Recent food safety threats have demonstrated the importance of FDA's emergency response system. Contaminant tracing—or identifying where the contaminant has traveled within the food or feed supply—is critical in rapidly containing potential risks. Working with partners, FDA will pursue improvements to the current trace-back process and develop an action plan for implementing process improvements to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

As part of that effort, FDA will work with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members.

FDA will also increase collaboration with foreign, state, and local regulators to identify the source of contamination, remove contaminated products as quickly as possible, and implement measures needed to prevent future contamination.

These improvements will allow FDA to quickly isolate problems, prevent contaminated products from reaching consumers, and ensure targeted recalls of products. Such steps aim to minimize the public health and economic impact from an outbreak.

FDA's current and planned actions, along with the proposed legislative changes, would:
- Enhance the nation's food emergency response system.
- Expand the FDA's trace-back process.
- Improve multi-partner collaborations, including with foreign regulators.

3.2 Improve Risk Communications to the Public, Industry, and Other Stakeholders

Strengthen FDA Actions

- Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies.
- Update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers.
- Build a consumer Web site to communicate relevant food protection information.
- In a food-related emergency, implement this communications plan, including utilizing all relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population.

No additional legislative authority needed.

Why These Actions Are Important and What They Will Accomplish

Consumers protect themselves and their families from foodborne illness by responding promptly to FDA alerts. Important messages must be communicated clearly and through multiple forms of media to be effective, because different segments of the population use different technologies, ranging from television and newspapers to text messages and podcasts. In addition, major segments of the population do not use English as their primary language and rely on still other sources of information. This increases the challenge of implementing effective communication strategies.

Retailers, public health officials, industry and other key stakeholders likewise use an array of communications vehicles and sources. FDA's communication strategy during emergencies must use all such media to reach these different audiences and ensure that potentially harmful products are removed promptly.

FDA will enhance its risk communication program through aggressive, targeted food safety campaigns that disseminate clear and effective messages and regular updates through multiple venues to all targeted audiences. This program's designers will solicit input from the

new FDA Risk Communications Advisory Committee, which is tasked with obtaining expert advice in the field of risk communications.

CORE ELEMENT #3 RESPONSE continued

FDA's current and planned actions will enable the FDA to:
- Communicate more effectively with consumers.
- Provide more rapid alerts to all stakeholders, including retailers, industry, public health officials, and the consumers.

VI. ENHANCE INFORMATION TECHNOLOGY

In support of all three components of the Food Protection Plan, FDA plans to enhance its IT systems related to both domestic and imported foods. The focus will be to help the FDA more rapidly identify food importers, and maintain, update, and search records on food facilities and shipments more efficiently.

In particular, FDA will enhance collaboration with CBP on IT systems to more accurately identify firms involved in the food import supply chain during the import screening and review processes. These systems will allow for analysis of historical risk data about firms when making entry decisions for the firms' products.

A new systems approach can eliminate many problems with our current data. For example, assigning a unique identifier will eliminate duplicate records and make risk data about a firm easier to access. Policies for requiring the use of the new single national identifier will need to be established and agreed upon, recognizing the impact on industry worldwide.

Nearly all FDA business processes will benefit from more reliable and accurate information. Implementation of a new system will require a coordinated multi-agency effort that will benefit all federal agencies that process imported foods. CBP's existing data and ongoing activity will play a key role.

Finally, FDA will ensure that its infrastructure and disaster recovery system for IT systems and data are ready to deal with planned (maintenance and upgrades) and unplanned outages. This will provide the necessary support for import operations, which require the availability of multiple FDA systems around the clock. As an example, shipments arrive at U.S. ports day and night, and Prior Notice data are submitted at all hours. IT systems provide screening of the data as they are submitted, and Prior Notice Center (PNC) staff work around the clock to review the risk presented by shipments before their arrival. The PNC needs to review shipment data in as little as two hours from submission. Any interruption in the availability of the computer systems prevents the filing and timely review of information. This affects the flow of goods into the United States, and poses a safety risk to consumers.

An integrated, IT infrastructure—with data gathering, sorting, mining, and trending capability built into the systems—is critical to the success of FDA's food protection efforts.

VII. CONCLUSION

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission—to protect and promote public health. The FDA remains committed to working closely with its partners to protect the nation's food supply.

In the United States, market forces give companies a strong motivation to be vigilant and even innovative in ensuring food safety. The laws of regulation must encourage, not disrupt, these motivations. Rather than taking over responsibility from food companies, FDA wants to protect their flexibility to pursue it vigorously.

Although we have made progress, much remains to be done. Recent incidents of contaminated food and animal feed have highlighted the importance of a strong food protection system. Americans rightly expect to purchase food without having to worry about safety.

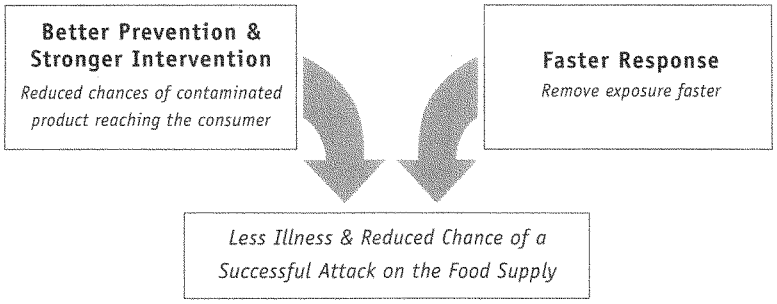
Rising food imports, increasing consumption of convenience foods, and new foodborne pathogens are among the challenges we face. To address these challenges, we must move toward a food safety and defense system that is more proactive and strategic.

FDA's Food Protection Plan contains three core elements—prevention, intervention, and response—with greater emphasis on preventive measures that keep contaminated food from ever reaching consumers. The Plan operates through a set of integrated strategies that address the product life cycle, a risk-based allocation of resources, the integration of food safety and food defense, and builds on a foundation of science and modern information systems.

FDA's Food Protection Plan complements the nation's strategic framework for import safety, which was released by the U.S. Department of Health and Human Services in September 2007. Both plans focus efforts on working smarter and better with importers, manufacturers, and other government agencies.

FDA will aggressively pursue the Food Protection Plan so that U.S. consumers can be assured that their food remains among the safest in the world.

The Public Health Impact of the Food Protection Plan



Department of Health and Human Services
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
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Congress of the United States
House of Representatives
Washington, D.C. 20515

February 4, 2008

Gail H. Cassell, Ph.D., D.Sc.
Vice President, Scientific Affairs
Distinguished Lilly Research Scholar for
Infectious Diseases
Eli Lilly and Company
Lilly Corporate Center, DC 1050
Indianapolis, IN 46285

Dear Dr. Cassell:

Today, President Bush released his Fiscal Year (FY) 2009 Budget for the Food and Drug Administration (FDA). We are deeply concerned that the budget submitted by the President is grossly inadequate to meet the many challenges at FDA as identified by the Science Board. It barely covers the cost of inflation and continues the trend of the inadequate budgets of previous years that have led to the current crisis at the agency. We want to ensure that funding for FDA is sufficient to permit the agency to fulfill its many regulatory responsibilities. We are therefore writing to seek your assessment of the budget and your guidance as a member of FDA's Science Board and as the former head of the Science Board's Subcommittee on Science and Technology.

In December 2006, FDA Commissioner Andrew von Eschenbach requested that the Science Board form a special subcommittee to assess whether "science and technology" at the agency is capable of supporting existing and future regulatory operations. The subcommittee had extensive input from 30 external advisors representing industry, academia, and other Government agencies. These experts were chosen based on their extensive knowledge of cutting-edge research, budget, science, and management operations. Their assessments were compiled in a report entitled, "FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology."[1] The report was released in early December of last year and was posted on FDA's Web site.

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[1] *FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology*, Nov. 2007 (online at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007 4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf).

The subcommittee review was unique in many respects. First, it is only the second time in more than a century that the agency has been reviewed as a whole by an external committee. Second, the committee was composed of leaders from a number of sectors with knowledge of FDA that include industry, academia, and other Government agencies. Third, the expertise and level of accomplishments of the members are almost unprecedented in a single committee, especially considering their scope of knowledge in regulatory science and understanding of the agency's regulatory mission. In fact, the subcommittee included members with extensive credentials ranging from a Nobel laureate in pharmacology, 14 members of the National Academy of Sciences, a renowned economist and specialist in workforce issues, a leader in healthcare policy and technology assessment, a former CEO of a large pharmaceutical company, a former Assistant Secretary for Health and Human Services, a former Chief Counsel for FDA, and a former Under Secretary for Food Safety at the U.S. Department of Agriculture.

While the team's findings were extensive, among the key concerns raised include:

1. FDA cannot fulfill its mission because its scientific base has eroded and its scientific organizational structure is weak;

2. The agency does not have the capacity to ensure the safety of the Nation's food supply;

3. The agency's ability to provide basic inspections, conduct key rulemakings, and carry out enforcement actions is severely eroded, as is its ability to respond to food-related outbreaks in a timely manner;

4. The decrease in FDA funding over the past 35 years has forced the agency to impose a 78 percent reduction in food inspections;

5. The agency faces substantial employee recruitment and retention challenges; and

6. The agency cannot fulfill many of its core regulatory functions because its IT infrastructure is obsolete, unstable, and inefficient.

As the Science Board points out, American lives are now at risk as a result of years of starving FDA of the resources necessary to maintain its scientific and regulatory strength. The subcommittee found that FDA's scientific capacity has been so eroded that it can no longer fulfill a frightening number of critical regulatory and public health responsibilities and many of these are, according to the report, related to a lack of resources. The Subcommittee recognized that the severe loss of scientific capacity at FDA threatens not only the health of our citizens, but the viability of the industries FDA regulates, the pace of medical innovation, and the security of our Nation.

Given these troublesome findings, we want to ensure that the FY2009 FDA Appropriations are based on the best available advice about the resources needed to allow the agency to avert the kind of catastrophe described in the Science Board's report. Consequently, we request that the Subcommittee on Science and Technology assist us by assessing whether the President's FDA budget will provide the increased resources needed to correct the serious deficiencies noted in the Science Board's report. We further request that the subcommittee provide the specific funding levels necessary to address the findings of your Science Board and enable the agency to fulfill its vitally important public health mission.

We recognize that the Subcommittee on Science and Technology of the Science Board was recently disbanded and no longer exists as a formal entity. We therefore request that you convene any available members from the Subcommittee to consider this request on an informal basis.

We appreciate the invaluable work that you and the Subcommittee have done thus far, and look forward to receiving this additional information as soon as possible.

Sincerely,

John D. Dingell
Chairman
Committee on Energy and Commerce

Henry A. Waxman
Chairman
Committee on Oversight and Government Reform

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Frank Pallone, Jr.
Chairman
Subcommittee on Health
Committee on Energy and Commerce

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Tom Davis, Ranking Member
The Committee on Oversight and Government Reform

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

FDA SCIENCE AND MISSION AT RISK

REPORT OF THE FDA SCIENCE BOARD'S SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY

ESTIMATED RESOURCES REQUIRED FOR IMPLEMENTATION

IN RESPONSE TO THE REQUEST OF REPRESENTATIVES DINGELL, WAXMAN, STUPAK AND PALLONE

SUBMITTED BY GAIL CASSELL, PH.D. ON BEHALF OF THE SUBCOMMITTEE AND ITS MEMBERS

FEBRUARY 25, 2008

FDA SCIENCE AND MISSION AT RISK

ESTIMATED RESOURCES REQUIRED FOR IMPLEMENTATION

SUMMARY

In order to address the deficiencies detailed in our report the Subcommittee recommends that the FDA's appropriated (non-user fee) budget be:

- Increased by $375M in FY 2009
- Increased by an additional $450M in FY 2010
- Increased by an additional $460M in each of FY2011, 2012 and 2013.

The FDA's base budget in FY2008 was $1,494,896,000 (salary and expenses minus rent and facility costs). The comparable appropriations (non-user fee) levels we recommend:

FY2009:	$1,870,000,000
FY2010:	$2,320,000,000
FY2011:	$2,780,000,000
FY2012:	$3,240,000,000
FY2013:	$3,700,000,000

Implementation of our recommendations will require some additional rent costs above these levels. However, the Subcommittee has omitted rent and facility costs ($219M in FY 2008) because of our inability to project future needs and costs in this area. It should also be noted that in years 2010-2013 additional increases may be needed to address importation and inspection issues and optimization of the National Center for Toxicological Research (NCTR). Our subcommittee recommended a more in depth review of the Office of Regulatory Affairs and NCTR be undertaken by the FDA Science Board to identify scientific and technology gaps. It is anticipated that FDA will need a

substantial increase in the number of FTEs to significantly expand the field force to do food, drug, device and other inspections.

BACKGROUND

In December 2006, the FDA Commissioner requested that the FDA Science Board establish a Subcommittee to assess whether science and technology at the FDA can support current and future regulatory needs. The Subcommittee's charge was to identify the broad categories of scientific and technologic capabilities that FDA needs to support its core regulatory functions and decision making, throughout the product life cycle, today and during the next decade.

The Science and Technology Subcommittee (hereafter called the Subcommittee) was composed of three members of the Science Board and 30 other experts representing industry, academia and other government agencies, and included individuals with extensive knowledge of cutting-edge research. Most importantly, these experts possess a deep understanding of regulatory science and the core mission of the Agency.

The Subcommittee was asked to review gaps in science and technology and not to assess available resources. However, it rapidly became apparent that the gaps were so intertwined with two decades of inadequate funding that it was impossible to assess one without the other. The Subcommittee found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society—including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function. The Subcommittee concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations.

The findings and recommendations of the Subcommittee were endorsed by all 33 members. On December 3, 2007 the Subcommittee officially transmitted their report ***FDA Science and Mission at Risk*** to the full Science Board. The Board unanimously accepted the report, accepted it as final, and dissolved the Subcommittee. Given the seriousness of the deficiencies noted and the urgency with which they need to be addressed, the Science Board was adamant that the report be broadly communicated to the public and to policy makers, including its posting in the *Federal Register* for public comment.

SUMMARY OF RATIONALE

The Subcommittee was in a unique position to develop reliable estimates of the resources required to implement the recommendations of its report. The Subcommittee membership had extensive experience in development and management of large R & D budgets and regulatory groups, including budget development and oversight for entire pharmaceutical companies (i.e. former CEO Merck; heads of research and development of Genentech, Abbott, Monsanto) and universities (Dean, Iowa State School of Agriculture; Dean, University of Texas Southwestern School of Medicine). The Subcommittee membership also included an economist with expertise in workforce issues, a former Assistant Secretary of Health and Human Services, and a former Chief Counsel of the FDA. In addition, despite the lack of access to internal data, the Subcommittee was able to review publicly available information and directly observe the overall stress within the Agency while conducting this review. Finally, as the Subcommittee became cognizant of the seriousness of the FDA's deficiencies and the magnitude of the crisis, the Subcommittee spent considerable effort garnering as much information as possible about the current roles and responsibilities of Agency staff and currently available resources.

The Subcommittee also had exceptional expertise in budget development and oversight with respect to developing budgets for emerging sciences, food safety and information technology. Members included leaders of relevant research institutes (founders and leaders of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania, the Institute for Systems Biology, the Broad Institute Harvard/MIT, Brown Institute of Molecular Medicine in the University of Texas Health Science Center Houston), research intensive departments in academic institutions (departmental chairs from Univ. Penn., Univ. of Alabama Birmingham, Univ. of Wisconsin), and other government agencies (i.e. HHS, NIH, CDC, USDA), a former Under Secretary for Food Safety, a VP of Information Technology of two major pharmaceutical companies, the Assistant Chief Information Officer for the Center for Infectious Diseases of the CDC and leader of the IT Influenza Pandemic preparedness team of CDC.

Based upon their best professional judgment and publicly available information, the Subcommittee budget estimates are summarized and linked to the major recommendations.

Of course, these estimates have several associated caveats. One is that the FDA, as part of the administration, is required to support the resource needs identified in the President's budget. As a result, the Subcommittee was unable to incorporate internal FDA estimates of what is needed to address the deficiencies noted. Another is a lack of data. The Agency does not have a historical budget data base, and as a result the Subcommittee was not in a position to conduct a zero-based budget analysis for FDA.

Of the information available from FDA, was FDA 's (and OMB's) acceptance of 5.8% as the core inflation rate for the Agency. The Agency needs that amount (currently $100 million) just to keep program and staffing levels constant with the previous year.

Although significant new resources are needed immediately, there is also need for a phased-in approach, which is why the Subcommittee is providing 5-year cost estimates. The Subcommittee recognizes that the timing of expenditures will depend on both institutional and market forces. The Subcommittee strongly recommends that a regulatory science business plan be developed within an upgraded science organization led by a new chief scientific officer and new scientific directors in each of the centers (as recommended in the Subcommittee's report). Recruitment of some of the new positions needs to follow the new, more centralized, planning the Subcommittee recommends. Similarly, some of the IT purchases and personnel should follow, not precede, the enterprise plan recommended. The Subcommittee feels strongly that the new External Advisory Committees for each Center be put in place immediately. The Subcommittee strongly recommends that an ongoing dialog take place between Subcommittee members and the Science Board and FDA leadership during the implementation process. The rebuilding of FDA science will be a long-term effort in the current budgetary environment. New resources must be targeted and wisely used for addressing priority gaps.

Another caveat is that while additional funding is essential, it must be accompanied by increased flexibility. Most critically, direct hiring authority must be returned to the Agency as opposed to being centralized within the Department of HHS. This is critical if the Agency is to be able to hire in a timely manner and be able to recruit top talent.

DETAILED RECOMMENDATIONS

There are many ways to allocate resources – whether by type of need, organizational structure, or overarching characteristic. The Subcommittee recommends that Congress and the FDA phase in the funding increases carefully, and refrain from arbitrarily allocating fixed percentages across each Center.

Year	2009	2010	2011	2012	2013
Food Supply	128	283	441	598	755

Biological Sciences with emphasis upon drug safety and full implementation of the IOM Report, the Critical Path, IIRIS, and external collaborations	136	301	468	634	800
Organization of Science	18	38	58	79	100
Scientific Capability, including development of robust training and visiting scientist program	18	38	58	79	100
Information Technology	75	165	260	355	450
Recommended Increase over 2008 Budget: by year and	375	450	460	460	460
cumulative	**375**	**825**	**1285**	**1,745**	**2,205**
Total Budget	1,870	2,320	2,780	3,240	3,700

Costs, linked to Findings and recommendations

Findings	Summary of Recommendations	Estimated 2013 Cost
The **capacity of science to support the FDA mission is dangerously constrained** from the effects of a long period of expanding Agency mandates and responsibilities, chronic under funding, and the extraordinary advance of scientific discoveries, the complexity of new products and claims submitted to the FDA for premarket approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates.	Every part of FDA is in need of more resources. The committee's priorities fell into 5 categories: the nation's food supply, rapid development in biological sciences; overall organization of science; scientific capability and capacity; and information technology capability and capacity.	Sum of all elements: FDA Budget $3.7 Billion in 2013 (non-user fee, non-rent) Incremental Cost increase relative from 2008: $2.205 Billion
The **nation's food supply** is at risk due to lack of resources and technology to sufficiently monitor the tremendous volume of products manufactured domestically as well as exponential growth of imported products.	Develop risk-based approaches to the inspection of the nation's food supply, support the development of new technologies to automate sampling, and assure that the FDA works closely with other government agencies to identify and control outbreaks of corrupted, contaminated food, infected food supplies and to establish an integrated surveillance system. It is critical that FDA give more resources and attention to the challenges posed by nutritional supplements, cosmetics, and animal food.	**Increase FDA's base by $755M by 2013 (includes $350M to strengthen Imports and $100M to strengthen nutritional supplements, animal health, and cosmetics)**
Rapid developments in biological sciences are exceeding current science capacity to keep pace and adequately support the agency's safety mission.	Fully implement the Critical Path Initiative giving priority to those components likely to have the biggest impact. Be more aggressive in partnering with sister agencies, academia, and industry to access emerging science. Fully implement the Institute of Medicine's recommendations for improving the drug safety system giving highest priority to development of a modern active postmarked safety surveillance network for	**Increase FDA's base by $800M by 2013 (including $450M for IOM Drug Safety; $100M Critical Path; and $250M IIRIS and external collaborations)**

	drugs, biological products, and medical devices. Develop new quantitative methods to assess new products and guide sponsors to valid and informative study designs. Develop a program, i.e. IIRIS, to manage "emerging science" beginning with an integrative, cross-disciplinary program in systems biology and genomics. Initiate other programs in highest priority areas of emerging sciences; including nanotechnology, cell and tissue based therapies, and imaging. Emphasis should be placed upon external collaboration and partnering with sister agencies.	
The **overall** **organization of science** lacks a coherent structure and vision, and effective coordination and prioritization.	Strengthen the role and authority of the newly appointed Deputy Commissioner/Chief Medical Officer and recruit an outstanding Chief Science Officer (CSO) to lead the transformation of science infrastructure; create Deputy Directors for Science in each of the Centers with dotted line reporting to the CSO, establish Board of External Scientific Counselors for each Center, establish standardized processes to promote scientific excellence. Maximize opportunity for consolidation at White Oak and better integrate NCTR. Be more aggressive in partnering with sister agencies, academia, and industry to access emerging science.	**Increase FDA's base by $100M by 2013 (including funding for external collaborations)**
Scientific capability and capacity are inadequate to achieve the regulatory mandate. Recruitment, retention, and professional development programs are inadequate as well.	Put in place personnel systems which facilitate recruitment and retention of outstanding people as well as providing for termination of individuals whose work is of inadequate quality or productivity. Develop and implement a robust training program for visiting scientists and postdoctoral fellows.	**Increase FDA's base by $100M by 2013 (including $75 M for fellowship and visiting scientists program)**
FDA lacks **information technology (IT) capability and capacity** to support monitoring of drug and food safety and is	Develop and execute a comprehensive IT modernization plan driven by the regulatory mission and based on best IT	**Increase FDA's base by $450M by 2013**

particularly challenged in the regulation of products based upon new science. The FDA technology platform is outdated and unstable (>80% network servers beyond recommended service life and no continuity operations plan in the event of an infrastructure disaster). Inadequate communications platforms are significantly limiting FDA's ability to effectively communicate with consumers and industry stakeholders	practices that addresses the immediate regulatory science and services needs of FDA as well as the rapidly emerging IT needs required to support new technologies, scientific methodologies, products, and global business activities. Expand and improve risk communication with external scientific/medical community, the public, and policy makers.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

May 5, 2008

Honorable Arlen Specter
Ranking Member, Subcommittee on Labor,
Health and Human Services, Education, and Related Agencies
Washington, DC, 20510

Dear Senator Specter:

Thank you for your May 1 letter, and for your interest in ensuring that FDA has the tools it needs to meet its public health mandate.

Recent events such as worldwide contamination of heparin and the contamination of food products with melamine underscore the urgent need to accelerate the modernization of FDA and further enhance FDA's capability to protect the American public from unsafe foods and medical products. FDA has responded to these events by establishing comprehensive risk-based plans to protect the food supply and assure the safety of FDA-regulated imports, and by advancing a comprehensive response to Institute of Medicine recommendations for assuring the safety of the drug supply. These plans also require that we improve FDA's science capacity and achieve a modern, bioinformatics focused IT system so that we support the revolution that is transforming medicine today.

As you requested in your letter, I am providing to you an assessment of immediate resource needs based on my professional judgment as the FDA Commissioner and without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed. The amounts identified in the attached document support FDA's food, medical product, science, and information technology needs. These additional resources will accelerate the changes required for FDA to protect and promote the health of all Americans in a rapidly changing world that poses new, emerging threats to the safety of food and medical products.

Sincerely,

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

$275 Million in FY 2008 to Supplement FDA's Budget: Professional Judgment Budget in response to the request from Senator Specter

Strategic Investments (Dollars in Millions)	**FY2008**
Food Protection	$125
Safer Drugs, Devices, and Biologics	$100
Modernizing FDA Science and Workforce	$ 50
Total	**$275**

The amounts identified in this document for three strategic investment areas – protection of our food supply, assuring safer drugs, devices, and biologics, and modernizing the essential infrastructure of FDA's science and workforce. The amounts are in addition to amounts appropriated to FDA in FY 2008.

Investing in these three strategic areas permits FDA to rapidly achieve important goals that cut across strategic components of the Agency. For example, these investments will allow FDA to begin to implement the Import Safety Action Plan (relating to both foods and medical product imports), fulfill new requirements under the FDA Amendments Act of 2007, and modernize its Information Technology systems,

This document responds to the above request for the FDA Commissioner's professional judgment concerning resource needs, and was developed without regard to the competing priorities that the President and his advisors must consider as budget submissions to the Congress are developed.

Supplement to FDA's FY 2008 Budget: Food Protection Plan (+$125 million)

Core elements and strategic activities	FPP Output	$	FTE
Prevention			
1.1 Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses: FDA will ensure the safety of imports by increasing FDA's presence beyond our borders and building capacity with foreign partners.	▪ Increase FDA presence beyond our borders. Offices in two additional countries with 7/8 FDA FTE and 4/5 foreign nationals per country/region) (yields FDA presence in three of five proposed sites)	10,000,000	15
	▪ Increase technical assistance on food standards in at least 3 of the countries accounting for the major share of imports	5,000,000	2
	▪ Develop systems and tools for an international information exchange database related to inspections and quality	5,000,000	3
1.2 Identify Food Vulnerabilities and Assess Risks: FDA will conduct risk-based prevention to better protect America's food supply. FDA will better understand food safety and food defense risks and use this understanding to define the optimum preventive controls to establish.	▪ Increase capacity to collect & interpret data for risk-based prevention for products of greatest concern	5,000,000	10
	▪ Research and develop risk-based prevention strategies based on scientific data and protocols	7,000,000	20
1.3 Expand Understanding and Use of Effective Mitigation Measures: FDA will develop and validate rapid detection tools to quickly detect and mitigate a potential problem.	▪ Develop and validate rapid detection technologies and assays (see 2.3 for deploying technologies and assays); For high risk foods, commence work to develop two new priority tools and to validate two test methods for toxic chemicals or microbes developed by industry.	5,000,000	10
Sub-Total		***$37,000,000***	***60***
Intervention			
2.1 Inspections and Sampling Based on Risk: FDA will apply risk analysis to set priorities for food inspections and interventions.	▪ 20,000 more import food exams at the port of entry[1] ($300 each)	6,000,000	36
	▪ 150 more foreign food production and/or processing facility inspections and support for foreign inspections[1] (2nd year = 600 inspections @ $16.7K each)	10,000,000	33
	▪ 1,000 more domestic food safety inspections[1] (2nd year = 1,250 insp. @ $8k ea.)	10,000,000	50
2.2 Enhance Risk-Based Surveillance of Imported Foods at the Border: FDA will design and build risk-based algorithms to conduct inspections and detect food risks. Understanding the risks defines the number and types of inspections and tests needed to ensure that preventive controls are working.	▪ Integrate and assimilate risk-based information into data systems	10,000,000	15

[1]FDA will hire and train additional field inspectors throughout FY 2008. As a result, by FY 2009, the proposed investment will allow FDA to increase its inspection and surveillance capacity by the amount identified in this FPP output.

Strategic Activity	Output	$	FTE
2.3 Better Detect Food System Signals that Indicate Contamination: FDA will deploy rapid detection technologies and assays and build laboratory infrastructure for faster testing. FDA will deploy state-of-the-art technology to improve the integration of incoming signals and achieve faster mitigation and response	• Improve signal detection of intentional and unintentional chemical and microbial contamination	5,000,000	5
	• Deploy 1-2 rapid detection assays to test high risk foods. Acquire advanced technology and deploy such equipment to FDA field and conduct technology transfer to industry.	5,000,000	5
	• Build high throughput rapid detection technology into laboratory infrastructure	17,000,000	10
Sub-Total		***$63,000,000***	***154***
Response			
3.1 Improve Immediate Response: FDA will enable real-time communication of lab results. FDA will develop protocols to facilitate tracebacks of foodborne illnesses. FDA will rapidly detect and respond foodborne outbreaks.	• Develop and implement a system for traceback from product consumption back to the source of production using, for example, electronic pedigrees and industry applied technologies of bar coding and radio frequency identification	10,000,000	20
	• Enhance interoperable information technology networking system between FDA and federal, state, and local testing labs	10,000,000	6
3.2 Improve Risk Communications to the Public, Industry, and Other Stakeholders: FDA will enhance risk communication though aggressive, targeted food safety campaigns that disseminate clear and effective messages with regular updates through a variety of media to all target audiences.	• Create a "health hazards alert" communication system using multiple media outlets to quickly inform a broad cross section of the public	5,000,000	10
Sub-Total		***$25,000,000***	***36***
GRAND TOTAL, Food Protection Plan		**$125,000,000**	**250**

Background on FDA's Food Protection Plan

On November 6, 2007, FDA unveiled its Food Protection Plan (FPP), an integrated strategy to protect America's food supply[2]. The FPP is a risk-based strategy to assure the safety of domestic and imported food. The cornerstone of the FPP is a rigorous science and information technology infrastructure designed to assure food safety at all points in the production-to-consumption cycle.

In FDA's professional judgment, the proposed increase for FY 2008 allows FDA to implement key initiatives across the core elements of the FPP: prevention, intervention, and response. This increase will allow FDA to achieve essential FPP priorities:

- identify and target the greatest threats from intentional and unintentional contamination
- perform essential research on mechanisms of food contamination and deploy new rapid food defense and food safety screening technologies for microbial and chemical contaminants
- conduct more risk-based inspections, enhance electronic systems of surveillance and establish additional multidisciplinary "rapid response" teams
- expand FDA's international presence beyond the planned office in China to include offices in India and Latin America, and establish the groundwork for offices in Europe and the Middle East
- establish IT systems to support interoperable databases that will enhance food research, threat assessment, and surveillance of adverse events.

With these investments, FDA can continue to reduce the risk to Americans from food-borne illnesses. These investments also allow FDA to respond to three of the six concerns raised by GAO in its February 2007 report designating food safety as a high-risk program[3].

[2] For FDA's Food Protection Plan, see http://www.fda.gov/oc/initiatives/advance/food/plan.pdf .
[3] For the GAO report, see http://www.gao.gov/new.items/d07449t.pdf .

Supplement to FDA's FY 2008 Budget: Ensuring Safe and Effective Medical Products (+$100 million)

Strategic Activity	Output	$	FTE
Safer Drugs, Devices, and Biologics			
1.1 Science to Improve Medical Product Safety and Development: Use new science and analysis to improve the safety of medical products. In some cases, new science creates opportunities to leverage advances from one product area to promote safety in a different area.	• Establish a unique device identification system to track devices, facilitate recalls, and support inventory management during disasters and terrorism response	7,500,000	17
	• Implement FDAAA safety requirements related to pediatric drugs and devices, postmarket study commitments, clinical trials, active drug surveillance, labeling and safe use of drugs.	17,000,000	15
Sub-Total		***24,500,000***	***32***
1.2 Data Analysis Tools to Identify Safety Issues: Develop and implement quantitative decision-making tools to assess the safety and effectiveness of drugs, biologics, and devices throughout their lifecycle	• Build Regulated Product Information Data Warehouse that will enable intelligence sharing with other regulatory agencies	15,000,000	0
	• Data access and analysis for active safety surveillance with development of scientific methods of data mining for signals of adverse events	15,000,000	6
Sub-Total		***30,000,000***	***6***

May, 2008

Strategic Activity	Output	$	FTE
	• 120 more foreign medical product facility inspections[4] (uc=$45K)	5,400,000	24
	• Increase FDA's presence beyond our borders to three of five geographic regions of the world	7,800,000	13
1.3 Risk-Based Inspection and Compliance: Strengthen field operations to better protect public health. The sheer volume of products, manufacturing plants, distributors, and importers demands a more robust inspection force with better capacity to reach the community that FDA regulates.	• 575 more domestic medical product inspections[4] (uc=17.7K)	10,200,000	40
	• Improve lab infrastructure and tools for rapid analysis of product/ingredient content	7,500,000	5
	• Increase import exams (10,000) and sampling/ laboratory analysis (300)	6,600,000	35
	• IT systems to achieve an integrated inventory database	3,000,000	0
	• Improve risk communications to public and industry	5,000,000	5
Sub-Total		***45,500,000***	***122***
GRAND TOTAL, Medical Product Safety and Effectiveness		**100,000,000**	**160**

[4] FDA will hire and train additional field inspectors throughout FY 2008. As a result, by FY 2009, the proposed investment will allow FDA to increase its inspection and surveillance capacity by the amount identified in this output.

Background on FDA Medical Product Programs: Drugs, Devices, and Biologics

The medical products that FDA regulates – human drugs, medical devices, vaccines, blood and blood products, other biological products, and animal drugs and feeds[5] – touch the lives of millions of Americans each day. FDA is responsible for the entire life-cycle of medical products, from pre-market testing and development through approval, post-market surveillance, and risk management.

FDA faces growing challenges due to the globalization of medical product development and manufacturing. Medical products are more often developed, evaluated clinically, and manufactured, in whole or in part, beyond our borders. This fundamental shift requires FDA to perform more complex analysis and deploy more sophisticated technology to ensure the safety and effectiveness of medical products before they arrive in our country through multiple portals to be processed, packaged, and disseminated in our health care delivery system.

FDA is reinvigorating and reengineering its foreign inspection program for medical products to build quality in and assure integrity of the supply chain. This includes more foreign inspections and equipping inspection teams with information and laboratory technologies to precisely target foreign inspections through accurate risk profiling. Moreover, FDA is establishing IT systems that support delineation of medical product risk profiles, detection of subtle and early signals of compromised product integrity and analysis of hazards points in the process requiring targeted inspection. These systems will also allow FDA to respond to deficiencies described by Government Accountability Office reports, such as a need to establish and maintain a comprehensive list of FDA-approved medical products, foreign manufacturing sites, clinical trials, and post-market study commitments.

[5] Assuring the safe use of animal drugs and medicated feeds in food-producing animals is essential to protect the health of the American public.

Background on Modernizing FDA Science and Workforce

In FDA's professional judgment, the additional funds to support FDA regulation and emerging science will allow FDA to improve its science capacity and better support the revolution in science that is transforming the practice of medicine and advancing the promise of personalized medicine. These efforts help respond to the report of FDA's Science Board in late 2007 which outlined a series of urgent scientific priorities for the Agency. These efforts will improve health and quality of life for patients by supporting greater safety, efficiency, and predictability of medical products. The additional funds will also allow FDA to expand its capability to effectively model food supply risks and support the regulation and inspection of the food supply.

Summary of FDA's FY 2009 Budget

Total Budget: For FY 2009, the FDA requests a total budget of $2.4 billion. This amount is $129.7 million more than FY 2008 and represents a 5.7 percent increase.

Budget Authority: The FY 2009 budget requests $1.77 billion in budget authority and contains a net increase of $50.7 million over FY 2008 for high priority initiatives. This represents a 2.9 percent increase.

User Fees: Finally, the FDA's budget proposes $628 million in industry user fees, an increase of $79.0 million over FY 2008. This represents a 14.4 percent increase.

Specifics on FY 2009 Initiatives: The FDA's FY 2009 budget advances the agency's core mission: promoting and protecting public health. The budget funds initiatives above FY 2008 in priority areas:

- +$42.2 million for a total investment of $662 million to implement the Food Protection Plan. The FY 2009 investments in the Food Protection Plan will strengthen food safety by preventing foodborne illness outbreaks, intervening when food defense or food safety vulnerabilities emerge, and rapidly responding to food defense and food safety threats.
- +$17.4 million for a total investment of $887 million for medical product safety and development. This initiative allows the FDA to improve the safety of medical products, including human tissues, blood and blood products, human drugs, medical devices, and animal drugs.
- A savings of -$8.9 million due to administrative and management efficiencies, generated by productivity gains.
- $25.0 million is included in the initiatives listed above to fund cost of living increases for the FDA's world-class workforce.

The full details of the FY 2009 FDA budget request appear at:
http://www.fda.gov/oc/oms/ofm/budget/documentation.htm

Overview of FY 2009 Initiatives

Initiative	Amount	FTE	Synopsis
	Budget Authority		
Protecting America's Food	+$42,232,000	94	This initiative supports the FDA's shift to a comprehensive, preventative, and risk-based approach to safeguard the food supply and the American homeland. The investment allows the FDA to implement major components of the Food Protection Plan, Import Safety Action Plan, the December 2007 agreements with China, and a possible FDA office in China. Includes a pay increase for agency personnel to sustain current services and conduct the FDA mission.
Medical Product Safety and Development	+$17,395,000	8	This initiative provides targeted resources to improve the safety of human and animal drugs, blood, human tissues, and medical devices. The investment will strengthen the FDA's ability to effectively monitor the safety of medical products, including imported products. The FDA will also assist medical product manufacturers to develop new products to treat life-threatening diseases and conditions. Includes a pay increase for agency personnel to sustain current services and conduct the FDA mission.
Administrative Savings and Management Efficiencies	- $8,918,000	- 11	In FY 2009 the FDA will redirect savings and management efficiencies to high priority activities.
	Current Law & Proposed User Fees		
Current Law User Fees	+$57,534,000	239	The budget request includes inflationary increases for FDA user fee programs as well as other

			increases authorized by law under the prescription drug and medical device user fee programs. Three FDA user fee programs facilitate premarket review for human and animal drugs and human devices. Three other user fee programs support the mammography facilities inspection program and provide certification services for color additives and for drug and device products exported from the United States.
Proposed Generic Drug User Fee	+$16,628,000	34	The proposed user fee for Generic Drug Review will provide additional resources to improve the generic drug review process and to respond to the growing number of Abbreviated New Drug Applications.
Proposed Animal Generic Drug User Fee	+$4,831,000	22	The proposed user fee for Animal Generic Drug Review will provide additional resources to improve the animal generic drug review process and to respond to the growing number of Abbreviated New Animal Drug Applications.
Total Program Level Increase over FY 2008	***+ $129,702,000***		
Proposed Mandatory User Fees (Non-Add)			
Reinspection User Fee	+$23,276,000 (Non-Add)	118	Re-proposed new user fees to reimburse for reinspection of FDA-regulated facilities.
Food and Animal Feed Export Certification User Fee	+$3,741,000 (Non-Add)	23	Re-proposed new user fees to reimburse for issuing food and feed export certificates.
Mandatory User Fees	***+$27,017,000***		

FOOD PROTECTION OPERATIONS PLAN

Strategic Action Funding	Strategic Actions	Strategic Components	Outputs	2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Food Protection Plan Core Element #1: Prevention			**1,767,000**	**8,257,000**	**11,414,000**
	Key Prevention Step #1.1: Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses			**278,000**	**2,830,000**	**6,311,000**
FY 2008 Increase= $278,000 7/1/2008 Increase=$0 FY 2009 Increase=$0	1. Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply	Stakeholder outreach on food protection	* Output 1a: Meet with wide array of FPP stakeholders and other government partners (Federal, State, and local and foreign) to solicit their input on identifying and implementing preventive approaches to protect the food supply.	✓		
		Stakeholder engagement/leveraging in implementation of food protection plan	Output 1b: Draft a plan based on summary of stakeholder input on how best to involve stakeholders in the implementation of the prevention, intervention and response elements of the FPP.			
		Stakeholder and FDA field support	* Output 1c: Develop a list of specialties that would enhance the effectiveness of food inspections. Identify a team of technical experts with capacity to assist rapid response teams in outbreak investigations and provide liaison and training with ORA field staff, state, and local staff that conduct prevention activities.			
FY 2008 Increase=$0 7/1/2008 Increase=$993,000 FY 2009 Increase=$1,256,000	2. Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines	Understand industry prevention best practices	* Output 2a: Meet with food and feed industry representatives to discuss how to achieve corporate responsibility, understand industry best practices, and identify how and where preventive controls will work best.		✓	
		Promote voluntary preventive controls	* Output 2b: Promote the adoption of voluntary preventive controls throughout the food supply based on industry best practices by collaborating on training workshops to assist industry in achieving prevention objectives.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$695,000 FY 2009 Increase=$1,139,000	3. Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b) implement other measures to promote corporate responsibility	FDA Prevention Guidance/Regulations, Outreach & Training	* Output 3a: Develop plan to address other specific high-risk foods of concern from intentional or unintentional contamination.			
			* Output 3b: Develop specific guidance and implement guidance through outreach and training.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$201,000	4. Issue in Spring 2008, a final regulation requiring measures to prevent salmonella in shell eggs and resulting illnesses	Salmonella regulation	* Output 4: Work to deliver final regulation defining preventive management practices to salmonella from eggs and resulting illnesses. Implement regulation through outreach and training.			✓
FY 2008 Increase=$0 7/1/2008 Increase=$397,000 FY 2009 Increase=$101,000	5. Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source	Collaboration with foreign governments	* Output 5: Share risk- and life-cycle-based surveillance approaches, examples of corporate food protection plans, and other results of domestic prevention efforts for improving food safety at the source. * Examine best practices around the food safety control systems of other countries as well as increase understanding of the difficulties faced in implementing food protection measures.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$298,000 FY 2009 Increase=$201,000	6. Provide foreign countries with technical assistance so that they can enhance their regulatory systems	Provide technical assistance to foreign governments	* Output 6: Develop mechanisms/protocols to provide technical assistance to foreign countries so that they can enhance their food and drug regulatory systems.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$372,000 FY 2009 Increase=$301,000	7. Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk	Import Trend Data for Risk Ranking	* Output 7: Produce analysis of food import data, including a ranking of food imports according to risk. Work with ORA to update future import inspection work plan based on risk ranking of imports.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$75,000 FY 2009 Increase=$0	8. Focus foreign inspections on high-risk firms and products	FDA Risk-Based Foreign Inspections	* Output 8: Formalize the high risk criteria used to identify foreign facilities. Increase foreign inspections of high-risk firms identified by more accurate risk profiling.		✓	
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$3,112,000	9. Improve FDA's presence overseas	FDA Foreign Presence	* Output 9a: Establish FDA Field Office in China.			✓
			Output 9aI: Conduct bilateral meetings as agreed to under the China MOA.			
			** Output 9b: Develop a plan to increase FDA presence in other countries/regions of concern, such as India.			

*Base funds are being used to initiate these outputs.

**Base funds are being used to plan for an increased FDA presence overseas, such as India.

FOOD PROTECTION OPERATIONS PLAN

Strategic Action Funding	Strategic Actions	Strategic Components	Outputs			
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Key Prevention Step #1.2: Identify Food Vulnerabilities and Assess Risks			1,489,000	4,091,000	4,302,000
FY 2008 Increase=$0 7/1/2008 Increase=$1,911,000 FY 2009 Increase=$1,901,000	1. Work with the food industry, consumer groups, and Federal, State, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities	Data Gathering	* Output 1a: Identify additional information needs to strengthen FDA understanding of food safety and food defense risks and vulnerabilities.			
			* Output 1b: Conduct research and obtain scientific data to identify and counter unintentional and intentional food contamination.		✓	✓
FY 2008 Increase=$1,489,000 7/1/2008 Increase=$1,311,000 FY 2009 Increase=$3,301,000	2. Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful	Risk Ranking, aid industry efforts to achieve corporate responsibility	* Output 2a: Build a team to enhance modeling capability for relative risk ranking.		✓	✓
			* Output 2a1: Conduct research to evaluate and prioritize risks of food and feed agents that may be harmful.			✓
			* Output 2b: Determine a ranking of the top priorities for risk evaluation of commodity-agent combinations.		✓	
			* Output 2c: Increase software capacity to assist industry with identifying areas of food safety risk through CARVER-type model for domestic manufacturer and grower use.			
			* Output 2d: Using findings from the research of Salmonella strains, initiate development of an integrated genomic database to be used for the risk assessment of foodborne pathogens.	✓	✓	
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	3. Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease	Risk-Based Process for Targeting FDA actions/resources	* Output 3a: Develop a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.			
FY 2008 Increase=$0 7/1/2008 Increase=$869,000 FY 2009 Increase=$0	4. Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated	Better attribution data collected	* Output 4a: In collaboration with CDC, identify data needed for optimal attribution needs. Work with CDC to help design better tools for use by States and locals in conducting epidemiological investigations to obtain the data.		✓	
		Data analysis, real time reporting of data, risk communication	* Output 4b: Work with CDC on analysis of the data that CDC acquires and provides.		✓	
		Risk ranking, apply findings to review of product life cycle	* Output 4c: Determine which food/pathogen pairs present the highest risk, i.e. develop a risk ranking of food/pathogen pairs.			
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Key Prevention Step #1.3: Expand the Understanding and Use of Effective Mitigation Measures			0	1,336,000	801,000
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	1. Focusing on higher risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination	Identify research needs for high risk foods	* Output 1a: For higher risk foods, work to understand, identify and target effective mitigation strategies through the development of a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination for higher risk foods.			
FY 2008 Increase=$0 7/1/2008 Increase=$318,000 FY 2009 Increase=$801,000	2. Research, evaluate, and develop new methods to detect food contaminants	Conduct basic research	* Output 2a: Based on research plan for high risk foods, initiate basic research and leverage with outside organizations to determine possible mitigation steps to identifying and mitigate unintentional and intentional food contamination.		✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$1,018,000 FY 2009 Increase=$0	3. Encourage outside development of new contamination detection and prevention technologies	Develop new platform technologies	* Output 3a: Encourage the development by outside parties of new and innovative platform technologies for detecting contaminants in foods. Meet with various outside groups to encourage development of microarray, optical mapping, and biosensors for detect and ID of enteric bacteria that may be accidental or intentional contaminants in the food supply.		✓	
		Develop better detection tools	* Output 3b: Encourage the development by outside parties of hand held rapid detection tools to identify an increased number of foodborne pathogens.		✓	
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	4. Develop websites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities	Communicate research results, aid industry efforts to achieve corporate responsibility	* Output 4a: Produce website for disseminating research results and guidance to industry on effective steps to mitigate vulnerabilities.			

*Base funds are being used to initiate these outputs.

FOOD PROTECTION OPERATIONS PLAN

Strategic Action Funding	Strategic Actions	Strategic Components	Outputs			
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Food Protection Plan Core Element #2: Intervention			9,578,000	8,931,000	15,606,000
	Key Intervention Step #2.1: Focus Inspections and Sampling Based on Risk			9,578,000	6,609,000	14,864,000
FY 2008 Increase=$9,578,000 7/1/2008 Increase=$461,000 FY 2009 Increase=$12,787,000	1. Focus food and feed safety inspections and sampling based on risk	Focused, risk-based inspections and sampling	* Output 1a: Domestic inspection and sampling activities. •Target domestic food field exams	✓		✓
			* Output 1b: Foreign / import inspection and sampling activities. • Target import food field exams. • Reengineer Foreign Inspection Program inspections to be based on risk.			✓
		Enhance State inspections	* Output 1c: Prioritize inspections based on risk using tools that include FDA and State inspection and enforcement data.		✓	
			* Output 1d: Improve State access (current 40 states food and BSE) to eSAF (electronic State Access to FACTS) to include elimination of duplicate entry, electronic Seafood HACCP forms, better work planning, and assignments. View other state inspection data.	✓		
FY 2008 Increase=$0 7/1/2008 Increase=$5,259,000 FY 2009 Increase=$1,678,000	2. Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample	Rapid Detection and Testing	* Output 2a: Choose and evaluate methods appropriate for detecting contaminants in foods. • Develop enhanced screening kits and new methods to address new pathogens and speed analysis • Develop fast and inexpensive techniques using microarray technology to detect antibiotic resistance markers in Salmonella and E-coli 157:H7.		✓	✓
			* Output 2b: Initiate work with industry and States to establish the means to rapidly determine exact sources of contamination and halt further distribution.			
FY 2008 Increase=$0 7/1/2008 Increase=$889,000 FY 2009 Increase=$0	3. Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies	Inspector Training	* Output 3a: Update existing FDA and state investigator training to incorporate new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment and modern inspectional strategies. Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies. • Develop a training program to ensure food inspections conducted by our state counterparts meet FDA standards for inspections.		✓	
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$399,000	4. Collaborate with foreign authorities to reduce risk of imported food	Leverage with Foreign Counterparts	* Output 4a: Review and enhance existing information sharing agreements and explore developing new information sharing agreements with foreign authorities to leverage their inspection and certification data. Plan to prioritize information sharing agreements based on the value of such agreements to FDA and consumer protection.			✓
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	5. Voluntary certification programs for foreign firms and importers	Voluntary Certification	*Output 5a: Work to understand existing standards and certification programs and consider incentives to encourage broader participation.			
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Key Intervention Step #2.2: Enhance Risk-Based Surveillance of Imported Foods at the Border			0	2,322,000	742,000
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	1. Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule by the end of 2007 as part of Bioterrorism Act implementation	Tools to target high-risk foreign firms	* Output 1: Work to publish the Prior Notice of Imported Foods Final Rule as part of Bioterrorism Act implementation.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$742,000	2. Conduct foreign food and animal food inspections more efficiently using the tools designed to target high-risk firms		* Output 2a: Enhance FDA Import Programs to focus on imported product life-cycle. • Update the inspection work plan to use the tools designed to target high-risk firms.			
			* Output 2b: Redesign sampling strategies.			✓
FY 2008 Increase=$0 7/1/2008 Increase=$2,222,000 FY 2009 Increase=$0	3. Use advanced screening technology at the border	Automated screening technologies	* Output 3: Identify and deploy advanced screening technology for border control. • Identify advanced screening technologies that would have a big impact in terms of improving risk-based screening of food imports at the border. Compare these screening technologies against PREDICT and choose the technology to be deployed widely. • Expand software capacity for risk-based sampling strategies (PREDICT model or other) for imported products and domestic retail. • Expand staff to redesign sampling strategies. • Deploy advanced screening technology, contingent on availability of risk-based criteria and maturity of PREDICT.		✓	

*Base funds are being used to initiate these outputs.

FOOD PROTECTION OPERATIONS PLAN

Strategic Action Funding	Strategic Actions	Strategic Components	Outputs			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	4. Improve data quality and handling capacity for food imports	Better data on food imports	* Output 4a: Enhance data capture for imports • Increase access to data across agencies (e.g. USDA, Customs), contingent upon IT integration at FDA and participation of other agencies.			
		Import Alert System	* Output 4b: Improve Import Alert System • Automate the Import Alert/Bulletin System to receive recommendations; shorten the development, clearance and implementation timeframes; include mandatory time frames for the clearance process. • Develop a system that will allow Import Alerts (IA's) and Import Bulletins (IB's) to be written, issued, and stored in a manner that would allow easy search, tracking, and trending capability. • Develop an automated system to cross reference various agency databases. • improved data quality and handling capacity for imports.			
FY 2008 Increase=$0 7/1/2008 Increase=$100,000 FY 2009 Increase=$0	5. Enhance information sharing agreements with key foreign countries	Information sharing	* Output 5: Enhance use of information sharing agreements with foreign countries on mutually agreed upon food products where there is a measurable benefit to FDA.		✓	
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Key Intervention Step #2.3: Improve the Detection of Food System "Signals" that Indicate Contamination			0	0	0
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	1. Deploy new rapid detection tools and methods to identify pathogens and other contaminants	Deployment of new rapid detection tools and methods	Output 1a: Train analysts and investigators on new tools and methods.			
			Output 1b: Evaluate and identify additional inspection tools; conduct inspections and investigations using these new rapid detection tools and methods.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	2. Improve FDA's Adverse Event and Consumer Complaint Reporting System, including capturing complaints made to food manufacturers and distributors	Trace-back software	* Output 2a: Enhance and test software for mapping adverse events to causes.			
		Adverse event and consumer complaint reporting	Output 2b: Improve the Consumer Complaint Reporting System so that it captures complaints made to food manufacturers and distributors.			
		Dietary Supplements	* Output 2c: Develop and implement a plan to enhance surveillance of dietary supplements.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	3. Work to create a Reportable Food Registry for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]; under FDAAA, industry is expected to report such situations to the FDA within 24 hours	Reportable Food Registry	* Output 3a: Establish a *Reportable Food Registry* for industry reports of certain adulterated foods.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	4. Work to create an Early Warning Surveillance and Notification System to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)].	Pet food safety database	* Output 4a: Establish an early warning surveillance and notification system to identify adulteration of pet food supply and outbreaks of illness associated with pet food.			
			* Output 4b: Develop a centralized database for veterinarians that captures data on food safety incidents and causes.			

*Base funds are being used to initiate these outputs.

FOOD PROTECTION OPERATIONS PLAN

Strategic Action Funding	Strategic Actions	Strategic Components	Outputs			
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Food Protection Plan Core Element #3: Response			**8,973,000**	**10,616,000**	**3,174,000**
	Sub-Element #3.1: Improve Immediate Response			**8,973,000**	**10,616,000**	**2,954,000**
FY 2008 Increase=$640,000 7/1/2008 Increase=$0 FY 2009 Increase$202,000	1. Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System	Emergency Operations Network Incident Management System	* Output 1: Improve data collection and incident reporting. - Enhance mapping capability of emergency response scenarios, in coordination with the HHS Office of the Secretary and other HHS agencies.	✓		✓
FY 2008 Increase=$0 7/1/2008 Increase=$3,889,000 FY 2009 Increase=$0	2. Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients	Trace-back process	* Output 2a: Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.			✓
			Output 2b: Improve trace-back process protocol.		✓	
FY 2008 Increase=$8,333,000 7/1/2008 Increase=$505,000 FY 2009 Increase=$2,752,000	3. Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions (ISAP lead with FFP coordination)	Emergency response coordination	* Output 3a: Enhance FDA's ability to coordinate a comprehensive FDA response to foodborne illness events, outbreaks and emergency situations by reviewing and improving the protocol and roles and responsibilities for emergency coordination. - Acquire staffing resources to provide optimal Agency response (OCM). - Hire and train emergency coordination staff (CVM). - Coordinate Agency participation in exercises and workgroups related to emergency preparedness, response and counterterrorism, such as the TOPOFF 5 Exercise.			✓
			* Output 3b: Work with states to initiate the establishment of state and regional rapid response teams.	✓	✓	✓
FY 2008 Increase=$0 7/1/2008 Increase=$6,222,000 FY 2009 Increase=$0	4. Enhance information technology networking with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members	IT networking with partners	* Output 4a: Enhance information technology networking with selected federal, state, and local testing labs to communicate timely testing results among FDA and lab members, contingent on training.			
		Lab capacity	* Output 4b: Expand FDA, State, and foreign lab capacity, contingent on availability of FERN training and equipment for disciplines in biological, chemical, and radiological methods.		✓	
				2008 Increase	7/1/2008 Increase	FY 2009 Increase
	Sub-Element #3.2: Improve Risk Communications to the Public, Industry and Other Stakeholders			**0**	**0**	**220,000**
FY 2008 Increase =$0 7/1/2008 Increase=$0 FY 2009 Increase=$220,000	1. Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies	Communication working group and research	* Output 1: Consider appropriate methods for consumer communications.			✓
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	2. Based on that research, update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers	Updated communication plan	* Output 2: Update the Food Protection Risk Communication Plan using the most effective strategies for sharing information with consumers. - Improve control process for handling consumer complaints and inquiries based on needs assessment. - Review and improve food protection communication process to increase timeliness of food protection messages.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	3. Build a consumer website to communicate relevant food protection information	Food protection website for consumers	* Output 3a: Build a consumer website to communicate relevant food protection information.			
			* Output 3b: Strengthen interagency coordination and public communications during food recalls.			
FY 2008 Increase=$0 7/1/2008 Increase=$0 FY 2009 Increase=$0	4. In a food-related emergency, implement the communications plan, including utilizing all relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and then more resilient population	Communication plan implementation, monitoring and continuous improvement	* Output 4a: Establish a monitoring system to assess whether communication plan was followed.			
			* Output 4b: Develop a continuous process improvement infrastructure for the communication plan.			

*Base funds are being used to initiate these outputs.

Sub-Total, Food Protection Plan	**20,318,000**	**27,804,000**	**30,194,000**
Cost of Living pay increase for onboard food protection employees			**12,038,000**
Total, Food Protection Plan			**$42,232,000**

FOOD PROTECTION OPERATIONS PLAN

Strategic Actions	Strategic Components	Outputs
Food Protection Plan Core Element #1: Prevention $11,413,778		
Key Prevention Step #1.1: Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses		
1. Meet with states and consumer groups to solicit their input on implementing preventive approaches to protect the food supply	Stakeholder outreach on food protection	**Output 1a:** Meet with wide array of FPP stakeholders and other government partners (Federal, State, and local and foreign) to solicit their input on identifying and implementing preventive approaches to protect the food supply.
	Stakeholder engagement/leveraging in	**Output 1b:** Draft a plan based on summary of stakeholder input on how best to involve

	implementation of food protection plan	stakeholders in the implementation of the prevention, intervention and response elements of the FPP.
	Stakeholder and FDA field support	**Output 1c:** Develop a list of specialties that would enhance the effectiveness of food inspections. Identify a team of technical experts with capacity to assist rapid response teams in outbreak investigations and provide liaison and training with ORA field staff, state, and local staff that conduct prevention activities.
2. Meet with food industry representatives to strengthen science-based voluntary prevention efforts, including developing best business practices and food safety guidelines	Understand industry prevention best practices	**Output 2a:** Meet with food and feed industry representatives to discuss how to achieve corporate responsibility, understand industry best practices, and identify how and where preventive controls will work best.
	Promote voluntary preventive controls	**Output 2b:** Promote the adoption of voluntary preventive controls throughout the food supply based on industry best practices by collaborating on training workshops to assist industry in achieving prevention objectives.
3. Develop written food protection guidelines for industry to a) develop food protection plans for produce and other food products, and b)	FDA Prevention Guidances/Regulations, Outreach & Training	**Output 3a:** Develop plan to address other specific high-risk foods of concern from intentional or unintentional contamination.

implement other measures to promote corporate responsibility		**Output 3b:**-Develop specific guidance and implement guidance through outreach and training.
4. Issue in Spring 2008, a final regulation requiring measures to prevent salmonella in shell eggs and resulting illnesses	Salmonella regulation	**Output 4:** Work to deliver final regulation defining preventive management practices to salmonella from eggs and resulting illnesses. Implement regulation through outreach and training.
5. Meet with foreign governments to share results of domestic prevention efforts and develop approaches for improving food safety at the source	Collaboration with foreign governments	**Output 5:** Share risk- and life-cycle-based surveillance approaches, examples of corporate food protection plans, and other results of domestic prevention efforts for improving food safety at the source. • Examine best practices around the food safety control systems of other countries as well as increase understanding of the difficulties faced in implementing food protection measures.
6. Provide foreign countries with technical assistance so that they can enhance their regulatory systems	Provide technical assistance to foreign governments	**Output 6:** Develop mechanisms/protocols to provide technical assistance to foreign countries so that they can enhance their food and drug regulatory systems.

7. Analyze food import trend data and integrate it into a risk-based approach that focuses inspection resources on those imports that pose the greatest risk	Import Trend Data for Risk Ranking	**Output 7:** Produce analysis of food import data, including a ranking of food imports according to risk. Work with ORA to update future import inspection work plan based on risk ranking of imports.
8. Focus foreign inspections on high-risk firms and products	FDA Risk-Based Foreign Inspections	**Output 8:** Formalize the high risk criteria used to identify foreign facilities. Increase foreign inspections of high-risk firms identified by more accurate risk profiling.
9. Improve FDA's presence overseas	FDA Foreign Presence	**Output 9a:** Establish FDA Field Office in China.
		Output 9a1: Conduct bilateral meetings as agreed to under the China MOA. **Output 9b:** Develop a plan to increase FDA presence in other countries/regions of concern, such as India.
Key Prevention Step #1.2: Identify Food Vulnerabilities and Assess Risks		

1. Work with the food industry, consumer groups, and Federal, State, local and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities	Data Gathering	**Output 1a:** Identify additional information needs to strengthen FDA understanding of food safety and food defense risks and vulnerabilities.
		Output 1b: Conduct research and obtain scientific data to identify and counter unintentional and intentional food contamination.
2. Use enhanced modeling capability, scientific data, and technical expertise to evaluate and prioritize the relative risks of specific food and animal feed agents that may be harmful	Risk Ranking, aid industry efforts to achieve corporate responsibility	**Output 2a:** Build a team to enhance modeling capability for relative risk ranking.
		Output 2a1: Conduct research to evaluate and prioritize risks of food and feed agents that may be harmful.
		Output 2b: Determine a ranking of the top priorities for risk evaluation of commodity-agent combinations.
		Output 2c: Increase software capacity to assist industry with identifying areas of food safety risk through CARVER-type model for domestic manufacturer and grower use.

		Output 2d: Using findings from the research of Salmonella strains, initiate development of an integrated genomic database to be used for the risk assessment of foodborne pathogens.
3. Establish a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease	Risk-Based Process for Targeting FDA actions/resources	**Output 3a:** Develop a risk-based process to continuously evaluate which FDA-regulated products cause the greatest burden of foodborne disease.
4. Work with CDC to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated	Better attribution data collected	**Output 4a:** In collaboration with CDC, identify data needed for optimal attribution needs. Work with CDC to help design better tools for use by States and locals in conducting epidemiological investigations to obtain the data.
	Data analysis, real time reporting of data, risk communication	**Output 4b:** Work with CDC on analysis of the data that CDC acquires and provides.
	Risk ranking, apply findings to review of product life cycle	**Output 4c:** Determine which food/pathogen pairs present the highest risk, i.e. develop a risk ranking of food/pathogen pairs.
Key Prevention Step #1.3: Expand the Understanding and Use of Effective Mitigation Measures		

1. Focusing on higher risk foods, develop and implement a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination	Identify research needs for high risk foods	**Output 1a:** For higher risk foods, work to understand, identify and target effective mitigation strategies thorough the development of a basic research plan on sources of contamination, modes of spreading and best methods to prevent contamination for higher risk foods.
2. Research, evaluate, and develop new methods to detect food contaminants	Conduct basic research	**Output 2a:** Based on research plan for high risk foods, initiate basic research and leverage with outside organizations to determine possible mitigation steps to identifying and mitigate unintentional and intentional food contamination.
3. Encourage outside development of new contamination detection and prevention technologies	Develop new platform technologies	**Output 3a:** Encourage the development by outside parties of new and innovative platform technologies for detecting contaminants in foods. Meet with various outside groups to encourage development of microarray, optical mapping, and biosensors for detect and ID of enteric bacteria that may be accidental or intentional contaminants in the food supply.
	Develop better detection tools	**Output 3b:** Encourage the development by outside parties of hand held rapid detection tools to identify an increased number of foodborne pathogens.
4. Develop websites and other platforms for disseminating research results and new steps industry can use to address vulnerabilities	Communicate research results, aid industry efforts to achieve corporate responsibility	**Output 4a:** Produce website for disseminating research results and guidance to industry on effective steps to mitigate vulnerabilities.

Food Protection Plan Core Element #2: Intervention $15,606,555		
Key Intervention Step #2.1: Focus Inspections and Sampling Based on Risk		
1. Focus food and feed safety inspections and sampling based on risk	Focused, risk-based inspections and sampling	**Output 1a: Domestic inspection and sampling activities.** •Target domestic food field exams.
		Output 1b: Foreign / import inspection and sampling activities. • Target import food field exams. • Reengineer Foreign Inspection Program inspections to be based on risk.
	Enhance State inspections	**Output 1c:** Prioritize inspections based on risk using tools that include FDA and State inspection and enforcement data.
		Output 1d: Improve State access (current 40 states food and BSE) to eSAF (electronic State Access to FACTS) to include elimination of duplicate entry, electronic Seafood HACCP forms, better work planning, and assignments. View other state inspection data.

2. Identify, evaluate and, if appropriate, validate and implement innovative foodborne pathogen detection methods and tools capable of quickly and accurately detecting contaminants in foods, such as real-time diagnostic instruments and methods that allow for rapid, on-site analysis of a particular sample	Rapid Detection and Testing	**Output 2a:** Choose and evaluate methods appropriate for detecting contaminants in foods. • Develop enhanced screening kits and new methods to address new pathogens and speed analysis. • Develop fast and inexpensive techniques using microarray technology to detect antibiotic resistance markers in Salmonella and E-coli 157:H7. **Output 2b:** Initiate work with industry and States to establish the means to rapidly determine exact sources of contamination and halt further distribution.
3. Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies	Inspector Training	**Output 3a:** Update existing FDA and state investigator training to incorporate new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment and modern inspectional strategies. • Train FDA and state investigators on new, technically complex, and specialized food manufacturing processes, as determined by a risk-based needs assessment, and modern inspectional strategies. • Develop a training program to ensure feed inspections conducted by our state counterparts meet FDA standards for inspections.

4. Collaborate with foreign authorities to reduce risk of imported food	Leverage with Foreign Counterparts	**Output 4a**: Review and enhance existing information sharing agreements and explore developing new information sharing agreements with foreign authorities to leverage their inspection and certification data. Plan to prioritize information sharing agreements based on the value of such agreements to FDA and consumer protection.
5. Voluntary certification programs for foreign firms and importers	Voluntary Certification	**Output 5a:** Work to understand existing standards and certification programs and consider incentives to encourage broader participation.
Key Intervention Step #2.2: Enhance Risk-Based Surveillance of Imported Foods at the Border		
1. Further enhance FDA's ability to target imported foods for inspection based on risk and publish the *Prior Notice of Imported Foods* Final Rule by the end of 2007 as part of Bioterrorism Act implementation	Tools to target high-risk foreign firms	**Output 1:** Work to publish the Prior Notice of Imported Foods Final Rule as part of Bioterrorism Act implementation.

2. Conduct foreign food and animal feed inspections more efficiently using the tools designed to target high-risk firms		**Output 2a:** Enhance FDA Import Programs to focus on imported product life-cycle. • Update the inspection work plan to use the tools designed to target high-risk firms.
		Output 2b: Redesign sampling strategies.
3. Use advanced screening technology at the border	Automated screening technologies	**Output 3:** Identify and deploy advanced screening technology for border control. • Identify advanced screening technologies that would have a big impact in terms of improving risk-based screening of food imports at the border. Compare these screening technologies against PREDICT and choose the technology to be deployed widely. • Expand software capacity for risk-based sampling strategies (PREDICT model or other) for imported products and domestic retail. • Expand staff to redesign sampling strategies. • Deploy advanced screening technology, contingent on availability of risk-based criteria and maturity of PREDICT.
4. Improve data quality and handling capacity for food imports	Better data on food imports	**Output 4a:** Enhance data capture for imports • Increase access to data across agencies (e.g. USDA, Customs), contingent upon IT integration at FDA and participation of other agencies.
	Import Alert System	**Output 4b:** Improve Import Alert System

		• Automate the Import Alert/Bulletin System to receive recommendations; shorten the development, clearance and implementation timeframes; include mandatory time frames for the clearance process. • Develop a system that will allow Import Alerts (IA's) and Import Bulletins (IB's) to be written, issued, and stored in a manner that would allow easy search, tracking, and trending capability. • Develop an automated system to cross reference various agency databases. • improved data quality and handling capacity for imports.
5. Enhance information sharing agreements with key foreign countries	Information sharing	**Output 5:** Enhance use of information sharing agreements with foreign countries on mutually agreed upon food products where there is a measurable benefit to FDA.
Key Intervention Step #2.3: Improve the Detection of Food System "Signals" that Indicate Contamination		
1. Deploy new rapid detection tools and methods to identify pathogens and other contaminants	Deployment of new rapid detection tools and methods	**Output 1a**: Train analysts and investigators on new tools and methods.
		Output 1b: Evaluate and identify additional inspection tools; conduct inspections and investigations using these new rapid detection tools and methods.

2. Improve FDA's Adverse Event and Consumer Complaint Reporting System, including capturing complaints made to food manufacturers and distributors	Trace-back software	**Output 2a**: Enhance and test software for mapping adverse events to causes.
	Adverse event and consumer complaint reporting	**Output 2b**: Improve the Consumer Complaint Reporting System so that it captures complaints made to food manufacturers and distributors.
	Dietary Supplements	**Output 2c**: Develop and implement a plan to enhance surveillance of dietary supplements.

3. Work to create a Reportable Food Registry for reports of a determination that there is a reasonable probability that the use of or exposure to an article of food will cause serious harm or death to humans or animals [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)]; under FDAAA, industry is expected to report such situations to the FDA within 24 hours	Reportable Food Registry	**Output 3a:** Establish a *Reportable Food Registry* for industry reports of certain adulterated foods.
4. Work to create an Early Warning Surveillance and Notification System to identify adulterated pet food products, outbreaks of pet illness and to provide notice to veterinarians and other stakeholders during pet food recalls [as defined in the 2007 Food and Drug Administration Amendments Act (FDAAA)].	Pet food safety database	**Output 4a:** Establish an early warning surveillance and notification system to identify adulteration of pet food supply and outbreaks of illness associated with pet food.
		Output 4b: Develop a centralized database for veterinarians that captures data on food safety incidents and causes.

Food Protection Plan Core Element #3: Response $3,173,667		
Sub-Element #3.1: Improve Immediate Response		
1. Enhance the data collection, incident reporting and emergency response mapping capabilities of FDA's Emergency Operations Network Incident Management System	Emergency Operations Network Incident Management System	Output 1: Improve data collection and incident reporting. • Enhance mapping capability of emergency response resources, in coordination with the HHS Office of the Secretary and other HHS agencies.
2. Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients	Track-back process	**Output 2a**: Working with stakeholders, develop an action plan for implementing more effective trace-back process improvements and technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. **Output 2b**: Improve trace-back process protocol.

3. Increase collaboration with foreign, federal, state, and local FDA partners to identify a contamination source, remove contaminated products, and implement corrective actions (ISAP lead with FPP coordination)	Emergency response coordination	**Output 3a:** Enhance FDA's ability to coordinate a comprehensive FDA response to foodborne illness events, outbreaks and emergency situations by reviewing and improving the protocol and roles and responsibilities for emergency coordination. • Acquire staffing resources to provide optimal Agency response (OCM). • Hire and train emergency coordination staff (CVM). • Coordinate Agency participation in exercises and workgroups related to emergency preparedness, response and counterterrorism, such as the TOPOFF 5 Exercise.
		Output 3b: Work with states to initiate the establishment of state and regional rapid response teams.
4. Enhance information technology networking with selected federal, state, and local testing labs to communicate real-time testing results among FDA and lab members	IT networking with partners	**Output 4a**: Enhance information technology networking with selected federal, state, and local testing labs to communicate timely testing results among FDA and lab members, contingent on training.
	Lab capacity	**Output 4b**: Expand FDA, State, and foreign lab capacity, contingent on availability of FERN training and equipment for disciplines in biological, chemical, and radiological methods.

Sub-Element #3.2: Improve Risk Communications to the Public, Industry and Other Stakeholders		
1. Work with communications and media experts, including FDA's Risk Communication Advisory Committee, to design and conduct consumer communications and behavior response studies	Communication working group and research	**Output 1:** Consider appropriate methods for consumer communications.
2. Based on that research, update the Food Protection Risk Communications Plan using the most effective strategies for sharing information with consumers	Updated communication plan	**Output 2**: Update the Food Protection Risk Communication Plan using the most effective strategies for sharing information with consumers. • Improve current process for handling consumer complaints and inquiries based on needs assessment. • Review and improve food protection communication process to increase timeliness of food protection messages.
3. Build a consumer website to communicate relevant food protection information	Food protection website for consumers	**Output 3a**: Build a consumer website to communicate relevant food protection information.
		Output 3b: Strengthen interagency coordination and public communications during food recalls.
4. In a food-related emergency, implement this communications plan, including utilizing all	Communication plan implementation, monitoring and	**Output 4a**: Establish a monitoring system to assess whether communication plan was

relevant media and technologies to reach consumers, retailers, industry, public health officials, and other stakeholders resulting in a better informed and thus more resilient population	continuous improvement	followed. **Output 4b**: Develop a continuous process improvement infrastructure for the communication plan.
	Subtotal	**$30,194,000**
	Cost of living pay increase for onboard food protection employees	**$12,038,000**
	Total	**$42,232,000**

Protecting America's Food Supply: An Investment in the FDA Food Protection Plan
+$42,232,000 / 94 FTE

1. Why is this funding necessary?

A. Background

The U.S. food supply has changed dramatically in recent years due to consumer demand, changes in processing and distribution practices, and increasing globalization of the food market. The result is faster and more widespread distribution of food and increasing specialization in the manufacture of food ingredients.

At the same time, the volume of imports continues to outpace FDA's ability to respond. Imports have doubled during the past five years. The volume of FDA-regulated foods now exceeds 9.5 million import entries annually.

To respond to these challenges, FDA must shift to a comprehensive, preventative, and risk-based approach to safeguard the food supply and the American homeland. FDA also must reengineer domestic and import-related policies and procedures. These changes must focus on the most important food defense and food safety considerations throughout the entire product life cycle – from production through consumption.

On November 6, 2007, FDA issued the Food Protection Plan, *An Integrated Strategy for Protecting the Nation's Food Supply* (FPP). The FPP is a comprehensive FDA initiative to protect food and feed. The FPP advances an integrated strategy based on three core elements: prevention, intervention, and response. The foundation of the FPP is identifying potential food defense and food safety threats and counteracting them before they harm consumers.

Today, FDA devotes most of its food-related resources to post-market surveillance and to responding to food contamination events. Under the FPP, FDA will continue to invest in post-market activities and maintain the capability to respond rapidly to incidents of food contamination when they surface. However, FDA will also invest more resources to prevent intentional and unintentional food contamination before problems appear. Only by focusing greater attention on food production and food handling sites – wherever they are located – can FDA protect the American homeland and the U.S. economy from food safety and food defense threats.

B. FDA's Food Protection Plan

FDA is responding to food defense and food safety challenges with FPP, a risk-based, production-to-consumption strategy to ensure the safety of domestic and imported food. FPP integrates food and feed safety with food and feed defense.

The three core elements of FPP – prevention, intervention, and response – are based on a rigorous science and information technology infrastructure. The FPP strategy focuses on

preventing foodborne illness outbreaks, intervening when vulnerabilities surface or problems emerge, and rapidly responding to threats. With the investments in this FY 2009 initiative, FDA will work with the Department of Homeland Security, the U.S. Department of Agriculture, the Centers for Disease Control and Prevention, state, local, and foreign governments, and the domestic and international food industry to safeguard America's food and the national infrastructure of vital food commodities.

FDA has prepared an Implementation Plan for FPP that appears in the exhibit section of this Congressional Justification document. The Implementation Plan contains additional details of the steps that FDA is taking to implement the FPP.

C. Import Safety Action Plan

In conjunction with the November 6 release of the FPP, the Administration announced the release of the Import Safety Action Plan. The Import Safety Action Plan includes short- and long-term recommendations to improve the safety of imports entering the United States. Implementing the Import Safety Action Plan recommendations in conjunction with FPP will result in a system that builds safety into imported foods every step of the way.

D. Cost of Living Pay Increase for FDA Food Defense and Food Safety Programs

FDA regulates a diverse and complex portfolio of products that account for 20 percent of U.S. consumer spending. FDA can only accomplish these responsibilities if it has sufficient resources to pay the scientific, professional, and technical staff that is essential to FDA operations.

Performing the FDA mission is a personnel-intensive agency. FDA delivers its public health mission through a highly trained professional workforce. Personnel and related costs account for 80 percent of FDA's annual expenditures. To maintain a strong scientific capability, FDA must employ, train, develop, and retain highly trained professionals to perform the mission critical work of protecting public health.

The Protecting America's Food Supply Initiative includes funds for the cost of living pay increase for employees who contribute to FDA's food defense and food safety programs. If FDA does not receive the resources to pay these costs, FDA cannot fulfill its fundamental mission to the American public. Providing funds to meet the annual pay increase allows FDA to achieve performance commitments and ensures that FDA can anticipate and respond to public health emergencies.

2. What activities will the funds support?

A. Funding Table

The table below displays the distribution of funds for this initiative across FDA programs.

Protecting America's Food Supply

Dollars in millions

Program	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	+/- FY 2008
Foods	**$453.700**	**$505.110**	**$537.777**	**+$32.667**
Center	157.631	169.588	179.640	+$10.052
Field Activities	296.069	335.522	358.137	+$22.615
Animal Drugs and Feeds	**74.833**	**76.653**	**82.271**	**+$5.618**
Center	40.265	41.219	45.305	+$4.086
Field Activities	34.568	35.434	36.966	+$1.532
National Center for Toxicological Research	**3.441**	**4.323**	**6.056**	**+$1.733**
Headquarters and OC	**31.559**	**33.526**	**35.740**	**+$2.214**
Total, Budget Authority	**$563.533**	**$619.612**	**$661.844**	**+$42.232**

[1] *Includes funds for Dietary Supplements and Nutrition/Food Labeling activities (FY 2007=$23.686 M, FY 2008 and FY 2009=$27.220M)*

B. Specific Activities Funded by this Initiative

FDA's FY 2009 budget proposes the following investments to protect America's food supply:

i. Prevention–

Prevention is the cornerstone of an effective, proactive food defense and food safety strategy. Assisting industry to implement preventive control measures is essential to prevent intentional or unintentional contamination of the food supply. The prevention element of the FPP allows FDA to support industry with scientific and analytical tools to better identify and understand food defense and food safety risks and the effectiveness of control measures used to protect the food supply.

In FY 2009, FDA will make priority prevention investments in the following areas:

- FDA will **Facilitate Corporate Responsibility** by working with domestic and international partners to support industry efforts to institute corporate prevention

responsibilities and objectives. This component of the prevention strategy facilitates appropriate food defense and food safety standards for all phases of food production.

- FDA will **Determine Vulnerabilities and Areas of Risk** through improved surveillance systems, risk assessments and risk modeling, and statistical sampling. FDA will establish the capacity to target high-risk food defense and food safety threats.

- FDA will **Establish an FDA Office in China** to better protect American consumers from unsafe products. As recent events highlight, China is a leading source of food imports into the United States. A full-time office in China is necessary due to the increased risk and volume of food and feed imports arriving from China.

- FDA will **Expand Science** that identifies food safety threats, sources of contamination, their mode of spread, and options to prevent contamination. A risk-driven, science-based approach to understanding threats to the food supply is the foundation of FDA's food protection strategy.

ii. Intervention–

Risk-based intervention supplements the protection element of the strategy by monitoring the success of, and identifying weaknesses in preventive measures. Intervention augments prevention through inspection and sampling techniques that use modern detection technology.

FDA will strengthen the information technology systems that support intervention activities. Modern IT systems improve FDA's ability to target and conduct inspection and surveillance, perform laboratory analysis, and achieve reliable 24/7 operations.

In FY 2009, FDA will make priority intervention investments in the following areas:

- FDA will **Ensure Adequacy of Industry Prevention Strategies** through increased risk based inspections, audits of controls designed to prevent contamination, and sampling at the source.

- FDA will **Conduct Expanded Risk-Based Surveillance** across the food and feed chain to identify gaps in detecting food and feed threats and to institute corrective action before illness or injury occurs.

- FDA will **Enhance the Ability to Detect** and quickly identify risk signals by deploying new rapid screening tools and methods to identify pathogens and other contaminants in food and feed.

- FDA will **Increase Food and Feed Sampling and Testing** through improved laboratory analysis. FDA must increase surveillance of animal food and feed ingredients to protect consumers from intentional and unintentional threats to vital components of the food chain.

iii. Response–

The response element of the strategy will reduce the length of time between detecting and containing foodborne illness. FDA's recent experience with spinach and leafy greens, melamine, peanut butter, and other contaminated products demonstrates the need for more effective response strategies. FDA must respond faster, communicate more effectively to consumers and FDA food safety partners, and limit economic consequences for affected industries. FDA also must strengthen its response systems and further integrate them with state, local, federal, and international agencies.

In FY 2009, FDA will make priority response investments in the following areas:

- FDA will **Enhance Rapid Response Capacity** by leveraging state resources and strengthening FDA and state rapid response capability.
- FDA will **Upgrade Emergency Response** and traceback capabilities and systems. These systems are critical for quick response during an outbreak of foodborne illness.
- FDA will **Improve Risk Communication** to rapidly and effectively respond to consumer concerns during and after an event, and educate consumers about food safety issues.

iv. Food Defense and Food Safety IT Investments–

To support all three elements of the strategy to Protect American's Food Supply, FDA will upgrade IT systems to rapidly identify food importers and facilitate FDA's ability to maintain, update, and search records and data on food establishments and shipments. FDA will collaborate with Customs and Border Protection on systems to accurately identify firms involved in the food import supply chain.

v. Cost of Living Pay Increase for Food Defense and Food Safety Programs–

Funding the cost of living pay increase allows FDA to retain its professional workforce by paying salary increases that track the cost of living. Without these funds, FDA must reduce the number of inspectors, consumer safety officers, food defense researchers, food safety technologists, and other health experts that perform essential functions in FDA's mission to protect and promote public health.

3. What are the risks of not proceeding with the initiative?

A. FDA Food Defense and Food Safety Programs

Not funding this initiative threatens the Federal government's ability to protect the American public from unsafe food. Not funding this initiative also diminishes FDA's ability to prevent or respond to a terrorist attack or a public health emergency related to food. Not providing sufficient resources to launch the Protecting American's Food Supply strategy will have far-reaching consequences:

- Significant outbreaks of foodborne illness will continue in the United States because FDA does not have the scientific- and risk-based techniques to identify and eliminate foodborne hazards and prevent contaminated foods from reaching American consumers.

- Imported foods will remain a safety and security threat. Products from countries with high-risk food production, manufacturing, and distribution systems will continue to enter U.S. commerce without appropriate surveillance.

- FDA and our industry partners will not achieve the ability to rapidly trace the origin of foods implicated in intentional or unintentional adulteration.

- American consumers will continue to suffer significant adverse health consequences, including morbidity and death, because FDA cannot establish a strong, science-based regulatory framework with prevention standards to ensure the safety and defense of food.

- The confidence of American consumers in the safety and security of the food supply will remain low. Consumers will avoid certain foods such as fruits and vegetables and will not fully benefit from foods that are essential to a healthy diet. This will increase morbidity and mortality from chronic diseases and impose significant public health impact and costs.

B. Cost of Living Pay Increase for Food Defense and Food Safety Programs

Failing to fund this initiative means that FDA must reduce core public health programs, including our professional staff that performs the FDA mission. Failing to fund the cost of living pay increase will result in an FDA-wide loss of 90 FTEs. This total includes 54 Field FTEs who perform work in food protection program areas.

If FDA does not receive these funds, FDA must reduce staff so that FDA can pay mandatory cost of living increases for the remaining staff. The loss of these scientific and technical experts will impair FDA's ability to fulfill its public health responsibilities and to recruit, train, and retain a world-class scientific workforce. A diminished FDA workforce will limit FDA's ability to reduce food defense and food safety threats, secure the homeland, and to protect the health and security of the American people.

4. How does this initiative support Executive Branch public health priorities?

The FDA Protecting America's Food Supply Initiative implements the Food Protection Plan, the Import Safety Action Plan, the December 11, 2007 agreements with China on food protection, and elements of the Food and Drug Administration Amendments Act. This initiative also secures the homeland and strengthens the nation by improving food safety and food defense through better oversight of manufacturing, production, and distribution here and abroad. The strategy achieves core FDA responsibilities under Homeland Security Presidential Directive 7 (Infrastructure) and Homeland Security Presidential Directive 9 (Food Defense).

5. What will FDA accomplish with this initiative?

The Protecting America's Food Supply strategy will allow FDA to achieve significant near-term food protection accomplishments in FY 2009. These accomplishments will provide a foundation for substantially reducing illnesses caused by contamination of the food supply in the following years.

The foundation of this strategy is a risk-focused science-based approach that builds new and greater food protection capabilities over several years. While there are significant early benefits to this comprehensive approach, FDA and its partners will achieve even greater reductions in risk to the food supply as the prevention strategies mature and FDA implements risk-based improvements to field operations.

During FY 2009, FDA will achieve significant results that contribute to food protection:

A. Prevention–

FDA will begin to provide industry with new control measures throughout all levels of the food production and processing chain. For example, control measures will include practices and intervention steps to prevent or reduce the growth and survival of pathogens on produce.

By establishing an FDA presence in China, FDA will more effectively implement the December 11, 2007 Agreement with China to improve the safety of food and feed. An office in China is an essential platform to conduct training, audits, and technical assistance in China to better protect American consumers.

FDA will develop the food safety and food defense science upon which regulatory decisions and enforcement rely. FDA will also increase food safety and food defense technical assistance to industry groups, other agencies, and FDA's international partners.

FDA's Animal Drugs and Feeds Program will improve the animal seed safety system to better safeguard animal feed and feed ingredients from food defense and food safety threats. FDA will also protect animal feeds from harmful ingredients, tampering, and contamination.

B. Intervention–

FDA's field operations will ensure the adequacy of industry prevention strategies through increased risk based inspections, audits of controls designed to prevent contamination, sampling, and surveillance. Specifically, FDA will conduct the following field operations with base funding and the FY 2009 increase proposed in this initiative:

- 20,000 additional import food field exams
- 1,057 additional domestic food safety inspections
- 50 additional foreign food inspections
- an additional 30 domestic and 30 import food sample collections and analyses
- an additional 30 domestic and 35 import animal feed sample collections and analyses

- 90 additional imported and domestic cheese program inspections
- 92 additional domestic low acid canned food inspections
- 50 additional domestic fish and fishery Hazard Analysis and Critical Control Point (HAACP) inspections
- 85 additional juice HAACP inspections.

C. Response–

FDA will strengthen its emergency response infrastructure to respond to incidents. FDA will also enhance the functionality of essential systems to respond to emergencies.

FDA's field operations will develop three cooperative agreements to support state food defense and food safety infrastructure. FDA's field operations will develop and maintain rapid response teams.

FDA will begin to develop a Risk Communication Program to provide transparent outreach to consumers via website, press releases, and other means of communication to ensure that FDA shares information with consumers and industry in a timely and efficient manner.

D. Cost of Living Pay Increase for Food Safety and Food Defense Programs–

Funding the annual cost of living increase allows FDA to extend through FY 2009 the strong performance levels that FDA has targeted for FY 2008. In contrast, failing to fund the cost of living pay increase will cause deterioration in performance across all FDA program areas.

Source: FDA website June 05/2008

Implementing FDA's Food Protection Plan

On November 6, 2007, FDA issued the Food Protection Plan, *An Integrated Strategy for Protecting the Nation's Food Supply* (FPP). This document is a comprehensive FDA initiative to protect food and feed.

The FPP advances an integrated strategy based on three core elements: prevention, intervention, and response. The foundation of the FPP is to identify potential food defense and food safety threats and counteract them before they can harm consumers.

On December 26, 2007, the President signed the Consolidated Appropriations Act into law, which provides appropriations for FDA for FY 2008. The Congressional statement to accompany the conference agreement for this appropriations act advised FDA to articulate a plan for organizational, managerial, statutory, and regulatory changes to protect the food supply that FDA regulates.

This exhibit responds to the request for FDA to articulate the implementation plan requested in the statement to accompany the conference agreement. This exhibit refers to three components: the FPP, the FPP organizational plan, and the FPP operations plan. These three components are part of the FDA response to the statement in the conference agreement.

The full text of FDA's Food Protection Plan, which also is a component of this exhibit, appears at: **http://www.fda.gov/oc/initiatives/advance/food/plan.html**. Finally, the business case paper, "Protecting America's Food Supply: An Investment in the FDA Food Protection Plan" also is a component of this exhibit. This business case paper is printed in the Executive Summary of the FY 2009 Congressional Justification.

The statement to accompany the conference agreement requests that FDA provide a plan to improve food defense and food safety. The November 6, 2007, Food Protection Plan responds to the request in the conference agreement. The FPP Operations Plan, which is a component of this exhibit, also responds to the request in the conference agreement.

The FPP Operations Plan charts FDA's strategic actions, components, and outputs to achieve the food defense and food safety goals in FDA's Food Protection Plan. As the statement to accompany the conference agreement requests, the detail in the FPP Operations Plan reflects benchmarks and goals to improve the safety of domestic and imported foods over a multiyear period. The information in the FPP Operations Plan contains the detail that responds to the request in the conference agreement. The FPP Operations Plan also supplements and expands on the goals that FDA articulated in the Food Protection plan.

The FPP Operations Plan is a multiyear implementation plan. FDA will use FY 2008 and requested FY 2009 resources to initiate the actions identified in the Food Protection Operations Plan and achieve the food defense and food safety priorities in the Food Protection Plan.

The statement to accompany the conference agreement also requests that FDA describe organizational, managerial, statutory, and regulatory changes necessary to achieve the goals of

the Food Protection Plan. The two section headings that appear below (FPP Organization and Management Structure; FPP Proposed Legislative and Regulatory Changes) contain FDA's response to this request.

Finally, the statement to accompany the conference agreement requested that FDA include statutory language for legislative proposals that strengthen food defense and food safety. FDA identified and described ten proposed statutory changes in the text of the Food Protection Plan. The Administration intends to provide technical assistance to Congress to enact the ten legislative proposals in the Food Protection Plan.

Background on the FPP

The FPP details FDA's food safety and food defense goals. The FPP is a comprehensive approach to food safety and defense, covering both domestic and imported food. The FPP includes actions tied to risk-based preventive controls (HAACP-like systems) and a process for reviewing the food safety systems in countries that export food to the United States. Finally, the FPP contains other important prevention, intervention, and response actions.

The FPP operates through a set of integrated strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems

FDA's Integrated Strategy Provides Three Elements of Protection.

Prevent Foodborne Contamination:

- Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses
- Identify Food Vulnerabilities and Assess Risks
- Expand the Understanding and Use of Effective Mitigation Measures

Intervene at Critical Points in the Food Supply Chain:

- Focus Inspections and Sampling Based on Risk
- Enhance Risk-Based Surveillance
- Improve the Detection of Food System "Signals" that Indicate Contamination

Respond Rapidly to Minimize Harm

- Improve Immediate Response
- Improve Risk Communications to the Public, Industry and Other Stakeholders

FPP Organization and Management Structure

Due to the overlapping nature of the FPP and the related Import Safety Action Plan (ISAP), FDA established a structure to ensure that each FDA component has a clear lead(s) and that the implementation of these plans is fully coordinated. As shown in the organizational chart in this exhibit, Dr. David Acheson, in his role as Associate Commissioner for Foods within the Office

of the Commissioner, has the overall management lead for implementing the Food Protection Plan. Assistant Commissioner for Policy Jeff Shuren and Associate Commissioner for Regulatory Affairs Margaret Glavin have overall responsibility for implementing the IASP.

Cross-cutting Implementation Teams supports the implementation of the FPP and IASP. These teams have representation from the following organizations within FDA:

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Office of the Commissioner (OC)
- Office of External Relations (OER)
- Office of Crisis Management (OCM)
- Office of General Counsel (OGC)
- Office of Information Technology (IT)
- Office of International Programs (OIP)
- Office of Management (OM)
- Office of Policy and Planning (OPPL)
- Office of Regulatory Affairs (ORA)

An Internal Steering Committee, which has oversight of the implementation and integration of the FPP with the Import Safety Action Plan, coordinates the FPP and the ISAP. Dr. Acheson reports on implementation efforts to the Commissioner and to the FDA Management Council, which is comprised of FDA Center Directors and other FDA leadership staff.

FPP Operations Plan

The FPP Operations Plan appears at the end of this exhibit. The Operations Plan contains the goals of the FDA Food Protection Plan, divided into specific multiyear activities. The FDA Food Protection Operations Plan provides measurable benchmarks for achieving the FDA goals set forth in the FDA Food Protection Plan.

FPP Proposed Legislative and Regulatory Changes

The Food Protection Plan proposes ten proposals for legislative authority to safeguard Americans from food defense and food safety threats. The details of the 10 legislative authorities appear on pages 15, 18, 19, 20, and 22 of the FPP. Where necessary, FDA will implement the legislative changes through regulations or guidance to industry.

FDA recognizes the need to partner with Congress to make the changes necessary to transform the safety of the nation's food supply. The FPP identifies the administrative and regulatory actions FDA is proposing to take within the Agency. This Plan also recommends legislative changes to strengthen FDA's ability to continue to protect Americans from foodborne illnesses.

Additional Protections that Involve Legislative Changes to FDA's Authority:

Prevent Foodborne Contamination

- allow FDA to require preventive controls to prevent intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain
- authorize FDA to issue additional preventive controls for high-risk foods
- require food facilities to renew their FDA registrations every two years, and allow FDA to modify the registration categories

Intervene at Critical Points in the Food Supply Chain

- authorize FDA to accredit highly qualified third parties for voluntary food inspections
- require new reinspection fee from facilities that fail to meet current good manufacturing practices
- authorize FDA to require electronic import certificates for shipments of designated high-risk products
- require new food and animal feed export certification fee to improve the ability of U.S. firms to export their products
- provide parity between domestic and imported foods if FDA inspection access is delayed, limited, or denied

Respond Rapidly to Minimize Harm

- empower FDA to issue a mandatory recall of food products when voluntary recalls are not effective
- give FDA enhanced access to food records during emergencies

Following the release of the FPP, FDA immediately began to implement many of the FPP elements. FDA will implement the remaining elements of the FPP over time as noted in the FPP Operations Plan.

courant.com/business/hc-longterm0605.artjun05,0,7696600.story

Courant.com

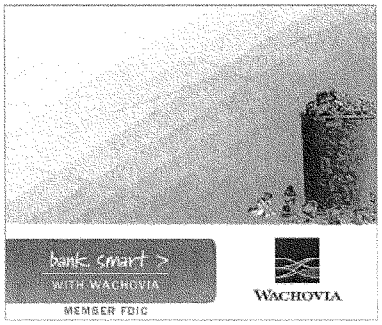
Public May Get Say On Long-Term Insurance Rate Hikes

By DIANE LEVICK

Courant Staff Writer

June 5, 2008

Two Connecticut officials want the state to mandate public hearings on proposed rate increases for long-term care insurance after senior citizens complained about one company's 9 percent jump.



Ironically, Genworth Life Insurance Co.'s 9 percent increase is the smallest sought for such a policy here recently, dwarfed by proposals from other insurers of 29 percent to 49 percent or higher.

A series of large rate increases on older long-term care policies — proposed around the country in recent years — has stirred outrage and raised concern about whether the policies were underpriced initially and that the increases are justified.

In Connecticut, state Sen. Edith Prague, D-Columbia, and state Healthcare Advocate Kevin Lembo say they'll pursue legislation next year to require hearings on insurers' rate filings for the policies, which cover nursing home and at-home care.

The aim is to have the Connecticut Insurance Department hold forums on each proposed long-term care rate increase so consumers can comment and ask questions before regulators rule.

Long-term care policies, after all, aren't cheap to begin with. Even typical policies bought in the late 1980s by a 65-year-old could cost roughly $1,500 a year and top $4,000 if bought at age 75.

Former Connecticut residents Martin and Betty Rogan are each paying $1,460 a year for their long-term policies bought from a Genworth predecessor in 1992, when they were 62 and 61, respectively.

Now the couple, who are in their late 70s and live in Florida and spend summers in Rhode Island, face a choice from Genworth: the 9 percent rate increase approved by regulators April 1 or a comparable cut in the benefits their policies would pay.

"That's entirely unacceptable," said Martin Rogan. It's hard enough for elderly policyholders to keep paying the original rates, and "it's going to be tough to take almost a 10 percent increase," he said. His complaint to Prague and the Insurance Department led to the idea for public hearings.

The department has received 39 complaints so far about the Genworth long-term care increase, but it stands by its approval of the filing. It applies to certain old policies issued to 1,861 Connecticut policyholders.

Although Genworth is raising rates 9 percent, its claim costs have been 15 percent higher than expected, said Paul Lombardo, insurance actuary at the Insurance Department.

"We felt the 9 percent was warranted at this time," Lombardo said, adding that the department is mindful of how rate increases can affect consumers. If regulators don't approve appropriate increases, they may have to worry about companies' solvency later, he said.

A major reason for the rate increase, which Genworth is seeking in other states too, is that far fewer customers let their policies lapse than expected, said Tom Topinka, a Genworth Financial spokesman. When companies set rates for policies such as life or long-term care insurance, they factor in a certain percentage of customers giving up the policies.

Genworth had anticipated that about 5 percent of policyholders a year would voluntarily stop paying their premiums on the long-term care policies. As it turns out, only about 1 percent of policyholders have stopped paying, Topinka said, and more people keeping their policies translates to more claims.

The "modest" rate increase, he added, means about 80 percent of affected policyholders will see a premium increase of less than $20 a month.

Lombardo said the Insurance Department, in about the past 10 months, has rejected these proposed long-term care rate increases from other companies as unjustified:

•American Network, part of Penn Treaty Group, increases ranging from about 15 to 250 percent.

•Life Investors, part of Aegon USA, 29 percent.

•Transamerica, 49 percent.

•Bankers Life and Casualty Co., 27 to 39 percent.

•Lincoln Benefit Life, part of Allstate Financial, an average 31.7 percent.

In addition, the department approved a 10 percent increase for RiverSource Life Insurance Co., part of Ameriprise Financial Group, instead of the 35 percent requested.

Prague says she'll ask the General Assembly's insurance and real estate committee to raise a bill next year to require public hearings on long-term care rate increases. State law has long required hearings on rate filings for Medicare supplement insurance, which some seniors buy to fill in gaps left by the federal Medicare program.

Seniors ought to be heard on long-term care rates, too, because it's often not feasible for them to switch to another long-term care insurer, Prague said. That's because as they age, they're more likely to have health problems that would cause their applications to be rejected. Also, the premiums for a new policy at an advanced age could be prohibitive.

Public hearings on long-term care rate increases give people "an opportunity to participate, ask questions, and feel less like things are [just] happening to them," Lembo said.

He and Prague noted that few, if any, consumers attend hearings on Medicare supplement rates and say that any legislation on long-term care hearings needs to spell out better ways to notify policyholders about hearings and make them more accessible.

Lombardo said that although the department doesn't oppose public hearings, more hearings would tax the agency's resources. Lembo, noting the department is funded by the industry, says money should be available to make the hearings possible.

Contact Diane Levick at dlevick@courant.com.

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For Discussion

Status of Information Technology

June 2008

Overview

1. Past and Current Challenges with FDA Information Technology
2. Solutions to Address the Challenges
3. Resources Associated with Solutions

Past and Current Challenges

- Decentralized approach to IT with minimal or no coordination across FDA
- Antiquated Data Center
- Lacking steady platforms needed to meet Agency wide IT initiatives and dated hardware

For Discussion

Past and Current Challenges

- Extraordinary effort required to prepare, retrieve, and match data for evaluation/analysis due to the varying systems
- Lack of data integration internal and external to FDA

Solutions/Approaches to Address the Challenges

2006-2007:

•Implemented Bioinformatics Board (BIB) to provide strategic direction and coordination of business process and information management (IM) harmonization initiatives.

•5 Business Review Boards to harmonize business processes across FDA strategic lines of business

- Pre-Market
- Post Market Safety
- Product Quality and Compliance
- Administrative Services
- Scientific Computing/Computational Science

•Established Chief Operating Officer (COO) and elevated CIO to respond to the importance and criticality of IT issues/concerns.

Solutions/Initiatives to Address the Challenges

2007

- Business Review Boards identified 5 year goals & strategic objectives for Information Management
- Established 5 FDA-wide IM initiatives
  - Information & Computing Technologies for 21st Century (ICT 21)
  - MedWatch**Plus**
    - Adverse Event Portal
    - FDA Adverse Event Reporting System
  - Harmonized Inventory Project
  - Common Electronic Document Room
  - FDA Advanced Submission Tracking and Review: Information Bus Exchange

Solutions/Initiatives to Address the Challenges

2007 to Present-Continued

- Realigned all IT resources, both project and personnel to the CIO
- Restructured decentralized IT components across FDA to the CIO
- Developed timelines and dashboards for Agency initiative
- Established disciplined focus on cost and standards creating a foundation for long term savings

Solutions/Initiatives to Address the Challenges

2008 & Beyond

- Business driven IT managed as the FDA IT investment portfolio
- Standardize approach to systems development and stabilize platforms based on business modeling to increase interoperability
- Data clean up and elevate data to a Corporate Level Asset through development and implementation Data Standards Strategy
- Minimize redundancy by centralizing IT and obtaining economies of scale across FDA through leveraging Indefinite Delivery/Indefinite Quantity Contracts

Next Steps

- Deliver the infrastructure, systems and functionality to support:
  - FDA Amendments Act (FDAAA)
  - Food Protection Plan (FPP)
  - Import Safety Action Plan (ISAP)
- Pending legislative authority to increase frequency of reporting requirements from industry

Resources for Modernizing FDA Science and Workforce (ICT21)

	FY2008*/FY2009 President's Budget	FY2009 Supplemental	FY2009 Additional Request Beyond Supplemental
Budget Amounts		$5 million	$5 million
Expected Deliverables -	Begin the design and implementation for: •Steady bioinformatics platform •Hardware and software upgrades •Data Standards •Network Connectivity •Computational Science •Improve Disaster Recovery Capability	Implementation and Migration of: •Steady bioinformatics platform •Hardware and software upgrades •Data Standards •Network Connectivity •Computational Science •Disaster Recovery Plan	Future Innovations: •Ability to institute 3 year infrastructure refresh process •Increase network connectivity •Share higher volumes of data •Research and development in partnership with industry to develop innovative information technology •Ability to respond to new and emerging challenges

For Discussion

Food Protection Plan

	FY2008/FY2009 President's Budget	FY2009 Supplemental	FY2009 Additional Request Beyond Supplemental
Budget Amounts	$4.8/$7.9 million	$25 million	$75 million
Expected Deliverables -	Response Enhance current IT infrastructure and systems to better support the FDA's response to food related emergencies.	Intervention and Response •Develop systems to support international data collection and is robust enough to assimilate risk based information for rapid detection •Enhance IT systems network to improve and expedite communications between FDA and federal, state, and local testing labs •Develop systems to traceback products from consumption back to production	Prevention, Intervention, and Response •IT support for data management, storage and analysis & analytical tools to support genomic science •New data mining tools to develop predictive models on health and safety •Applications/tools to support trending capabilities •Advance screening technology •Ability to respond to new and emerging challenges

For Discussion

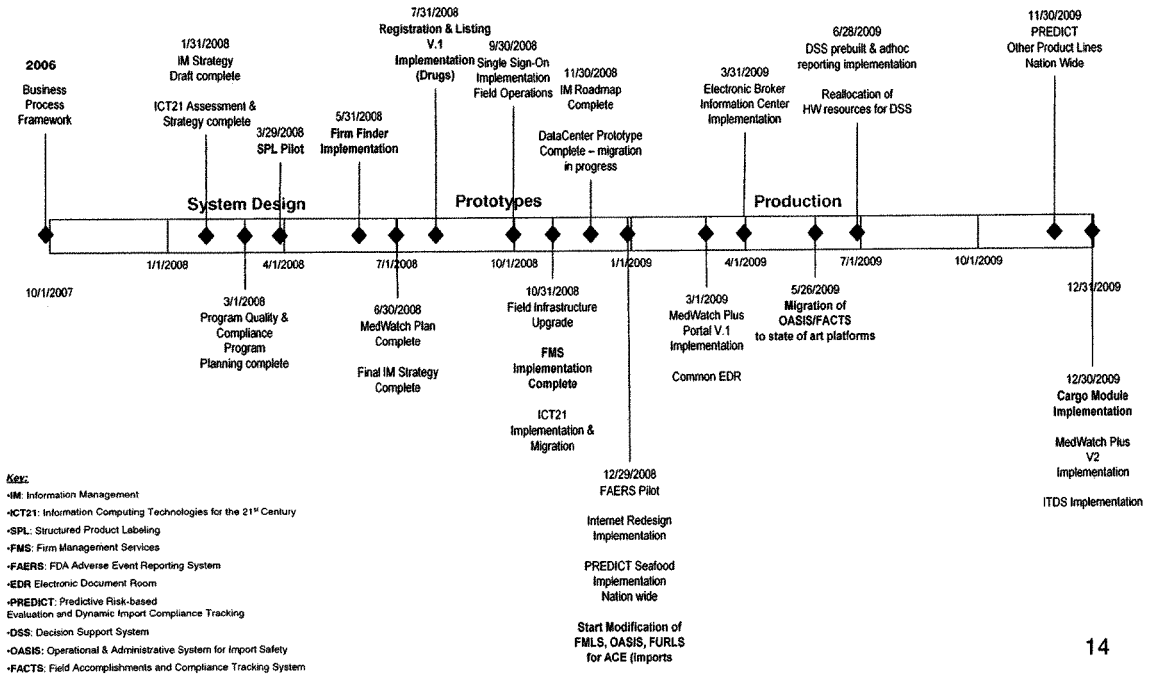
Safer Drugs, Devices and Biologics

	FY2008/FY2009 President's Budget	FY2009 Supplemental	FY2009 Additional Request Beyond Supplemental
Budget Amounts	$125/$125 million	$35 million	$20 million
	Enhance current IT infrastructure and systems to support the FDA's regulatory responsibility to ensure safe use of Drugs, Devices, and Biologics	Design and develop IT systems to support the FDA's goals of strengthening product development, approval, improve manufacturing & quality, strengthen post-marketing surveillance & safety, and support electronic prescribing & clinical decision support. •Clean and integrate data •Develop tools to share data from pre-approval through post-marketing	Plan and design new and innovative Information Technology to support and expedite the FDA's Public Health mission, which include: •Mature electronic health records •Personal health records •Integration of multiple clinical and diagnostic endpoints •Sophisticated software for rapid detection of safety signals and efficacy information •Ability to respond to new and emerging challenges

Solutions

Strategic Investments	Initiatives contained within Strategic Investment
Food Protection Plan	1. Harmonized Inventory ♦ Paperless submissions ♦ FURLS REALMS ♦ Supply Chain Management ♦ SEDS – DUNS Number pilot 2. MARCS 3. PREDICT 4. ACE/ITDS 5. RBIS 6. eLexnet- ♦ Expanded laboratory network support
Safer Drugs, Devices, and Biologics	1.Medwatch Plus Portal ♦Early warning surveillance and notification system ♦FDA Adverse Event Reporting System 2.Common EDR 3.FASTAR (Information Exchange Bus)
Modernizing FDA Science and Workforce:	1.ICT 21 ♦Data Center (White Oak Networking) ♦Hardware and Software ♦Security ♦Networking/Connectivity ♦Computational Sciences

IM Initiatives Timeline



Key:

- **IM**: Information Management
- **ICT21**: Information Computing Technologies for the 21st Century
- **SPL**: Structured Product Labeling
- **FMS**: Firm Management Services
- **FAERS**: FDA Adverse Event Reporting System
- **EDR** Electronic Document Room
- **PREDICT**: Predictive Risk-based Evaluation and Dynamic Import Compliance Tracking
- **DSS**: Decision Support System
- **OASIS**: Operational & Administrative System for Import Safety
- **FACTS**: Field Accomplishments and Compliance Tracking System
- **ITDS**: International Trade Data System

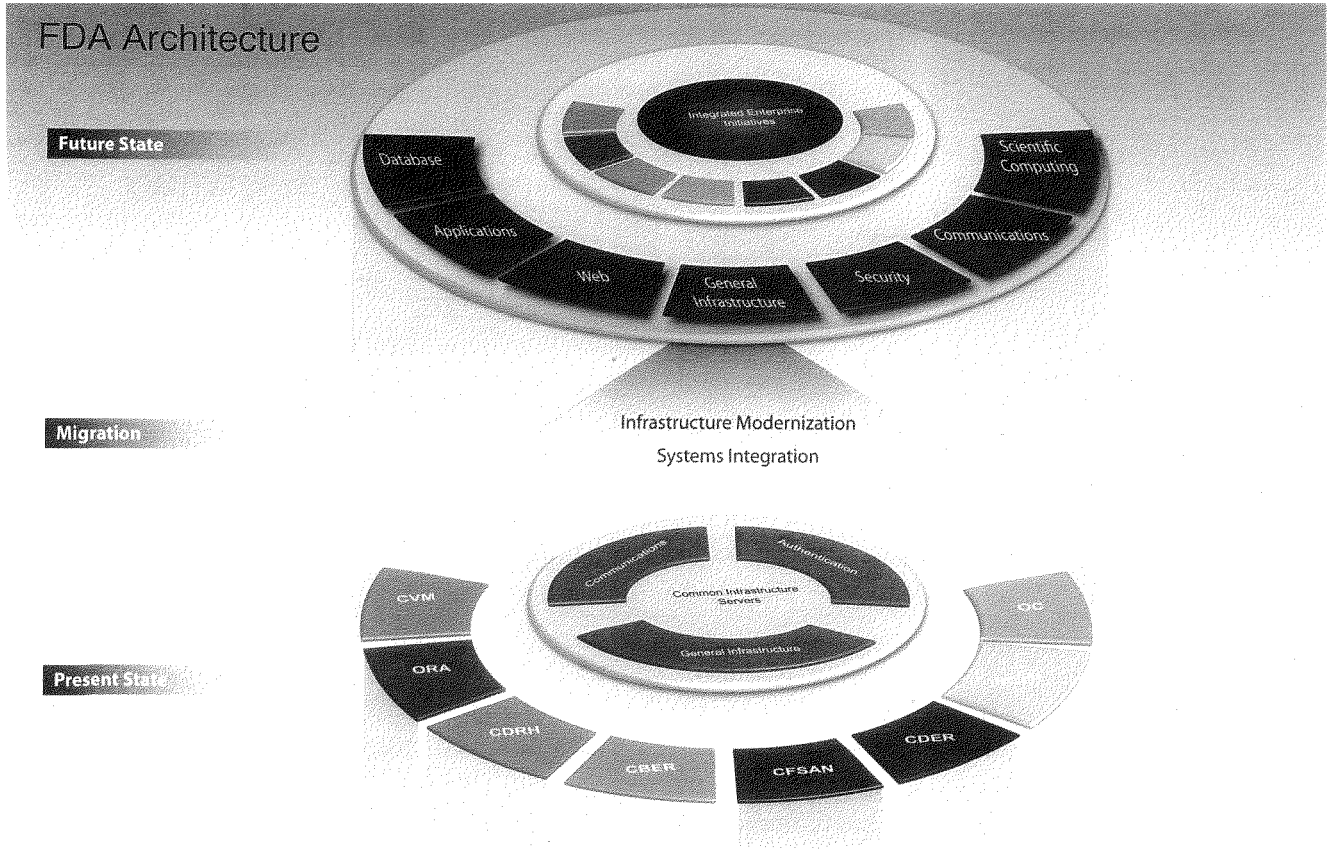
For Discussion

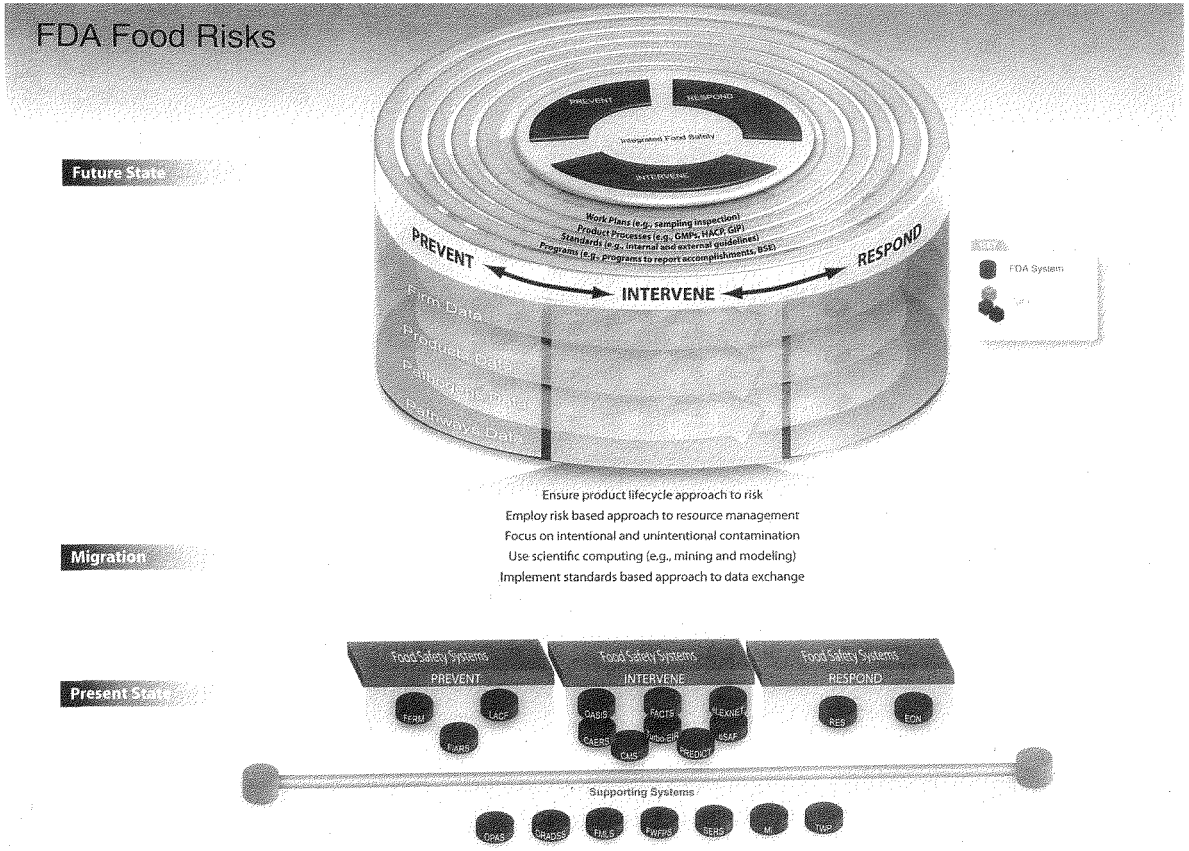
IT Budget for 2004-2008 (in Millions)

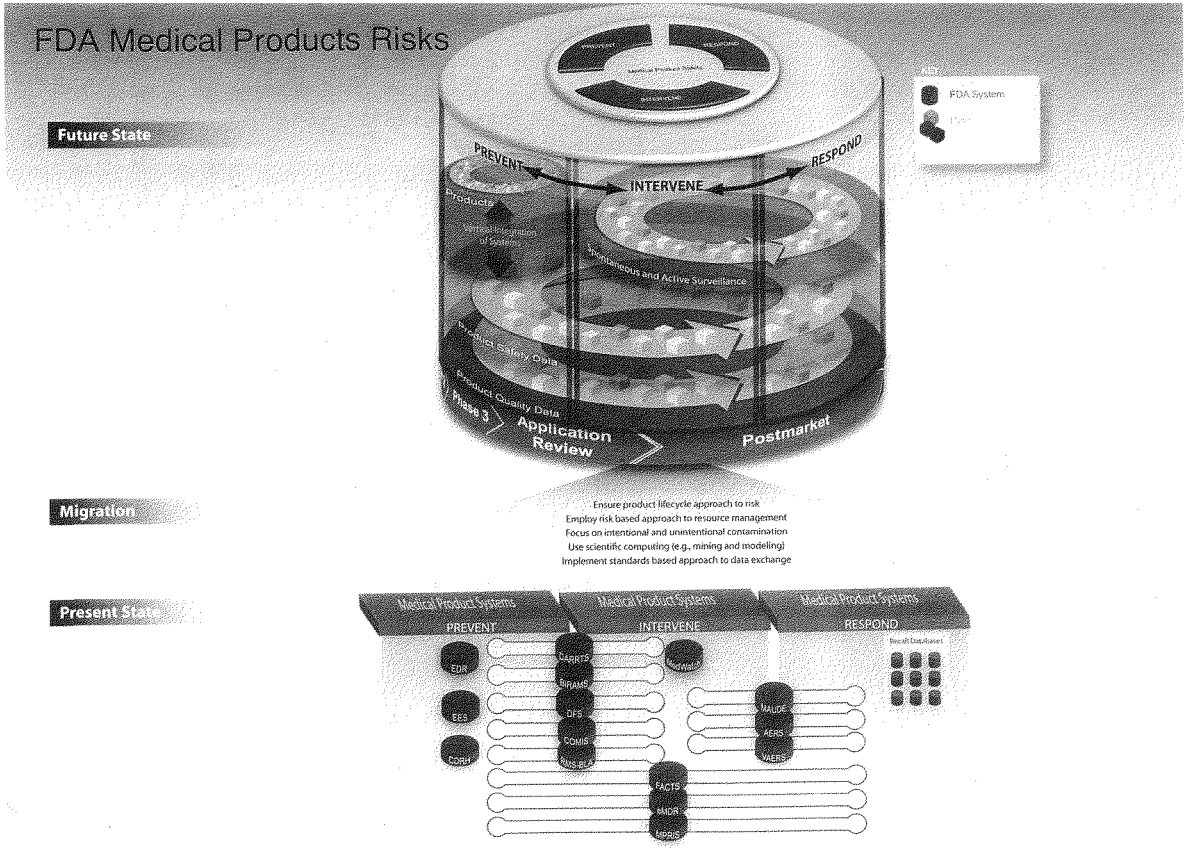
	FY2004 Actuals	FY2005 Actuals	FY2006 Actuals	FY2007 Actuals	FY2008 Estimated	FY2009 Estimated
FTE			46	48	58	58
Non-FTE			166	172	190	194
Total Budget	183*	199*	212	220	248**	252**

*Unable to break out budget based on FTE and Non-FTE

**Pre Supplemental


FDA Architecture
Future State
Integrated Enterprise Initiatives
Database
Applications
Web
General Infrastructure
Security
Communications
Scientific Computing
Migration
Infrastructure Modernization
Systems Integration
Present State
Communications
Authentication
Common Infrastructure Servers
General Infrastructure
CVM
ORA
CDRH
CBER
CFSAN
CDER
OC


FDA Food Risks
Future State
PREVENT
RESPOND
INTERVENE
Work Plans (e.g., sampling inspection)
Product Processes (e.g., GMPs, HACCP, GIP)
Standards (e.g., internal and external guidelines)
Programs (e.g., programs to report accomplishments, BSE)
Firm Data
Products Data
Pathogen Data
Pathways Data
FDA System
Migration
Ensure product lifecycle approach to risk
Employ risk based approach to resource management
Focus on intentional and unintentional contamination
Use scientific computing (e.g., mining and modeling)
Implement standards based approach to data exchange
Present State
Food Safety Systems
PREVENT
FERM
LACF
FIARS
Food Safety Systems
INTERVENE
OASIS
FACTS
FLEXNET
CAERS
Info-EIR
iSAF
CMS
PREDICT
Food Safety Systems
RESPOND
RES
EON
Supporting Systems
OPAS
ORADBS
FMLS
FWPS
SERS
IM
TMP


FDA Medical Products Risks
Future State
PREVENT
INTERVENE
RESPOND
Products
Vertical Integration of Systems
Continuous and Active Surveillance
Product Safety Data
Product Quality Data
Phase 3
Application Review
Postmarket
FDA System
Migration
Ensure product lifecycle approach to risk
Employ risk based approach to resource management
Focus on intentional and unintentional contamination
Use scientific computing (e.g., mining and modeling)
Implement standards based approach to data exchange
Present State
Medical Product Systems
PREVENT
INTERVENE
RESPOND
EDR
EES
CDRH
CURRTS
BIRAMS
DFS
COMIS
MNS-BLA
MAUDE
AERS
VAERS
FACTS
MUCR
MPRIS
Recall Databases

Recent Accomplishments

- Single Sign On implemented for two major systems utilized by the field
- Server Virtualization to modernize and consolidate the total number of servers in use
- Initiated network and server upgrades in the Field with completion targeted for the end of FY2008
- Refreshed 68% of PCs that were identified for refresh at headquarters in addition to performing approximately 600 new pc installations due to new requirements

HHS News

U.S. Department of Health and Human Services www.hhs.gov/news

Press Release

FOR IMMEDIATE RELEASE
June 9, 2008

HHS Press Office
(202) 690-6343
FDA Press Office
301-827-6242

Administration Proposes Additional Funding for FDA to Improve Food and Medical Product Safety

Funds will support framework to enhance import safety presented last year

HHS Secretary Leavitt today announced that the Administration is amending its budget request for fiscal year (FY) 2009 to include an additional $275 million for the U.S. Food and Drug Administration (FDA). He called on Congress to act quickly on this budget amendment and pending Administration legislative proposals to strengthen FDA.

Today's action supports the fundamental change in strategy currently underway at FDA to adapt to the demands of the rapidly growing and changing global economy. These funds will expedite implementation of the strategy outlined in the Action Plan for Import Safety and the complementary Food Protection Plan, both released in November 2007.

"Last year we outlined important changes in how this nation deals with imports. We are moving from an intervention strategy – where we stand at the border and try to catch things that are unsafe – to an integrated strategy of prevention with verification. We are rolling the borders back and seeking to build safety and quality into products at every step of the way before they reach American consumers," Secretary Leavitt said.

The Secretary continued, "Combined with crucial legislative proposals, this increase will allow FDA to continue to transform its regulatory strategies to meet the challenges of the evolving global marketplace. I urge Congress to act quickly to give FDA the authority and funding it needs to enhance the safety of our food and medical products."

Under the budget amendment, FDA will be able to expedite steps to improve import safety, including:

- FDA will significantly expand its reach beyond American borders by establishing a presence in five countries or regions and by implementing other measures that will help ensure greater foreign compliance with FDA standards.
- Another initiative will offer expedited entry for goods bearing certification by trusted parties.
- FDA will modernize its information technology infrastructure.
- Finally, FDA will conduct at least 1,000 more foreign inspections of food and medical product facilities and an additional 1,000 domestic inspections with funds in the budget amendment.

The increase brings the Administration's total proposed increase in the FDA's budget for FY 2009 to $404.7 million – a 17.8% boost in funding from FY 2008.

Some new authorities requested for federal agencies in the Action Plan for Import Safety that Congress has not yet granted include:

- Authorizing FDA to accredit highly qualified third parties to evaluate compliance with FDA requirements.
- Authorizing FDA to require certification of designated high-risk products as an additional condition of importation.
- Authority to refuse admission of imports from a firm who delayed, limited, or denied FDA access to its facilities.
- Empowering FDA to issue a mandatory recall of food products when voluntary recalls are not effective.

"FDA's mission to protect and promote the health of the America public will be greatly aided by these additional funds to implement our strategic plan," said Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs. "FDA has already embarked on an ambitious program to transform the Agency. This added funding will ensure that FDA can move ahead with these proposals more rapidly."

Consistent with the Administration's emphasis on fiscal discipline, the budget amendment is fully paid for within budgetary totals.

The budget amendment proposes the following increases for core FDA programs:

Protecting America's Food Supply (+$125 million)

The increase allows FDA to intensify actions to implement FDA's Food Protection Plan. Announced on November 6, 2007, the Food Protection Plan is an integrated, risk-based strategy to help ensure the safety of domestic and imported food and feed. The $125 million increase adds to the $42.2 million increase proposed for food protection in the budget announced in February 2008.

The increase in food protection activities will allow FDA to reduce threats to the food supply, expand FDA's international presence, and increase technical assistance to help ensure that foreign and domestic food facilities comply with food safety standards. FDA will also be able to improve the risk-based approach it uses to conduct more targeted import exams and foreign and domestic inspections of food manufacturing, processing, and packaging facilities. FDA will pursue additional research on ways to prevent intentional and unintentional contamination, deploy screening technologies to identify microbial and chemical contamination, and respond more quickly to contain outbreaks of food-borne illness.

Safer Drugs, Devices, and Biologics (+$100 million)

The increase of $100 million for the FDA's medical product programs will strengthen FDA's ability to ensure the safety and effectiveness of medical products, from product development and pre-approval testing, through approval, and post-approval safety surveillance. FDA faces growing challenges from the globalization of medical product development and manufacturing. The increase for medical product programs will allow the FDA to respond to this trend.

FDA will more aggressively conduct active safety surveillance to identify early signs of adverse events linked to medical products. FDA will also implement new requirements under the FDA Amendments Act of 2007 related to clinical trials, pediatric drugs and devices, postmarket study commitments, and the labeling and safe use of drugs. FDA will also establish unique device identifiers to track devices, facilitate device recalls, and support inventory management during disasters and the response to terrorism events. Finally, FDA will conduct more import exams and foreign and domestic inspections of medical product manufacturers.

Modernizing FDA Science and Workforce (+$50 million)

The budget amendment also proposes increases to strengthen FDA's capacity to support product safety and development in areas of emerging science such as nanotechnology, cell and gene therapies, robotics, genomics, advanced manufacturing, and the critical path initiative. FDA will also improve laboratories and other facilities that are essential to carrying out FDA's mission and invest in science training, professional development, and fellowship programs to strengthen and modernize the FDA workforce.

The program increases listed above include $65 million to modernize FDA's information technology infrastructure.

Additional information is available online at:

www.importsafety.gov

www.fda.gov

http://www.fda.gov/oc/initiatives/advance/food.html

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FDA Fact Sheet: Investing in FDA's Transformation

RSS Feed for FDA News Releases [what's this?]

Get free weekly updates about FDA press releases, recalls, speeches, testimony and more.

Nationally Available Import Databases:

OASIS

OASIS is an acronym which stands for Operational and Administrative System for Import Support. It is an automated FDA system for managing FDA regulated products offered for import into the United States.

For each product offered for entry, OASIS receives data transmitted electronically from the entry filer to Customs' Automated Commercial System (ACS) and relayed to FDA. OASIS checks the data against automated screening criteria previously set by the Division of Import Operations & Policy (DIOP). The product is either allowed to proceed into commerce if it is low-risk, or flagged for further review by an FDA employee.

FACTS

FACTS is an acronym which stands for the Field Accomplishments and Compliance Tracking System. It is an agency-wide computer based program for the entry and monitoring of all work performed in the field. This includes investigational work such as inspections, investigations, and sample collections; laboratory receipt and transfer of samples, sample analysis and results; and the processing of compliance cases and actions. It is also used to maintain the inventory of regulated firms and their registration, as required, and their compliance status, which determines their ability to fulfill government contracts.

ORADSS

ORADSS is an acronym which stands for ORA Reporting Analysis and Decision Support System. ORADSS is a warehousing and data reporting system which has been implemented to help the Agency make informed regulatory and compliance decisions. ORADSS is comprised of many import, domestic, Turbo EIR, and RES (Recall Enterprise System) "canned" reports, as well as data marts and universes designed to provide advanced users with the means to develop their own reports. Users can analyze shipment trends, disposition analysis, and work management planning for import operations in addition to reviewing information about firms, inspections, collections, laboratory analysis, and several other areas related to domestic data.

CENTER VIEWS

MARCS Center Views provides FDA personnel with more efficient access to data, thereby improving productivity in an area of field operations where the workload is particularly high. The new single point of entry enables import reviewers to easily retrieve data from multiple Center databases without cumbersome multiple logins.

Center databases included in this system are:

CBER:

• The Regulatory Management Systems - Biological Licensing Application (RMS-BLA) supports CBER's Managed Review Process for the review and approval of applications for biological derived drugs, blood products, and IVD Test Kits (the BLAs) that are regulated by CBER. RMS-BLA also tracks Post Marketing Commitments related to these approved products. RMS-BLA interfaces with several other CBER systems for document tracking and routing (DATS), reviewer time resource reporting (RRS), tracking of Investigational New Drug Applications (BIMS), Blood Logging and Tracking (BLT), Lot Release (LRS), Electronic submissions (EDR), and a system for the maintenance of valid person names and associated information.

• Biologics Investigational and Related Applications System (BIRAMS) tracks the regulatory activity of Investigational and Related Applications (IRAs) submitted to CBER including: Investigational New Drug (IND) applications, Master Files (MFs), Investigational Device Exemptions (IDEs), and Emergency Use Authorizations (EUAs). The system supports CBER review management by maintaining information on the receipt, content, and status of IRA submissions, as well as FDA-generated communications, and electronic routing and review.

• Blood Logging and Tracking (BLT)is used to maintain information related to the status and review progress of applications for the approval of devices and products related to blood screening, transfusion, and other analogous products.

CFSAN:

• The Low Acid Canned Foods (LACF) system is the FDA's data repository and monitoring tool for managing low acid and acidified canned food processes and facility information. Submission by regulated producers of detailed food processing information and facility registration is mandatory under CFR 108, 113, and 114. LACF provides a means for FDA field staff to immediately review the current status of filings of imported and domestic regulated low acid and acidified products. FDA import entry reviewers use the LACF tool to identify facilities on import alert and validate commodities for import into the United States.

CDRH:

• CDRH CTS (Center Tracking System) is a web-based workload management and tracking system that contains information on pre-market applications; Investigational Device Exemption (IDE), Premarket Notification (510(k)) and Premarket Approval (PMA). CTS is integrated with the CDRH electronic document room, Image 2000, which provides reviewers access to submission and review documents.

• eCIRS. eCIRS, an acronym which stands for enhanced CDRH Information Retrieval System, is a program that allows the user to search data collected and retained by CDRH and display formatted output or print reports containing the desired information, without

having to develop complex computer programs. CIRS contains information on pre-market applications such as an Investigational Device Exemption (IDE), Premarket Notification (510(k)) and Premarket Approval (PMA). Post-market data such as Adverse medical device incidents can also be found in CIRS.

CVM:

Searchable web application that has information about Animal Drugs. It includes information about the Drug included in the Code of Federal Regulations (all animal drugs are codified) as well as additional information that comes available through CVM during the life of the drug.

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