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DEVELOPING A COMPREHENSIVE RESPONSE TO FOOD SAFETY

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

EXAMINING DEVELOPING A COMPREHENSIVE RESPONSE TO FOOD SAFETY PROBLEMS

DECEMBER 4, 2007

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DEVELOPING A COMPREHENSIVE RESPONSE TO FOOD SAFETY

TUESDAY, DECEMBER 4, 2007

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:29 a.m., in Room SD–430, Dirksen Senate Office Building, Hon. Edward M. Kennedy, chairman of the committee, presiding.

Present: Senator Kennedy, Harkin, Murray, Enzi, Burr, Murkowski, Roberts, and Allard.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. We'll come to order.

The most basic duty of any government is to protect the safety of the people it serves. A recent report to the FDA Science Advisory Board raises troubling questions about the Administration's ability to meet this basic responsibility with regard to food safety and many other areas where American families count on FDA to protect their health. Instead of improving matters the White House is poised to make them worse by threatening to veto the very bill that funds the FDA.

The report's conclusions cannot be more stark or more shocking. FDA does not have the capacity to ensure the safety of the food for the Nation. FDA's ability to provide its basic food system inspection, enforcement, and rulemaking function is seriously eroded, as is its ability to respond to the outbreaks in a timely manner and to develop the new regulatory approaches needed to prevent future problems.

Every time American families go to the grocery store, they worry about the safety of the food that they buy. Every time parents buy toys for their children, they worry if the paint is contaminated or the materials are defective. They ought to be able to count on the FDA and other health agencies to stand guard for them to use the latest and best science to protect them and to stop at nothing to detect dangerous products.

But the Advisory Committee report reveals that FDA's promise to protect America's families is too often an empty one because of the starvation budgets and absent leadership that the FDA has endured in recent years. The plain truth is the FDA doesn't have the money it needs to do the job it has to do. If the problems revealed by the report were confined to food safety they'd be disturbing

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enough, but the study shows that the effectiveness of the entire agency has been eviscerated by neglect.

The major findings of the report read like an indictment. Finding No. 1, the FDA cannot fulfill its mission, the FDA cannot fulfill its mission, because its scientific base has eroded and its scientific organizational structure is weak. No. 2, the FDA cannot fulfill its mission because its scientific workforce does not have sufficient capacity and capability. And finding No. 3, the FDA cannot fulfill its mission because its information technology infrastructure is inadequate.

I'm pleased that we are joined by Secretary Leavitt today. I welcome him to our committee. And I hope he'll take this opportunity to explain to the American people how FDA has been allowed to reach this sorry state.

I also look forward to a thorough examination of how to improve food safety. Even a brief review of recent food safety concerns must ring alarm bells in every community. Salmonella was found in domestic peanut butter. Botulism was found in chili. An adulterant from China in pet foods led to illness and deaths in cats and dogs.

An *E. coli* outbreak in spinach from California last summer killed three and sickened more than 200 others. I don't have to look far to see the threat from *E. coli*. On Cape Cod last month we were told to boil our drinking water because it was contaminated with these dangerous bacteria.

The Administration's food safety plan offers recommendations on improving food safety. And I look forward to hearing Secretary Leavitt's discussion of this proposal. However many experts believe we ought to do far more and I look forward to the views of our distinguished panel on the matter.

Both the European Union and the Japanese have more robust food safety programs than we do. And we can learn from them. Most significantly they have much stronger programs to police imported food, combining inspections in the country of origin and testing of imported foods. And we should be able to do at least as well.

We need to give the FDA the tools it needs to identify food safety problems more quickly and respond more effectively. Most importantly we need to focus on preventing outbreaks in food. I know the Secretary's proposal is going to talk about the issues of prevention. And we'll have a discussion on these matters.

Each part of the food industry must have an effective plan in place to prevent hazards in the food it makes and markets. Preventive controls aren't new and they work. The FDA has had regulations in effect since 1973 to require safety processing for many canned foods. Because of these regulations, there are now virtually no problems with botulism in these foods.

FDA issued regulations in 2001 to require safety processing for juices after *E. coli* in apple juice killed or injured children. Most manufacturers now pasteurize their juice, which eliminates this contamination. And despite the effectiveness of these regulations the Administration plan proposes to expand this authority only with major limits. Under the proposal FDA will be able to impose preventive controls only for foods that have repeatedly been associated with serious adverse health consequences or death.

Essentially this provision is a requirement that people be injured or even killed before FDA can act. Such a requirement undermines the basic goal of preventing illness. Every manufacturer should be required to implement effective preventive controls and we must give the FDA the authority to enforce the requirement before people are injured, not make them wait until the damage is done.

The HELP committee worked together this year to reauthorize user fee programs that provide significant resources for FDA. We need to be similarly creative to meet the agency's other pressing needs. It is a privilege to work with Senator Enzi on this hearing and I look forward to working with him and our committee colleagues to develop a response to food safety.

Mr. Secretary, we welcome you. We have the extraordinary circumstance where the head of the FDA asked the Science Advisory Committee to give guidance with regards to what the agency needs in terms of expertise and science advice. And they made a series of recommendations on it and what can be done in terms of safety.

So we want to give credit to the agency in trying to look at itself about how it ought to improve itself. And for going outside and asking the distinguished panel, who, I think, have demonstrated with their recommendations a willingness to give us the unvarnished situation, which I think the American people are entitled to.

You have gone and traveled the world to look at food safety and you've been kind enough to come and brief me. I'm sure you have briefed others on the committee about what you have been attempting to do. But you've landed in the hot spot right now.

Because, food safety must be of central concern to American families and this advisory panel report raises issues of what is needed by way of resources to give protection to the American people through food safety. And we are confronted with the President stating that he's going to veto the FDA funding that would help address these very needs. All of these have come together right now in terms of the public policy issue.

We have a clear, unbiased series of recommendations that are about as fierce an indictment of a governmental agency as I've seen in 45 years of being in the U.S. Senate, certainly with regards to the HELP panel. I'm someone who's been deeply committed to the FDA, as others have been on this panel. We've worked very closely with Senator Enzi and Senator Burr, Senator Harkin who's been a real leader, Senator Murray and my friend Senator Hatch as well.

And now we have the clear recommendations of the Appropriations Committee on what is necessary to move ahead. The President's request for FDA was $467 million. Senate Appropriations recommended $522 million. Not an overly dramatic increase, but at least, a very important down payment to address food safety. And now we're facing a President of the United States who is saying he's going to veto the bill.

Every family in America that looks to this agency for their food safety, that goes down to that market today has to ask, What in the world is going on? We're going to give you a chance to speak to that, Secretary Leavitt, but before we'll hear from our friend, Senator Enzi.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Thank you Mr. Chairman. My message will probably be a bit more optimistic.

[Laughing.]

But I would like to thank the Chairman for working with me and working with me in a very bipartisan manner, not just recently but for a long time. And it was exactly a year ago that this committee held a hearing on bagged spinach because there was a national problem with it. It was contaminated with *E. coli*, as the Chairman mentioned, and we wanted to evaluate the local, State and Federal response.

Now I think the most amazing thing that came out of that hearing was that we have three agencies that are involved in isolating and determining there's a problem and then solving the problem. And all of the testimony that we got was a tremendous cooperation between three agencies. We never hear about that with the Federal Government. But three agencies with as few as 30 cases are able to determine that there's a problem and get the product pulled off the market. And that's out of thousands of daily reports of potential problems. To sort through those things and come up with a solution is absolutely amazing to me.

Of course, we also heard a lot about some up and coming technologies to improve food safety and of course, I particularly noticed that those were developed by innovative small businesses. And it's important for us all to remember that small businesses are the engine of the economy. They represent more than 99 percent of the businesses in this country and they employ millions of people. Small businesses have a lot to contribute.

But we also have to keep in mind that their resources are not the same as the big companies. We do have to hold big and small companies to the same high food safety standards but we have to recognize that one-size-doesn't-fit-all when it comes to regulation. So there's plenty of work to be done on food safety at all levels of business, government and consumers. And today we're here to evaluate and assess two new reports about import safety and food protection.

Food safety is an issue that affects all of us. It's not a partisan issue. We all want the safest food supply possible. It's our shared goal. A goal that requires cooperation and teamwork through a very complicated process and we'll examine that process today.

The United States does have one of the best food safety systems in the world. I appreciated the Chairman's comments about a couple of other countries. Again, there are some limited areas where they're doing better and we ought to take a look at those and see if that won't improve our system too. But we do have the best food safety system in the world. There is room for improvement and those improvements can take many forms.

For example, we can address how food becomes contaminated in the first place and make improvements in that. We can look at the advances in processing and handling the food to prevent future outbreaks. We can also improve the testing and inspection capabilities. For far too long the number of inspectors at FDA has been decreasing even as imports rose exponentially and new food safety prob-

lems arose. And finally we do have to consider whether new authorities are needed to respond to those problems that are not detected and corrected.

I'm pleased the Administration takes these issues as seriously as I do. There's a lot to like in Secretary Leavitt's report and the FDA Food Protection Plan. However we need to carefully review the recommendations in those reports before we rush to action.

I like to say that if something's worth reacting to in Congress, it's worth overreacting to. So food safety is critical to every American. And it's up to us to make sure that we take the time to get it right.

Senator Kennedy and I just spent 2½ years working on fixing the drug safety system in this country. Half of all Americans take a prescription drug daily. One hundred percent of them eat.

I will be studying these reports and details as I work on a comprehensive approach to improve the safety of the food we eat. Of the 50 suggestions for food safety, many concentrate on high priority areas, those most susceptible to problems. Other recommendations would provide more transparency on which companies and food products are safe and which are not. They would establish best practices and provide some incentives—kind of a mix of the carrot and the stick.

When Americans purchase a snack, eat at a restaurant or sit down to dinner with their families, they should be able to expect that the food they eat will not make them sick. We need to restore that faith. And I'm working with my colleagues across party lines to develop a comprehensive, effective strategy to enhance food safety.

Senator Kennedy and I began that effort in May working with Senator Durbin to establish standards for pet food and set up early warning systems for any problems with pet foods to improve communication systems about all food recalls and to coordinate State and Federal activities on fresh and processed produce. Finally our efforts led to the creation of a database of instances of tainted food so that the FDA can better track patterns of problems and target its limited resources to where they're most needed.

We still have a ways to go. New programs, tools, technologies and authority are important and needed. But they mean nothing if they don't restore consumer confidence in our food supply.

Again, I thank the Chairman for holding the hearing and for the witnesses, particularly the Secretary agreeing to participate and I look forward to hearing the testimony today. Thank you Mr. Chairman.

The CHAIRMAN. Thank you very much. We've been joined by Senator Harkin, Senator Burr, Senator Allard, and Senator Murray. I'd like to hear from the Chairman of the Agriculture Committee. That committee has interest in food safety and eggs, poultry and meat, so I ask Senator Harkin to say a word, then Senator Burr if you wanted to speak. I don't want to cut off the others.

We'd like to get to the hearing, but I do think there's a special set of circumstances when we have both a member of our committee and someone who's involved in the issue of food safety as much as Senator Harkin is. So, Tom, we'd be glad to hear from you

and then I'd be glad to have a word from our other side here. And then we'll get on with the Secretary.

STATEMENT OF SENATOR HARKIN

Senator HARKIN. Thank you very much Mr. Chairman. I appreciate the kindness. And thank you very much for you and for Senator Enzi for holding this hearing.

I'll just ask that my statement be made a part of the record and I'll just say a couple of things here. I know you want to move on and I apologize in advance that I will not be able to stay for the whole hearing.

We have a real crisis of confidence in America today in our food safety system. Every day we're reading about all these problems. First, we had the *E. coli* outbreaks last year that the Chairman spoke about. One hundred and ninety-nine people were sickened. There were 31 cases of hemolytic uremic syndrome, a severe kidney disorder, 102 hospitalizations, 3 deaths. Since then we've had recalls involving pet food, peanut butter, lettuce, ground beef, chicken pot pies, pizzas, etc. In September, more than a million pounds of hamburger were recalled and then just last month another million pounds of ground beef were recalled.

Again, as this committee knows our food safety inspection system started years ago with meat and then poultry and then eggs. And that was under the jurisdiction of the Department of Agriculture, where it remains today in the Food Safety and Inspection Service. Later on with the establishment of the Food and Drug Administration, other food products came under their jurisdiction. So we have a split system now where the FDA has everything except meat, poultry and egg products and therein lies a problem.

With meat, poultry and egg products there are slaughter plants, facilities, and processing facilities. We have an inspection system that dates back to more than half a century. It's been modified and updated. But there are basically narrow channels through which these products go and inspections can be conducted in a fairly good manner.

Now, since that time we have seen the blending of meat and meat products, including meat from other countries that come into this country to get blended. That's why we have a problem with ground beef all the time. You don't have big problems with cuts of meat. Most of the problems are with ground beef blended together from different areas. So that's an area in which we need to have better oversight and better inspections on the part of the Department of Agriculture.

But then think about how our eating patterns have changed. The challenges we face today are broader and more complex than they ever have been. Our entire food supply domestic and imported, I think, needs to be examined. Fifty years ago we gave little thought to problems with fresh produce. That's one of our big challenges today.

So we have changing production methods. We have changing eating habits, of course, and different technologies. Now the Food and Drug Administration's plan that the Chairman spoke about, I'm encouraged by some of it, but I'm very concerned that the plan falls

well short of a truly comprehensive strategy for ensuring the safety of our food.

The Department of Agriculture and the FDA either need to work together more closely in a harmonized, integrated system for the safety of our food supply both from farms here to dinner plates in this country or from imported food coming into this country. Again now with the Department of Agriculture, I would say to my friends here, we have an equivalency standard for meat, poultry and egg products when we import them from other countries. In other words the slaughtering facilities, the inspection facilities in other countries must be equivalent to our own when it comes to meat, poultry and egg products.

But when it comes to fruits and vegetables and other foods, we have no equivalency standard, none whatsoever. And so, we don't know about all these products coming in from other countries. I mean every once in a while we detect antibiotics in food from China. Once in a while we detect pesticides in food. But FDA, right now, inspects, and I could be corrected on this, but I think I'm right. FDA inspects less than 5 percent of the food coming into this country.

What kind of assurance is that to our public, when first we don't have an equivalency standard and then we inspect less than 5 percent of food coming into this country? Because of the changing patterns and the huge increase of imported foods coming in, the changing patterns and the changing farming technologies in our country with produce—fruits, vegetables, which we want our people to eat more of because we know it's healthy—perhaps it's time to think about a different system of inspection. Maybe it is time to think about a single food inspection agency charged with responsibility of all food inspections.

I know Senator Durbin has an amendment to the Farm bill which we have on the floor. Maybe we'll get to it one of these days. But his amendment would sunset the FDA and the FSIS at the end of 2010 which means that the next Congress would have to do something and come to grips with this issue.

I don't know. I'm not here to tout his amendment, but quite frankly I think it has a lot of promise. I think that there's some validity to that approach of saying we're going to sunset it and we better come up with something that harmonizes and integrates all of our food inspection for domestic and imported foods. And maybe sun setting everything would force Congress to finally do something which we haven't done yet.

And so I just say to my Chairman here I look forward to working with you and with Senator Enzi, both in my capacity as a member of the committee but also as my capacity as Chairman of the Agriculture committee to get to a better system that harmonizes, that has equivalency standards, that really does give better assurance to our people that their food is indeed safe. So I look forward to working with you, Mr. Chairman in this endeavor.

[The prepared statement of Senator Harkin follows:]

PREPARED STATEMENT OF SENATOR HARKIN

I would like to thank Chairman Kennedy and Ranking Member Enzi for holding this hearing on developing a comprehensive re-

sponse to food safety. As we all recognize, food safety is of critical importance not only to our food and agriculture sectors, but also to public health. The results of weak food safety oversight are human victims of foodborne illness and severe economic consequences to our Nation's food and agriculture industry. These problems can be prevented by strengthening the Federal Government's ability to ensure a safe food supply.

Today, we have a real crisis of confidence in this country when it comes to food safety. Over the last year, the American public has been bombarded with repeated recalls and alerts with regard to adulterated food. In September of last year, an outbreak of *E. coli* caused by contaminated spinach sickened 199 people, including 31 cases of Hemolytic Uremic Syndrome—a severe kidney disorder. There were 102 hospitalizations, and 3 deaths. Since then, we've seen recalls involving pet food, peanut butter, lettuce, ground beef, chicken pot pies, and pizzas. In September, more than a million pounds of hamburger patties were recalled because of contamination with *E. coli*. There have been 40 cases of foodborne illness related to that recall. Just a little over a month ago, there was another million-pound recall of ground beef.

Now, I am not saying that our food safety system is entirely broken. After all, recalls are a normal and necessary part of the system. There have been too many, however, and in the past year, the authorities have been tardy in catching and responding to food-contamination problems. Gaps and lapses in the food safety system have human and economic costs.

As this committee knows, government food inspection got its start early in the 20th century with the publication of Upton Sinclair's exposés of horrific conditions in the meat packing industry. Since Sinclair's day, meat and poultry have been the subject of intense scrutiny. But the food safety challenges we face, today, are broader and more complex. Today, our entire food supply, domestic and imported, needs to be examined. Fifty years ago, we gave little thought to the safety of fresh produce, but that is one of our challenges today. It is time for our laws and regulations to be changed to reflect changing production methods, eating habits, and technologies.

The Food and Drug Administration (FDA) released a "Food Protection Plan," which it describes as "an integrated strategy for protecting the Nation's food supply." I am encouraged by some of the recommendations and action items the Plan addresses. But I am very concerned that the Plan falls well short of a truly comprehensive strategy for assuring the safety of our food. The Department of Agriculture (USDA) and FDA must work closely together towards a harmonized, integrated strategy for our entire food supply, from farm to fork instead of fixing problems in a piecemeal fashion for a portion of our food supply. There are very good reasons for the differences between how USDA and FDA regulates the food supply. However, most of those differences have more to do with history than science. Congress, government agencies, consumers, and the food and agriculture sector must work together to modernize our food safety system with the best available science to prevent further losses in consumer confidence, and most importantly, to prevent the loss of human lives. This is an enormous under-

taking, but as a member of this committee and in my role as Chairman of the Agriculture, Nutrition and Forestry Committee, I am committed to working on this issue of critical importance to consumers and to American agriculture.

The CHAIRMAN. Senator Burr, if you'd want to make a comment.

STATEMENT OF SENATOR BURR

Senator BURR. Mr. Chairman, I'll be extremely brief because as I heard your points that you got from the Scientific Advisory Committee, I'm not so sure I found it a condemnation of FDA as I did the American education system because we're falling deficient in educating the talent that we need in the future, especially as the pool of scientific brain power begins to be attracted by more than just the Federal Government. Everybody runs short of what they need. So I think we're going to do as much good by making sure we fix education as we are by orchestrating something that Congress believes the FDA should or shouldn't do or creating a new agency.

Let me just implore my colleagues. Let's give the FDA a chance. The Secretary asked for these comments. He got the comments. I found him always to be one that acts when he's presented with information that's valuable to the agencies. I think he deserves a chance.

Unfortunately we can't point at food safety and just look outside our borders and say there's our problem. Our problems have been inside our borders before. And it means collaboration between the Federal Government and private sector companies. That collaboration has started. We've got to see whether it can grow into a defense mechanism that truly is one that we can all be proud of and more importantly, that we can trust the system. And I look forward to hearing the Secretary.

The CHAIRMAN. Well, Senator Allard.

STATEMENT OF SENATOR ALLARD

Senator ALLARD. Mr. Chairman if I might just make a brief comment here. As a veterinarian I've had the experience of actually doing food inspections. I belong to a profession who a good deal of those members are active in the FDA and the Department of Agriculture on food quality. And I would just have to say that my personal view is that I think we shouldn't lose our perspective here.

The American food supply is the best quality and the safest in the world and that's because we do a lot scientifically. We do a lot diagnostically to recognize problems. And then we adjust that using good science and as a result, we tend to report problems that don't get reported in other countries. And we have a good quality food supply here. I don't think we should forget that perspective.

Now, do we have problems? Sure, we have some problems. But I think we have to keep a proper perspective in this. And I would agree with Senator Burr. A lot of this is educational. You know, if you have *E. coli* in hamburger, just make sure your hamburger is well cooked. That will take care of the *E. coli* problem. You don't need to have books and books of rules and regulations on *E. coli*.

The American public needs to understand that there's different types of *E. coli*. There's *E. coli* that's normal in your bowel. There's *E. coli* that causes disease. And they need to understand that.

So, I see a big need for improving our educational effort. We need to continue to look at diagnostic ways in which we can monitor food to make sure it is safer. And we need to make sure we have the proper balance of enforcement and proper education.

So I'm looking forward, Mr. Chairman, to the comments from the Secretary to understand what the FDA is doing and how they're managing this and how they're responding to these reports. And so, this is a very timely hearing. And I want to complement you, Mr. Chairman for holding this hearing and working with Senator Enzi. I think you make a great team on this committee. And this is an important issue, something I'm interested in. Thank you.

The CHAIRMAN. Thank you very much. Mr. Secretary, we look forward to your comments. You've heard from us. We want to hear from you. Welcome.

STATEMENT OF HON. MICHAEL LEAVITT, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC.; ACCOMPANIED BY DR. DAVID ACHESON, DEPUTY COMMISSIONER, FOOD SAFETY

Secretary LEAVITT. Well, thank you, Senator. I'm going to acknowledge that I'm here with David Acheson, who is the Deputy Commissioner for Food Safety. I may call on him at various points for technical advice.

May I just acknowledge that the American people have high expectations of quality and safety and they ought to? And I acknowledge that my wife and I, my children, my grandchildren all eat from the same food supply you and other members of the Senate do. We have a very serious personal interest in this being well developed. I would like to also associate myself with those who have acknowledged that our food supply is among the safest in the world.

We have a good system. It is not adequate for the future. And I believe that's what this hearing is about. It's about how do we take what we have and there's an old saying in the hockey world, "you have to skate where the puck's going to be." How do we create a system for the 21st century that will accommodate the very basic changes that are beginning to change our market?

Over the course of the last several months as you have suggested, I've seen sea ports, I've seen freight hubs at border crossings, wholesale, retail, processing of food, drugs. I've inspected everything from tire irons to gingerbread houses. I've had a chance to see a pretty good fraction of this on 300 ports of entry for imports. I've been able to get a sense of how big this is. And it's clear to me that we have seen warning signs in the last several months that our current system is not keeping up and we have to respond.

I'd like to also point out that this is not an issue that we are facing uniquely in the United States. About a month ago I had the Ministers of Health and Food from eight of the largest industrial countries in the world come to the United States including the European Union. Every one of them are dealing with this issue in the

same way we are. Why, because something very basic has changed. We're now in a global marketplace.

I had a meeting in a grocery store some weeks ago, a couple of weeks ago. I met a man named Dan who was the produce manager. Dan told me that he had been in the produce business for some 30 years. I'd asked what has changed most. He said, "it's what the customers want." They want to have fresh strawberries in January. They want blooming sunflowers in November. And we can give it to them. But we now operate in a global market.

So, what's changing here? The reason we're seeing these warning signs is because our system, while good, is not adequate for the future and it does not allow us, at this point, to respond to those needs. And we need to change it.

I think appropriately the President responded to those warning signs and asked that a group of his Cabinet—he appointed a working group. He appointed me as Chairman. I think it's an important point.

I'd like to just read the list of the Departments in the Federal Government that are involved in this because it, I think, demonstrates that this isn't just about the FDA or the Department of Agriculture. This is a government-wide, society-wide task that requires a coordinated and collaborative approach. HHS, the Department of State, there's a lot of international relationships involved here. The Department of Treasury, the Department of Justice, the Department of Agriculture, the Department of Commerce, the Department of Transportation, the Department of Homeland Security, the Office of Management and Budget, the Trade Rep, the EPA, the Consumer Product Consumer Commission, all of these have a very important role in how we develop a 21st century system of import safety.

Now I hope we get a chance to talk about the report today some. I'd like to just summarize it if I could. I recognize that the time is somewhat limited. I'd like to give you my impressions after having been in, I think, a fairly sizable fraction—seeing a sizable fraction of the system firsthand. First, it is so large we will never inspect ourselves to safety. We simply have to change our strategy. Rather than try to inspect everything that comes across our borders and stand at the border and simply try to catch things as they come. We need to begin building quality into the system every step of the way.

Now, I met the manager of a lettuce processing plant out in Texas. He said to me, "our motto here is you need to know your grower." I said, "what do you mean?" He said, "I want to know where that lettuce came from. I want to know who planted it. I want to know what nutrients they put on it. I want to know the quality of the water they used. I know when they picked it. I want to know how it was treated after it was picked. I want to know who shipped it. In other words I want to see that quality was put into that product every step of the way." That's the future, in my judgment, building quality in.

Now, we divided our task, given to the President to take an overall look at this system, into two parts. The first is we took all of those Departments and developed teams and made very deep looks into every one of those departments and asked questions that I

think, you would have asked, Senator. What are the authorities that you currently have? Are they adequate? What are the changes that we need to be responding to? Do you have the authority and the budgets that are necessary? What kind of limitations do you have right now that need to be overcome? What do you need to do the job?

I then fanned out and went, as I mentioned, I went to over 30 different places and saw, I think, the totality of this system. The good news is that the themes that began to boil up from our deep look into the government response and began to match those that we found in the field. We came back with a report. There are 50 specific recommendations within 14 different categories.

Now I won't take the time to go through all of them. Let me just give you seven or eight brief headlines that I think will populate our conversation. The first is the need for us to have a stronger certification process. It's my view that products need to be not just inspected, we need to assure that the process that's being used to provide safety has been inspected by somebody we trust.

Now in some cases that's an FDA inspector or a Department of Agriculture inspector or someone from the Customs and Border Protection. In other cases it might be an independent certifying body. For example, many of us are familiar with the Good Housekeeping seal of approval. When we see that seal we feel confident because we can trust them. We see Underwriter Laboratories. Those are independent inspections. When they're on it we assume that they have looked through and we can have confidence in it. There are other independent inspections that if the government has accredited them we could use to expand what the current system has.

Now there was a blue uniformed FDA agent who taught me this lesson. He said, "Mr. Secretary, our job is like finding the needle in the haystack. Our first job is we've got to shrink the haystack. We've got to use certification processes to figure out who the bad actors are and who the good ones are so that we can concentrate on where the trouble's going to be."

His point, I think, that leads to the second point I wanted to make in addition to certification. We need to promote good importing practices. We need to make it harder for people to get goods into this country if they don't follow the rules. And we need to make it easier for those that do.

The third point is greater transparency. People deserve to know who it is that imports safe products and those that don't. We need to give people their names. Why is that important? Time after time I've had members of the retail community say, "I'm telling my suppliers, before you can put something on my shelf, I want to know it's safe because my reputation is at stake." We need to tell retailers and consumers who those people are so that the marketplace has a chance to do its magic on this problem as well.

Increase presence overseas. We need to have more U.S. personnel in exporting areas or in ports so that we're able to not only look at goods before they come, but we can use their presence there to teach people how to meet our expectations. We need to build this into our trade agreements. We need to have physical inspections as well.

Stronger penalties, higher standards, better systems. We did find places where our systems are deficient. They need to be improved. For example, FDA inspectors over and over tell me that we have five passwords on our system that I have to remember because I can't get all of the information I need from one screen.

I had members of the Customs and Border Patrol tell me we have seven different passwords that we need to receive and sometimes they can't get the information between them. There are times that the FDA can't get the information that's necessary from the Department of Agriculture. That's a problem we need to respond to.

The President recently issued an Executive order requiring all the Federal agents to come together to create interoperable systems. We need to have faster response tools. And these are happening.

I was in a grocery store in the Midwest. I asked them about their recall. They told me some impressive stories about the way our recall system works. I might add, the fact that we have recalls doesn't entirely mean we've had a failure. It means the system found something and we're responding.

We have systems in most major retail outlets in this country that if a retail product is known to need to come off the shelf, it can happen in a matter of hours. They can shut the cash registers down where no more products can get out until they can get the product off the shelf. They're now moving to a point where they can use their value cards and the various communications vehicles they have with their systems to notify customers. One grocery store told me that they can now identify a canned good or some kind of produce item that was sold in a previous period and within literally, minutes, contact as many as 2 million consumers who may have in fact purchased that product.

So, just to summarize, a change in strategy, Mr. Chairman, needs to occur. We can't just stand at the border and hope to catch things as they come in. We have to build quality in every step of the way. We need to have stronger certification processes. We need to promote better import practices.

Reward those who follow the rules, punish those that don't. We need to have transparency where consumers know who it is that produces a safe product and who doesn't. We need to have an increased presence overseas, enhanced standards, stronger penalties. We need to have better interoperable systems and we need to have faster tools of response.

Now you raised the point about budget. And I'd like to talk a little bit about our response in the report. The report makes very clear that this will require more resources. We chose not to try to replicate the entire budget process because there are 12 different departments involved. And if we were to try to put what the amount is in the report we would essentially be replicating that process.

Every budget that we have put forward in the last 3 years while I've been involved has asked for more resources. Our current budget will as well. So there's no question that building that system for the future will require investment.

Mr. Chairman, I look forward to having this discussion. I hope it's robust and it's complete. As I mentioned, my wife and I, my

children, my grandchildren, all eat from the same food supply that committee members do and the American people deserve to have these expectations and we need to meet them. Thank you.

[The prepared statement of Secretary Leavitt follows:]

PREPARED STATEMENT OF MICHAEL O. LEAVITT

Chairman Kennedy and members of the committee, I am pleased to be with you today to discuss the Action Plan for Import Safety. The Plan, which I delivered to the President on November 6, puts us on the verge of a major transformation in the way we view imported consumer products and assure their safety. At the request of the President, I chaired the interagency working group on import safety which included representatives from 12 Departments and Agencies. The Plan was developed following a careful examination of import product safety issues, and it contains 14 broad recommendations and 50 short- and long-term action steps that will enhance the safety of imports entering the United States for the 21st Century. Today I want to cover some of the key elements of the Action Plan and explain our strategy for implementing them.

First, it is important to mention why this effort is so important and the challenges involved. Today, Americans import approximately $2 trillion worth of goods from over 800,000 importers through 300 ports of entry. The growth in the volume of imports over the last two decades has been nothing less than astounding and it shows no signs of slowing. The expansion of imports is driven by growth of trade in a global economy. There are many benefits to consumers. A wide variety of fresh fruits and vegetables, seafood, and a range of ethnic and other foods from foreign countries are available year round in our grocery stores in a way that our parents could not have imagined. International trade provides Americans access to innovative products and productivity enhancing technologies from other countries which add to our quality of life.

Imported products are generally safe in the United States and Americans enjoy one of the safest food supplies in the world. Yet, we are all aware of recent incidents with unsafe toys and tainted pet foods from China. In addition, there have been concerns about the safety of imported drugs. These incidents of unsafe imports raise legitimate concerns. However, we should not conclude that imports are unsafe or that all products from China or other countries are to be avoided. Instead, these incidents point to the need to revamp the way we deal with import product safety. To put it another way, imports are safe today but, due to the high volume of trade, we need to transform the import system and change the way we verify product safety to meet the challenges of a global economy.

This problem is not unique to the United States. I have raised these issues with the ministers of health from eight of our closest trade partners, and they all have the same concerns. The growth of the global economy has created new challenges for ensuring the safety of imported products. Some of these challenges are: the large and growing volume of imported products; the large number of ports of entry and the need to process imported products quickly at the ports; the increased volume of imports from less developed countries; the complexity and variety of products which carry increased risk; and, the need for stronger safety and quality standards around the world. Further, as global trade has grown, so has the value of trade and the opportunity for unscrupulous businesses to short circuit safety standards or engage in the sale of counterfeit products. Our 20th century approach to ensuring import safety of attempting to screen products at the border is a "snapshot" approach that will not work for the 21st century. The Federal Government cannot, and should not, attempt to physically inspect every product entering the United States This is like trying to find the needle in the haystack. The Action Plan we are discussing today addresses this challenge.

Now, let me turn to our Strategic Framework for enhancing import safety and some key elements of the Action Plan. The organizing principles fall into three major areas: prevention, intervention, and response, and we have a number of recommendations and specific short- and long-term action steps in each of these areas.

Our overall goals are to:

- Promote a common vision of import safety with our trading partners and foster a culture of collaboration;
- Focus on risks over the product life cycle rather than a snapshot at the border;
- Increase accountability, enforcement and deterrence;
- Build interoperable data systems and encourage data sharing; and
- Promote technological innovation and develop new tools to enhance import safety.

The Action Plan covers all imported consumer goods that could pose a potential safety threat to U.S. consumers—from toys and tires to drugs, medical devices, dietary supplements, cosmetics, and all foods for both humans and animals. The general thrust of the plan is to broaden our focus from examining products as they enter the United States to monitoring imported products throughout their life cycle from production to consumption, paying particular attention to the critical points of risk along the way where safety can be compromised and safety standards are most needed.

Some of the highlights of the Action Plan are:

• **Creating new and strengthening existing standards.** We will work with international standard-setting organizations and foreign government regulators around the world to develop international standards that reflect the same level of protection maintained for consumer products in the United States.

• **Verifying compliance with safety standards.** We are proposing a voluntary certification program whereby products could be certified as meeting U.S. safety standards. This may involve verification—for example, testing or inspection by third parties or by domestic or foreign regulatory bodies. In addition, if HHS is provided the necessary authority, importers of certain high risk products could be required to certify that those products meet certain standards before they are exported to the United States.

• **Encouraging Good Importer Practices.** Import guidance documents will be developed to encourage the adoption of best practices to improve import safety.

• **Enhancing enforcement.** While voluntary product recalls are usually adequate to protect consumers, we are recommending authority for mandatory recall for the FDA in certain instances.

• **Expediting consumer notification of product recalls.** Track and trace technologies will enable officials to pinpoint where the problem occurred and intervene quickly. In addition, other technologies such as integrated circuit cards, also known as Smart Cards, may allow retailers to notify consumers of potential safety problems.

• **Exchanging import data.** U.S. Customs and Border Protection, the FDA, USDA and other agencies will increase coordination with real-time sharing of product safety information to better inform decisions about clearing or rejecting import shipments. In addition, we are exploring ways to expand the sharing of key data with foreign governments, consistent with applicable law, and gaining more access to data existing in the private sector as well.

The 12 Departments and Agencies involved in the generation of the Action Plan each have a role in the implementation of its recommendations. We also anticipate involvement of private sector stakeholders—retailers and manufacturers, importers, consumer groups, and others. Many of the Action steps can be accomplished by administrative changes, but some will require changes in the law and we are looking forward to working with Congress to accomplish these.

FDA FOOD PROTECTION PLAN

Earlier this year, I directed the FDA Commissioner to develop and submit to me a comprehensive plan for protecting the Nation's food supply. This plan, the FDA Food Protection Plan, was released at the same time that I submitted the Action Plan for Import Safety to the President. It utilizes the same framework as the Action Plan: Prevention, Intervention, and Response, and its action steps are consistent with and complementary to the recommendations of the Action Plan. One distinction is that the Food Protection Plan applies to domestic food producers as well as all imported foods regulated by the FDA. I would now like to provide an overview of the Food Protection Plan.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. There are three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses; (2) identify food vulnerabilities and assess risk; and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry.

First, to promote increased corporate responsibility, we 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. FDA will continue to work with industry and State and local governments to further develop the tools

and science needed to identify vulnerabilities and determine the most effective approaches. With regard to imports, we will work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with U.S. safety standards.

New authorities will be needed to accomplish this first goal. For example, the Food Protection Plan outlines new authorities to require entities in the food supply chain to implement measures *solely* intended to protect against intentional contamination of food by terrorists or criminals at points of high vulnerability. We have also proposed authority to issue regulations in certain circumstances requiring that high-risk foods be prepared, packed, and held under a system of preventive food safety controls.

Second, to identify food vulnerabilities and assess risk, we will 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. A comprehensive, risk-based approach will maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health. By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks. Working with the Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. When established and emerging risks are identified, assessed, and ranked, we are able to more effectively allocate our available resources to manage these risks.

Third, in order to expand the understanding and use of effective mitigation strategies, we will initiate additional risk-driven research about the sources, spread, and prevention of contamination. We will also develop new mitigation tools and implement appropriate risk management strategies. Building on risk assessments, we will initiate basic research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information will inform FDA's efforts to promote increased corporate responsibility to implement effective preventive steps. Focusing on higher risk foods, we need to increase research and leverage relationships with outside organizations in order to develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety.

Intervention

Because no plan will prevent 100 percent of food contamination, targeted, risk-based interventions are needed to provide further protection. The Food Protection Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance and improve the detection of food system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense and continues to increase. Therefore, legislation is needed to authorize FDA to accredit or recognize and use highly qualified, independent third parties to evaluate compliance with FDA requirements, thereby allowing the Agency's resources to be more effectively allocated. 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. FDA would not be bound by these third-party inspections in determining compliance with FDA requirements. However, use of accredited third parties could be taken into consideration when setting inspection and surveillance priorities.

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

Also, as part of the fiscal year 2008 budget, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of re-inspections and associated follow up work when FDA reinspects facilities due to failure to meet current Good Manufacturing Practice (cGMP) 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 fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Further, we recommend the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's reg-

ulatory authority for that entity (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 to imported products that have been shown to pose a threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, we will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with FDA's. The Agency will also have to take several steps to ensure a secure system that prevents counterfeiting of the certificates and takes into consideration trans-shipment of products as a way to avoid certification. FDA would use nondiscriminatory, scientific, and risk-based criteria to determine the focus of this proposed authority.

As noted earlier, improving the detection of food system "signals" that indicate contamination is an important component of enhancing our intervention capabilities. We can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing our ability to "map" or trace adverse events back to their causes by improving the Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for trending emerging food protection problems.

The recent pet food recalls showed us that we must continue to focus our efforts on animal as well as human food. For example, to provide the information necessary to allow for early detection of, and intervention with, contaminated pet food, FDA will work with the veterinary community, veterinary hospitals, and other private sources to develop an early warning surveillance and notification system to alert veterinarians and others about problems with the pet food supply.

Response

To improve our immediate response, we will 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. We will also increase collaboration with foreign, Federal, State, and local partners to identify a contamination source, remove contaminated products, and implement corrective actions.

Another key component of improving FDA's response is additional authority for emergency responses. The Food Protection Plan recommends requesting mandatory recall authority and enhanced access to food records during emergencies. This recall authority would be used only when the current voluntary recall process fails to promptly remove foods that present a threat of serious harm to humans or animals. Although FDA has the authority to seize adulterated or misbranded food, this is not the most efficient option when the contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there may be rare instances in which a firm was 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 from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays 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.

We are also seeking authority that would give the FDA more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food-related emergencies. Improved access to information concerning the safety and security of food, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health. The requirement would not impose any new recordkeeping burdens and would maintain the current statutory exclusions for the records of farms and restaurants.

Currently, access to records under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the act) 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.

As we continue to move forward with the Food Protection Plan, we will work with other Federal agencies, State, local, and foreign governments as well as industry to develop the food science and tools necessary to better understand the current risks of the food supply, develop new detection technologies, and improve response systems to rapidly react to food safety threats.

U.S.–CHINA CHALLENGES

Now I want to turn to the issue of imported products from China. As I have mentioned, although there have been some recent problems with Chinese imports, we must not conclude that all products made in China are dangerous. However, as noted below, we are currently taking a number of steps to improve the flow of information on the risks of imports from China and efforts will be made to increase the safety of Chinese imports through certification of quality controls in goods produced in China for export.

Let me provide some context for the discussion. China has a complex product safety regulatory system that consists of the Ministry of Agriculture which monitors food production and regulates farm inputs; the General Administration of Quality Supervision, Inspection and Quarantine [AQSIQ] which monitors processing and trade, the Certification and Accreditation Administration, which regulates the production certification, and the State Food and Drug Administration [SFDA] which coordinates food and drug policies and investigates safety mishaps. The Chinese system is challenged by rapid growth and decentralization of power which has resulted in overlapping authorities in some areas and gaps in regulatory control.

I have met with Chinese officials on several occasions to discuss import regulatory issues and we are in the process of finalizing negotiations on two binding Agreements that we expect to sign soon. One will cover the safety of food and feed, and the second will cover the safety of drugs and medical devices. These agreements outline the processes and points of contact for both countries to follow when the importing country rejects a shipment.

We expect that the provisions of the Action Plan will be instrumental to improving the safety and bolstering consumer confidence in Chinese imports.

CONCLUSION

Implementing the Import Action Plan and the Food Protection Plan will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities. We plan to coordinate with Federal departments and agencies to carefully plan the implementation and submit funding needs through the normal budget process in February 2008 and in subsequent years. To the extent that additional statutory authority is needed to implement the Import Action Plan, we look forward to working with this committee on import product safety legislation.

U.S. imports are large and growing rapidly. American consumers like the variety and abundance of consumer goods and the competitive prices that result from global trade.

The American people, however, have reasonable expectations that the products they buy for their families will be safe. We can and must do more to honor that trust.

The Action Plan will lead to both short- and long-term improvements in the way we view and regulate imported consumer products and implementing these recommendations will enable us to meet the additional safety challenges of imports in the 21st century. We appreciate the support of this committee and Congress as we move forward with our recommendations.

Thank you for the opportunity to discuss this important topic. I will be pleased to respond to your questions.

The CHAIRMAN. Well, thank you very much, Mr. Secretary. And I was looking through your report earlier and it has the features that you've mentioned here. I looked at it in terms of prevention and what's happening, currently. The authority you need to deal with the challenges that you're facing, and you've reviewed those.

I'm concerned about the current situation. As I'm looking down the road I wonder how we're going to be able to build in the future if we haven't got the underpinnings we need out there at the

present time. The advisory committee has questioned the whole scientific workforce and infrastructure, the underpinnings, when it describes the agency not having adequate investment in information technology and the use of antiquated equipment out there at the FDA.

And having to bring in people who have retired in order to repair equipment at the agency because it's so antiquated. And that the total number of inspectors is down, and the difficulties and challenges getting the kind of scientific workforce the agency needs. I agree that we have educational issues, and we have to work on those matters.

But the core factor about the agency and it being able to function is money. Money doesn't solve everything, but it is an indicator of a nation's priorities.

I think the commissioner of FDA is to be commended for requesting a review about where the agency is and what it needs. I mean, that's a bold request. It could have been done in house. And I think if it had been done in house, a lot of this would have been smoothed over. But, as it is, we have very distinguished individuals on that advisory committee and they have pointed out the extraordinary challenge that the agency is facing.

How are we going to look at the future when you've got the underpinnings that are crumbling now? It does seem to me we've got the central challenge now, to be able to look down the road at how we're going to coordinate different kinds of inspections in the future.

We have to talk about the condition of the underpinnings, which this report has put out and examined. And when you've got these kinds of conclusions, we would expect to hear from you that the FDA does not have the capacity now to ensure the safety of the food of the Nation. We can't worry about where we're going to be in 10 years when the report indicts the current situation. The report says, "does not." It doesn't say, "didn't have" or "will not." It says, "does not have the capacity to ensure the safety of food for the Nation."

Now, there are a lot of good things that are happening at the FDA, and some of them have been mentioned in the course of this morning's hearing. But, when you have an FDA that does not have the capacity to ensure the safety of food of the Nation, and the report has specific findings about how the scientific base is eroded, how scientific organizational structure is weak, and about weaknesses in the workforce and in information technology.

It would seem to me that we have to get that in shape to be able to build the follow up that you have talked about in your testimony. And we can get into some of those matters as well in the time that I have left. But, I would think the American people would want a sense of urgency from their person leading the agency, a sense of urgency about how you're going to respond to the effective indictment in the report. I think that's what they're waiting to hear. And I want to give you an opportunity to address it.

Secretary LEAVITT. Well, thank you Senator. Well, I think the response is right here.

The CHAIRMAN. That's not the current situation.

Secretary LEAVITT. Oh, yes it is. It is very much the current situation. We're implementing major parts of this.

This Friday I will leave for example, for China where I will sign agreements that we've negotiated with the Chinese that will move us a great step forward in being able to deal with the challenges of importing from China and other parts of the world. We're already in the process of developing a system I've spoken of. We're implementing this strategy.

What we have now for the first time is, we've taken a comprehensive look at the system. We have a clear plan to move forward. We have an action plan that not only includes the FDA, but includes 12 different departments and agencies of the Federal Government and a comprehensive way to go about it.

And we're reaching out to the private sector. It will not be government alone. It's going to require a coordinated effort. The urgency, we could not be responding more urgently. I'm spending a very high percentage of my time as it goes from the other departments to make certain that this is driven forward.

And we're looking forward to working with you in assuring that the legislative authorities that are necessary to make this work are in place.

The CHAIRMAN. Well, you might have that new, fancy system on papers but, you have an FDA that has broken information technology equipment today. You can get the most dramatic system on paper and it ain't going to work, it ain't going to work. And this advisory committee went to the core, to the basics, about what that agency needs. What is going to be necessary out there to do the job?

And what's in this report is nothing new. Many of us who've been following this agency and have been out to the agency, have seen this for ourselves. I haven't been out there for 2 or 3 years, but I've been out there. And at that time these same points could be made as are made by this independent, scientific report.

You can have all of these other actions that you're talking about internationally. My time is expired, but I will try and get back to question you about them. But if we don't deal with what this scientific advisory board says now, we are betraying the commitment that the agency has to the American people to protect them and their food supply.

Senator Enzi.

Senator ENZI. Thank you Mr. Chairman. And I want to thank the Secretary for his usual, very concise, well laid out presentation. I'm always impressed with that and impressed with the results that he gets from his agency.

I think it's important with all of these discussions that we don't move people into a state of fear that we keep them in a state of education or in the State of Wyoming, either one.

[Laughter.]

When I was first elected Mayor, one of my first visitors was a food inspector. And from the discussion I had with him I was under the impression that it was my job to go around to the restaurants with him and to see what sorts of things he was finding there. As an accountant I should have known that the job of a person like that is to find the bad things and to find as many of the bad things

as possible because their job is prevention. And I went with him and he did a good job. And I didn't eat in a restaurant for several months.

There are a lot of things behind the scenes that are being taken care of. They have to be found first and yes it does take people and it takes knowledge and it takes training and it takes money in order to be able to do that. And I have some confidence that the agency will do that.

You mentioned that you're going to be going to China and working on a Memorandum of Agreement with them on import issues. I'm pleased that you're going to do that. What do you hope will come out of those discussions? What sorts of things can be covered by a Memorandum of Agreement?

Secretary LEAVITT. We're sending a very clear and unequivocal message to any country or any organization that desires to import goods into the United States for American consumers. If they want access to American consumers they need to produce goods that are meeting the safety requirements of the United States and the quality requirements of the United States.

We want them to have access to our markets. We want to have access to theirs, and we'll help them know what our standards are and we'll help them know how to meet them. But this is a very important step in our relationship with China as well as other countries that we will negotiate subsequent agreements with.

Senator ENZI. You mentioned the high risk products. Some of the items in the food protection plan would focus on those higher risk products. Our food supply is very diverse. How do you propose to determine the relative risk?

Secretary LEAVITT. Well there are certain things that are perishable, for example. Food inspectors will tell you these are always things they look at. But as you talk to inspectors at the borders and as you talk to those people who are involved they'll tell you there's a whole myriad of things they look at to determine who's a risk.

For example, one wouldn't necessarily think about an importer who routinely does not keep the rules. They view that person to be a high risk and they want to focus more attention on them. And potentially need to spend less of their time on people who always keep the rules and in whom they have confidence because of their own experience and because they have chosen to have their products and their processes certified. So they'd like to focus more of their attention on people who are historically producing problems and less of their attention on people who always keep the rules.

Senator ENZI. Thank you.

We all agree that the food and import safety are critical issues and the Chairman has raised the comment about the resources that have been needed to carry out the plans and I'm sure all of us want to work with you and your Department to make changes to the food safety system, but no one can expect a blank check. So we need to figure out what this is going to cost so we can set priorities and get started on fixing the problems. What can you tell me about the kind of resources that will be needed?

Secretary LEAVITT. Well for the first time we have a master plan that lays out in the future what we need to do in order to accom-

plish a 21st century system. We now need to take the 2009, 2010, 2011, 2012, and 2013 budget and apply it to that master plan and invest every year. Now last year the Administration proposed more money in each of those categories. We'll undoubtedly do the same in 2009 and we now need to then apply those appropriations to this plan and the authorities that we need Congress to provide us to make this plan work and then drive forward.

Frankly, the advisory panel that the Senator has referenced reached many of the same conclusions that we did in our very comprehensive look at this system. This report clearly manifests that more resources will be necessary. We did not attempt to substitute this effort for the regular budget process, but it makes very clear that additional sources will be necessary to make this work.

Senator ENZI. Well, I thank you for the courage it took to put a plan in writing. We've had a Government Performance and Results Act in place for the Federal Government for I think about 15 years and this is the sort of thing that we're hoping will happen. Where people take a comprehensive view of what they are doing as well as any outside groups that might be taking a look at it and figure out what needs to be done. And I know that that takes a lot of courage and I thank you for it.

The CHAIRMAN. Thank you very much.

Senator Murkowski.

STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Thank you, Mr. Chairman and thank you, Secretary Leavitt.

I too, appreciate the efforts that have gone into this. When you think about things that can rattle a family, rattle a community, when the food that you have purchased at a grocery store and brought home to feed your family makes them ill, it is the most invasive, frightening thing that can happen to a family. I shouldn't say most. It is a very invasive thing. It is a very frightening thing that happens and I think people look to the government and say, "What are you doing about it? What have you done to make sure that my family is safe?"

I want to ask you about the request in the plan for the recall. The mandatory recall authority would be used only when the current voluntary recall process fails to promptly remove foods that present a threat of serious harm to humans or animals. Tell me what that really means in application. If you're a grocery store and selling spinach and somebody's gotten sick, you're going to pull that off because you want people, your customers, to keep coming back.

What has to happen before there is a step in and there's a mandatory recall?

Secretary LEAVITT. Senator, I'm going to confess to you that it was a surprise to me to find out that the FDA didn't have that authority. Now I assumed they did. This goes back a couple of years when I discovered this. Why? Because there's no indication that it's ever been a serious problem up to this point.

When I talked to the FDA people about how it works, they tell me that they say to the manufacturer or the processor, "we think your food is unsafe and we're prepared to make public notice that

your food is unsafe and recommend that people not buy it." And people routinely then recall their product. There may be circumstances where they refuse to do that.

Senator MURKOWSKI. Have we had any who just refuse to take it off?

Secretary LEAVITT. I'll ask David Acheson to answer that since he's involved every day in it.

Mr. ACHESON. Yes, we've had several. In the last few years it's been two or three issues particularly in the pet food industry where companies have absolutely refused and we've had to use the strategy that the Secretary's pointed out of alerting the public through the media.

Senator MURKOWSKI. Huh. I guess I assumed that there was some authority in place as well.

Let me ask a question that is more local. We've had some situations where there's been seafood, tainted seafood, that's come from China and probably from other countries as well. And for a market like the Alaska market where we rely on the reputation of a good and a safe seafood market when we have the news come out that this fish is tainted. Stay away from it.

Oftentimes the distinction may not be made as to where it's coming from. And then the consumer just says, "Well, the safest thing to do is stay away from all fish including the domestic product that we worked hard to build the reputation for." How can we do a better job of making sure the consumer is appropriately alerted while at the same time we don't hamper or lose ground in promoting our own domestic products where we know we've got a level of safety?

Secretary LEAVITT. I'm going to ask David to comment on this. But you referenced something that I think is an important thing to acknowledge. Earlier we had some conversation about lettuce. If there's one incident regarding lettuce then people assume all lettuce is tainted and they quit eating it. If they have a situation with fish then they assume fish is not good and they quit eating fish. And that's a serious threat.

And frankly it's a big problem to those particular industries. And for that reason those industries have begun to say, "We need to have standards that assure that everyone is maintaining quality and building it into their product because if there isn't, we all suffer."

So in the case of lettuce, for example, the produce growers got together and the processors and said, "let's develop some standards." They then came to the FDA and said, "here are standards that we think are extraordinarily high and would protect us, as an industry, by making certain that a few bad actors don't spoil the market for everyone." And FDA has now begun the process of incorporating those standards. We think there are other areas where that could and should occur.

For example in fish where a standard can be developed in cooperation with the industry who very much wants what you've suggested not to happen. And then use regulatory authority to incorporate that process using certification to say once we have a standard let's get people we trust to make certain that every single processor is meeting that standard. And if they're not, we're going to watch them more closely than those that do.

David, do you want to comment on that?

Mr. ACHESON. I think one of the key elements that you're getting at is the importance of communication.

Senator MURKOWSKI. Yes.

Mr. ACHESON. And making sure that consumers really understand what's implicated in a food safety situation and get that information to them quickly. And it's not just consumers. We need to apply that down to the stores at the local retail level. So if there is a recall product it's removed expeditiously.

The corollary of that is that following a recall, as with spinach, is to let consumers know that the product is back on the market and that it's safe to consume again. So, again it really boils down to communication and how to improve on that. And a part of the food protection plan is focused on communication around the response element.

Senator MURKOWSKI. Communication by way of advertising?

Mr. ACHESON. By all means. I mean I think part of this strategy that we'll use at FDA is to use a new risk communications advisory committee that we've established and really address what are all the modes by which we can communicate with people: media, TV, Internet. And as the Secretary pointed out part of that communication is in a recall situation of an individual store informing a consumer that the product that they may have purchased is a recalled item.

So there's many, many modes of communication that we need to look at because it's not a single one that's going to work.

Senator MURKOWSKI. Thank you Mr. Chair.

The CHAIRMAN. Thank you very much.

Senator Murray.

STATEMENT OF SENATOR MURRAY

Senator MURRAY. Mr. Chairman, thank you so much for having this hearing today. I heard your opening statement. I've got several meetings going on but I wanted to come back to ask a few questions.

I agree this is just absolutely a critical issue, a very difficult issue. I came into Congress in 1992. And before I even got my nameplate we had the *E. coli* issue with Jack in the Box and I had three young kids in my State who lost their lives as a result of that. And I know personally how important it is that we assure our consumers, our families everywhere, that the food they buy is safe. And we have a challenge doing that in this country. And we have to continue to take steps forward.

It's fun to bash government. It's everybody's game, but the fact is that government is who regulates food safety and it's our agencies who oversee this and the consumers depend on us and we've got to be doing the right thing. So I really, truly appreciate your having this hearing.

Secretary Leavitt, thank you for being here today and thank you to all of our panelists.

Secretary Leavitt, I've looked at the food safety plans that the FDA has put forward and they contain some recommendations for new legislative authorities by the FDA, such as the ability to mandate food recalls. I think some of those are positive steps, but I'm

concerned that the plan doesn't go far enough to ensure the public safety because a lot of the recommendations involve voluntary approaches. I wanted to ask you why you focused on voluntary approaches instead of required compliance measures?

Secretary LEAVITT. Our desire was to focus the energy of whatever resources we have in the areas where there is most risk and to be able to expand that by rewarding people who go to the point of adopting standards and certifying them to expand our reach. If we have more eyes we're able to, in essence, reach more. We think we can get people to voluntarily do that because of the advantages it gives them for example, on imports and being able to get their products into the country safely.

Senator MURRAY. What if somebody doesn't do it?

Secretary LEAVITT. Then we need authority to be able to police that.

Senator MURRAY. Which means you need additional resources to be able——

Secretary LEAVITT. Which means we need to be able to have the authorities to use the resources that we have to enforce it.

Senator MURRAY. Well, authority is one thing and resources another. If you don't have enough inspectors and you don't have enough ability to go out there and make sure that people are voluntarily complying then, all the voluntary measures in the world don't work. I mean we've certainly seen that over and over again.

I know Senator Enzi asked about the resources as well, but I know, we all know, we're in tight budget times, but I think safety of our food is a really critical issue. And I wanted to ask you what we can expect to see from the Administration in the fiscal year 2009 budget request for this?

Secretary LEAVITT. We'll be requesting more money to support this plan, as we did in 2008. We're in the process of developing that budget along with the Office of Management and Budget. So, I'm not in the position to say the precise amount, but I can tell you I have requested substantial additional budget for the FDA and for the other parts of HHS that are relevant to this matter, as I know other departments have.

I think it's again important to point out that when we looked at the totality of the system there were 12 different departments and agencies that were involved. This can't be just the FDA budget. It's got to be the entire budget based on a plan that coordinates all of it.

It also needs to coordinate what goes on in the private sector. Now, retailers today are saying to their producers, "if you want space on my shelf, you need to show me, to the point that I have no question, about the quality and safety of your goods because I'm putting my reputation on your good when I put it on my shelf." And some of the most aggressive inspection, some of the most aggressive oversight on food and product safety is coming from those whose brand depend on it.

Senator MURRAY. Ok, I understand that. But did—can I go back just a second?

Then I heard you say that we will see an increase in the budget, when it comes from the President, to cover these agencies.

Secretary LEAVITT. Well what I'm able to tell you is that I have proposed substantial additional resources from the HHS level. History tells me I usually don't get as much as I ask for, but I expect that there will be more in this budget.

Senator MURRAY. Thank you. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Senator Roberts.

STATEMENT OF SENATOR ROBERTS

Senator ROBERTS. Thank you Mr. Chairman. First I'd like to associate myself with the remarks by my friend and colleague from Colorado, Senator Allard, who indicated that despite all of the problems we have and the challenges we have, and as the Secretary has indicated, the current system is not adequate for the future, that we still have the safest food supply in the history of the world and by the way, at the lowest cost.

I do not think that we have a full blown crisis in regards to public confidence of our food supply. I hope that's not the case. Having said that, I can certainly appreciate it because I can remember very well going to the State of Washington at a Trade Round between what I'll affectionately call the Tear Gas Round. That was some years ago in the State of Washington, in Seattle and that was just following the tragedy in regards to Jack in the Box and that 100 percent loss for those families involved.

I must tell you as Chairman of the House Agriculture committee at that particular time we conducted an inquiry, not an investigation into that, and found out it was a good idea to cook the meat. And from that time on I think most Americans decided that medium and well would be better served than rare.

I ordered a cheeseburger by the way. I would tell my colleague, the Senator from Washington, the distinguished Senator from Washington and I couldn't get a cheeseburger, because of that situation and the turmoil and the trauma that all of that caused. I finally signed a liability statement so that I could get a cheeseburger. Now that's carrying this thing entirely too far. By the way it tasted like shoe leather. I didn't ever do that again.

I can remember too that, you know, pointing out the problem. Congressman Dooley will be part of a panel coming up. And I hope everybody pays attention to Cal because he does have a tremendous experience in the Congress and in the private sector in regards to what he has to say on some positive measures that the private sector will implement or is trying to implement in regards to food safety.

But we have a parts per trillion technology now, Mr. Chairman. It's very difficult. There's a little bit of something on everything. Parts per trillion.

And I can remember a case, again back in the House, and I apologize for going back to those days when I was somebody. But at any rate, this was a situation on an additive in regards to peanuts and there was an effort, an amendment on the floor of the House to terminate the use of that additive. And we figured out finally as we extrapolated what happened in regards to the test to determine whether it was safety or not that a person would have

to eat 600 pounds of peanuts a day for that to become a problem. There were some people in the House at that time that I recommended eat 600 pounds of peanuts a day, but we didn't get into any names.

And I'm not trying to be glib. I'm not trying to be sarcastic. I'm just trying to point out that we do have a parts per trillion technology that enables you to do a tremendous job in terms of enforcement, if in fact, you can go beyond what we have now and have the resources to do it and I applaud your efforts.

What I would like to ask is this. As we review this issue it seems there may be some things we can look to that may serve as a model. That we might consider. And my druthers are this, or my prejudice is this, because I think it would work.

It seems part of the solution would lie with getting the entire food supply chain, the entire food supply chain, to act on their own to the benefit of food safety. For the entire food chain to be the owners of prevention-based interventions built on some form of accountability, primarily based on traceability and then your enforcement capability. All this accomplished under some form of government certification and oversight than in the worst case scenario you can act.

And it's my understanding that today there are prevention-based interventions. And I'm really talking to the agriculture side, but it can apply to the FDA as well, that exceed minimum government requirements that exist today which can accomplish a safer food supply. But there's very little incentive for them to be implemented by our current system.

How can we incentivize them other than being punitive for them to do that? Obviously it would be in their best interest. And I would imagine that Mr. Dooley, who is sitting patiently here with his arms crossed, would speak to that. But could you respond to that in regards to incentivizing the private food system to go beyond the government standard in their own best interest?

Secretary LEAVITT. Dave, would you like to comment on that?

Mr. ACHESON. Yes, happy to. I think probably the easiest example to give to you is one in relation to imports. As the Secretary has pointed out, the current system is based on inspection at the port of entry. And the vision that we're moving forward is this whole part of life cycle process.

If, in that process, we understand the preventive controls that work in foreign manufacturers and we know through our risk assessments that they're implementing those preventive controls. Then I think a significant incentive would be that those products would be less likely to be inspected at the port of entry because we know already that they're being manufactured under a system using preventive controls. If they're going beyond what we do, so much the better, but at least to the minimum of what we expect for FDA.

So I think in that context through working with our stakeholders, working with foreign governments, the private sector, we can provide information about what are those preventive controls. Where are the risks? What are the concerns? And essentially help drive the system. Pushing the resources where we need to, to the

areas of greatest risk and thereby providing incentives to industry to adopt those preventive measures.

Senator ROBERTS. Mr. Chairman, my time is up. I didn't know if the Secretary wanted to add anything or not.

Secretary LEAVITT. Well, I would simply say that if we assume that government will own the entire system, it will not be as good a system as one government organizes that incorporates all of the aspects of government, both State, local and the private sector. And the remarkable incentives that are there for those who desire to have products that are delivered to consumers on a safe and effective basis.

I mentioned, I think you were here, but perhaps not, the circumstance with lettuce a couple of years ago where the lettuce producers said, "anytime a bad actor performs in a way that taints us all, we all lose." And so let's get together and harness our capacity to hold everyone to a standard. And if we do, the market improves. And we can then use government as a means to discipline those who do not meet that standard in addition to what the market does, then we'll get to the point that we're building quality into the product as opposed to standing at the border hoping to catch a few that try to cheat.

Senator ROBERTS. Mr. Chairman, I don't want to open up an old wound, but I also remember the case of Alar and apples. It cost the apple industry $600 million one year. We had people in a school lunch program throwing away apples. It wasn't Mom and apple pie anymore.

It was quite a few years ago and that was a shelf preserver, but the consumer did not want to buy the apple that did not have the shelf preserver because it didn't look that good. Now there's some question as to whether Alar was proper or not, but the industry suffered $600 million. And at that particular time they would have done anything, anything, in terms of public information through the FDA, through themselves, but they just didn't have the wherewithal to do it.

And so we really went through a very difficult time which is why I think it is so important that you are having this hearing Mr. Chairman and why you have asked for additional funding and knowing that we have to go beyond what we have now. Thank you, sir.

The CHAIRMAN. Thank you.

Senator Allard.

Senator ALLARD. Thank you Mr. Chairman. And Mr. Secretary, you know as Governor, I think that your health department and the various county departments are extensions of State government and I think most States organize like this because they have uniform rules and regulations. They put out to the States and the States adopt them, have the authority to close down a business if they wanted to do it.

And so we get to the issue well, is it more appropriate at the Federal level? Is it more appropriate at the local level as far as enforcement is concerned? And having been in an enforcement process myself, I mean, if you go in and you close down a business, they're out of business if it's a grocery store.

And so what happens, you know if you saw a bad can on the shelf that was distended indicating there was gas production then you took it off immediately. And the owner usually did that because they understood that you had the power to close down their business if they didn't because it was a human health issue. I'm talking about human health. So it's a human health issue.

So if you look at this I think you will find that there's adequate enforcement and a lot of enforcement that happens through the State Health Departments as well as the local health departments work as an extension of the State health. At least that's what happens in my State, in Colorado. And I think that happens in most States.

From my personal experience, if we have a problem at a local level with a retailer, he's going to respond. Not only for public relations purposes, because he realizes that the local health department inspector has pretty good control over getting something off the shelf that's going to be an immediate public health problem. And as soon as it gets recognized, if necessary, you go to the judge, and you can go to the judge and get a quick court order, locally and get it done.

My question is that with these various issues that have been brought up in the last year and particularly the spinach and the salmonella in the peanut butter and the *E. coli* in the spinach. With the recommendations that you're now dealing with that's come out of the working group, how would you handle this situation differently in the last year? Would there have been a change in the way you've managed those situations which you're talking about with new recommendations from the working group and yourself and what we now do? Is there going to be any change there?

Secretary LEAVITT. I will ask David to respond from a food regulator standpoint. But let me make this point as a policymaker. Consumers will punish harshly and rapidly those that don't produce safe and quality products. There are times when government is necessary to go further and to use different authorities to do that.

I think you've asked a very important question about the circumstances that occurred recently. I think it's important to acknowledge we cannot eliminate all risk from society. There will always be circumstances that occur where something goes wrong and something that isn't as safe as our expectations, as we aspire it to be. That's why we have this system—to catch those moments and to make certain that they do not become public health problems.

David.

Mr. ACHESON. I think one point that probably won't change a great deal is our ability to respond. When we have an outbreak in spinach we get on it quickly and we respond. And I'd like to find ways to improve that but substantially that system is working.

What will change is to try to prevent it ever happening in the first place. What we've got to do is maintain that rapid response when we need it. But really figure out how to prevent the problem from ever happening in the first place through targeted risk-based prevention and intervention strategies.

Senator ALLARD. I do agree with Secretary Leavitt's comments. You're not going to have it completely risk-free. We do things in

public health that reduce the risk. For example in handling foods on a butcher table we go out and do swabs on the butcher table and if the bacteria count is too high it indicates there's improper sanitation. If it's at a low it indicates that they're using proper sanitation, but you never completely get rid of the bacteria.

But it's safe bacteria that we test for. It's *E. coli*, as a matter of fact, that we test for. It's not the hazardous *E. coli* that causes human disease, but we look for the safe. And so, you know if the *E. coli* count is too high it indicates there's improper sanitation, but there's always that risk that some move forward.

So there's also an important educational element here that the food preparer needs to know that if you're dealing with salmonella you don't take eggs and mayonnaise and put them in a potato sack and let it sit in the sun. You know, I don't care how rigorous your inspection is, that's going to be a problem. Same thing with raw meats, I mean, if you've got raw hamburger that's ground and you don't cook it properly you run a high risk of eating the pathogenic, the one that causes disease, *E. coli*. If you cook it thoroughly the risk isn't there.

So, there's a big educational effort there and in the working group's recommendations did they say anything about educating food preparers so that they would be more aware of that? I don't think people are as aware of that as at some other past time in our history. It seems like that is one area where we're falling down is the educational side.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you Mr. Secretary. I just want to mention one last point here with regard to the FDA Science Advisory Board and I'll submit some other questions.

The CHAIRMAN. This is what they pointed out with regard to resources. In the recent Executive order announcing the interagency working group on import safety, President Bush stated that the current system must be fixed "within available resources."

Now this is what they conclude. This is the FDA Science Advisory Board. "We can state unequivocally that the system cannot be fixed within available resources." That's what they say. That's the Advisory committee.

They've just made the finding that the system is broken. We're talking about what's going to happen off in the future and they say, "we can state unequivocally that the system cannot be fixed within available resources. Infrastructure improvements to enhance existing laboratories, equipment and personnel will require additional $10 million for CFSAN, $40 million for ORA. These estimates do not include funds required to modernize the assessment of animal-derived products" and all the rest.

So, this is the Science Advisory Board talking about the existing system here. We're concerned. We've heard your testimony about the future, what's necessary for that. They're talking about today. What is the here and now that is threatening the agency's ability to provide safety.

Now what are you going to do about it? The American people are watching. You're the man. They want to know whether you have a sense of urgency to make sure there's going to be adequate re-

sources. Not this proposal here. It isn't dealing with FDA science and technology. Your proposal does not deal with it.

So we want to know what you're going to do about their conclusions that the agency is in trouble and needs help. And you're the man. This is the time. What's your response? Are you going to get them additional help and assistance so that they can do the job to protect the American food supply?

Secretary LEAVITT. Senator, I am the man and here is the plan. [Laughter.]

It is a road map for continual improvement starting today. We're implementing parts of this now. You referenced the Executive order that indicated that this would need to be implemented within available resources.

Now the working group went back to the President when we made our report and said, "we do not find that possible." And the report itself says this will require additional resources. And I believe you will see additional resources in the President's budget and in future Presidents' budget to implement this very comprehensive plan.

The CHAIRMAN. Ok. Thank you very much.

Secretary LEAVITT. Thank you.

The CHAIRMAN. I appreciate it. We'll move on to our next panel.

Our witnesses are Michael Taylor, a former USDA and FDA food safety official now at George Washington University.

Paul Young of the Waters Corporation, a Massachusetts Company. Dr. Young was a food safety inspector in Great Britain, with expertise on the EU and Japan.

Cal Dooley, a former Congressman from California, family farmer, is the president of the Grocery Manufacturers Association.

Caroline Smith DeWaal. Is that pronounced correctly?

Ms. DEWAAL. Yes.

The CHAIRMAN. Thank you. Is the Director of Food Safety, the Center for Science in the Public Interest. She is a lawyer and has laryngitis today. So Mr. Plunkett will deliver her testimony, but she's here and going to help us with some questions.

And Joe Corby, the Director of Food Safety, New York State, 37 years experience in food safety.

Senator ENZI. Mr. Chairman.

The CHAIRMAN. Yes?

Senator ENZI. While they're getting seated there I'd also ask unanimous consent to include a statement from an outside group, the American Frozen Food Institute.

The CHAIRMAN. It will be so included.

Senator ENZI. Thank you.

[The information previously referred to follows:]

PREPARED STATEMENT OF THE AMERICAN FROZEN FOOD INSTITUTE (AFFI)

Chairman Kennedy, Ranking Member Enzi and members of the committee, thank you for the opportunity to submit this statement for the record. We appreciate your commitment to food safety and commend the committee for holding this important hearing.

The American Frozen Food Institute (AFFI) is the national trade association that promotes and represents the interests of all segments of the frozen food industry. AFFI fosters industry development and growth, advocates on behalf of the industry before legislative and regulatory entities, and provides additional value-added services for its members and for the benefit of consumers. AFFI members manufacture

and distribute frozen foods throughout the United States and globally and are committed to ensuring that these products are produced in accordance with strict standards of safety and quality.

U.S. FOOD AND DRUG ADMINISTRATION FUNDING

Americans spend more than $1 trillion on food—nearly half of it in restaurants, schools and other places outside the home. Consumers have a reasonable expectation that the food products they buy are safe. While much is being done to ensure the safety of these products, safeguards must be continually updated to meet the changing demands of a global economy.

The combined efforts of the food industry and government agencies are credited with making the U.S. food supply among the safest in the world. Recent food safety incidents, however, have spurred debate about whether our regulatory agencies have adequate resources to do their jobs as effectively as possible, and whether the current Federal food safety laws have kept pace with the significant advancements in food production, processing and trade.

While it is impossible to eliminate all potential food safety risks, we can work smarter to reduce risk. It requires the creation of new and innovative ways to protect American consumers and continual improvement in managing the safety of our imports, in addition to our domestic production. Approximately $2 trillion of imported products entered the U.S. economy last year and expert's project this amount will triple by the year 2015. Meanwhile, the major U.S.-food regulatory agencies continue operating at budget levels well below amounts needed to keep up with the influx of imports.

Food safety always has been and continues to be a top priority for AFFI and its more than 500 member companies. This year, the Institute joined the *Coalition for a Stronger FDA* in its efforts to build public support for increased funding for the U.S. Food and Drug Administration (FDA).

The *Coalition for a Stronger FDA* is comprised of consumer and public health advocates, food and medical industry representatives, and more than 50 patient groups working to ensure FDA remains well-positioned to protect Americans. Funding for FDA is critical, especially because the agency will be called on to address an increasing array of domestic and international issues in the coming years—including revolutionary food and medical advancements. The Coalition is undertaking a multi-year effort to ensure FDA has sufficient resources to protect patients and consumers, and to maintain and build public confidence and trust in the agency.

The frozen food industry will continue to work with government leaders, as well as others within the business community and the general public to ensure government agencies with oversight over food safety have the necessary resources to fulfill their responsibilities. The work that the dedicated men and women of these agencies, particularly FDA, do every day directly affects the lives of every American—from public health to nutrition assistance, both at home and abroad. Failure to adequately invest in these programs will have serious long-term consequences for our country and its consumers.

Although the U.S. food industry has a tremendous track record of supplying the world with safe, high quality food, we certainly recognize the necessary and complementary role that FDA and other regulatory agencies play. These entities ensure public health through the establishment of food safety standards and by carrying out necessary testing, inspections and scientific research.

In the wake of recent, highly publicized food safety concerns, significant budget increases will allow agencies such as FDA to help reassure consumers, speed innovation in food safety and medical technology, and ensure the U.S. remains competitive in foreign markets. A $115 million increase in the food budget, for example, would allow FDA to hire more food inspectors, speed approvals for safe new food technologies and products, and provide leadership in protecting the food supply from intentional threats.

The proposed increase in funding that AFFI and the *Coalition for a Stronger FDA* seek will assist FDA in developing new strategies and continuing important work in the areas of regulatory enforcement, monitoring and inspection, international harmonization, science-based oversight, foreign food safety assessments and technical assistance, and trade. These efforts are intended to enable the agency to remain an effective force in resolving international issues bearing on the safety, quality, and labeling of foods and other products.

This budget increase also will allow FDA to hire the next generation of highly qualified scientists and other career agency personnel who will be the future recipients of critical institutional knowledge on a wide range of food safety issues. Without these funds, the agency will face a critical shortage of expertise in the future.

FOOD SAFETY SYSTEMS

Although the food industry has developed and implemented sophisticated food safety assurance methods, Federal and State regulatory officials have traditionally depended on spot-checks of conditions and random sampling of final products to monitor compliance with applicable regulations. This approach has tended to be reactive rather than preventive with limited ability to address the many challenges with which an industry as dynamic as the food industry is increasingly faced.

Among the most important challenges in recent years has been the increasing number of new food pathogens. There was also increasing public health concern about chemical contamination of food products. Other key challenges confronting the industry and regulatory agencies over the years has been the increasing size of the food industry, diversity of products and processes, amount of domestic food manufactured, and the number and kinds of foods imported. At the time, FDA and State and local agencies had similar levels of resources to ensure food safety.

The food industry has effectively and, for the most part, voluntarily employed the Hazard Analysis and Critical Control Point (HACCP) system to identify and address potential hazards in food processing. But HACCP is a dynamic system tailored to the unique conditions in each individual processing facility. A foundation of complementary preventive control programs is necessary for HACCP to be effective. For example, the Current Good Manufacturing Practices (CGMPs) are fundamental building blocks that can be applied generally to all food facilities. By strengthening the preventive controls, food safety can also be enhanced.

AFFI has been working with FDA and a coalition of more than 60 food companies and trade associations to modernize CGMPs regulations for foods. These building blocks include employee training, allergen management, environmental monitoring, sanitation practices, and other critical tools.

For more than 25 years, CGMPs have formed the basis for safety assurance programs in food manufacturing facilities, and they have been very effective. Given today's food safety concerns and the development of new technologies for addressing such concerns, AFFI supports FDA's efforts to modernize food CGMPs and ensure their application in all processing facilities. In so doing, we have urged the agency to build on and enhance the existing regulations, which should continue to serve as foundational, prerequisite conditions for producing safe food products.

CONCLUSION

In today's global economy, continued and enhanced cooperation between industry and government is critical to ensure the safety of the U.S. food supply. The regulatory agencies, especially FDA, need adequate resources now, and in the future, to carry out their mission and mount the challenges of a continually growing global marketplace. Working with FDA, the food industry needs to employ preventive control programs that take advantage of modern technology.

Once again, thank you for the opportunity to submit this statement for the record. We look forward to working with members of the committee on this and other issues of relevance to the frozen food industry.

The CHAIRMAN. OK. Mr. Taylor.

STATEMENT OF MICHAEL R. TAYLOR, RESEARCH PROFESSOR OF HEALTH POLICY, THE GEORGE WASHINGTON UNIVERSITY, WASHINGTON, DC.

Mr. TAYLOR. Mr. Chairman, Senator Enzi and members of the committee I do appreciate greatly this opportunity to testify today on strategies to improve food safety and on the FDA's Food Protection Plan.

Earlier this year the Government Accountability Office declared the Federal Government's Food Safety Program at high risk of failure due to its outdated laws, fragmented structure and inefficient use of resources. This conclusion came after a decade of recommendations from GAO and the National Academy of Sciences to modernize the system, legislatively and organizationally so that it can be effective in preventing food safety problems instead of simply reacting to problems after the fact.

The consequences of not acting on the GAO and NAS recommendations are clear. We've heard about them today. They include an unacceptably high burden of preventable foodborne illness, a chronic inability to keep up with the food safety challenges of today's global food system and declining public confidence in the safety of the American food supplies.

So Mr. Chairman, it is time, at last, to begin the reform process. It won't be easy. I can assure you of that. We're talking about a food safety system that has evolved over many decades without a coherent plan or strategy and that now includes some 20 components of FDA, USDA, EPA and CDC, 3,000 State and local agencies and a myriad of obsolete laws.

The needed modernization of this complex system will take time to design and implement and should be pursued with due deliberation and care. But it must be pursued starting now. And I believe the right starting point is the Food and Drug Administration.

Among all of our agencies involved in food safety, FDA has long been looked to as the natural focal point for food safety leadership in the United States and internationally. It oversees 80 percent 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. As we now know however, FDA's ability to provide the needed food safety leadership is badly constrained, not only by obsolete statues that focus more on reaction than prevention, but also by plainly inadequate resources and an internally fragmented and ineffectual organizational structure. I believe all of these problems must be addressed for FDA to be successful in an increasingly complex globalized food system.

Now as we embark on a comprehensive modernization process we need to get the basic policy principles right. And I think you will find good agreement among experts on the following five principles around which resources and institutions should be mobilized.

First, you must treat food safety as a farm-to-table systemwide problem. This simply recognizes that hazards can be created and minimized at many points across the system and we should take advantage of all opportunities to reduce risk.

Second, we must make prevention of food safety problems the central focus of the system, as we've been hearing today because this is the only way. Preventing problems is the only way to protect public health and maintain public confidence.

Third and very critically, we have to recognize again as we've heard here today that the primary duty for prevention falls on the food industry. The food industry, after all, not government produces food and only the industry can make it safe.

Equally important however, we must focus, this is the fourth principle. We must focus FDA's program on setting and enforcing standards that make the food industry accountable for prevention. I believe ensuring accountability for prevention by setting and enforcing standards is the unique and most essential government role on food safety.

Fifth and finally, we do have to strengthen FDA's mandate for providing national leadership on food safety. And we've got to bolster the agency's tools for managing the science and risk-based regulatory program and of course the FDA Science Board report cer-

tainly underscores this need to bolster FDA's science tools. This includes the ability to exercise—national leadership includes working with State and local governments and the industry to build a modern, nationally integrated system that harnesses the best science and that makes good use of all of its resources.

Mr. Chairman I'm glad to say that FDA's food protection plan embraces many of these principles at least conceptually, including the need for a farm-to-table approach, focus on prevention and industry responsibility for prevention and it contains many specific ideas that are worthy of adoption. I do applaud the Secretary and the FDA staff for the effort and thought that I know went into developing the plan.

The plan falls critically short however on implementation of what I consider the most fundamental policy change required to make the FDA's program effective which is as I've indicated, establishing clear and comprehensive industry accountability for prevention and doing this with respect to both domestic and imported food. Rather than establish that accountability the FDA plan relies almost entirely on voluntary approaches to implementing preventive controls in the food industry. In fact under the plan as the Chairman indicated in his opening remarks, FDA would be able to require preventive controls only if it could establish through rulemaking, that a particular food has been associated with repeated, serious, adverse health consequences or death.

This standard is actually more restrictive of FDA's ability to act preventively than the authority FDA has been able to use under current law to require preventive controls for seafood and juice. Moreover, requiring FDA to prove that such serious harm has already occurred treats preventive process control as a tool for reacting to problems rather than systematically and comprehensively building prevention into the system.

Mr. Chairman, we should not be afraid to regulate in the name of food safety. We know that preventive process control is the standard of care that many leading and responsible companies have developed themselves and are already observing. It should be the standard of care for everyone in the business of producing and marketing food to American consumers. In my view we would neither accomplish our public health goal nor have a system that is credible in the eyes of the public if we make the basic commonsense preventive control optional and leave FDA in the role of encouraging progress rather than being a credible source of standards and accountability for doing food safety right.

Of course we have to be smart about regulation. Old fashioned command and control regulation can impose unnecessary cost and stifle innovation. The food industry itself has historically been the source of much valuable innovation to improve food safety. Regulations should foster that innovation, not stifle it.

To that end modern effective regulation is clear in setting performance standards for companies and flexible in how companies can achieve the standard. It's not a one-size-fits-all approach and we should work to assist small businesses. But the public rightfully looks to government to set and enforce standards to achieve goals like food safety that people can't achieve solely on their own.

In sum Mr. Chairman, I hope this committee and Congress will move forward in concert with the many stakeholders in the food safety system to modernize FDA's food safety authorities in accord with the five principles I've outlined today. I hope Congress will work also to solve the serious resource and organizational problems that are obstacles to FDA's success. And we've heard about that today and I won't elaborate. But the resources of FDA's food program have eroded down to a level where they really are unable to take leadership and take initiative.

Mr. Chairman we need to get FDA's food safety policies right and we need to then back them up with the resources and organizational structure to do the job. Thank you again for this opportunity to testify. I look forward to questions.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF MICHAEL R. TAYLOR *

Mr. Chairman, Senator Enzi, members of the committee, I appreciate this opportunity to testify on strategies to improve food safety and on the Food and Drug Administration's recently issued Food Protection Plan.

INTRODUCTION

This hearing is timely and important. For over a decade, the Government Accountability Office (GAO) and expert committees of the National Academy of Sciences (NAS) have been documenting fundamental problems in the Nation's food safety system—a system that has evolved over many years without a coherent plan or strategy and that now includes some 20 components of FDA, USDA, EPA, and CDC, and 3,000 State and local agencies.

Among all these agencies, FDA has long been looked to as the natural focal point for food safety leadership in the United States and internationally. It oversees 80 percent 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 current ability to provide food safety leadership, or even meet its basic food safety responsibilities, is badly constrained by:

- *Obsolete statutes* that date back to the 1930's and focus more on reacting to problems than preventing them;
- *Inadequate resources* that are dwindling in the face of an increasingly complex, global food supply; and an
- *Internally fragmented and ineffectual organizational structure* that makes FDA incapable today of providing effective food safety leadership.

Certainly, FDA could be doing more with its present tools to address some of today's pressing food safety problems. I believe, however, that FDA will continue to fall short of what the public needs and expects from this critical public health institution until Congress provides a modern statutory mandate, an adequate and stable resource base, and an institutional structure capable of national and international leadership on food safety.

And that is why it is so timely and important for this committee to be focusing on how to improve FDA's food safety program. 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. This committee's leadership will be essential to achieving these outcomes.

In my testimony today, I will not linger over the litany of what's wrong with the FDA program. I will instead focus on what I believe are the core policy elements of a successful strategy for improving food safety, and I will assess the new FDA Food Protection Plan in light of those elements.

In general, I find that the FDA plan contains many of the policy ideas that experts agree are important to ensuring food safety—and thus provides a platform on which to build. It falls critically short, however, on clearly and properly defining the complementary but distinct food safety roles of the food industry and the government. As a result, the FDA plan does not include actions and recommendations that I think are vital to FDA's success.

I note also that the administration's plan is silent on FDA's resource and organizational problems, but I will focus in this testimony on the core policies that should underlie FDA's food safety strategy and program.

CORE POLICY ELEMENTS OF A SUCCESSFUL FOOD SAFETY STRATEGY

The following are the five core policy elements that I consider essential to a successful FDA food safety strategy.

1. Treat food safety as a farm-to-table, system-wide problem.

For most of the 20th century, food safety regulators focused largely on basic sanitation in processing plants, chemical contaminants in food, and the safety of chemical additives. It was possible then for FDA to focus on a relatively narrow set of establishments, commodities, and decision processes through which those concerns could be addressed. Over the last 20 years, however, the problem of foodborne illness caused by microbial pathogens has emerged as a central food safety concern and one that requires a broader, "farm-to-table" approach to ensuring food safety.

A farm-to-table approach is required due to the simple reality that dangerous bacteria and other pathogens can enter the food chain at almost any point, from production on the farm through processing, retail sale, and final preparation for consumption; they can grow; and they can be killed. Thus, whether someone gets sick depends not on any one contamination event but on a wide range of events and behaviors that occur across the entire farm-to-table food system and that, in combination, determine the likelihood dangerous levels of an organism will be present at the point of consumption.

This expanded understanding of food safety makes everyone—from farmers to consumers, as well as government food safety agencies—actors in the food safety system. It creates the opportunity and need for integrated action to minimize food safety risks at points all across the farm-to-table system—wherever pathogens can enter the food and grow or be reduced. FDA's food safety program must recognize and act on this reality, as recommended repeatedly by GAO and NAS.

2. Make prevention of food safety problems the central focus of the system.

Prevention is the core principle of public health and should be the central focus of the food safety system. Prevention of problems is certainly what consumers expect of the system, and it's the core principle that drives modern approaches to food safety. Most notably, HACCP (Hazard Analysis and Critical Control Points) is a system of preventive process control that was developed originally by the food industry as a method for anticipating and preventing food safety hazards in particular food production and processing operations.

FDA has adopted HACCP as a regulatory requirement for seafood and juice, but prevention is not an explicit part of its statutory mandate. In fact, FDA's food safety legal authorities are designed primarily for reacting to and correcting problems after they occur, not for preventing them. In an on-going outbreak of foodborne illness, swift reaction and containment measures are important and can reduce the number of illnesses associated with that outbreak, but, to protect public health and meet public expectations for food safety, preventive measures such as HAACP need to be built in to the system so that the risk of food safety problems occurring in the first place is minimized to the greatest extent reasonably possible.

FDA currently pursues prevention of this kind only on a selective and ad hoc basis. A comprehensive, systematic approach to prevention should be a core principle and central focus of the food safety system.

3. Recognize that the primary duty for prevention falls on the food industry.

This may be the most crucial point to emphasize in getting roles and relationships between government and industry right. The unavoidable reality is that government does not make food, and government cannot make it safe. That's the food industry's job, and making food safe—doing everything reasonably possible to prevent food safety problems—is the most fundamental duty food producers and processors owe to America's consumers.

Many of our Nation's leading food processors and retailers take this duty very seriously, and they make extensive efforts to fulfill it. They know food safety doesn't just happen; it's the result of a plan. So they impose safety specifications on their suppliers to be sure their raw materials and ingredients are safe; they implement HACCP and other preventive control measures within their processing plants; and they test their finished products to verify that their control systems are working. In fact, over the years, much of the food safety innovation in the United States has come from companies that take food safety seriously and have plans for achieving it.

The problem is that many of the Nation's 44,000 food manufacturers and processors, 114,000 food retailers, and 935,000 restaurants do not have effective food safety plans. And, at the farm level, systematic planning for prevention of food safety problems is in its relative infancy. This must change.

Any business involved in producing, processing, and marketing food must have a plan for making it safe, based on modern preventive controls. This does not mean a one-size-fits-all approach. It does not mean HACCP per se for every commercial participant in the food system. But it does mean that anyone producing food for today's marketplace should know how they are going to make it safe and should do that consistently, every day.

4. Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.

While the food industry is inherently responsible for making food safe by acting preventively, FDA's job as a public health regulatory agency is to set and enforce standards that make the industry publicly accountable for prevention, in accordance with a defined standard of care. Setting standards for prevention means defining the responsibility of food producers, processors and retailers to have and implement food safety plans based on modern preventive controls. It also means establishing performance standards that define the level of protection, or food safety performance, that is to be achieved through preventive controls, such as the levels of chemical residues or microbial contaminants that are deemed acceptable.

Standards protect food safety only if companies comply with them, and it is FDA's job to ensure compliance through inspection and enforcement. For many leading companies, compliance is not an issue: if the government sets a food safety standard, they will organize their systems to comply. In fact, many will go beyond what the government requires in response to the demands of their customers expressed in the marketplace. The food industry is, however, highly diverse, with some companies lacking the market incentive or an internal culture that ensures they meet high food safety standards. That's why government standards and government enforcement are needed, and it's why they are in the interest of both consumers and those in the industry who take their food safety job seriously and do it well.

Government regulation of food safety is essential, but it has to be smart regulation. We have learned that old fashioned "command and control" regulation - in which the government specifies not only the outcome to be achieved but how industry must achieve it—can impose unnecessary costs and stifle innovation. Instead, modern regulation is clear in setting performance standards for companies and flexible in how companies can achieve the standard. Thus, as a regulatory tool, HAACP sets a standard of care for implementing preventive process control but is inherently flexible in allowing companies to tailor their preventive controls to the particular hazards and circumstances in their operations. Performance standards for microbial contamination say what level and incidence are acceptable, but they do not dictate the interventions needed to achieve them.

In a food safety system based on holding the industry accountable for prevention, regulators have a duty not only to avoid stifling innovation but to affirmatively encourage it. This means among other things ensuring that regulatory review of new food safety technologies is done promptly and with an appreciation of the food safety benefits of technological innovation.

5. Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.

While FDA's core role on food safety is to set and enforce standards, it will be effective in this role only if it operates from a position of strength as the Nation's leading science-based, public health regulatory agency. To this end, FDA should have a clear mandate to drive research aimed at understanding food safety problems and solutions and setting science-based standards. It should work closely with CDC, other Federal food safety agencies, and State and local agencies to build an integrated, national system of food safety protection. And it should provide scientific and policy leadership to develop workable approaches to risk-based priority setting and resource allocation across the food safety system.

ASSESSMENT OF THE FDA FOOD PROTECTION PLAN

The five core policy elements outlined above reflect current thinking about the attributes of a modern, effective food safety system, as that thinking has evolved through the work of NAS, GAO and other experts. The language of the FDA Food Protection Plan is largely consistent with these ideas. It speaks of addressing risks of food "from production to consumption"; it makes prevention and corporate responsibility for prevention central themes of the plan; and it calls for risk-based ap-

proaches to inspection and better use of information to improve food safety. For this reason, the plan is a useful basis for discussion.

The shortcomings of the plan lie in the specific actions it proposes—and fails to propose—to implement these broad ideas. While many of the proposed actions are worth pursuing, they do not add up to an effective FDA strategy to improve food safety. In general, they fall short of the action that is needed to establish the food industry's farm-to-table accountability for prevention. To illustrate this key point, I will review the FDA plan in light of the five core policy elements discussed above.

1. Treat food safety as a farm-to-table, system-wide problem.

While stressing the importance of a farm-to-table approach to food safety, the FDA plan proposes no specific actions to improve food safety on the farm or at retail, beyond what it is currently doing.

At the farm level, the plan calls for FDA to meet with food industry representatives to strengthen "voluntary" prevention efforts and for FDA to develop guidelines for industry development of voluntary "food protection plans" for produce and other foods, but FDA has been meeting with the industry about produce safety for the last decade, and in 1998 issued non-binding "good agricultural practice" guidelines to address the microbial safety of fresh fruit and vegetables.

Early this year, an industry trade group, the United Fresh Produce Association concluded that the voluntary approach was insufficient and called for FDA to establish mandatory, enforceable, on-farm standards for safe produce production, but the FDA plan is silent on this idea. And, while the plan calls generally for strengthening FDA's ability to assess and prioritize risks and identify preventive strategies, it contains no specific proposals for driving the research and analysis needed to establish enforceable food safety performance standards on the farm.

On retail food safety, the plan makes several references to the need for dialogue with the States and localities, which play the frontline role on food safety in the Nation's grocery stores and restaurants. Such dialogue is important, but is has been ongoing for many years and has resulted in important collaboration through FDA's development and the adoption by many States of the Food Code, which is a model ordinance for regulating food safety at retail. In addition, FDA and the States collaborate on an innovative program to foster improvement in State and local food safety regulatory programs, based on uniform national standards. The FDA Food Protection Plan does not include ideas for improving these core FDA retail food safety programs or recommend any other specific actions to improve retail food safety.

While the FDA plan lacks concrete proposals for new actions to address food safety risks on U.S. farms or at retail, it does call for a number of actions to improve FDA oversight of food imports, including more affirmative efforts to work with foreign governments on food safety, develop knowledge needed to target high-risk imports, and improve FDA's ability to detect problems at the port of entry. These ideas are positive, but, as discussed below, the report does not address the accountability of importers for ensuring that the food they import was produced in accordance with U.S. standards.

2. Make prevention of food safety problems the central focus of the system.

The FDA plan gives great prominence to the concept of prevention, which would be an important and positive shift in emphasis in FDA's food safety program, but the plan's approach is to work collaboratively with the industry to foster voluntary adoption of preventive control plans. Such voluntary efforts can contribute to progress in the near term to the extent those not currently following recognized "best practices" are willing to emulate leading companies that are already implementing state-of-the-art preventive control plans. Such voluntary efforts will not, however, solve the food safety problems posed by companies that lack market incentives or are otherwise unwilling or unable to bring their food safety practices up to modern standards. Furthermore, voluntary approaches do not provide clear public accountability for prevention.

Even more fundamentally, the FDA plan does not address the agency's lack of a statutory mandate to make prevention the central focus of its program. While prevention is clearly the necessary strategy for the future, the basic food safety provisions of the Federal Food, Drug, and Cosmetic Act on which FDA relies to regulate microbial pathogens were enacted in 1938 and are silent on prevention. They consist instead of adulteration and enforcement provisions designed for reaction to problems and correction of them after the fact. To make prevention the central focus of its program, FDA should be calling for a new prevention mandate from Congress and the legal tools to back it up.

3. Recognize that the primary duty for prevention falls on the food industry.

Again, the FDA plan calls prominently for promotion of "increased corporate responsibility to prevent foodborne illness," which is a conceptual step forward, but the proposed implementation of this central concept falls far short.

In fact, rather than recognizing that all those involved in the food business have a prevention duty for which they should be publicly accountable, the FDA plan actually places the burden on FDA to determine case-by-case when preventive controls should be required. Moreover, it calls on Congress to limit FDA's power to require preventive controls to cases in which it can establish through rulemaking that a particular food has been associated with "repeated, serious adverse health consequences or death."

Placing the burden on FDA in this fashion is the opposite of a true prevention strategy. It treats preventive process control as a tool for reacting to problems after they occur rather than a tool for systematically and comprehensively building prevention into the system. And the stringent standard for requiring preventive controls that the FDA plan recommends is a step backward from the legal authority that FDA has under current law and has used already to require HACCP for seafood and juice. It is far from clear whether the Office of Management and Budget would have cleared, or the courts would have sustained, FDA's seafood and juice HACCP rules had they been subject to the standard recommended in the FDA plan.

The plan's lack of follow through on the principle of industry responsibility for prevention is evident also in its import proposals. These proposals focus on what FDA will do to work with foreign governments and to better detect problems at ports of entry, but they do not call for any new accountability on the part of importers to ensure that problems have been prevented up the supply chain to the point of production in the exporting country. 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.

4. Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.

Other than the provisions for requiring preventive controls on a case-by-case, reactive basis, the FDA plan does not address the need for setting and enforcing standards that make the food industry accountable for prevention. As noted earlier, the plan focuses on encouraging voluntary adoption of preventive controls.

The closest the plan comes to standards and enforcement is in its second core element of "intervention," where the plan calls for "targeted, risk-based interventions to ensure that the preventive measures called for are implemented correctly." The three "key intervention steps" do not, however, directly address prevention at all, nor do they involve any measure that would create accountability for prevention. The three proposed "interventions" are instead tools for detecting problems after the fact, including risk-based inspection, sampling, and surveillance and improved detection of food system "signals" that indicate contamination. These are all worthy approaches to better targeting the use of scarce resources, but they are more about detection and correction of problems than prevention.

The best way to ensure that necessary preventive measures are implemented is to hold companies directly accountable for prevention in accordance with a defined standard of care.

5. Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.

The FDA plan clearly envisions a food safety leadership role for FDA in relation to the food industry and State and local government, which is positive. The call for closer collaboration with State and local food safety agencies is especially important to building an effective, national food safety program and making good use of all available public resources. On the industry side, however, the proposed FDA leadership role in encouraging voluntary adoption of preventive controls may actually blur rather than strengthen responsibility and accountability for prevention.

The plan's call for FDA leadership on food safety research and on developing the tools for a science- and risk-based approach to setting priorities and allocating resources is an important strength. The plan also recognizes the need for FDA to take the lead in developing the tools and capacity for knowledge generation and information management to improve food safety, such as enhancement of FDA's Emergency Operations Network Incident Management System, more effective traceback systems, and improved sharing of information across the system. Better collection and use of information is obviously essential to our efforts to improve food safety.

RECOMMENDATIONS FOR IMPROVING ON THE FDA FOOD PROTECTION PLAN

FDA's plan has its clear strengths and weaknesses. On policy, the plan's major strength is that it embraces the concept of industry responsibility for prevention and calls for strengthening FDA's capacities in important ways. The plan's major policy weakness is that it fails to call for the statutory modernization and policy change that is needed to implement the prevention concept in a really substantial way and thus leaves FDA still relying too heavily on reaction. The plan does not address at all FDA's problems of dwindling resources and an ineffectual organizational structure for food safety.

With these points in mind, I offer the following major recommendations to augment FDA's Food Protection Plan and equip FDA for success on food safety.

Modernize FDA's Statutory Mandate

Congress should modernize FDA's food safety mandate to, among other things:

- Explicitly make prevention of foodborne illness FDA's primary food safety mission;
- Establish by law a duty for all those in the food business to implement preventive controls appropriate to their particular operation, subject to FDA's implementing regulations and guidance;
- Direct FDA to establish and enforce performance standards that make companies accountable for implementing effective prevention measures;
- Make importers legally accountable for assuring that foreign producers and processors shipping products to the United States are meeting U.S. standards;
- Provide leadership in building an integrated, national food safety system that is science- and risk-based and makes efficient use of available resources to improve food safety.

Provide FDA an Adequate and Stable Resource Base

FDA's resources for food safety have been eroding for years as the agency's food safety challenge gets larger. The total operating budget for FDA's Center for Food Safety and Applied Nutrition—the resources available to take action after the staff and rent are paid—is down to around $25 million, which is a paltry sum for an organization charged with driving food safety progress across 80 percent of the American food supply, while also regulating dietary supplements and food labeling, ensuring the safety of infant formula and food additives, and attempting to provide food safety leadership internationally. An agency with all these responsibilities that can't conduct or commission research, adequately equip its staff, or travel simply can't do its job.

Despite this well-documented resource reality, and despite the fact that the FDA plan includes 38 actions to strengthen FDA's food safety program, the plan is silent on resources. Presumably, the President's 2009 budget proposal will include the resources needed to implement the plan.

Congress, however, has a responsibility to act. In addition to meeting FDA's immediate needs through the 2008 and 2009 budget processes, Congress should undertake a serious study of how to establish an adequate and stable funding base for FDA's food safety program for the long-term. Just as it is fair to hold the food industry accountable for doing its food safety job, it is fair to hold FDA accountable for the leadership and effective action we expect from that agency, but only if it has an adequate and predictable resource base.

Congress should explore a range of resource options, including:

- Requiring FDA to prepare for Congress a 5-year financial plan and an annual "professional judgment" budget sufficient to implement a modernized statutory mandate.
- Establishing by law a statutory inspection mandate, with consequences built in for failure to meet it, to serve as an anchor for appropriated resources.
- Authorizing FDA to collect establishment registration fees and import fees to provide a steady base of resources for the food safety program.

Unify and Elevate the Organizational Elements of the FDA Food Safety Program

The third key ingredient for the success of any agency—after an appropriate statutory mandate and adequate resources—is an organizational framework suitable for its purpose. For food safety, FDA needs a framework that enables it to provide national leadership on food safety and 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 re-

sources. 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 establishment in the Office of the Commissioner of an Assistant Commissioner for Food Protection, who serves as a spokesperson and coordinator but lacks budget or line authority for programs, 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.

The FDA Food Protection Plan did not address these structural obstacles to the success of the food safety program. Congress should address them by unifying the food-related components of FDA into a single organization and elevating 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.

**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).*

The CHAIRMAN. Thank you very much.

Mr. Corby.

STATEMENT OF J. JOSEPH CORBY, DIRECTOR, NEW YORK DEPARTMENT OF AGRICULTURE & MARKETS, ALBANY, NY

Mr. CORBY. I wish to offer my sincere thanks to you, Senator Kennedy, Senator Enzi and this committee for providing me the opportunity to testify today and to discuss the role of State and local government in our country's food safety system.

I've spent my entire working career of over 37 years as a State food safety regulator for New York's Department of Agriculture and Markets beginning as a food inspector in 1970. During this time I've witnessed many changes in the manner in which food protection programs have been conducted within the country and have also seen the consequences when these programs become weakened or ineffective. I continue to remain optimistic about FDA as a partner in our efforts with food safety. Many of the innovative food safety programs in existence today in New York State, including our work with imported foods, are there because we established a close working relationship with FDA's New York district. A relationship that recognizes each others strengths and weaknesses and

one that promotes efforts for working together rather than on our own.

We certainly do not agree with FDA on all food safety matters. And we realize there is some bureaucratic obstacles to our achieving success together. But we have always remained close working partners on many issues and have a mutual respect for one another.

My written testimony provided to the committee suggested that this country is looking for leadership in the arena of food safety and FDA must be more aggressive in developing strategies that will ensure consumers they continue to have the safest food supply in the world. I strongly believe the success of FDA and other food safety agencies at the Federal level depends on a large extent on effective coordination and collaboration with food safety regulators and health officials at the State and local level. There are more than 3,000 State and local agencies involved in food safety and we've long been on the front line in conducting foodborne illness surveillance, investigating and containing illness outbreaks, conducting food safety inspections at grower level, at processors and packers, at warehouses, food processing plants and retail establishments in taking regulatory action to remove unsafe products from the market.

State and local food safety officials are much closer to consumers than Federal agencies and under direct pressure to respond to food safety concerns in their communities even when the problems originate elsewhere. One need only ask themselves who would they call when sickness associated with food strikes them or a member of their family. In almost every circumstance they would call the local health department or the State health department or the State Department of Agriculture, seldom do they call FDA. Furthermore when the news media discovers recalled food products still on grocery store shelves months after a recall was announced by a Federal agency they will contact local or State food safety officials and demand to know why.

To many of us in State and local food safety programs, it appears that Federal policymakers do not have a clear understanding of the food safety roles of State and local agencies and the issues we face. The need for Federal-State partnership in collaboration is well recognized and often voiced. But absent some affirmative effort, Federal food safety reform is unlikely to address the roles and the needs of State and local agencies that are critical to achieve real progress.

This would be so unfortunate in today's world where food safety and a defense of our food supply have become very much linked together. We must build a system that contains the elements of early detection, rapid response and quick recovery. This cannot be done in my view without the active participation of State and local government resources.

I have provided the committee with a survey summary of State food protection programs conducted by the Association of Food and Drug Professionals. This survey which was conducted several years ago illustrates a very clear picture of the enormity of food safety work that is performed at the State and local level. What the survey reveals more than anything else however, is that the safety of

our food supply is not a Federal matter only, but an issue to be dealt with by government at all levels in a comprehensive and coordinated fashion.

AFDO and its State members have voiced for years the need for a fully integrated food safety system in this country. With the implementation of the new action plan set forth by FDA, the ability and willingness of State and local agencies is to share their resources and authorities and a sincere desire of FDA to work with their State and local partners to restore consumer confidence, we can build a seamless food safety system once and for all.

Thank you and I look forward to your questions.

[The prepared statement of Mr. Corby follows:]

PREPARED STATEMENT OF J. JOSEPH CORBY

I wish to offer my sincere thanks to Senator Kennedy, Senator Enzi, and this committee for providing me the opportunity to testify before you and to discuss the role of State and local government in our country's food safety system. I have spent my entire working career of over 37 years as a State food safety regulator for the New York State Department of Agriculture & Markets (NYSDAM) beginning as a Food Inspector in 1970. I have witnessed many changes in the manner in which food protection programs are conducted within the country and have also seen the misfortunes of many, especially children, when these programs become weakened and ineffective. I have interviewed victims of foodborne illnesses and listened in great horror to the tragic tales of mothers whose children had succumbed to an illness that was hidden within their hamburger, vegetable salad, or apple cider. In recent years, I began to wonder what food would we next learn could make us sick and what emerging pathogen would now cause such danger and concern for us. It seems to me that this Nation is screaming out for leadership and demanding that its government build a seamless food safety system that will restore their confidence in the food supply and in us. This, in my view, is the challenge before us today.

The success of the Food and Drug Administration (FDA) and other food safety agencies at the Federal level depends to a large extent on effective coordination and collaboration with food safety regulators and health officials at the State and local level. The more than 3,000 State and local agencies involved in food safety have long been on the frontline in conducting foodborne illness surveillance; investigating and containing illness outbreaks; conducting food safety inspections at the processing, warehousing and retail area; and taking regulatory action to remove unsafe products from the market. State and local food safety officials are much closer to consumers than Federal agencies and under direct pressure to respond to food safety concerns in their communities, even when the problems originate elsewhere. One need only ask themselves who they or their doctor would call when sickness associated with food strikes them or a member of their family. In almost every circumstance, they call the local health department or the State health or agriculture department. Seldom do they call the FDA. Furthermore, when the media finds recalled food products still on store shelves months after a recall is announced by the FDA, the media will contact local or State food safety officials and demand to know why.

To many of us in State and local food safety programs, it appears that Federal policymakers do not have a clear understanding of the food safety roles of State and local agencies and the issues we face. The need for Federal-State-local "partnership" and "collaboration" is well recognized and often voiced, but, absent some affirmative effort. Federal food safety reform is unlikely to address the roles and needs of State and local agencies with the specificity required to achieve real progress. This is an important concern because, like many elements of the public health system, State and local food safety agencies operate under disparate and sometimes outdated statutory authorities, face the challenge of working within a complex web of local, State and Federal agencies having complementary and sometimes overlapping roles, and are usually under funded.

Notwithstanding budgetary concerns within the States, there remains a skillful, knowledgeable, and in many aspects untapped resource for the FDA to collaborate with on matters of food safety and food defense. In 2001, the Association of Food & Drug Officials (AFDO), the primary organization that represents government food safety regulators, conducted a survey of State food protection programs to quantify the amount of food safety work performed there. The survey represented all 50

States, with at least one administrator from every State responding. The results clearly demonstrated how huge a role the States play in the overall food safety efforts that exist in this country. Appendix B on the last page of this document summarizes the AFDO survey.

What is most alarming about this data is that the majority of this work identified at the State level may not be accepted or even acknowledged by Federal agencies. This is true despite the fact that nearly 50 percent of the food inspections claimed to be performed by the FDA annually are actually performed by State agencies under contractual agreement. While there may be a number of reasons for this (such as equivalency issues and differences in authorities and laws), in my opinion we do a great disservice to consumers by not better coordinating our overall food safety efforts in this country.

Another unfortunate matter is the fact that over 320,000 food samples collected and analyzed by State food safety programs are, for the most part, ignored by Federal agencies. Again, this may be a result of the FDA's concern for equivalency or how samples are collected and processed by State officials, but it seems very unwise to ignore such a huge amount of important information relating to domestic and foreign-produced foods. Why the FDA does not better utilize this data and recognize its relevance to the protection of public health has remained a mystery to State food safety program managers for some time.

I have had the great fortune of working for an agency that has had the courage to meet food safety challenges very aggressively and the willingness to explore innovative strategies to better deal with these challenges. NYSDAM has gained its national reputation in food protection because we recognize the value in resource integration, partnering with Federal agencies, and pursuing a course that recognizes that there is but one food supply to be protected regardless of the number of government agencies involved.

There are certain components of New York State's food protection program that I believe forge innovative, "cutting edge" partnerships with the FDA and serve as models for other States. Our "Integrated Food Safety System" is a partnership program with the FDA's New York District, and perhaps most noteworthy is our Imported Food Initiative agreement we have with that district's Upstate and Downstate Import Operations.

The purpose of the Integrated Food Safety Partnership is to establish an agreement that coordinates the food protection efforts of NYSDAM's Division of Food Safety and Inspection and the FDA's New York District Office. This agreement reduces consumer risk, eliminates duplication, defines regulatory roles and improves channels of communication. All manufacturing food establishments and food storage facilities licensed or inspected by NYSDAM are covered by this agreement and it serves as a pilot to demonstrate the effectiveness of integrating the Federal/State responsibility for the food manufacturing and storage industries. The partnership includes data and information sharing, training, recalls, and enforcement strategies. It allows the FDA and NYSDAM to share each other's resources and authorities. We could have never implemented this partnership program without mutual respect and the recognition that we both play critical roles in protecting New York citizens.

Our Import Initiative pilot is the project of which I am most proud because it is most timely and truly effective in dealing with the overwhelming burden of imported foods. It is very clear that the number of goods imported into this country has increased dramatically, and the majority of these imports are foods (See Figure 1). The FDA's ability to handle the enormous surge of imported products, however, is increasingly limited; in fact it is estimated that less than 1 percent of imported products are physically examined (See Figure 2). As a result, the FDA is contracting out more and more domestic inspections to State agencies in order to focus more resources to imported products. Unfortunately, they cannot meet this huge demand, yet little has been done to allow State agencies to play a greater role in the surveillance and inspection of these foods. Imports have essentially remained a role of the Federal Government through the efforts of U.S. Customs and Border Protection [CBP], the U.S. Department of Agriculture (USDA) and the FDA. The Import Initiative, however, allows the FDA and NYSDAM to work more collaboratively on imported food oversight.

This cooperative effort is essential because approximately 33 percent of the imports coming into this country enter through New York State. Because of our diverse population, many of these products remain in New York and are marketed domestically here. These domestic channels—which include food warehouses, processing plants, and retailers—are the areas for which State and local food safety regulators are primarily responsible. To summarize, one can conclude that any imported food that makes its way through the scrutiny of the Federal Government becomes primarily the responsibility of State and local government regulators.

FIGURE 1

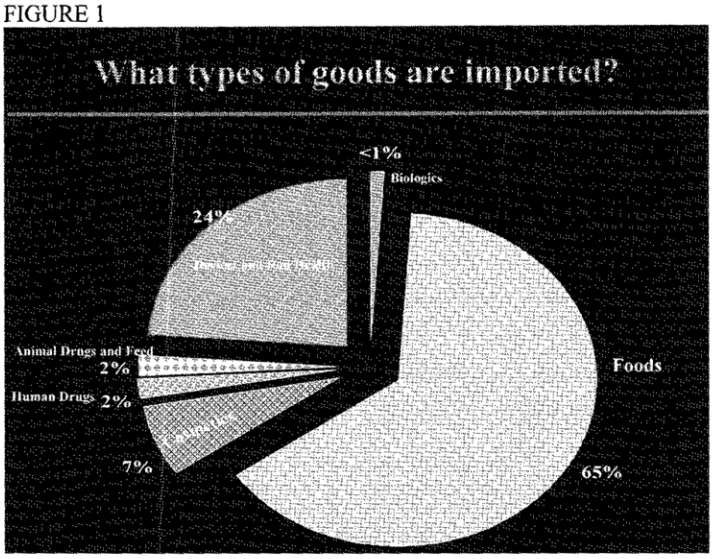
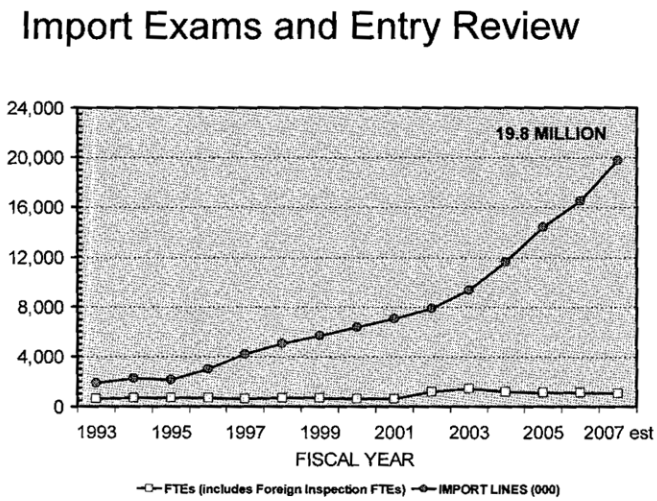


FIGURE 2



Note that although large volumes of imported food enter the United States via ports of entry in New York State, food of import origin offered for sale at New York wholesale/retail establishments can, and does, enter the United States via any of the 400+ ports of entry scattered throughout the country. NYSDAM's surveillance of foods of import origin at the wholesale/retail level not only protects consumers in New York State, but also provides valuable information to the FDA regarding how the national import program is working. Subsequent joint investigations of violative food product will enable the FDA to determine why the violative food was not detected and detained and take affirmative steps to do so in the future.

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A good illustration of the dilemma for State agencies with imported foods is depicted in Figure 3 below. This chart is a 5-year summary of food recalls coordinated by NYSDAM. With a field staff of a little over 100 Food Inspectors, we are averaging over 350 food recalls a year. This number is greater than the number of recalls coordinated by the FDA and USDA annually. Of the 1,786 food recalls coordinated in New York since 2002, 1,304 of these (or 73 percent) involved foods of foreign origin. Of that amount, 1,030 (or 79 percent) were categorized as Class I or Class II (health impacted).

FIGURE 3

5 Year Recall Summary 2002- 2006				
Year	Class I	Class II	Class III	Totals
2002	129	187	42	358
	101 Imported	141 Imported	38 Imported	280 Imported
	28 Domestic	46 Domestic	4 Domestic	78 Domestic
2003	101	187	65	353
	54 Imported	122 Imported	52 Imported	228 Imported
	47 Domestic	65 Domestic	13 Domestic	125 Domestic
2004	73	183	102	358
	55 Imported	123 Imported	67 Imported	245 Imported
	18 Domestic	60 Domestic	35 Domestic	113 Domestic
2005	70	192	77	339
	46 Imported	164 Imported	49 Imported	259 Imported
	24 Domestic	28 Domestic	28 Domestic	80 Domestic
2006	23	241	114	378
	15 Imported	209 Imported	68 Imported	292 Imported
	8 Domestic	32 Domestic	46 Domestic	86 Domestic

Rather than ignore the matter or simply forward all of our concerns to the FDA, we decided to be more aggressive in our response. A vision for integrating FDA and NYSDAM resources was developed into a project that would allow NYSDAM to collaborate with FDA in the following three basic areas:

1. Develop a Better Understanding of Laws and Authorities for Each Agency

The FDA's strongest enforcement tool with imported food is the "Import Alert" (formerly known as "Automatic Detention"), which authorizes FDA detention without physical examination when suspect foods, which "appear" to be in violation, are presented for entry into this country. NYSDAM's strongest enforcement authority tool is the "Food Seizure" which prohibits the commercial movement of food anywhere within the State. Merging and utilizing, where appropriate, these authorities have produced influential impact on controlling violative food imports.

2. Sharing of Resources

NYSDAM has ample resources in domestic channels, and the FDA has focused resources at New York border entry points. Working jointly on foods of import origin in New York State at both points is optimal and allows the FDA to make better decisions on products to detain for examination at the border.

3. Sharing of Intelligence and Information

NYSDAM shares inspection and sampling information relating to foods of import origin in domestic commerce with the FDA. Where possible, we also provide import entry numbers for adulterated imported foods so the FDA can determine which of

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the 400 border entry points was involved and the mechanism of distribution. The FDA provides immediate notice to NYSDAM of imported food concerns so that State inspectors can take prompt action in domestic channels.

As a result of this imported food initiative, a number of very successful investigations have been conducted. Several of these are worth noting as follows:

1. When a young female child died from choking on an imported gel candy product, NYSDAM received information from the FDA that 18 other children from around the world had met similar fates due to this type of product. We further learned that an ingredient in this food ("konjak") prevented the candy from dissolving once placed in ones mouth. This information was sufficient for New York and other States to take immediate action against this product. In New York we coordinated around 54 recalls and supervised the destruction of over 60 tons of this product. It would have taken FDA approximately 8 months to outlaw the use of this ingredient in these products. The States, on the other hand, were able to respond quickly, and I have no doubt that our actions saved children's lives.

2. An infant's sole source of food and nutrition is oftentimes the infant formula provided to them. Without receiving the required nutrition from these products, they can become ill and even die. A scandal existed several years ago with Chinese manufactured infant formula where manufacturers there were producing products absent a number of required nutrients, causing the deaths of a number of Chinese infants. The FDA advised NYSDAM that no entries for this imported infant formula had been listed for the country. Nevertheless, we sent Inspectors into Chinese-American neighborhoods, where we found this product. We utilized our food seizure authority, sampled and tested the product, and supervised its destruction following acknowledgement from our Food Lab that the product failed to have much of any nutritional value. A press release was issued through the Chinese media in New York City cautioning anyone who may have purchased the product. Here as well, I believe infant lives were saved.

3. In this country a manufacturer of a Grade A pasteurized dairy product such as fluid milk or cream, yogurt or ice cream can not ship their products out of State or country without verification that their milk suppliers (dairy farmers) and manufacturing facility have received and passed a food safety inspection. Unfortunately, a number of imported Grade A dairy products are allowed to enter this country for marketing without the same requirement being met. States, in most cases, have approved source requirements for foods sold in their States and are able to take action against these foreign dairy firms, which do not have inspection verification. The FDA provides information to NYSDAM of where these products are shipped in New York, and we dispatch an inspector to the warehouse location. Products from foreign firms that are not inspection-verified are either exported back to the country of origin or removed from sale here and destroyed.

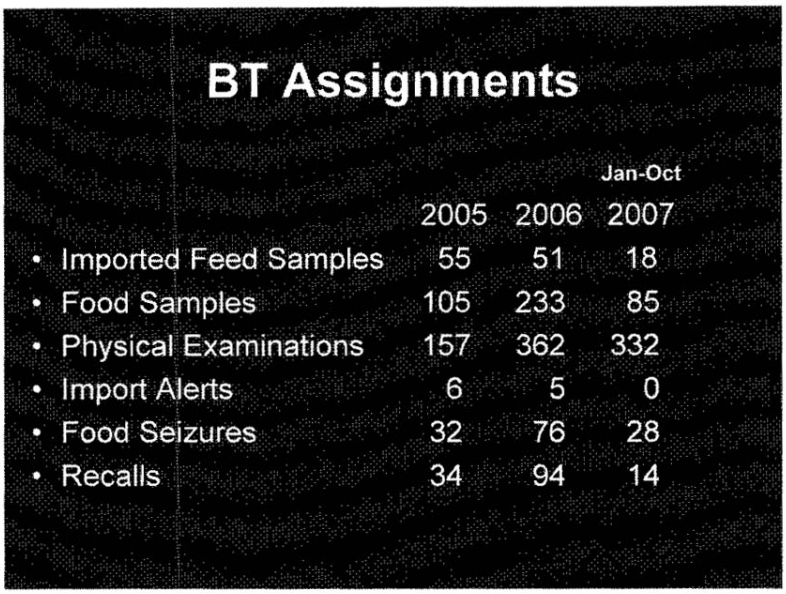
Our imported food initiative with the FDA has been so successful that we have expanded the program and are now collaborating with other Federal agencies involved with imported foods. These include U.S. Customs & Border Protection (CBP), USDA's Food Safety and Inspection Service Import Liaison, USDA's Smuggling & Interdiction Trade Commission (SITC), and the Department of Homeland Security (DHS). Our collaborative efforts with these agencies have allowed us to take the following actions:

1. Removal of illegally imported or smuggled raw poultry from China (avian Influenza concern).

2. Removal of illegally imported or smuggled meats from BSE designated countries (BSE concern).

3. Surveillance activities for the illegal distribution and marketing of African "bush meat" (Endangered species/potential human virus concern).

Figure 4 below quantifies our imported food activity we typically conduct.



BT Assignments

	2005	2006	Jan-Oct 2007
• Imported Feed Samples	55	51	18
• Food Samples	105	233	85
• Physical Examinations	157	362	332
• Import Alerts	6	5	0
• Food Seizures	32	76	28
• Recalls	34	94	14

The other very important element of our initiative has been the development of educational programs for importers, import food distributors, and retail food stores to assist them in protecting themselves from receiving adulterated or misbranded imported foods. These programs are especially useful to small businesses. In October of this year we held a program for the Chinese American business community and have another similar program planned for January with Russian American businesses.

Our goals for this coming year is to train two additional FTE's to perform the inspection and investigational work associated with imported foods. We also hope to develop additional training courses for small businesses and other industry officials that distribute and sell imported foods. These courses will be designed to offer basic assistance of what food safety concerns exist with imported food products so that these firms can set specifications with foreign manufacturers to assure violative products are not delivered into the country. Distributors will further be trained in food labeling matters so they can easily detect violative concerns such as illegal food additives, illegal food colors, and undeclared food allergens and sulfating agents.

We believe our import initiative has contributed to the adoption by the Federal and State regulatory agencies of the best available practices for controlling food safety and defense hazards associated with imported foods. The program leverages current Federal and State food safety activities to more effectively protect consumers, and it provides a degree of innovation.

This kind of idea is not new, however. A program funded by the FDA beginning in 1998 called the "National Food Safety System" (NFSS) was intended to integrate the food safety resources of government at all levels. A primary objective of that project was to improve food safety through a collaborative effort of Federal, State and local government agencies. It was believed then that a fully integrated, seamless and science-based system would build consumer confidence and address all of our food safety challenges. It would be foolish to ignore some of the progress already in place, which resulted from the activities of the National Food Safety System (NFSS) project. The following are examples of significant NFSS accomplishments that have been achieved since the inception of this project in 1998:

• eLEXNET.—A secure electronic data sharing system for food safety laboratory data.

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• ISO Accreditation.—An internationally recognized laboratory accreditation program aimed at assuring uniform methodologies for Federal, State and local laboratories.

• Directory of Laboratory Capabilities.—A compilation that identifies Federal, State and local laboratory capabilities in preparation for emergency needs.

• AFDO Recall Workgroup.—An effort involving State and Federal (FDA and FSIS) officials to streamline and better coordinate recalls for increased effectiveness in removal of contaminated product from the marketplace.

• Validation of Laboratory Methodologies.—A joint Federal/State effort to standardize and develop national rapid detection methods.

• Foodborne Illness Outbreak Coordination Guidelines.—Developed to provide uniform investigational procedures and information-sharing protocols.

• ORA-U.—Development of a comprehensive national training and certification system to better facilitate uniform food safety activities among all Federal, State and local field inspectors.

• Uniform Criteria Workgroup.—Development of uniform national regulatory standards.

• Integrated Food Safety Partnership.—A pilot program that integrates the food safety functions of a State and the FDA. A pilot of this partnership, as described above, is currently in its early stages of application.

The goals of the NFSS project were to establish a system that would better utilize and leverage all the committed food safety resources at all levels of government, build uniformity and consistency with inspectional, analytical, enforcement and surveillance activities, increase the level of consumer confidence by improving food safety, and encourage the implementation of *ONE* food safety system. The projected roles for Federal and State agencies envisioned in this seamless food safety system were identified as follows:

The Federal Government would provide oversight in the following areas:

• Training
• Certification
• Risk Assessment
• Program Evaluation
• Imported Foods
• Research
• Science
• Standards
• Lab Practices
• Additives
• Packaging
• Funding

State and local government agencies would share field resources in the following areas:

• Inspections
• Investigations
• Complaints
• Sampling
• Analysis
• Compliance
• Enforcement

Clearly, if we are to have a comprehensive, uniform, seamless and risk-based food safety system for the Nation, a development strategy that only examines the Federal component cannot be utilized. If it were, then any attempt to correct the deficiencies in the current system or to provide strategic plans for developing a truly effective national food safety system is destined to fail.

The FDA Food Protection Plan and Action Plan for Import Safety are the latest efforts by the agency in setting strategies for protecting the Nation's food supply. These plans have great promise and both rely very heavily on working collaboratively with stakeholders including State and local agencies. The Action Plan for Import Safety speaks specifically for considering cooperative agreements with States. The Food Protection Plan uses less specific, more general language such as "collaboration with" and "working closely with" States in several areas of the document. In my opinion, FDA should strive to work more strategically with the States on a variety of functions including food safety inspections, food product surveillance, and imported food evaluations. In order to accomplish this, FDA would need to do the following:

1. Accelerate the Manufactured Food Regulatory Program Standards process so more States can participate and demonstrate their equivalency to the FDA. The FDA can then share inspection work plans with State agencies to avoid duplication of efforts.

2. The FDA must begin to accept State food laboratory analysis of foods so they can better work with the States on sampling assignments and the sharing of surveillance data. Work performed here should include both imported and domestic products.

3. The FDA must improve their presence in foreign countries. By gaining confidence with State and local governments handling most of the domestic burden, FDA should be able to achieve this goal. A number of States are performing inspection verification for foreign dairy manufacturers of Grade A products. FDA should be performing these inspections.

4. A number of States are leading the way in mandatory requirements for vegetable growers and packers. California, Florida, and Virginia have all introduced mandatory programs for specific commodities in their States. The FDA should model these programs so they become nationally accepted.

5. There is a huge need to improve our response efforts with food recalls. Recent national recalls for peanut butter, spinach, and chili sauce were confusing and ineffective. North Carolina employed an Incident Command System [ICS] utilizing State and local government officials from a multitude of agencies for the chili sauce recall. They performed more recall audit checks in North Carolina than the rest of the country combined. They also found a large number of these botulism-tainted products in children's camps and other non-traditional food venues ready for sale or service. The FDA needs to review their response efforts with recalls and establish a formalized strategy with State and local government to better deal with recalls.

6. The FDA needs to be granted recall and record review authority by Congress to properly function as a regulatory public health agency.

While the country debates how to best protect our food and what agency and how many will lead this effort, the fact remains clear that whatever strategy is used the States and local agencies must be recognized for the critical role they play.

Developing a new, comprehensive regulatory structure at the Federal level will be an enormous task. It must include elements that address human and animal health and nutrition, controls for foodborne pathogens, surveillance of potential hazards, monitoring foodborne illnesses, research and consumer education. Additionally, food safety must now be part of any national security strategy.

Given the scope of the matter and the newfound critical importance of food safety and security, it is difficult to argue against the strategies outlined in FDA's Food Protection Plan and Action Plan for Import Safety. What must not be overlooked, however, is the fact that most of the food safety and food defense activities that occur in this country occur at the State and local levels. The idea that food safety or food defense is somehow only a Federal Government responsibility is grossly inaccurate and misguided. There is great need for leadership, however, and the FDA, assuming full implementation of these plans, seems well suited.

Thank you for the privilege to present my views on these very important matters.

APPENDIX B. AFDO NATIONAL SURVEY—SURVEY SUMMARY

Food Safety Regulatory Activities Conducted by Local and State Government Agencies in Year 2001 [1]

Inspections:	
Food processing/repacking facilities	56,644
Dairy plants	7,562
Manufactured milk plants	5,956
Dairy farms	159,483
Retail food service establishments	1,178,348
Institutional food service establishments	51,290
Retail food stores	516,033
Intrastate wholesale meat processors	418,844
Custom exempt meat plants	12,310
Small animal slaughter houses	24,395
Feed manufacturers and distributors	19,904
BSE inspections	3,475
Rendering plants	605
Food transportation vehicles	9,481
Food salvage operations	2,067

Food Safety Regulatory Activities Conducted by Local and State Government Agencies in Year 2001 [1]

Farm productions (GAPS)	311
Food warehouses	20,624
Other	15,525
Total	2,500,857
Investigations:	
Foodborne illness outbreaks	3,075
Tracebacks (not recalls)	154
Consumer complaints	46,019
Shellfish growing areas	20,870
Commecial fishing areas	5,251
Farm pesticide residue	472
Chemical residue in meat, milk, fish, and eggs	7,855
Disasters and/or emergency response	2,816
Animal health matters (food safety related)	204
Other	3,199
Total	89,915
Do high risk establishments receive more inspections per year than lower risk establishments?	
Yes	69
No	15
Number of licensed/permitted establishments	755,123
Number of unlicensed/not permitted establishments	60,910
Number of FTEs (field)	3,685
Number of FTEs (administrative and support)	873
Entry Level Requirements:	
High school	17
Two-year college degree	10
Four-year college degree	65
Other	29
Do you require continuing education for inspectors or investigators?	
Yes	55
No	32
Do you require field inspectors or investigators to be registered?	
Yes	26
No	52
Do you require field inspectors or investigators to be commissioned?	
Yes	20
No	57
Enforcement Activities:	
Embargo/seizure	13,910
Stop sale	31,546
Health Advisories	90
Monetary penalties	9,878
License/permit revocation	2,899
Injunctions	74
Criminal prosecutions	4,048
Warning letters	36,346
Informal hearings	1,102
Food recalls	660
Other	28,537
Total	128,430
Laboratory Capabilities:	
Food chemistry	52
Microbiology	63
Pesticide residue	43
Number of samples analyzed:	
Food chemistry	59,991
Microbiology	252,307
Pesticide residue	15,767
Total	328,065

[1] Association of Food and Drug Officials. State Food Safety Resource Survey, 2001.

The CHAIRMAN. Thank you very much. Congressman, glad to have you here.

STATEMENT OF HON. CAL DOOLEY, PRESIDENT & CHIEF EXECUTIVE OFFICER, GROCERY MANUFACTURERS ASSOCIATION, WASHINGTON, DC.

Mr. DOOLEY. Thank you. Thank you, Mr. Chairman. I'm delighted to be here and I commend you for holding this hearing.

You know Americans enjoy the safest food supply in the world, but the food companies I represent recognize that steps must be taken to make our food supply even safer. Ensuring the safety of our products is the single most important goal of the food industry. And our industry devotes enormous resources to ensure that our products are safe.

As we've heard earlier this morning increasing imports and changing consumer preferences pose new challenges for food companies and for the FDA. To address those challenges we need to modernize our food safety system. At GMA, our industry has adopted a wide variety of preventative controls to confront the causes of contamination at the source. We believe that the prevention of contamination through the adoption of preventative controls should continue to be the foundation of our Nation's food safety strategies.

To improve the safety of imported foods we believe that Congress should mandate by statute that every food importer implement a supplier quality assurance program based upon FDA guidance and subject to FDA review. Under this proposal food companies would have to document that their foreign suppliers were implementing good manufacturing practices and other preventative controls. We also believe that Congress should expand FDA's ability to develop the capacity of foreign governments to detect threats and to harmonize food safety standards.

FDA should also be given the authority to certify the safety of high-risk imports, now subject to automatic detention and permitted to credit third party inspectors, auditors and labs to assist in these efforts. To improve our ability to detect threats at the border we believe that FDA must be given more resources to hire inspectors and to train other Federal and State officials to inspect imported foods. But we also believe that Congress must help focus FDA's inspections on those imports posing the greatest risks to human health by creating a voluntary program to expedite food imports posing little or no risk.

To improve the safety of food produced in the United States we believe that Congress should permit FDA to mandate that fruits and vegetables be produced according to good agriculture practices. Rising consumption of fruits and vegetables represent and reflect the good news that more Americans are making healthier food choices, but also create new food safety challenges that should be addressed through strong produce safety standards that can be tailored to reflect differences among crops.

Congress should also direct FDA to modernize preventative controls for packaged food products to reflect scientific advances. But we object to prescriptive mandatory approaches. Especially in light of the resource constraints at FDA that will undermine the scientific advances in the foundations of seeing the advances that

could be incorporated through the private sector. Finally we support granting FDA the authority to issue a mandatory recall if a company has refused to conduct a voluntary recall and there is a significant risk to human health.

Let me close by saying a few words about resources. A FDA Science Board concluded yesterday Congress and Administration have simply failed to provide the agency with adequate resources. As a result the agency lacks the scientific capacity to fulfill its mission. Providing FDA adequate resources to help defend the public from foodborne illness should be as fundamental as defending the public from other threats foreign and domestic.

Our companies do not depend upon FDA inspections to ensure the safety of their products and they should not be asked to pay a fee because Congress and the Administration has failed to perform its most basic function, protecting the public. What's more, taxing food imports or food facilities—as some have proposed—to finance this basic function of government would inevitably fall more heavily on some countries, some companies and some consumers. And it would not employ a risk-based allocation of those fees.

We can look to the simple fact that 33 percent of the imports of food products coming into the United States are coming from Canada. A country that has systems that are very similar to ours in their food safety. And if you imposed an import fee you would see in fact a disproportionate share of that cost being funded by Canada.

I urge you to give FDA the resources and the additional authority needed to meet the challenges posed by rising food imports and changing consumer preferences. And just my last statement I want to make it clear, Mr. Chairman and the other members of the committee that I have been most pleased by the constructive dialogue that we have had with CSPI and Mike Taylor and many other groups on this. And we are committed to working with you to ensure that we can collectively find a system that really can meet the needs of consumers.

[The prepared statement of Mr. Dooley follows:]

PREPARED STATEMENT OF THE HON. CAL DOOLEY

Good morning. I am Cal Dooley, President and CEO of the Grocery Manufacturers Association.

Americans enjoy the safest food supply in the world, but food and beverage companies recognize that steps must be taken to make our food supply even safer. Ensuring the safety of our products—and thereby maintaining the confidence of consumers—is the single most important goal of the food and beverage industry. Product safety is the foundation of consumer trust, and our industry devotes enormous resources to ensure that our products are safe.

Steadily increasing food imports and changing consumer preferences pose new challenges for food and beverage companies and for the Food and Drug Administration. In recent years, we have experienced dramatic changes in the volume and variety of food imports. The percent of food imported into the United States increased by nearly 40 percent between 1995 and 2005 to 15 percent of the U.S. food supply. In particular, roughly 60 percent of the fruits and vegetables and roughly 80 percent of seafood now consumed in the United States are imported.

To address the challenges posed by rising imports and changing consumer choices, food and beverage companies and Federal and State agencies have placed continually greater emphasis on the prevention of food contamination. By constantly identifying and addressing the sources of contamination throughout each product's life cycle, we continually reduce the risk of food-borne illness to consumers. We believe

that the prevention of contamination—through the adoption of preventive controls—should continue to be the foundation of our Nation's food safety strategies.

As you seek to modernize food safety legislation, we urge you to focus on programs and policies that will prevent food contamination and to consider the following recommendations. Many of these recommendations were included in *Commitment to Consumers: the Four Pillars of Imported Food Safety*, a comprehensive food safety proposal released this fall by the Grocery Manufacturers Association.

One, we urge you to require that every food importer of record institute a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements. To assist companies in developing these supplier quality programs, we propose that FDA issue guidance on key elements—including, as appropriate, audits, testing, good manufacturing practices, food defense programs, good agricultural practices, and other preventive controls. Requiring food importers to ensure the safety of their supply chains—and giving FDA the authority to oversee industry's implementation of these programs—would significantly reduce the likelihood of contamination.

Two, we further urge you to expand FDA's ability to build the capacity of foreign governments to prevent and detect threats to food safety. In particular, FDA should be directed to work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, and harmonize food safety requirements among countries. FDA should also be given the authority to detain food imports if inspections of foreign facilities are warranted but are unduly delayed or refused, as proposed by FDA in the agency's Food Protection Plan.

Three, we urge you to enhance FDA's ability to target those imports that pose the greatest risk to consumers. In particular, we urge you to create a voluntary program to permit expedited entry of foods that pose no meaningful risk. By permitting food importers who demonstrate the existence of a secure supply chain and who meet FDA's standards and conditions to receive expedited entry, FDA could focus more scrutiny on those imports that are more likely to pose a risk to public health. A risk-based approach to food inspections, combined with enhanced training of FDA and other Federal and State inspectors, would significantly improve our ability to detect contaminated food. In addition, FDA should build upon existing efforts to ensure the safety of imported foods from countries or companies with a history of problems by working with those foreign governments and food companies to certify the safety of such products before they are offered for import into the United States. Increasing our ability to scrutinize and oversee imports based on risk would greatly enhance our ability to detect threats to public health without crippling commerce or violating our trade commitments.

Fourth, we urge you to take steps to continually improve the safety of food produced in the United States. In particular, we urge you to provide FDA authority to mandate that produce be produced following good agricultural practices. Rising consumption of fruits and vegetables, including ready-to-eat foods, reflects growing consumer demand for healthier food choices but also creates new food safety challenges that should be addressed through strong and enforceable produce safety standards which can be tailored to reflect differences among commodities. Similarly, we support modernizing preventative controls for packaged food products to reflect scientific advances and thereby strengthen the foundational elements of our food safety system. We also support proposals to require facility registrations once every 2 years, as suggested in FDA's Food Protection Plan, and we support increased frequency of facility inspections, provided that such inspections are based upon a scientific assessment of risk and upon history of compliance.

Fifth, we urge you to give FDA the authority to order a mandatory recall when a company has refused to conduct a voluntary recall and there is a significant risk to public health. Specifically, where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary should be permitted to order the company to conduct a recall.

We believe the adoption of these and other recommendations identified in our *Four Pillars* proposal will, in combination, ensure that Americans continue to enjoy the safest food supply in the world. By focusing our efforts on prevention, by using limited FDA resources wisely, by leveraging the expertise and resources of the food industry, and by working in partnership with the Food and Drug Administration, we believe Congress can help us meet the challenges posed by rising imports and changing consumer preferences.

Our industry has made substantial investments in food safety and has increased and will continue to increase our investments to address the challenges posed by rising imports and changing consumer preferences. We believe that Congress must

also make significant new investments in food safety. That's why we have joined forces with groups like the Center for Science in the Public Interest to advocate for major increases in FDA appropriations. We also think foreign governments and suppliers should upgrade their food safety systems to ensure that foods exported to the United States meet our high standards. Although we support giving FDA more resources and more authority, we strongly oppose proposals to tax food companies or impose other fees on the food industry.

The benefits of a safer food supply accrue to the public generally, much like the benefits of a strong national defense. A user fee is appropriate when the benefits of the government service flow to an individual (such as recreation fees, public transportation, or postage stamps) or to a particular business (such as harbor maintenance fees, accelerated review of prescription drugs, or bankruptcy filing fees). But, the benefits of inspections, effective science-based standards, and research and enforcement flow to all Americans, not simply to food companies. What's more, such taxes or fees will fall unequally on some companies—and, ultimately, on some consumers—and could violate our trade commitments, inviting reciprocal taxes and fees on U.S. food exports.

The food industry is eager to work with Congress to craft modernized food safety legislation that makes the prevention of contamination the foundation of our food safety system and which builds upon a public-private partnership between the food industry and the Food and Drug Administration.

The CHAIRMAN. Thank you very much.

Ms. DeWaal.

STATEMENT OF CAROLINE SMITH DEWAAL, FOOD SAFETY DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, WASHINGTON, DC.; ACCOMPANIED BY DAVID PLUNKETT, SENIOR STAFF ATTORNEY

Ms. DEWAAL. Thank you very much. This is not a tragedy for my children, but it definitely is because it is such an important day. David Plunkett, senior staff attorney will give my remarks and then I'll preserve my voice for questions if there are any.

The CHAIRMAN. Ok.

Mr. PLUNKETT. Thank you Mr. Chairman and Senator Enzi for calling this hearing for giving us an opportunity to testify on behalf of consumers.

Late last week science advisors to the FDA released a report indicating that the agency is in dire need of a modern mission and sufficient resources to make its food safety program credible. Given the numerous foodborne illness outbreaks and recalls over the last 18 months from spinach, lettuce, peanut butter, pet food, canned chili and others together with these expert evaluations, the timing is excellent to put forward fundamental reform of FDA's food program on Congress' agenda for next year.

While FDA's food protection plan clearly signals the end of the Administration's willingness to make changes in order to restore credibility to FDA's program, Congress must go beyond the limited reforms contained in the plan. CSPI recently released a white paper, building a modern food safety system for FDA-regulated foods, that's included in our testimony, that lays out the principles of comprehensive food safety reform. Congress passed several important food safety reforms when it passed the Bioterrorism Act in 2002. Unfortunately, those reforms were not effective enough to ensure discovery of an intentionally contaminated ingredient that would ship to the United States—incorporated widely in pet food. The next disaster might be worse affecting humans as well as their pets.

In the Food Protection Plan the legislative authority proposed by FDA is too narrowly targeted to effectively address today's food safety challenges. Congress can learn from the past and adopt comprehensive food safety reform.

The heart of any effective reform effort lies in prevention. Congress should require every food plant regulated by FDA to have food safety plans that demonstrate the companies are aware of potential hazards and are taking steps to avoid them. This would mean the companies that rely on ingredients would have to exercise due diligence to ensure those products have not been tampered with or otherwise arrived contaminated whether they are from domestic or imported sources. Food safety plans help ensure safe production and should be a prerequisite for all food processors both domestic and foreign. Under a modern statute these plans would also form the basis for food safety audits and inspections done by the Federal Government.

The gaps in FDA's food protection plan are numerous. It puts the burden on FDA to determine risk before requiring process control programs. It does not provide adequate inspection authority. It fails to require certification of foreign facilities. It exempts farms. And it does not provide for traceability.

The plan would do little to address the problems with contaminated spinach, lettuce and peanut butter that led to so many illnesses and hospitalizations or even melamine-tainted wheat gluten that resulted in the massive recall of pet food. It simply does not go far enough to address the very real problems with a food supply that U.S. consumers have experienced over the last 18 months, problems that have resulted in a 16 percent decline in consumer confidence.

U.S.-food safety laws are antiquated and were never designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The recent outbreaks serve as a reminder that much is needed to protect the food supply. Congress needs to enact a food safety program that puts public health at the forefront of food safety in America.

On behalf of the 900,000 consumers, represented by CSPI, we urge Congress to go beyond the incremental changes proposed in the food protection plan and adopt comprehensive reforms to modernize food safety laws in the United States.

[The prepared statement of Ms. DeWaal follows:]

PREPARED STATEMENT OF CAROLINE SMITH DEWAAL

My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a non-profit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for the opportunity to address this committee and comment on the Food and Drug Administration's (FDA) Food Protection Plan. Before getting to FDA's new plan, I would like to provide some background. In the 2002 Public Health Security and Bioterrorism Preparedness and Response Act ("Bioterrorism Act"), Congress passed new authorities designed to increase FDA's ability to prevent intentionally contaminated food from reaching U.S. consumers. These new authorities included mandatory registration of domestic and import food facilities, prior notice for import food shipments, enhanced recordkeeping and administrative detention. Despite mounting evidence at that time that FDA's legal authorities were inad-

equate to address the threat, Congress chose in 2002 to apply a targeted approach, adding these few additional authorities, instead of tackling the more difficult job of enhancing FDA's overall mission to ensure food safety and food protection. Unfortunately, that approach failed to prevent the many food outbreaks and recalls of the last year, including one involving a toxic substance intentionally applied to a food ingredient regulated by FDA.

Since September 2006, nationwide outbreaks of foodborne illnesses and subsequent recalls have exposed glaring holes in the safety net guarding U.S. consumers from contaminated food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; canned chili with *Clostridium botulinum*; pet food with toxic chemicals—these were not isolated events. FDA-regulated foods are responsible for many outbreaks each year as documented in CSPI's Outbreak Alert database.[1] But each of these tragedies in 2006–2007 demonstrated a distinct gap in FDA's system for regulating the food supply that underscores the need for farm-to-table reform.

Today FDA's ability to protect the food supply is being questioned by consumers and Congress alike. Overall consumer confidence in FDA has plummeted. A Harris Poll has documented that those who thought FDA was doing an "excellent" or "good" job went from 61 percent in 2000 to 36 percent in 2006. In addition, over the last year, consumers' overall confidence in the safety of foods has fallen dramatically. The Food Marketing Institute reported a 16 percent decline in consumer confidence in the safety of food they purchase at grocery stores, according to its annual survey. *USA Today* reported in July that 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.[2] And based on many supermarket conversations, these concerns have affected purchasing behavior as well.

This loss of consumer confidence has palpable effects on food suppliers as well. After the spinach scare of 2006, spinach farmers reported losing $350 million, and had still not recovered when a second leafy green outbreak occurred in August of this year.[3] But these outbreaks were entirely predictable—and preventable—if FDA had the resources to look beyond the next crisis and the authorities to compel the food industry to take steps to prevent problems before they occur.

CSPI applauds FDA for putting forward its Food Protection Plan and for finally signaling to Congress the need to give FDA additional authorities. But Congress should recognize that this plan outlines only a few incremental steps that are not sufficient to prevent the food safety problems consumers experienced just last year. Reforming our outdated food safety laws could have tremendous public health benefits, as each year 76 million Americans experience foodborne illnesses that hospitalize 325,000 and result in 5,000 deaths.[4] It is time for Congress to institute real solutions—not stop-gap measures that will fall short in a few years time.

FDA's Food Protection Plan calls for several authorities that CSPI has long advocated, like mandatory recalls, and proposes changes to address shortcomings in the implementation of the Bioterrorism Act's food facility registration program. But its shortcomings are numerous:

- It is not enough to ask for new authority to mandate recalls but fail to ask for authority to require traceability standards and impose civil penalties so that recalls are effective.
- It is not enough to require strict food security plans but fail to require food safety plans that would protect the public from the inadvertent contamination of food that annually sickens and kills so many Americans.
- It is not enough to identify a need for the full life-cycle approach to food safety but fail to ask for authority to implement programs on the farm or in the country of origin.

In sum, the Food Protection Plan underscores the need for reform, but Congress must take stronger action if it is to ensure the safety of the food supply and protect Americans from preventable illnesses and deaths.

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[1] Center for Science in the Public Interest, *Outbreak Alert! Database*, 2007 at *http://www.cspinet.org/foodsafety/outbreak/pathogen.php*.

[2] Elizabeth Weise, *Buying Only U.S. Food is a Tall Order*, USA Today, July 10, 2007, *available at http://www.usatoday.com/news/health/2007–07–10-american-goods_N.htm*.

[3] Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA Today, Sept. 20, 2007, *available at http://www.usatoday.com/money/industries/food/2007–09–20-spinach-main_N.htm*.

[4] Paul S. Mead, et al., *Food-Related Illness and Death in the United States*, 5 Emerging Infection Diseases 607, Sept.–Oct. 1999.

100-YEAR-OLD FOOD SAFETY LAWS CREATE CONFUSION AND INEFFICIENCY

Today, our Federal food safety system functions under two distinct statutory frameworks: one in operation at the U.S. Department of Agriculture (USDA) and another at FDA. USDA has responsibility for the safety of meat, poultry and certain egg products, covering about 20 percent of the food supply. Its statute provides for carcass-by-carcass inspection in all meat and poultry slaughter plants and daily inspection in meat and poultry processing plants using government-funded inspectors. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act give FDA responsibility for regulating the safety of the remaining 80 percent of the food supply, but the statutes are reactive, giving the agency authority to act principally when food is found to be "adulterated" or "misbranded." Plants that produce products regulated by both agencies see a stark disparity between the programs, as when a frozen pepperoni pizza processing line regulated by USDA is subject to daily inspections, while a frozen cheese pizza line in the same plant is inspected by FDA about once every 10 years.

The disparity carries over into the programs that are responsible for ensuring the safety of imported foods—a key concern driving delivery of FDA's Food Protection Plan. While USDA has a fairly intensive program for ensuring the safety of imported meat and poultry products, FDA's program is anything but comprehensive. Unlike USDA, FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures.[5] Instead the agency relies on border inspections, but has the capacity to inspect only 1 percent of food at the U.S. border. Although imports of FDA-regulated foods have more than doubled in the last 7 years—from 4 million shipments in 2000 to approximately 9 million shipments in 2006—the rate of inspections has remained woefully low.[6] Of these 9 million shipments, only 0.2 percent were analyzed in a laboratory as part of its inspection process.[7]

As with domestic food safety programs, import programs sometimes overlap, but resources are not shared. For example, USDA and FDA inspect food imports at 18 ports, but they do not share inspection resources at these locations. In fact, according to the Government Accountability Office, some USDA-approved import inspection facilities store FDA-regulated products, and although USDA maintains a daily presence at these facilities, FDA products can languish at the port waiting for FDA inspectors.[8] When it comes to authority and resources, FDA remains the neglected stepchild of our food safety system.

EMERGING HAZARDS AND INTENTIONAL THREATS TO THE FOOD SUPPLY

One of the most-widely discussed food safety catastrophes this year began in March when pet food manufacturers recalled more than 100 brands of cat and dog food after receiving complaints of cats and dogs developing sudden kidney failure from eating pet food. For weeks after, new brands were pulled from shelves as processors tracked the tainted ingredient—wheat gluten.

FDA investigations revealed that the pet foods that sickened so many pets were contaminated with melamine and cyanuric acid, two industrial chemicals. These toxins were found in wheat gluten imported from China and used in many pet food and animal feed products manufactured in the United States. Chinese wheat gluten producers are believed to have intentionally contaminated the product with melamine to give the appearance of increased protein content. According to an investigation by *The New York Times*, cutting grain products with melamine to fool protein tests is common practice among producers in China, yet the contaminated wheat gluten passed across our borders without being found or stopped by FDA.[9]

Tracing the pet food back through its supply chain, FDA eventually identified the Chinese company that shipped the adulterated wheat gluten into the United States. According to reports, however, the company was little more than two rooms adjoin-

[5] FDA's Import Program System Information Web site does not delineate an audit system for imported product and directs users to cross-reference the U.S. Customs Office for additional requirements. FDA Office of Reg. Affairs, Import Program System Information, (Sept. 21, 2004), *at http://www.fda.gov/ora/import/ora_import_system.html*.

[6] Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. Times, May 1, 2007, at *http://www.nytimes.com/2007/05/01/business/01food.html*.

[7] *Id.*

[8] Gen. Acct. Off. Rep. No. GAO–07–449T, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, (Statement of David M. Walker, Comptroller General of the United States) (Feb. 8, 2007).

[9] David Barboza & Alexei Barrionuevo, *Filler in Animal Feed Is Open Secret in China*, N.Y. Times, April 30, 2007, at *http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html*.

ing a warehouse in China.[10] Clearly the registration of importers, even coupled with prior notice, was not sufficient to prevent the importation of this purposefully contaminated product. FDA needs much stronger authorities.

In 2004, Tommy G. Thompson, the former Secretary of Health and Human Services, expressed deep concern, saying that he was "shocked" that terrorists had not struck the Nation's food supply "because it is so easy to do," and that he "worried every single night" about food safety.[11] We share his concern, and hope that Congress treats the pet food contamination incident earlier this year as a "wake up call." It could have been much worse if instead of melamine, a more potent chemical was applied to a food ingredient widely used in the human food supply. The United States should adopt modern systems that prevent or promote early discovery of such problems, rather than relying on FDA's limited ability to respond to food safety emergencies.

SHORTFALLS IN RESOURCES AND AUTHORITIES AT FDA

Imports are not the only food safety challenge facing FDA. Outbreaks linked to fresh spinach and lettuce and processed peanut butter and canned chili in 2006 and 2007 are just the latest symptom of an agency that is overwhelmed by responsibility, but lacking the staff and resources to function effectively. Current FDA funding shortfalls have reached a critical level and budget cuts have left the agency with fewer inspectors, even as the workload continues to increase. Since 1972, domestic inspections conducted by FDA declined 81 percent.[12] Just since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, there was a 47 percent drop in Federal inspections.[13] These declines in inspectors and inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars.[14]

The Peter Pan peanut butter outbreak and recall shows the consequences of this gap in inspection capacity and the inadequacy of FDA's Food Protection Plan. Last winter, the Centers for Disease Control and Prevention determined that *Salmonella*-contaminated peanut butter was responsible for causing illness in over 600 people in 47 States. This outbreak could likely have been prevented with a more robust inspection program at FDA.

In 2005, FDA inspected the ConAgra facility where the peanut butter was produced because of complaints about conditions at the plant. The inspectors learned from plant managers that the company had destroyed some product due to "microbial problems" in 2004, but the managers did not disclose the problem was *Salmonella* contamination.[15] When FDA's oral request for documents from the plant went unanswered, FDA did not follow up until 2007 when the agency conducted inspections of the plant during the outbreak investigation.[16] This is unacceptable both to Congress and to consumers.

The legal structure of the current system tilts Federal food safety resources toward USDA. While USDA regulates the 20 percent of the food supply known to cause 27 percent of attributed outbreaks, its food safety appropriations are *double* that given to FDA.[17] This is due primarily to the legal requirements that the meat and poultry products regulated by USDA must be approved before sale, while foods regulated by FDA do not require pre-market approval.[18] USDA employs more than

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[10] David Barboza, *Clues to Pet Food Recall Traced to Chinese City*, Int'l Herald Tribune, April 11, 2007, at *http://www.iht.com/articles/2007/04/11/asia/gluten.php*.

[11] *Tommy Thompson Resigns From HHS*, The Wash. Post, Dec. 3, 2004.

[12] House Comm. On Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, (October 30, 2006), 2, *available at http://oversight.house.gov/documents/20061101115143–67937.pdf*.

[13] Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Lanquish*, Associated Press, February 29, 2007, *available at http://abcnews.go.com/Health/wireStory?id=2905819*.

[14] Last year, one FDA budget official estimated a funding shortfall in the food safety program of $135 million, which he described as equivalent to a 24 percent budget cut. House Comm. on Gov't Reform, *supra* at 2.

[15] The plant manager stated the FDA would have to submit a written request if it wanted more information on the incident. *See,* Joseph S. Enoch, *FDA Failed to Follow Up on 2004 Peanut Butter Contamination*, ConsumerAffairs.com, Oct. 19, 2007, at *http://www.consumeraffairs.com/news04/2007/10/peanut_butter_recall17.html*.

[16] Marion Burros, *Who's Watching What We Eat*, N.Y. Times, May 16, 2007, at *http://www.nytimes.com/2007/05/16/dining/16fda.html*.

[17] Center for Science in the Public Interest, Outbreak Alert!, Dec. 2006, 2, at *http://www.cspinet.org/foodsafety/outbreak_alert.pdf*.

[18] The differences between USDA and FDA regulatory authorities are detailed in "Overseeing the U.S. Food Supply: Steps Should be Taken to Reduce Overlapping Inspections and Activities," Gen Acct Off Rep. No. GAO–05–549T (May 17, 2005).

7,600[19] inspectors who are stationed in 6,282 establishments to carry out its inspection mandate.[20] FDA, meanwhile, has fewer than 2,000 inspectors who are spread over 210,000 domestic food processors and warehouses.[21]

Unfortunately, the Food Protection Plan does not address these problems, and could in fact add new ones. The requirement that foods only come under process control programs if they have been linked to "repeated, serious adverse health consequences or death" could potentially block needed action on foods like peanut butter and spinach, where outbreaks are rare. By putting the burden on FDA rather than the food industry, this standard could stop FDA from taking necessary action to address problems by requiring preventive control systems.

In summary, FDA's Food Protection Plan falls short of the transformative reforms that are needed to remedy the shortfalls in resources and antiquated authorities at FDA. Congress should implement comprehensive reform of FDA's statutory mandate in order to better protect the American public.[22]

CSPI'S PRINCIPLES FOR MODERNIZING FDA'S FOOD SAFETY MANDATE

The timing is excellent to put fundamental reform of FDA's food program on the agenda of Congress over the next 12 months. A Sense of Congress included in the recently enacted Food and Drug Administration Amendments Act states Congress's readiness to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission. Additionally, the emergence of coalitions of traditionally estranged consumer and industry organizations, like the Coalition for a Stronger FDA and the FDA Alliance, gives Congress a unique opportunity to appeal to many constituencies as it rebuilds the agency.

While the Food Protection Plan clearly signals the Administration's willingness to make changes in order to restore consumer confidence, Congress must enact more comprehensive reform than those contained in the Food Protection Plan. CSPI's recently released white paper, "Building a Modern Food Safety System: For FDA Regulated Foods," lays out the principles of comprehensive food safety reform. To meet the need for prevention, intervention and response, Congress should require food safety process control programs for all food processors that meet performance standards established by FDA. Regular risk-based inspections by FDA would ensure that food facilities are following good safety practices and meeting the safety standards set by the FDA. Under CSPI's principles, the registration program for importers would be joined to a certification process to ensure foreign producers are meeting the same standards as their U.S. competitors. A strong research component is also necessary, as is a requirement that FDA build a strong on-farm safety program. Finally, CSPI urges Congress to give FDA five new enforcement authorities: (1) mandatory recall, (2) effective and mandatory traceability, (3) detention authority, (4) civil and criminal penalties, and (5) whistleblower protection.

The legislative authority sought by FDA is too narrowly targeted to encompass the principles that are critically important to comprehensive food safety reform. The heart of any effective reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have food safety plans, like HACCP,[23] that demonstrate the companies are aware of potential hazards and are taking steps to avoid them. This is already a requirement for all meat and poultry plants, and it should be a prerequisite for all food processors that want to sell food in the United States. This provides the basis for establishing the industry's fundamental responsibility for ensuring food safety.

The gaps in the FDA's Food Protection Plan are both numerous and dangerous: it puts the burden on FDA to determine risk before requiring process control programs; it does not provide adequate inspection authority; it fails to require certifications of foreign facilities; it exempts farms; and it does not provide for traceability. The plan would do little to address the problems with spinach, lettuce, peanut butter, or even melamine-tainted wheat gluten. It simply does not go far enough to address the very real concerns with the food supply that U.S. consumers have faced over the last 18 months.

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[19] *USDA, Farm Bill Forum Comment Summary and Background: Food Safety,* (undated) at *http://www.usda.gov/documents/FOOD_SAFETY.doc.*

[20] *USDA, FY 2008 Budget Summary and Annual Performance Plan,* 59, *available at http://www.obpa.usda.gov/budsum/fy08budsum.pdf.*

[21] FDA, Food Protection Plan, (Nov. 2007) 6.

[22] While food safety problems have garnered the most attention, many other parts of the agency's responsibilities are not getting adequate attention—issues such as obesity, the safety of dietary supplements, and appropriate oversight of new technologies. In cases like the Castleberry botulism recall, inspectors are literally taken off other tasks to meet emergency needs.

[23] Hazard Analysis and Critical Control Points.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The heightened awareness of terrorism over recent years has demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. Congress needs to enact a food safety program that puts public health at the forefront of food safety in America. On behalf of the 900,000 consumers represented by CSPI, I urge Congress to go beyond the incremental changes proposed in the Food Protection Plan and adopt comprehensive reforms to modernize food safety laws in the United States.

The CHAIRMAN. Thank you very much.

Dr. Young.

STATEMENT OF PAUL YOUNG, Ph.D., SENIOR MARKETING MANAGER, WATERS CORPORATION, NEWTOWNARDS, N. IRELAND

Mr. YOUNG. Mr. Chairman, Senator Enzi, members of the committee, I'd like to thank you very much for giving me the opportunity to testify today. I consider it a great honor and particularly, Mr. Chairman, as you have already pointed out that Waters Corporation is based in your own constituency of Massachusetts. Despite taking my position, my current position, with Waters in March of this year, I am still currently based in Ireland where I have worked for more than 25 years as a scientist involved in the regulation of food safety of food destined for the European market.

Effective food safety control within a country requires not only a comprehensive set of standards but also significant collaboration. That involves collaboration between governments and producers, but also needs to involve the processors, the importers, the exporters. Indeed we in Waters acknowledge that we also have an important role to play in delivering purposeful innovations that address the needs of the scientist's tasks with monitoring the compliance with food safety regulations.

Regulation of food safety standards of imported food present yet another set of challenges. In an ideal world all countries would apply and enforce the same set of standards for food production. Indeed this is the goal of the Codex Alimentarius Commission. Unfortunately however, the Codex standards are not regarded as being comprehensive enough and as a result individual countries or regions have independently developed their own specific standards for imported food.

Faced with known harmonized country specific regulations, producers in exporting countries tend to focus on producing food under schemes designed to meet the requirements of the intended recipient country. For example, one producer may entirely focus on producing food under conditions that meet the demands of the Japanese import regulations that we heard the Congressman talk of earlier.

Japan relies very heavily on imports for more than 60 percent of all of the food consumed in the country. Faced with a high level of food contamination the Japanese recently revised their food standards and simultaneously placed the onus on importers to ensure that imported food meets these new standards. Compliance is monitored through an import testing program in which approximately 10 percent of all of the food consignments undergo laboratory analysis.

The European Union has adopted a more comprehensive farm-to-table approach as we've heard mention of earlier. This applies to all domestic production. As a prerequisite for accepting imported food the EU demands that the exporting country demonstrate equivalence with EU regulations. In this way the EU approves countries and establishments for listed commodities. These approvals are subject to satisfactory inspection audits, carried out by the EU Commission.

In addition to regular inspection visits, compliance is monitored through an import testing program. With non-compliant findings being communicated through a rapid alert system to all EU member states. The member states can then use this information for recall if that action is required, but also to stimulate increased vigilance. Faced with these differing standards exporters will endeavor to meet the demands of their chosen export markets.

However, difficulties are likely to arise when new standards are ambiguous or are not clearly defined and enforced. In the past I have read a seafood export action plan that clearly stated that if product was found to be noncompliant with EU standards than it could be sold into markets where the regulations were less stringent. This may sound shocking but different countries assess risk in different ways and the EU applies the precautionary principle as is their right under the SPS, the Sanitary and Phytosanitary Agreement. But the application of this in other countries may be neither uniform nor clearly stated.

In short, ensuring food safety requires collaboration between all interested stakeholders. This includes governments, producers, processors, and technology leaders. We've heard that word collaboration quite a lot today, but I also believe there's a serious risk that voluntary compliance may be interpreted as being optional and regarded as representing less stringent regulations.

Regulation alone cannot ensure that the food supply is safe. This must be backed up by a well-resourced and robust monitoring program. In this regard technology leaders such as Waters also have responsibility to take part in these discussions to ensure that our innovations are purposeful and adequately address the challenge at hand. Ensuring food safety is about protecting consumers first and foremost. But it also plays a key role in maintaining consumer confidence and thereby protecting the interests of our producers and their integrity of their export markets.

Thank you once again for the opportunity to be here today. And I will be happy to field any questions the committee might have.

[The prepared statement of Dr. Young follows:]

PREPARED STATEMENT OF PAUL B. YOUNG

ABOUT WATERS CORPORATION

For 50 years, Waters has developed innovative analytical science solutions to support scientists around the globe who focus on meeting the stringent laboratory demands for food safety regulation and analysis.

Waters Corp., a publicly traded corporation (NYSE:WAT) headquartered in Milford, MA, holds worldwide leading positions in three complementary analytical technologies—liquid chromatography, mass spectrometry, and thermal analysis. Specifically, the company designs, manufactures, sells and services ultra performance liquid chromatography (UPLC), high performance liquid chromatography (HPLC), chromatography columns and chemistry products, mass spectrometry (MS) systems, thermal analysis and rheometry instruments.

In addition to providing solutions in food safety, Waters creates business advantages for laboratory-dependent organizations by delivering sustainable scientific innovation to enable advancement in healthcare delivery, environmental management, and water quality. Waters products are used by pharmaceutical, life science, biochemical, industrial, academic and government organizations working in research and development, quality assurance and other laboratory applications.

Waters Corp. employs approximately 4,700 employees worldwide, operating in 27 countries.

SUMMARY OF STATEMENT

The global trade in food is increasing significantly, such that governments no longer have direct control over the production standards employed for much of the food consumed by their citizens. While governments do have a responsibility to promote and permit international trade, they also have a responsibility to protect the health of their citizens from the presence of potentially harmful contaminants in the food supply.

The Codex Alimentarius Commission was set up in 1963 by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) with the aim of developing harmonized food standards and guidelines. Codex therefore acts as a central point of reference with respect to food standards; however, it is generally believed that the current Codex standards lack sufficient scope to be either universal or comprehensive. Also, the implementation/enforcement of standards varies significantly from one country to another.

As a consequence, governments have been compelled to develop mechanisms to ensure that imported food and feed does not pose a hazard to the health of humans or animals.

These systems prove to be most effective when they involve collaboration of numerous bodies and organisations. This includes collaboration between governments and collaboration between regulatory authorities, producer organisations and technology providers (such as Waters Corporation) working together, ensuring that solutions are effective, robust and cost effective.

FDA currently regulates domestic food production, but has little control over the production standards employed for imported food. The European Union (EU) concluded that relying on voluntary compliance did not afford adequate assurances of protection and adopted an approach of licensing third countries and the individual food producing establishments therein. This involves frequent inspection audits of each country, examining the food safety regulations and the implementation of those regulations, to ensure that food destined for the EU is produced under rules that afford equivalent guarantees to those afforded by EU regulations. Compliance with these requirements is monitored through the implementation of an import testing programme, which includes, documentary checks (ensuring that food comes from an EU approved establishment), physical checks and laboratory examination. Noncompliance can result in withdrawal of permission to export to the EU.

In response to complaints from consumer organisations in 2002 regarding the presence of contaminants in imported food, the Japanese Government reviewed and revised The Food Safety Basic Law and the standards set for food safety. Initially the Japanese Government did not adopt a policy of third country approval/licensing, but rather placed the onus on the importers to ensure that imported food was compliant with the new Japanese food safety standards. Additionally, the new regulations imposed a mandatory requirement on importers to have new food imports tested to demonstrate that it met the standards. Compliance with these standards is assured by a high level of laboratory testing for a very wide array of chemical contaminants, which is carried out by the Japanese Government during importation. More than 10 percent of all Japanese food import consignments undergo laboratory testing. Subsequently the Japanese Government has begun licensing foreign establishments for some high-risk commodities.

Faced with the differing import requirements of each country/region, exporting producers tend to focus on meeting the demands of their chosen market. In the absence of exacting and robustly enforced import requirements, the United States (U.S.) faces a real risk of receiving product deemed unsuitable for markets with more stringent controls.

BACKGROUND ON INTERNATIONAL FOOD SAFETY STANDARDS

Article 20 of the **General Agreement on Tariffs and Trade (GATT)** allows governments to act on trade in order to protect human, animal or plant life or health, provided they do not discriminate or use this as disguised protectionism.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) permits governments to set their own standards, but requires them to apply measures only to the extent required to protect human health. It does not permit Member Governments to discriminate by applying different requirements to different countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so. It is indeed a basic precept of this agreement that there should be a sound scientific basis for food safety regulations. However, it does permit application of the precautionary principle when risks can not be quantified.

The **Agreement on Technical Barriers to Trade (TBT)** seeks to ensure that technical regulations and standards and analytical procedures for assessing conformity with technical regulations and standards do not create unnecessary obstacles to trade.

Both the SPS and TBT Agreements acknowledge the importance of harmonizing standards internationally to minimize or eliminate the risk of sanitary, phytosanitary and other technical standards becoming barriers to trade.

The General Principles of the Codex Alimentarius states:

> The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

CODEX AND THE ETHICS OF INTERNATIONAL TRADE

Codex Alimentarius Commission also encourages food traders to adopt voluntarily ethical practices as an important way of protecting consumers' health and promoting fair practices in the food trade. To this end, the Commission has published the *Code of Ethics for International Trade in Food*. A principal objective of this code is to stop exporting countries and exporters from dumping poor-quality or unsafe food onto international markets.

NATIONAL FOOD SAFETY STANDARDS

Harmonization of food safety standards may indeed be a very worthy cause, however, it is generally accepted that Codex standards currently lack sufficient scope to be comprehensive. Neither does Codex address substances for which acceptable daily intakes (ADI) have not been established. These include (but are not limited to) residues of nitrofuran group of compounds and the antibiotic chloramphenicol. Disputes over the presence of these substances in food have caused the largest disruptions to international food trade, resulting from contamination, in recent years. As a consequence, many countries have developed a complete set of independent food safety regulations (albeit ensuring conformity with Codex standards whenever possible).

Given the significant growth in global food trade in recent years, many countries are currently in the process of revising (or in many cases completely overhauling) their food safety legislation with regard to both domestic production and importation.

THE EUROPEAN UNION SYSTEM

In 2002, the European Union made major changes to the way food safety legislation is developed and implemented, when it passed Council Regulation 178/2002 into European law. This regulation established The European Food Safety Authority, an independent body with responsibility for risk analysis, but devoid of risk management responsibility. This ensured that risks would be evaluated independently from the effect any legislation may have on trade, or on the management of the risk (testing). It also ensured that the requirements of the SPS agreement would be met in establishing a scientific basis for the legislation.

This regulation also established the Rapid Alert System for Food and Feed (RASFF), whereby when violative food contaminants are detected either at market or at a Border Inspection Port (BIP) information relating to the product, the nature of the violation, the country of origin and the notifying country is published on a weekly basis, shared among the relevant competent authorities within the EU member states for action if necessary (recalls, increased vigilance, etc.) and simultaneously put into the public domain. Additionally, this legislation put in place an absolute requirement for traceability at all stages, from production, through processing, distribution and retailing.

In the same year, legislation was introduced which specified the criteria which must be applied when validating the analytical techniques used for detection of chemical contaminants in food. The EU Commission has chosen not to prescribe analytical techniques, instead allowing regulatory laboratories to develop their own

methods utilizing the latest advances and technological innovations to improve sensitivity, throughput and cost effectiveness. This is considered a significant factor in allowing laboratories in EU member states to respond rapidly to food safety issues and to keep pace with scientific advances. However, in Commission Decision 2002/657 validation criteria were laid down to ensure that laboratories demonstrate that analytical techniques are fit for purpose and suitably robust when detecting contaminants at the level of interest. The EU Commission demands that violative results be confirmed using an unequivocal, confirmatory technique and lays down the identification criteria that must be met in this decision. The use of a confirmatory technique is required to ensure that producers are not unfairly disadvantaged from the reporting of "false positive results" that can occur when screening tests are employed. This legislation also mandated that regulatory laboratories must be accredited under the international standard ISO 17025, ensuring that all laboratories are working to acceptable standards.

The European Union ensures the safety of domestic food production through the implementation of a comprehensive raft of food safety legislation, regulating the use of veterinary drugs in product of animal origin (POAO) and of pesticides in both POAO and non-POAO. Compliance with this legislation is monitored through a comprehensive testing programme the level of testing of which is based on a percentage of annual production. These testing programmes are funded from a levy imposed on producers (for example, a levy per head of animals slaughtered in the case of POAO). The EU Commission has fixed the minimum levels of this levy depending on the species.

It is noteworthy that for substances where the risk is established, but not quantified, the EU applies the precautionary principle. A significant number of contaminants are known to be carcinogenic and/or genotoxic, however the risk has not been quantified and they are seldom likely to generate acute conditions which can serve as signals of frequent violation. In these cases the EU has imposed a complete ban on their presence and requires laboratory analysis to demonstrate compliance.

HOW THE EU TREATS IMPORTS

Accepting that global trade in food is increasing year on year and that EU is probably the largest single market in the world, the EU Commission does not adopt the view that trading partners will automatically become food safety partners. Instead the EU makes the latter a precondition to becoming the former.

The EU Commission maintains lists of approved countries and establishments within those countries, which are approved by commodities. Therefore, as an example, China must be named on an approved list for the export of seafood before any product will be permitted entry into the EU. Additionally, individual establishments within China are maintained on an approved list for the export of seafood and only those establishments are permitted to export product to EU. This system is similar to that operated by the USDA for meat and poultry, but in 2004 the EU extended this to make provision for not just POAO, but for any foods which may constitute a risk (Council Regulation 882/2004).

A requirement for remaining on these lists includes the annual submission of details of control programmes which are in place regulating the safety of food produced for the EU including the results of regulatory monitoring. The underlying premise is that third countries must be able to offer assurances that food exported to EU is produced under a series of controls that offer at least the same guarantees of safety as is offered by European regulations. There must be a legal basis for enforcement of these regulations. Therefore, although the EU can not enforce its legislation on third countries, it does demand equivalence.

An additional prerequisite for remaining on these approved lists involves permitting regular inspection of competent authorities, production, processing, traceability and the laboratories involved in regulatory monitoring (including checking the efficacy of methods of analysis employed). The aim of these inspections is verification of the assurances given and the inspections are carried out by the staff of the Food and Veterinary Office (FVO) with the assistance of scientific "national experts." If a significant number of noncompliances are observed during an inspection mission, it can (and does) result in an establishment, or entire country being de-listed and therefore forfeiting the ability to export a given commodity to the EU.

In 2001, a World Health Organisation (WHO) committee examining coordination and harmonization of food safety control systems concluded that whilst it is not possible to test our way to safe food, a robust monitoring system is vital to ensure compliance with regulation controlling food production. The EU Commission has determined that no consignment from a third country should be permitted to enter the EU without being subject to veterinary checks and that fixed percentages must un-

dergo physical checks (Commission Decision 97/78). In practice, based upon assurances offered by third countries, a derogation regarding the level of these physical checks may be negotiated on a country-by-country basis.

A mechanism for recovery of costs associated with carrying out the import monitoring has been described in Council Regulation 882/2004. This legislation lays down minimum charges per consignment that must be applied, but makes provision for recovery of the full economic cost of inspection and any laboratory analysis. The importer or their agent is responsible for these charges. A significant level of violation detected during this import monitoring may result in 100 percent of product undergoing laboratory analysis before it is permitted to enter the EU. If the violation is deemed to constitute a significant risk then it may result in the country being delisted for that commodity.

THE JAPANESE SYSTEM

Japan is one of the least self-sufficient developed countries in the world, importing more than 60 percent of its food. Therefore, Japan has traditionally relied heavily upon the regulatory systems in the exporting countries for ensuring food safety. However, in 2002 a number of consumer organisations carried out surveys that found high concentrations of certain agricultural chemicals were present in imported crops. Many of the detected chemicals were banned from use in domestic Japanese production. This prompted a complete overhaul of the Food Safety Basic Law (the main statutory instrument regulating food safety in Japan). Central to this was the establishment of the Food Safety Commission, an independent body with responsibility for risk analysis. Additionally, the Specifications for Food and Food Additives was revised to include many more chemicals than had been previously addressed. This creation of the so-called Japanese Positive List (listing 799 agricultural chemicals) was prompted by the fact that the licensing of agricultural chemicals differs from one country to another. Prior to the creation of the positive list, when chemicals not licensed in Japan were identified in imported food, each violation was dealt with on a case-by-case basis. The maximum residue levels (MRLs) in the positive list are based on internationally accepted values where available, but a uniform limit of 10 parts per billion (ppb) is applied for substances for which safe levels had not been established.

It is worth noting that Japan does not demand equivalence in terms of analytical testing, since domestic produce is not tested for the full range of chemicals detailed in the positive list, but accepts that local legislation effectively controls the use of unlicensed chemicals. In addition, the change in Japanese legislation did not make provision for maintenance of approved lists of countries and establishments, for the purposes of import. Instead, the onus for ensuring compliance was placed on the importer combined with heavy penalties for violation. When violations are detected, subsequent consignments must undergo voluntary testing in Japanese laboratories, paid for by the importer, before the consignment can be released. If the violation rate exceeds 5 percent of consignments from an establishment (or country) then a complete ban on importation may result.

For substances not permitted to be present at any concentration (so-called Not Detect or ND), the challenge is ensuring that all laboratories are capable of offering the same assurances. EU does this by specifying a minimum required performance level (MRPL) that laboratories must demonstrate. Japan has adopted a different approach in prescribing methods that must be used by Japanese regulatory laboratories. It appears to be generally accepted by the Japanese scientists that this author has spoken to, that this is too restrictive and limits the ability of the laboratories to employ recent technological advances, such as Ultra Performance Liquid Chromatography (UPLC, developed by Waters Corporation) to increase throughput and improve cost effectiveness.

Although the Japanese government does not maintain approved lists for all commodities, when recurrent violations are detected, Japanese scientists may be dispatched to the offending country to offer technical assistance in a bid to correct the problem. The Japanese Government has subsequently introduced approved lists, but only for spinach imports. However, there is speculation that this may be extended to other foods.

DIFFERENCES BETWEEN THE EU, JAPAN

Whilst Japanese legislation appears similar to EU regulations, there are fundamental differences in the implementation. Whereas, EU demands equivalence in terms of legislation and levels of monitoring, Japan places the onus for compliance on the importer and ensures compliance through a very high level of import moni-

toring. The result is that Japanese importers will typically demand certification of compliance with Japanese regulations prior to dispatch.

Despite this high level of testing of produce destined for Japan, the Japanese authorities ensure compliance by carrying out laboratory analysis for a very large number of contaminants at import (around 10 percent of all imported food consignments undergo laboratory analysis) and publish the results of violations detected. It is interesting to note that a frequently used level of testing is designed to detect a 1 percent violation rate with reasonable efficacy (that is to say, if 1 consignment out of every 100 is violative for a particular substance then there is a 95 percent chance that violations will be detected), yet the dramatic changes in Japanese legislation were prompted by the discovery of a 0.4 percent violation rate across all commodities and chemical contaminants. It should also be noted that even a 10 percent inspection rate does not in itself constitute a significant level of protection. Rather, it serves as a monitoring tool to ensure compliance.

EXPORT FOOD SAFETY TESTING

It might be reasonable to assume that such a high level of interest in food safety from a number of very large food importers would itself create a harmonized set of standards resulting in the food safety equivalent of "herd immunity." In some instances, this may be the case. For example, the Thai Department of Fisheries has submitted a list of recommended establishments to the U.S. FDA which is very similar to the approved list maintained by the EU, but it is noted that use of these establishments by U.S. importers is voluntary and that some recent FDA refusals (October 2007) came from establishments not on the recommended list.

It is also noted that whilst only 4 countries appear to have submitted lists of recommended establishments for seafood to the United States, 95 have done so to the EU (where it is mandatory). One assumes that this arises because the standards are not harmonized internationally and the requirements are very different from one market to another. Therefore, in practice, exporting countries tend to focus on separate schemes depending on the intended recipient. This is borne out by the observation that many establishments on the FDA refusals list are not on approved lists for the EU and therefore would not be permitted to export to the European Union. This should not be interpreted as an indication that they are necessarily producing substandard goods, but rather that they may be focused on markets not requiring advanced approval.

CONCLUSION

It is clear that any food safety system which relies on voluntary compliance will be inherently risky, since even the very stringent systems employed by both the EU and Japan continue to give rise to a significant number of cases of violative food contamination (as published by each authority). Countries without unequivocal regulations governing the production of imported food run the risk of inviting the delivery of sub-standard products. This author has examined a seafood export action plan which clearly stated that seafood found to be in violation of EU regulations could be sold into markets where the regulations were less stringent. In the absence of comprehensive, internationally applied standards, imported food safety can only be ensured through the application of unambiguous legislation in combination with a robust enforcement and monitoring programme.

The CHAIRMAN. Well, thank you very much. Tell me, Dr. Young, the point that I gather that you're making is that the food safety, certainly in the EU, I imagine in Japan as well, is more stringent, more restrictive than we have currently in the United States. Is that so?

Mr. YOUNG. It would be my opinion that the regulations in Japan and Europe are quite different but the one thing that they do share in common is a very strict enforcement and they are very well-defined. They have very well-defined standards. So the exporters are aware of the standards that they must meet.

The CHAIRMAN. Well, if they do not meet the standards in terms of the EU, I think you mentioned that those food products, some of those can be sold to other countries?

Mr. YOUNG. The particular action plan that I was referring to was a document that I read a few years ago. And yes, it was clearly

stated in the document that if food did not meet the EU standards then it could be sold into markets where the regulations were less stringent. And essentially what that means is that if their rules are not clearly stated that this is what we demand. This is the quality of product we demand. These are the standards that you must meet. Then essentially that product could be deemed to be compliant with those rules and regulations.

The CHAIRMAN. Well, in a practical effect as some of that is sold in the United States. Is that correct?

Mr. YOUNG. I beg your pardon, sir?

The CHAIRMAN. Some of those food products are sold in the United States. They don't meet the European standard and they can be sold here in the United States.

Mr. YOUNG. That could be the case.

The CHAIRMAN. Well, is it the case? I mean you're an expert. I've got a limited period of time. It is the case, isn't it?

Mr. YOUNG. It probably is the case. I can't say for certain that those products were sold but one thing I can state is that products that are destined for Europe are tested before they're shipped to Europe. And I cannot say that the products destined for the United States undergo the same level of testing.

The CHAIRMAN. Ms. DeWaal do you know that to be the case, or not?

Ms. DEWAAL. I think, Senator, that a number of States have actually proven this. They have tested seafood products that FDA is not testing and they have found illegal antibiotic residues. So in fact we think and FDA actually, after the melamine incident, FDA actually had to ban certain seafood products that, Senator, they had known for 7 years that these products were coming in with illegal pesticide residues. Excuse me, antibiotic residues. And they didn't ban them until after the melamine incident.

The CHAIRMAN. You know, Mr. Taylor as I understand, the EU acted in 2002 to change the food safety system, establish the system that focuses on risk that provides for a rapid response when unsafe food is found. There is an absolute requirement to be able to trace all food to its source to retail and they have comprehensive testing on all foods. And countries that import to the EU must be pre-
approved, on lists of approved countries, from approved suppliers in those countries, and even the foods are approved to import.

Is that your understanding?

Mr. TAYLOR. Yes, Mr. Chairman. I think the traceability requirement in particular illustrates a commitment——

The CHAIRMAN. Do we have that type of system——

Mr. TAYLOR. We do not.

The CHAIRMAN [continuing]. Here in the United States?

Mr. TAYLOR. Not implemented, that sort of farm-to-table traceability and accountability system here.

The CHAIRMAN. And do you, just professionally, think that provides a greater degree of safety?

Mr. TAYLOR. I think traceability, being able to know where a product came from and the conditions in which it was produced, from farm to table is fundamentally important.

The CHAIRMAN. What about Japan?

Mr. TAYLOR. Well, again, the Japanese as Mr. Young indicated have much more clearly defined standards for imports and higher degrees of inspection and testing than we do. There's no question about it.

The CHAIRMAN. Don't you think a lot of Americans that might be watching this hearing could be saying, "Well, why does Japan and why do the Europeans have stronger protective systems than the United States?"

Mr. TAYLOR. I think it would be a fair question to ask. It is not as though we haven't known for a decade that our system can be improved in fundamental ways. GAO and the National Academy of Science have been telling us this for a decade. And so it is time to act to build this sort of systemwide prevention into our system.

The CHAIRMAN. How much additional burden, Congressman Dooley, would this type of system put on the food industry?

Mr. DOOLEY. Well, I think what we're suggesting, Senator Kennedy, is that we really have to define that public, private partnership that would be most effective in achieving that objective. And what we have proposed is that we would mandate that every importer on record, of every importer of food or food ingredient product in the United States would have to have a supplier quality assurance program. That would ensure that you would have in fact, the food safety audits that would be in place. That would ensure that those companies we're resourcing for have good management practices in place, sanitary practices in place. That we would develop these set of guidance with FDA, that you would then have the private sector being vested with a primary responsibility of preventing these occurrences.

And one of the reasons why we think this is the most appropriate alternative is that we have 190,000 different companies that are registered under the Bioterrorism Act that would be eligible to import food products into the United States today. And we do not think that if you go down a regulatory approach where you'd have FDA vested with that responsibility that you're ever going to have that capacity and the resources to certify those.

And so what we are suggesting is, we work in cooperation with FDA. That they help us set the standards and the guidance where the private sector then mandates to have the plans in place to ensure that we could have systems that would allow for greater traceability and greater confidence that we are having the food supplier require the audits are in place.

The CHAIRMAN. Senator Enzi.

Senator ENZI. Thank you Mr. Chairman.

Dr. Young, you note that the European Union found that relying on voluntary compliance was insufficient and that you instead licensed other countries and individual foreign establishments. The FDA Food Protection Plan proposes third party certification but not country certification. And I'm thinking particularly of China where the compliance is so varied.

You have some firms who definitely meet standards and others who have no intention of doing so. Could you elaborate a little bit on that role of certifying entire countries? Does that country certification have the unintended consequence of keeping good actors in

non-certified counties from doing business in European Union, or in the United States.

Mr. YOUNG. Yes, Senator. You're quite right. The business of certifying countries in addition to certifying particular establishments from the European Union point of view is of vital importance. The reason for that is the European Union believes that compliance will not be achieved unless the government is involved, unless there is government regulation.

I have acted as an EU inspector, involved in audits of third countries and the very first steps that are involved are inspecting the legislation to make sure that's there's a legal framework for taking action because the European Union believes that without that legal framework there will not be an effective system of control.

Does that answer your question?

Senator ENZI. That helps quite a bit. I'll have a follow up on that, probably in writing if you'd be so kind as to answer some more detailed questions that we don't have time to cover here.

Mr. Dooley, requiring importers to ensure the safety of their supply chains does make a lot of sense to me. And your larger members can easily travel to other countries and inspect the factories or have a long-term presence in those facilities. Big companies can have staff that are dedicated to those issues. What would a small business do?

Mr. DOOLEY. Well we think it's important that whether it's a small company or a large company that is engaged in international commerce and is sourcing products from outside the United States that they also have a responsibility to comply with putting in place the best practices which are going to ensure that we are mitigating and preventing food safety outbreaks. You know, you see today a lot of small and mid-size companies are resourcing products. They have the ability to contract with intermediaries that can, in fact, provide some of the food safety quality audits that would need to be put in place that have the contractual arrangements that would allow them to also comply with this suggestion that we are making that you have a mandatory supplier quality audit in place if you're going to be importing a product into the United States.

And if I could just briefly make one comment on your prior question on this whole issue of certification and equivalency, in theory that sounds like a very sound and fairly reasonable and simple approach. But I just want to caution people. We have been trying to negotiate with Canada an equivalency agreement on fish processing that they have similar standards in place that would meet ours. We have been trying to do that for 10 years and we have not been able to achieve that with Canada alone which would be a similar industrialized country as the United States.

So I think we have to be very cautious about going down a path in terms of thinking that this equivalency and the certification of a country and their standards being similar to ours is going to be easily obtained.

Senator ENZI. Thank you. And I'll have some follow up questions on that as well in writing.

Mr. Corby, why do you think you're able to detect problems at a much higher rate than the FDA or the USDA?

Mr. CORBY. Well, for one thing I think because of our resources. And we have quite a few inspectors. And we do a great deal of surveillance. And we do a great number of inspections.

Plus we're closer to the consumer in that we do the retail inspections, the restaurants, the grocery stores and we're the first ones to be contacted when there's an illness. So I think it's because we're alert of these problems probably firsthand.

Senator ENZI. Thank you. And again I'll have some follow up questions on that and some for Ms. DeWaal as well, but since your voice is going I'll let you do that in writing.

The CHAIRMAN. Thank you.

Senator Allard.

Senator ALLARD. Thank you Mr. Chairman. I'd like to start out with Dr. Young. We have different problems in, I mean, your uniformity issues that you're talking about in certification and assessment in different countries and in different companies, there's a lot of difference depending on what part of the world you're in and diseases that you might be dealing with that could affect the food supply.

How does a country like England for example or Ireland, set up a uniform assistance of assessing that or do you get very specific for each country and you look at those diseases from that country and you set up regulation just for that country or do you have a general set of rules? And then if you do this how do you reconcile that with trade agreements between the various countries?

Mr. YOUNG. Senator, the first thing I have to say is that my area of expertise is chemical contaminates, not microbial contamination and the way that the EU handles that level of chemical contaminate control is through a uniform set of conditions. The EU will draft legislation which can be based either as a regulation which does not need to be transposed into domestic law or it can set up these commission decisions which do need to be transposed.

So when the EU deems that it's important and it's important that everyone works to the same standards they will draft a regulation and that's of course across the entire European community. And those regulations then need to be also transposed into the domestic law of the exporting countries to ensure that the standards are the same. This is all with regard to chemical contaminates. And that includes not only the range of contaminates that need to be monitored which will be adjusted based on the commodity on a risk-based analysis but also includes things like the level of testing, the level of monitoring that need to be carried out to ensure that there is compliance with the local regulations.

Senator ALLARD. We have certain countries that recognize products as being hazardous and other ones don't, based on good scientific knowledge. For example, in Colorado or in the United States, the scientific literature and what we generally recognize here is that certain hormones to stimulate growth development in cattle are not harmful. Yet there are European countries, or Europe, I think, recognizes those as harmful.

How do you reconcile that and the scientific literature indicates, in the United States, that it's not harmful and in a European country they apparently feel it is or is it purely a trade issue?

[Laughter.]

Mr. YOUNG. That's a very difficult question to answer, sir. Is it a trade issue? Perhaps there's an element of trade associated with it, but, the argument I believe the European Union takes on that particular subject is that they adopt a precautionary principle. And that's to say that they are not sure whether the science is verified and therefore they will adopt a precautionary approach. And they will therefore ban those substances.

Senator ALLARD. So the World Trade Organization in these trade agreements allow you to take a precautionary approach so that if anybody makes an allegation as far as you're concerned from a protectoral standpoint whether you can prove that it's safe or not then you apply that standard just on the allegation itself whether you have the scientific body to support the rule or regulation.

Mr. YOUNG. Well certainly the Sanity and Phytosanitary agreement make provisions for the precautionary principle. I still believe that there's a need to prove that there's a reasonable basis for those precautions and whether or not Europe has done that with regards to hormones I'm not sure.

Senator ALLARD. Thank you. Mr. Coby. Is it Coby?

Mr. CORBY. Corby.

Senator ALLARD. Yes, Corby.

Mr. CORBY. Yup.

Senator ALLARD. In the State of New York you have authority to shut down a business if it creates a public health problem, don't you?

Mr. CORBY. Yes, we do.

Senator ALLARD. Yes. I think that's true in most States, isn't it?

Mr. CORBY. Yes, it is. Most all of the establishments are either licensed or permitted by State or locals.

Senator ALLARD. Right.

Mr. CORBY. And we can revoke the license, yes.

Senator ALLARD. You——

Mr. CORBY. And we also have the seizure authority which allows us to stop a product that we believe may be adulterated in its track.

Senator ALLARD [continuing]. You have inspected grocery stores I assume?

Mr. CORBY. Yes.

Senator ALLARD. Have you ever looked at the bulletin board on a grocery store? I have, at least in Colorado. They'll have a bulletin board up there that's maybe 2 feet square or 2 × 3 and it's plastered with permits and——

Mr. CORBY. Oh, yes.

Senator ALLARD [continuing]. All sorts of licenses and what not.

Mr. CORBY. Yes.

Senator ALLARD. And you wonder how in the world they can comply with all that, don't you from time to time?

Mr. CORBY. Yes.

Senator ALLARD. They do. But, I think we need to be careful on how much we force on a small business like that, you going to do that inspection.

Mr. CORBY. Well, there's a lot of things going on at the State and local level where they now will post inspection reports on a Web site or are required to post it at the front door.

Senator ALLARD. Yes. And so it quickly becomes available to——

Mr. CORBY. Yes.

Senator ALLARD [continuing]. The public if they're interested in one. And they'll do an evaluation on the store and how they're doing. And those reports are all made public I assume.

Mr. CORBY. Yes, they are.

Senator ALLARD. So they really have strong enforcement——

Mr. CORBY. We do.

Senator ALLARD [continuing]. Rules as far as that's concerned, yes.

Mr. Chairman, thank you.

The CHAIRMAN. Thank you very much. We'll submit to leave the record open and submit some questions.

I think it's been an enormously interesting and valuable hearing today. We've had a good explanation on the issues of food safety today.

The Advisory committee report is a clear call for action and our committee is determined to answer that call. I look forward to working with all of our colleagues to see that we develop a comprehensive approach to the challenges that the FDA faces both in food safety and in these other areas. This has been very, very valuable, very useful and we are very grateful to all of our witnesses and we will be submitting that we leave the record open for a week. We're going to be submitting some additional questions and calling upon you as we try to fashion and shape a legislative approach to ensure greater protection for American families.

Thank you very, very much. And the committee stands in recess.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SAFE FOOD INTERNATIONAL—WORLD HEALTH ORGANIZATION

PREAMBLE

Foodbome illnesses are prevalent in all parts of the world, resulting in millions of deaths each year. In developed countries, such as Australia and the United States, about one in three persons experience some type of foodborne illness every year, which can range from mild to fatal. In the developing world, the World Health Organization (WHO) estimates that contaminated food contributes to 1.5 billion annual episodes of diarrhea in children below the age of five and at least 1.8 million deaths. Food also can carry traces of hazardous chemicals, like pesticides or heavy metals, that cause neurological and hormonal damage as well as cancer. From production to consumption, it is the responsibility of national governments, the food industry, and consumers themselves to ensure that food is safe. However, governments have the pivotal role of providing a framework for establishing effective food safety programs.

UNITED NATIONS FOOD SAFETY RESOLUTIONS AND OTHER ACTIONS

While the need to ensure safe food was recognized when WHO was established more than 50 years ago, more recently the International Conference on Nutrition (Rome, 1992)—cosponsored by WHO and the Food and Agriculture Organization of the United Nations (FAO)—declared that access to nutritionally adequate and safe food is an individual right of all consumers. They specifically urged governments to "establish measures to protect the consumer from unsafe, low quality, adulterated, misbranded, or contaminated foods."

In 1993, the FAO held a Technical Consultation on the Integration of Consumer Interest in Food Control. The consultation, with inputs from organizations representing consumers' interests, identified the following issues as critical consumer concerns: nutritional quality; safety standards; labeling; environmental contaminants; food irradiation; and the application of modern biotechnology to food production and processing. It also identified barriers to consumer input in food control, particularly in developing countries.

The 53rd WHO World Health Assembly (Geneva, 2000) adopted a food safety resolution calling on its 192 Member States: "to integrate food safety as one of their essential public health and public nutrition functions and to provide adequate resources to establish and strengthen their food safety programs in close collaboration with their applied nutrition and epidemiological surveillance programs." The WHO World Health Assembly in a separate resolution adopted in 2002 also recognized the urgent need to protect food from threats of intentional contamination with biological and chemical agents and radiological materials.

In 2002, the United Nations in cooperation with consumer organizations drafted and eventually adopted guidelines for consumer protection that urges governments to "give priority to areas of essential concern for the health of the consumer, such as food, water, and pharmaceuticals. . . . Governments should maintain, develop or improve food safety measures, including, inter alia, safety criteria, food standards and dietary requirements and effective monitoring, inspection and evaluation mechanisms."

These international resolutions attest to the growing urgency of food safety. As food is increasingly traded globally, food safety has become a global public health issue. Dialogue between the United Nations' specialized agencies and groups representing consumers' interests is vital to improving national programs and protecting all consumers. Valuable contributions have been made by the long-standing involvement of international consumer organizations like Consumers International and the growing involvement of the International Association of Consumer Food Organizations in the work of the Codex Alimentarius Commission and its subsidiary bodies that deal with health and safety issues.

FORMATION OF SAFE FOOD INTERNATIONAL

In 2003, the Center for Science in the Public Interest (CSPI)* started the Safe Food International project with support from the WHO, FAO, and consumer organi-

*CSPI represents over 900,000 consumers in the United States and Canada and was also the founding organization for the International Association of Consumer Food Organizations.

zations in many parts of the world to promote stronger national food safety programs, to reduce food-related deaths and illness, and to deter the use of food as a target of intentional contamination.

Safe Food International was established on the principle that, while food-safety hazards vary from region to region, consumers in all parts of the world are critically concerned about the safety of the food they eat. As food production changes from local systems to international ones, consumers are demanding that food safety programs at home and abroad ensure that the food marketed to their families is safe to eat. National food-safety programs are usually funded by taxes paid by consumers, who depend on those programs to protect their health. However, in most countries, consumer and non-governmental public-health organizations have no formal role in the development of food-safety policies.

Consumer organizations can be instrumental in promoting effective national food safety systems. Encouraging greater coordination among interested groups, allocating additional resources to consumer representation, and providing more opportunities for consumer participation would be beneficial in many countries.

DEVELOPMENT OF THE GUIDELINES

Safe Food International developed these *Guidelines*† in consultation with consumer organizations in both developed and developing countries, based on WHO and FAO reports describing the elements of effective national food safety programs and CSPI's experience as a leading food safety advocate. Consumer organizations and national governments can use these *Guidelines* to strengthen their national food-safety programs and guard against any potential hazards in the food supply, including intentional contamination (food bioterrorism). Ultimately, the *Safe Food International Guidelines* assist both consumer organizations and governments in focusing on the basic requirements for national food safety programs in their countries.

With the cosponsorship of WHO and FAO, Safe Food International has convened an international conference that developed these *Guidelines* in consultation with the following consumer organizations: Union for the Protection of Consumer Rights (Armenia); Test-Achats (Belgium); Ligue pour la Défense du Consommateur (Benin); ProTeste (Brazil); Federation of Consumers in Bulgaria; Mouvement National des Consommateurs (Cameroon); Center for Science in the Public Interest (U.S. and Canada); Ontario Public Health Association (Canada); Union des Consommateurs (Canada); Organización de Consumidores y Usuarios (Chile); Pesticide Eco-Alternatives Center (China); EcoWomen (China); China Consumers' Association; Estonian Consumers Association; Federation of Consumer Organizations (India); Consumer Coordination Council (India); Voluntary Organization in the Interest of Consumer Education (India); Consumers Korea (Republic of Korea); Consumers Lebanon; Consumers Association of Penang (Malaysia); Pro Public (Nepal); Consumers' Institute (New Zealand); Asociación Peruana de Consumidores y Usuarios (Peru); Polish Consumer Association; Association Senegalaise pour la Defense de 1'Environnement et des Consommateurs (Senegal); National Consumer Forum (Seychelles); Consumers Union (United States); Consumer Education Trust (Uganda); Which? (United Kingdom); Centro de Estudios, Analisis y Documentación del Uruguay (Uruguay); Consumidores y Usuarios Asociados (Uruguay); International Association of Consumer Food Organizations; Consumers International.

Financial support for Safe Food International was provided by the NTI Foundation's Global Health and Security Initiative; the Center for Animal Health and Food Safety; the Philancon Fund; and the Center for Communications, Health and the Environment. The Canadian International Development Agency and the FAO provided travel funding to conference delegates from developing countries.

GUIDELINES TO PROMOTE NATIONAL FOOD SAFETY SYSTEMS

The Guidelines cover eight essential elements for an effective food safety program: **Food Laws and Regulations; Foodborne Disease Surveillance and Investigation Systems; Food Control Management; Inspection Services; Recall and Tracking Systems; Food Monitoring Laboratories; Information, Education, Communication, and Training; Funding and Affordability of the National Food Safety Program.**

†These *Guidelines may* be translated, quoted, and reproduced by bona fide consumer organizations to promote the development of sound national food safety programs. Reference to Safe Food International would be appreciated. For further information, please contact Safe Food International, 1875 Connecticut Avenue, NW, Suite 300, Washington, DC. 20009, (202) 777–8364, or by email at *sfi@cspinet.org*. To find the *Guidelines* and other related materials, please see the Safe Food International Web site, at *www.safefoodinternational.org*.

1. FOOD LAWS AND REGULATIONS

Each country must have effective, comprehensive food legislation to give its government the authority to ensure a safe food supply. Some countries have not developed specific laws to assure food safety—or they have developed such laws only recently. In other countries, food safety laws were drafted decades ago. Frequently, they do not address emerging hazards, like harmful bacteria, viruses, mycotoxins, pesticides, and prions, or new innovations, such as genetically modified plants and irradiation. Consumer organizations should be vigilant in identifying ways in which their national laws should be implemented, strengthened and modernized.

A modern national food law contains several essential elements. First, it should provide a framework for an integrated and coordinated food safety system. It should give food safety authorities effective tools to respond promptly to hazards in the food supply, especially during emergencies, and to remove hazardous food from the market in a timely fashion. Finally, it should promote the use of preventative food safety systems.

Food safety legislation should:

- Be developed with the participation of all stakeholders, and in particular consumer organizations.
- Articulate a high level of health protection, for example, food should be "safe for human consumption."
- Contain clear definitions to increase consistency and legal security.
- Be based on scientific advice that is high quality, transparent, independent, and at a minimum, in line with standards, guidelines and other recommendations of the Codex Alimentarius Commission.
- Ensure the food authority and food producers and processors give consumers accurate information about food products, including labeling on all matters relevant to their health and safety.‡
- Include mechanisms to facilitate traceback and recall of contaminated food.
- Put primary responsibility for producing safe food on producers and processors.
- Be regularly monitored and evaluated to ensure all stakeholders' requirements are being met.
- Apply to food aid, including during times of food security emergencies.

National legislation should require establishment of standards or other relevant management options for disease-causing organisms; naturally occurring contaminants such as aflatoxin; pesticide residues; and environmental contaminants, such as lead and methylmercury. It should enable monitoring and enforcement of these standards effectively and efficiently. The aim of such management options should generally be a continuous improvement of the national food safety situation.

Legislation should also establish requirements for labeling relevant to food safety and risk management addressing issues such as: ingredients in descending order by weight; presence of allergens; date marking; and instructions for safe use and storage. The labeling of food produced by genetically modified organisms is currently being discussed by the Codex Committee on Food Labeling.

All substances intentionally added to food and all new food technologies that may change the safety or nutritional qualities of food should be shown to be safe and suitable for their intended purposes. Food legislation should establish pre-market approval procedures for food additives, artificial food components and ingredients, foods derived from modern biotechnology, food processing technologies such as irradiation, and residues of food animal drugs and pesticides to ensure safety and nutritional adequacy of the food supply for consumers. These procedures should establish the safe conditions of use through labeling instructions and maximum residue limits or maximum levels.

Food legislation should require that feed for food-producing animals, including feed additives, and drugs for food-producing animals are safe for both humans and animals, including possible antimicrobial resistance. Feed for ruminants (cows, sheep, goats and others) grown for food should not contain ruminant tissues or byproducts.

2. FOODBORNE DISEASE SURVEILLANCE AND INVESTIGATION SYSTEMS

A foodborne-disease surveillance system tracks information on illnesses, gathers information to identify outbreaks (two or more illnesses linked to a single hazard), links outbreaks to food sources, and traces the food identified in the outbreak back to its origins.

‡Governments should follow appropriate Codex guidelines for the use of Halal claims in food labeling.

The first evidence of contamination of food will likely be found through the surveillance system. An effective surveillance system is one that identifies foodborne-illness outbreaks while there is still time to remove the contaminated food from the market and prevent illnesses. This is especially true for incidents involving food that has been intentionally contaminated.

Many countries have surveillance systems that rely on investigations of illnesses that are reported to medical officials. In some countries, sophisticated surveillance systems are designed to deliver a high degree of certainty before specific foods are linked to an outbreak. Such food attribution information is important to both risk managers and the public. However, some countries use systems that were developed to address food industry concerns that the wrong food might be blamed for causing a food-borne illness outbreak. Those systems can be too slow to operate effectively in an emergency.

To help risk managers issue more timely food recalls and to address the threat of intentional contamination, countries should review their surveillance systems with respect to their capacity to recognize emergencies rapidly.

1. A national food control system should establish links between the symptomatic foodborne-illness surveillance system and the food-monitoring system (see section 6 below).

2. Countries should establish or strengthen early warning systems to allow rapid detection of contamination incidents to ensure prompt public alerts.

3. Countries should ensure that their surveillance systems include data on the symptoms and effects of chronic exposure to foodborne contamination.

4. Identifying diseases in animals may provide a quicker indication of a problem in the food supply than waiting for human diseases to occur. Linking the veterinary health sector to the surveillance network might provide earlier warning of a problem in the food supply.

The public should have the right to information emerging from the surveillance systems, including all data to support:

- Annual foodborne disease incidence trends.
- Identification of susceptible population groups.
- Identification of hazardous foods.
- Results of routine sampling and analysis of food products.
- Identification and tracing of causes of foodborne disease from the farm to the kitchen.
- Early alerts for outbreaks and food contamination.

3. FOOD CONTROL MANAGEMENT

Many countries currently have more than one food safety agency, some with conflicting or overlapping responsibilities. An integrated national food control authority should address the entire food chain from farm-to-table and should have the mandate to move resources to high-priority areas.

The national legislation should define the food-control management structure. Core responsibilities of that system include establishing regulatory measures, monitoring system performance, facilitating continuous improvement, and providing overall guidance.

National legislation should define an integrated or coherent food safety system including designation of a lead food safety authority that should be empowered to:

- Develop and implement an integrated national food-control strategy.
- Set standards and regulations.
- Approve new food ingredients and food safety technologies.
- Participate in international food-control activities.
- Develop emergency response activities.
- Carry out risk analysis.
- Monitor enforcement activity and performance.
- Implement effective mechanisms for involving stakeholders, including Consumer organizations, at different steps of the decisionmaking process.
- Develop and promote food safety training curricula and programs.

Sufficient resources should be provided to the authority to carry out its mandate.

Risk analysis plays an important role for a national food control system. Risk analysis comprises of three stages: risk assessment, risk management and risk communication. Risk analysis involves identifying risks, weighing their likelihood and their impact, and establishing systems to manage and minimize risks. Risk management is the term given to the legal, regulatory, educational, and voluntary actions used to control risks. Risk assessment is a scientifically based process consisting of the following steps: Hazard identification, hazard characterization, exposure assess-

ment, and risk characterization. Risk assessment should always be carried out openly and transparently and ideally by independent scientific committees which are open to public scrutiny. While formal risk assessments can be highly beneficial, they can also be very time-consuming and expensive, beyond the reach of many governments. It is also essential that risk assessments answer the right questions and are explicit about any judgments or assumptions that have been made.

Where the science is uncertain or inconclusive, but there is evidence of a potential risk, it is important that a precautionary approach is adopted by risk managers. Failure to take action sufficiently early to protect the public can have devastating consequences.

Risk assessment is therefore an important aspect of risk management decisions, but not the only one. Other factors may also need to be taken into account by risk managers when determining the approach that has to be taken. Public involvement throughout the risk analysis process is essential in order to understand what these broader factors may be (including for example ethical, environmental or broader social aspects) which can affect people's willingness to accept a particular risk. It is essential that consumers are involved in determining an acceptable level of risk.

Risk communication is essential and has to be a two-way process between risk managers, risk assessors, consumers and their representatives, and other stakeholders.

Risk-management decisions should be based on the best available evidence and proceed within a timeframe that can minimize consumer harm. Risk managers can be informed by risk assessments conducted either in their own country or assessments done for international organizations, like the WHO. In order to respond to food safety emergencies, the government should establish a national food safety emergency coordination body. An effective emergency response system must be tailored to the circumstances and should include links to law enforcement and intelligence agencies, food-recall systems, risk assessment specialists, and the food industry, as well as the more traditional sectors of health care providers, laboratories, and emergency services. These systems should be tested to ensure that the communication and response systems work effectively.

4. INSPECTION SERVICES

Sound food safety legislation and policies are meaningless unless they are effectively enforced. Inspection services form the core of the food safety system, giving government regulators, customers, and consumers regular information regarding conditions throughout the food chain and on farms that can impact the safety of the food supply. In addition, inspectors give the government in-house expertise that can be used to conduct investigations and respond to food safety emergencies.

Food premises should be inspected as a matter of principle before they sell to the public to ensure that they meet hygiene requirements. Food inspection must ensure that all foods are produced, handled, processed, packed, stored, and distributed in compliance with legislation and regulations. Food inspection and regulation should extend from the farm to restaurants, street vendors, and other retail venues. There should be a sufficient number of inspectors to allow an adequate frequency of inspections. These inspections should be based on the risks posed by different foods and the history of problems in a particular sector of the food supply.

The food inspector is a key functionary who has day-to-day contact with the food industry, trade groups, and often the public. The inspector must therefore be honest and well-trained, independent, and be in a position to avoid external influence, including potential conflicts of interests. Training of food inspectors is an important component of an efficient food-control system. As national programs improve with the introduction of systems focused on controlling and preventing food safety problems (so-called Hazard Analysis and Critical Control Point (HACCP) systems) and the adoption of new technologies to improve food safety, retraining should be conducted to ensure that inspectors are providing optimal services.

Traditional inspection functions include responding to non-compliance with food laws, handling consumer complaints, and advising the food sector. In a modern food safety system, inspection functions include the following:

- Inspecting premises and processes.
- Evaluating HACCP plans.
- Sampling food during harvest, processing, storage, transport, or sale.
- Recognizing spoiled and hazardous food, food that is otherwise unfit for human consumption, or food that is deceptively sold to consumers.
- Recognizing, collecting, and transmitting evidence.
- Encouraging the use of voluntary quality assurance systems.

• Conducting inspection, sampling, and certification of food for import/export purposes.
• Conducting risk-based audits of food establishments with HACCP or other safety assurance programs.
• Recommending formal action, including prosecution, where food safety lapses could endanger public health.

Information on food inspection results, such as hygiene scores, should be made available to the public through, for example, web-based systems, media and other communication channels.

5. RECALL AND TRACKING SYSTEMS

Recall and tracking systems are vital to consumers and other actors throughout the food chain when food that does not comply with national standards, including contaminated food, inadvertently reaches any part of the food chain, including the consumer. The national food safety system should have comprehensive procedures covering the prompt removal of contaminated and mislabeled food products from the domestic market. Recalled products that are deemed to be unsafe should be properly disposed of and not exported to other countries.

Recalling contaminated food can be triggered by the food industry, consumer organizations, or the food control authorities. Tracking systems are used to trace the route of contaminated food or sick animals that may enter the food supply. Outbreak investigations often use tracking systems to trace back food linked to an outbreak to the farm or factory that produced it.

Tracking or traceback systems may also be required in order to give additional reassurances of safety, for example, to enable post-market monitoring of any unintended health effect. They are also important to ensure liability and compensation.

Tracking systems generally start with the food producers. In the case of live animals, it may include animal identification systems using ear tags and other devices. Processed foods should be clearly marked with a lot number and the time and date of production. Produce, grains and other plant-based foods should be labeled in a manner that clearly indicates the place of origin (country and State or province and preferably the farm or packing house). In all cases, packaged food purchased by the consumer should be marked to allow identification.

Recall systems should be a coordinated effort between the national government and the individual firm(s). If the government requests a recall, firms should have an affirmative duty to recover recalled products and to destroy or dispose of them properly. National laws should include penalties for companies that fail to comply with recall requests from national governments.

6. FOOD MONITORING LABORATORIES

Laboratories are an essential component of an effective food control system. They allow regulators, producers, and consumers to examine food for chemical and microbiological hazards that are not apparent through routine physical examination. Laboratory analysis can be critical to:

• Identifying contaminated foods.
• Identifying the source of an outbreak of food poisoning.
• Allowing regulators to bring enforcement action against adulterated and unsafe food.
• Confirming the safety of domestic food products as well as exports and imports.
• Allowing for dietary exposure assessments.
• Allowing consumer organizations and food processors to monitor and analyze the food quality at the user end.
• Assist in the regulatory decisionmaking process and evaluate the effectiveness of risk management interventions.

Effective food-control programs are able to monitor the quality and safety of the Nation's food supply. It is government's responsibility to ensure that mechanisms are put in place to make sure food is safe before it is marketed. A range of analytical capabilities are required for detecting a large variety of food contaminants, such as pesticides, pathogenic bacteria, pathogenic prions, foodborne viruses, parasites, radionuclides, environmental chemicals, and biotoxins. In addition, capabilities to test for spoilage and compliance with all other official food-control standards are needed.

The food-control management authority should establish quality assurance (proficiency) criteria for the operation of laboratories and should monitor their performance.

7. INFORMATION, EDUCATION, COMMUNICATION, AND TRAINING

Communication among food safety, agriculture and other relevant authorities, consumers and consumer organizations, and the food industry should be a vital and continuous function of a national food safety program. Communication with the public and the food industry in emergency situations, such as disease outbreaks or contaminated food alerts, is an increasingly important component of the national food safety system. Consumers should always be promptly, accurately and fully informed about any disease outbreak, contaminated food incident, or food recall through a sound alert system and traceability using effective and practical communication methods. Communication must be a two-way process to ensure that authorities are aware of and take account of consumer concerns and perceptions.

Wherever possible, risks should be explained in the context of the overall diet. Where it is not possible to give consumers clear information or advice about a risk, efforts should be made to explain as clearly as possible what is and is not known and what steps are being taken to address uncertainties.

Informing the public and the food industry about trends in food and foodborne diseases is an important role of government authorities. National governments should ensure communication during emergency situations by establishing industry alert and agriculture alert systems. Through the network of food safety regulators (INFOSAN), WHO, and in cooperation with FAO, operates an electronic information system to keep regulators informed of the emerging food safety issues, including emergency situations.

Giving consumers' advice regarding how to avoid foodborne illness is an educational function of the national food safety program. Education programs should begin in childhood using both formal and informal methods. Programs should also target high-risk groups and/or their caregivers. High-risk consumers include infants and young children, pregnant women, the elderly and immune-compromised individuals.

On-going training in specific skills, such as communication, and technical capacity building for inspectors, laboratory personnel, scientists, consumer organizations, and the food industry is critical to ensure that existing inspection programs are prepared to handle emerging hazards and to integrate new technologies to reduce hazards.

8. FUNDING AND AFFORDABILITY OF THE NATIONAL FOOD SAFETY PROGRAMS

National food safety programs must be funded sufficiently and transparently to conduct regular inspections of food-processing facilities and imports, to conduct laboratory tests of both domestic and imported food, to set standards and do risk analysis, as well as many other functions. The nature of the funding must not compromise their integrity and independence. Funds must be utilized efficiently to maximize public health protection and with accountability to the public.

Governments have the primary responsibility for ensuring the safety of domestic, imported, and exported food, and should provide core funding for such activities. However, support for building the capacities of such systems in the poorest countries should be the focus of bilateral and multilateral assistance, as appropriate.

Many countries fund food safety programs using cost-recovery systems. Cost-recovery options include a tax and/or specific fees for licensing, inspection activity, food sampling and analysis, and food safety training. However, those systems should not unfairly impact the poorest consumers and public health organizations.

Food safety programs must be structured to protect and promote public health and be affordable and accessible to small farmers and producers. This is important for preserving the diversity and quality of the food supply. Costly regulatory measures can put small farmers and producers out of business. Consolidation of the food industry can make food more vulnerable to large-scale contamination.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, HARKIN, MIKULSKI, BINGAMAN, BROWN, ENZI, BURR AND HATCH BY MICHAEL LEVITT

QUESTIONS OF SENATOR KENNEDY

Question 1. There's a lot of real value in the Food Protection Plan. One thing that concerns me, however, is that the plan proposes allowing the agency to require process controls for a food, but only after the food is associated with repeated instances of serious adverse health consequences or death. Why should the FDA have to wait for children or the elderly to die or be seriously injured by a food before companies making it are required to make it safely?

Answer 1. An overarching strategy of the Import Safety Action Plan and the Food Protection Plan is to target Agency resources to achieve maximum risk reduction.

FDA will primarily focus on promoting the use of risk-based, preventive systems that companies can voluntarily apply at all levels of food production and processing, when appropriate.

Potentially high-hazard food categories may require additional control measures. To address the potential need for additional control measures for high-hazard food categories, HHS has requested explicit authority to issue regulations requiring specific types of foods (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 HACCP or equivalent processes to reduce foodborne illness from high-risk foods. The criteria that the food be "associated with repeated instances of serious health problems or death to humans or animals for unintentional contamination" provides a clear and straightforward definition of high-risk foods or categories of food of greatest Agency concern. The identification of high-risk foods eligible for this provision can be made based on existing data and knowledge so FDA would not have to wait for further deaths or serious injury before these provisions could be implemented. By targeting recognized high-risk foods, but not limiting the overall preventative approaches to high-risk foods, we hope to achieve the greatest public health impact with the resources available.

Question 2. One recommendation in the Plan is that FDA should certify third parties to conduct food safety inspections. There may be real value in such a program, but we authorized such a program for medical devices in 2002 and very few device companies have taken advantage of it. What do you think will make food companies participate in a third party inspection program? What sort of resources will the FDA need to review and act on all the information that these inspections might generate?

Answer 2. One lesson learned from our experience with other third party inspection programs is that industry participation depends on appropriate incentives. Accordingly, we intend to seek input from stakeholders to best understand how to maximize participation in a third party inspection program for food. This will assist in estimating the resource requirements to review and act on the information that may flow from third party inspections.

Question 3. How much additional money do you think the FDA needs to carry out the Food Protection Plan?

Answer 3. The activities recommended in the Import Safety Action Plan involve 12 different Departments and agencies and we are currently working on the implementation plans for the 14 broad recommendations and the 50 action steps. The requests for additional resources will be coordinated through the budget process for the affected Departments and agencies and result in requests for additional funding over a number of years. The President's fiscal year 2009 budget request will soon be presented to Congress and will include the first installment of funds to carry out these activities.

Question 4. A significant impediment to the FDA doing a better job on food safety is its serious lack of adequate resources, as recently documented by the FDA Science Board Report. The Food Action Plan proposed two modest user-fee programs, on export certificates and re-inspections. How much money will each of these user-fees generate?

Answer 4. For fiscal year 2008, the proposed food and feed export certificate user-fee program was estimated to collect $3.7 million, and the proposed user-fee for re-inspections was estimated at $23.3 million including foods and medical products-related activities.

Question 5. Why does the Food Protection Plan propose requirements related to intentional contamination based on a risk assessment while allowing requirements for unintentional contamination based on repeated actual incidents of serious harm to consumers?

Answer 5. When FDA conducts a food risk assessment, we take the following variables into account:

- 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.

Both the proposal to require additional preventive controls for high-risk foods (unintentional contamination) and the proposal to require preventive controls against intentional adulteration (intentional contamination) take this type of risk assessment into account. For the foods or food categories covered by the unintentional contamination proposal, FDA can identify these foods as "high-risk" based on the known possibility of these foods causing illness, known instances of illness severity, and known data and experience around where the contamination is most likely to occur. The required preventive controls would then focus on known process control systems to reduce the possibility of contamination. The intentional contamination proposals take into account the same risk factors based on risk assessment modeling and best professional judgment in the absence of data and experience with these types of events in the United States. Therefore vulnerability assessments are required to suggest reasonable and appropriate mitigation measures given the number of uncertainties, and the fact that such attacks have not actually happened, around such events.

Question 6. What is the rationale for protecting from liability companies that comply with requirements related to intentional contamination of food?

Answer 6. This proposed authority would require companies to follow FDA requirements to prevent the intentional contamination of food. Recognizing that these requirements would be intended to help prevent the actions of third parties who may have ill intent and over whom the companies have no control, HHS determined that it would be appropriate to pair this proposal with an affirmative defense that would be of use if a third party were able to circumvent those required actions as fully implemented by the company. This does not provide full liability protection, but does allow a firm, if charged with negligence in a lawsuit, to have the benefit of an affirmative defense that it had fully complied with the relevant FDA requirements.

QUESTIONS OF SENATOR HARKIN

Question 1. I support mandatory recall authority for both USDA's Food Safety and Inspection Service (FSIS) and for FDA. However, I know that recall authority comes with a cost. How much would it cost to implement such authority and is FDA planning on requesting more funding for it in its fiscal year 2009 budget?

Answer 1. FDA is seeking mandatory recall authority to be used only when the current process of voluntary recalls fails to promptly remove foods that present a threat of serious harm to people or animals. While FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there have been rare instances in which a firm was 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 from distribution channels of food that presents a threat of serious harm to people or animals. In these rare situations this may result in a more efficient use of available FDA resources. The Administration is completing its work on the President's fiscal year 2009 budget request and will present the budget request to the Congress in February.

Question 2. In the submitted witness testimony for the hearing, we have read that statutes need to be significantly changed to modernize our food safety system. Do you agree? If so, does FDA have a legislative proposal?

Answer 2. The Import Safety Action Plan and the Food Protection Plan identify several legislative changes that would enable implementation of certain action steps and strengthen FDA's ability to continue to protect Americans from foodborne illnesses. Some of these are discussed in my written testimony. I look forward to working with you and other Members of Congress on these authorities.

Question 3. In the FDA Food Protection Plan, FDA places a renewed emphasis on the threat of an intentional contamination of food. Please describe FDA's relationship with intelligence officials and any ongoing collaboration the agency has with Federal Government intelligence agencies.

Answer 3. In July 2005, the Department of Homeland Security (DHS), the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Federal Bureau of Investigation (FBI) announced a new collaboration with private industry and the States in a joint initiative, the Strategic Partnership Program Agroterrorism (SPPA) Initiative. The SPPA Initiative is a true partnership program, where an industry member, trade association or State may volunteer to participate

in this vulnerability assessment program utilizing the "CARVER + Shock" method. The desired results of the SPPA Initiative include sharing:

- unclassified reports that detail generally identified vulnerabilities, possible mitigation strategies, and warnings and indicators of an attack. The unclassified reports will be distributed to all site participants;
- classified reports that outline sector-wide vulnerabilities and lessons learned to effectively and appropriately prioritize national assets and resources. The classified reports will be distributed to DHS, USDA, FDA, and FBI;
- the "CARVER + Shock" assessment tool, and adapting it, if necessary, to the unique production, processing, retail, warehousing, and transportation system for each sub-sector;
- lessons learned;
- assessment templates for each "system" by sub-sector that can be exported to other sites to identify vulnerabilities that incorporate existing tools;
- sector-specific investigative templates and field guides for the food and agriculture/intelligence sector; and
- research and development initiatives related to the food and agriculture sector.

DHS has established the Homeland Infrastructure Threat and Risk Assessment Center (HITRAC), where intelligence analysts and infrastructure specialists work to identify the threat to critical infrastructures, vulnerabilities and interdependencies, and the overall risk inherent in any potential attack against critical infrastructure. The HITRAC has worked closely with the food and agriculture sector to ensure that the most complete, actionable, accurate information regarding private sector assets is disseminated expeditiously to key stakeholders.

The Commissioner of FDA has designated the Office of Criminal Investigations (OCI) as the Agency's lead point of contact for liaison with the intelligence communities. OCI has several initiatives in place to fulfill their mission. Below is a sample and description of those initiatives.

OCI has a counter-terrorism section located at OCI Headquarters with the capability and background to analyze information from law enforcement and intelligence community sources so that they can assist in terrorism-related threat assessments involving FDA regulated products and respond to assist the FBI in counter-terrorism cases where an FDA regulated product is involved. OCI special agents are assigned and serve on several interagency terrorism-related task forces including the FBI Joint Terrorism Task Forces (JTTF), U.S. Attorneys' Office Anti-Terrorism Task Forces, and select Regional Task Forces around the country.

OCI's counter-terrorism efforts include daily contacts and interactions with the Central Intelligence Agency (CIA), the National Counterterrorism Center (NCTC), the Federal Bureau of Investigation (FBI), the Department of Homeland Security (DHS), the Defense Intelligence Agency (DIA), Customs and Border Protection (CBP), and the FDA-Prior Notice Center (PNC). In addition, OCI maintains relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding threats to FDA-regulated products or incidents of actual product tampering. OCI also actively participates in the SPPA Initiative.

Shortly after the September 11, 2001 attacks, the OCI counter-terrorism section organized an "Agriculture Intelligence" working group, referred to as "AgInt," to address threats to U.S. agriculture from "farm-to-fork." These monthly meetings include representatives from FDA (OCI, CFSAN, CVM, Import Ops, and PNC), the U.S. Department of Agriculture–USDA's Animal Plant Health Inspection Service (APHIS); Food Safety Inspection Service (FSIS); Agricultural Research Service (ARS); and the Office of the Inspector General (OIG), the FBI, the National Counter-Terrorism Center (NCTC), the CIA, the Department of Defense (DOD) and the Department of Homeland Security (DHS). These meetings are held at OCI Headquarters.

OCI's counter-terrorism efforts successfully established and strengthened relationships between Federal, State and local law enforcement, and the food and agricultural industry.

Question 4. Coordination across departments of the Federal Government is critical to ensuring the safety of our food supply. Does FDA currently use USDA resources (financial or personnel) for its food safety programs? Should this type of activity be encouraged to promote collaboration between the two agencies?

I agree wholeheartedly with you about the importance of coordination and a closer collaboration within the Administration is a key element of the Import Safety Action Plan. The import community, U.S. Customs and Border Protection and other agencies will exchange real-time product and compliance data on each import transaction to better inform decisions to clear or detain import shipments. We also will pursue information sharing agreements with foreign regulatory entities.

With regard to the relationship between the FDA and USDA, these agencies work closely together on food safety and food defense programs. This has been particularly evident in efforts to track cases of BSE in domestic cattle. FDA and USDA coordinate food safety research needs to address gaps and to avoid duplication. Another example of coordination with USDA is the Food Emergency Response Network (FERN). FDA has worked in close collaboration with USDA's Food Safety and Inspection Service to include a substantial number of laboratories capable of analyzing foods for agents of concern. FERN is a network of Federal, State, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity in case of emergencies. In addition, the FDA, USDA, and other Departments will collaborate to improve the rapid response to interdict unsafe imports, and to use electronic track and trace technologies, where feasible.

QUESTIONS OF SENATOR MIKULSKI

Question 1. In your testimony at the Senate HELP hearing on December 4, 2007, you noted that the FDA "plans to develop international standards that reflect the same level of protection maintained for consumer products in the United States." I applaud this initiative and some of the suggestions you have made to Congress as a first step, such as authorizing FDA to accredit third parties for food inspections abroad. However, making sure that imported foods meet the same safety standards of U.S. foods from handling to packaging, and processing is a tall order. How do you plan to implement this standard?

Answer 1. We have always required that imported foods meet the same safety standards as domestically produced products. However, the Import Safety Action Plan and the Food Protection Plan call for the implementation of export certificate programs for certain imported products and the development of third party certification programs to evaluate compliance with FDA requirements. In addition, we will continue to harmonize international standards through our participation in the Codex Alimentarious Commission and make import safety a key principle in our diplomatic relationships and trade negotiations with foreign countries. Together, these steps will help to elevate the standards of imported goods. Ultimately, however, import safety is a responsibility that must be shared by the public and private sector stakeholders involved in the imported products supply chain.

Question 2. What regulations will you establish to determine whether a food product imported from another country meets the same safety standards as those required of foods in the United States?

Answer 2. The Federal, Food, Drug and Cosmetic Act requires all food products distributed in the United States—whether produced domestically or abroad—to meet the same standards. In the Import Safety Action Plan and the Food Protection Plan we are proposing additional measures to supplement current authorities that would enhance FDA's ability to determine whether a food product imported from another country meets the same safety standards as those required of foods in the United States. In addition, stronger penalties and enforcement actions will be required to ensure accountability.

Specifically, we propose to:

- Accredit Highly Qualified Third Parties for Voluntary Food Inspections;
- Refuse admission of food, if FDA's efforts to conduct a foreign inspection are unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held; and
- Require electronic import certificates for shipments of designated high-risk products.

Question 3. What plans do you have to provide foreign producers with incentives to upgrade their food safety systems?

Answer 3. Under the current system, foreign producers and exporters already have a number of incentives for ensuring that their food products comply with U.S. safety requirements. First and foremost, foreign producers do not wish to run the risk of their product being refused entry into this country. In certain cases, after problems are encountered, future shipments are under more scrutiny through issuance of an import alert and, under FDA policies, may not be allowed to enter U.S. commerce unless the producer/exporter is able to establish that the products are in compliance, such as by satisfactory test results. Producers/exporters can suffer severe losses when their products are found not in compliance with FDA food safety requirements. For foods having a good record of compliance, on the other hand, FDA sets a higher "may proceed" rate so that the products are not held on

entry into the United States for examination and possible testing. This higher "may proceed" rate enables food products to enter U.S. commerce faster.

The Import Safety Action Plan recommends a number of additional steps to enhance foreign food safety systems. The certification programs which verify compliance of foreign producers with U.S. standards and the third party inspection programs will provide incentives to strengthen foreign food programs. In addition, we will step up collaboration and information sharing with foreign governments and regulatory bodies, develop good import practice guidances, best practices for track and trace technologies, and continue to work on food safety priorities through our diplomatic relationships and provide technical assistance to foreign regulatory entities. Finally, as we have done with China, we are entering into formal agreements with foreign governments.

Question 4. What do you do right now if you find imported food that was handled under unsanitary conditions or has not been subject to controls that meet the U.S. level of protection?

Answer 4. FDA can refuse admission of food offered for import if it appears that the food has been manufactured, processed, or packed under unsanitary conditions or is adulterated or misbranded. FDA gives notice to the owner/consignee stating the reason FDA believes the product is subject to refusal and explaining their right to provide evidence regarding the product's admissibility. If FDA ultimately concludes that a violation appears to exist, the product will be refused admission into the United States, and the importer is required to either export or destroy the product.

If FDA finds a problem with a product or range of products from a particular producer, shipper, or importer, FDA can issue an import alert or import bulletin to signal FDA field staff to pay special attention to those products. For example, FDA may issue an import alert for "detention without physical examination" explaining that FDA staff may initiate refusal of admission of a product as soon as it is offered for import without first examining it and taking a sample. An import alert for detention without physical examination is based on information, such as the past history of the company or product, sufficient to support refusal of future shipments of the product.

Question 5. How do you compare imported foods to those from the United States to determine if they meet the same level of food safety?

Answer 5. All imported products that are regulated by FDA are required to meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions.

FDA performs routine surveillance inspections of imported foods to check for compliance with U.S. requirements. While FDA is not able to physically inspect a large percentage of food entries, we electronically screen all import entries using an automated system, which helps our field inspectors determine which products pose the greatest risk and therefore should be physically examined.

FDA also performs laboratory analysis on a sampling of products offered for import into the United States and performs periodic filer evaluations to ensure that the import data being provided to FDA is accurate. Certain violations relating to imported food may lead to civil or criminal charges.

QUESTIONS OF SENATOR BINGAMAN

I was pleased FDA's Food Protection Plan discusses the importance of using risk-based technology to help FDA screen for potentially unsafe imports while facilitating the importation of safe products. For some time, I have helped fund the screening system called PREDICT (Predictive Risk-based Evaluation and Dynamic Import Compliance Tracking), which is under development for FDA by New Mexico State University. The concepts behind the PREDICT were proven in 2004 and successfully piloted this year as a part of FDA's import screening system.

Question 1. What is FDA's timetable and budget to fully implement the PREDICT system?

Answer 1. A pilot test of the PREDICT prototype system was conducted by FDA during the summer of 2007. The prototype system is currently limited to seafood and the pilot test was limited to seafood imported through a small number of ports in southern California. FDA has recently begun an expansion of the prototype to include all food products. Should this be successful, our plan is then to include other FDA-regulated commodities. The plan is to test the food prototype during fiscal year 2008 as it evolves, using the same few California ports, with feedback from the users. Considerable work must be done by subject-matter experts to develop the ex-

tensive risk-based criteria which will be required. Open-source intelligence activities must be expanded. A prototype integration of the PREDICT user screens into FDA's enterprise-wide import system will be developed. Technical requirements must be developed in order to ensure the final prototype represents a model which, when expanded to full production, will fully conform to applicable information technology standards. FDA estimates that completion of the prototype system will be accomplished during the first quarter of fiscal year 2009, and that deployment of a production version nationwide could begin thereafter within 6 to 9 months.

Question 2. What is FDA's estimate over the next 5 years of the amount of funding needed to bring PREDICT to full operational capability?

Answer 2. We have provided $1.0 million in fiscal year 2008 for this purpose and we intend to continue to support this important program. FDA is working to deploy these funds and will be able to determine estimates for future funding as we move forward.

QUESTIONS OF SENATOR BROWN

Question 1. How can we shift our focus at FDA to prevention in food safety rather than in responding to problems after they've already come about?

Answer 1. This is a key point and one of the underpinnings of the Import Safety Action Plan and the Food Protection Plan. These call for risk-based prevention steps, which will move forward concurrently.

1. Promote Increased Corporate Responsibility to Prevent Foodborne Illnesses.—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. 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 following 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 United States 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.

2. Identify Food Vulnerabilities and Assess 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.

3. Expand the Understanding and Use of Effective Mitigation Measures.—Building on risk assessments, FDA will initiate basic research to enhance our un-

derstanding 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.

Question 2. Last week, a draft report was released indicating that the FDA doesn't have the resources it needs to ensure the safety of our foods. What are you going to do to ensure that FDA has the funding it needs to do its job?

Answer 2. The activities recommended in the Import Safety Action Plan involve 12 different Departments and agencies and we are currently working on the implementation plans for the 14 broad recommendations and the 50 action steps. The requests for additional resources will be coordinated through the budget process for the affected Departments and agencies and result in requests for additional funding over a number of years. The President's fiscal year 2009 budget request will soon be presented to Congress and will include the first installment of funds to carry out these activities.

Question 3. Right now, the Food Safety Plan advocates a voluntary certification program where products are certified as meeting U.S. safety standards. Do you think these programs should really be voluntary? Wouldn't they be more effective if they were mandated?

Answer 3. Voluntary certification programs are useful in helping FDA focus its resources on the areas of highest risk and will allow us to leverage the resources of reliable third parties. FDA will be able to facilitate the entry of products from certified firms while focusing its own resources on non-certified firms or firms for which FDA has reason to believe there are safety or security concerns. Such programs would be audited by FDA, and FDA would retain its authority to inspect those establishments, as appropriate.

Mandatory certification can play an important role as well. For this reason, we recommend authority to require import certificates in certain circumstances. Mandatory programs require more time and resources to establish, but may be appropriate when the risks associated with a particular product, region, country, or producer are higher. Requiring mandatory certification for all products would be very resource intensive and could hinder trade unnecessarily.

QUESTIONS OF SENATOR ENZI

Question 1. You indicate in your testimony that building interoperable data systems and encouraging data sharing is important to import safety. Can you tell me more about what is required to achieve this interoperability? What sort of new legislative authority would you need?

Answer 1. FDA plans to enhance its information technology (IT) systems related to both domestic and imported foods. Many of these improvements will be implemented in the next 2 years; a few will extend beyond 2010. The enhancements described below do not require new legislative authority. The Mission Accomplishment and Regulatory Compliance Services (MARCS) program manages the integration, reengineering, and enhancing the legacy systems that support field activities. These systems include OASIS and other components which support import processing. Improvements range from replacing the current process that screens import entries; giving investigators faster access to product information via views of Center databases; improving sample collection/tracking on both desktop and mobile platforms; to developing a broker information center to allow Customs Brokers to quickly exchange information with import reviewers.

In addition to MARCS, FDA is working on a number of related projects that will improve import safety in the next 2 to 3 years. These include:

- Working closely with CBP to ensure that its planned Automated Commercial Environment, a component of International Trade Data System, will provide the functionality long sought by FDA.
- Developing a standard way of finding, creating, and updating the information about facilities/enterprises FDA regulates.
- Enhancing FDA's Decision Support System to boost performance and expand its ability to rapidly access information.
- Ongoing data cleanup and upgrade of internal system interfaces to synchronize and validate data across centers and ensure rapid access to correct information.
- Substantially improving in the IT infrastructure that helps staff exchange data among field offices and between the field and Headquarters.

• Expanding of the Electronic Exchange Network that facilitates data sharing among public health partners and collaboration among food safety experts.
• FDA's Unified Registration and Listing System (FURLS) integration of the registration and listing systems currently maintained in the individual Centers.
• Developing a Product Quality System to encompass an electronic mechanism for manufacturers' registration and product listings, and capture inspection data from compliance reviews.
• Implementing FDA's Information and Computer Technologies plan for the 21st (ICT21) century to ensure that FDA has the infrastructure needed to support these IT initiatives and move towards the Bioinformatics era.

Question 2. Third party inspection and review programs have a somewhat mixed track record. One common criticism is that companies don't use these programs because they would have to pay to be inspected more frequently, when they could just use the less-frequent and "free" government program instead. How do we ensure that third party review is sufficiently rigorous that it actually protects the public health, but isn't such a high standard that it deters people from using the program?

Answer 2. We have confidence in FDA's third party inspection programs. FDA trains, accredits, and oversees the work of third party inspectors to ensure that their inspections are as rigorous as if FDA employees had conducted them. Moreover, FDA also maintains the right to inspect at any time. While it is true that many firms have not taken advantage of this option in the past with respect to the medical device third party inspection program, FDA is working to increase participation and we are pleased that FDA included needed improvements. In the international context, these types of inspections can play an important role. Because other countries also accept third party inspections, firms may be able to have one inspection that satisfies the requirements of several regulatory bodies. This will help to streamline the movement of imports.

Question 3. I have some concerns about the proposed user-fee for re-inspections. I firmly believe that FDA needs more resources and more inspectors. However, if an inspector knows that FDA gets more money if he or she has to come back, I wonder if that creates a perverse incentive to find violations and fail companies. How do we guard against this potential conflict of interest?

Answer 3. FDA's decision to re-inspect a facility or initiate regulatory action after a violative inspection is informed by the applicable Federal statute (i.e., Federal Food, Drug, and Cosmetic Act and Public Health Service Act), regulations, and agency policies and procedures. Neither the decision to take a regulatory action nor the decision to re-inspect a facility rests with the FDA Investigator. An FDA Investigator inspects regulated industry based on previously established Agency policies and procedures. The FDA Investigator's role is to inspect FDA-regulated industry in accordance with the requirements of our statute, regulations, and established Agency policies and procedures and to prepare a written account of any findings that appear to the Investigator to be out of compliance with the Agency's laws or regulations. Once the Investigator has written the inspection report explaining the inspectional findings, including the evidence necessary to support the observations, the report is further evaluated by other FDA personnel within the chain of command. The first line supervisor will review the report for accuracy and assurance that the observations are based on facts and supported by the evidence collected. The matter may then be referred to a District Compliance Office for review and evaluation to determine if the Agency should consider regulatory action. Depending on the specific FDA commodity and the governing Center within FDA, the regulatory action may also require review by other FDA offices to ensure that the action is consistent with various requirements, policies, procedures, and practices. If an action is taken, the determination whether a re-inspection is warranted is also weighed carefully to ensure that the decision is consistent with Agency policies and procedures. We believe that any perceived conflict of interest regarding our current proposal for user-fees for re-inspections is addressed by the current evaluation process FDA utilizes. Moreover, the proposed re-inspection fee only covers the actual costs of the inspection. There is no net revenue gain to FDA from conducting re-inspections.

Question 4. Track and trace technologies are going to be an important part of our food safety system at some point, as you suggest. We heard a lot about Radio-Frequency Identification (RFID, a track and trace technology) at last year's hearing, but it seemed that the conclusion was that this technology isn't ready for prime time, at least at the unit-of-sale package level. What do we need to do to get to a point where track and trace is a reality?

Answer 4. Over the years, FDA has monitored industry efforts to develop and promote RFID track and trace technology in the context of prescription drugs. Section 505D of the Federal Food Drug and Cosmetic Act, as amended by the Food and Drug Administration Amendments Act, gives the agency the authority to develop standards for the identification, validation, authentication and tracking and tracing of prescription drugs, and to develop a standardized numerical identifier to be applied to prescription drugs. Recognized standards will be useful to help promote the use of this technology, which the standards must address.

For foods, however, it is not clear that RFID is the best, or only, technology appropriate for effective trace-back. HHS plans to 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. In so doing, it will be critical to identify best practices for the use of track and trace technologies to facilitate their adoption by industry.

Question 5. In all three of the focus areas—prevention, intervention and response—there is a clear need for new science and technologies. What do you believe is the role of FDA's Critical Path initiative and the new Reagan Udall Foundation for the FDA in developing these new tools?

Answer 5. Both the Import Safety Action Plan and the Food Protection Plan emphasize the need for new scientific and technology developments to ensure the safety of FDA regulated food products, both domestic and imported. These goals are also at the heart of the Critical Path Initiative, and activities under way under this Initiative directly support the achievement of these goals. For example, developing and implementing standards for data being collected and managed by FDA and progress the Agency is making to move into a wholly electronic environment will help the Centers identify and track problems, improving our ability to intervene and respond. Improving manufacturing approaches (one of the Critical Path's 6 key topics), such as building quality into manufacturing and packaging processes, will help ensure that products are manufactured, packaged, and stored safely.

The recently enacted FDA Amendments Act of 2007 provides for the creation of the Reagan Udall Foundation. The Foundation is charged with advancing the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerating innovation, and enhancing product safety. The statute specifically directs the Foundation to take into account the FDA's Critical Path reports and priorities. Thus, developing new science and technology for product safety in all three areas—prevention, intervention and response—should be within the Foundation's mission.

Question 6. I agree that we need to do a better job of communicating about product recalls. One thing I've been thinking about a lot is retail food safety. Big chains hear about recalls, smaller ones often don't. I've been looking at the reverse–911 system that was used in southern California during the recent wildfires to tell residents to evacuate. I feel like there's a role for a system like that for communications up and down the supply chain during a recall. What do you think?

Answer 6. Although companies generally comply with voluntary recalls, the Import Safety Action Plan includes a recommendation to seek authority for mandatory recalls when voluntary recalls are ineffective. Also, we are recommending cooperative agreements between Federal and State inspection entities and greater information sharing, the initiatives on track and trace technologies, and the proposal to develop a best practices model for expediting consumer notification of recalls. Together, these steps will significantly enhance the effectiveness of recall communications.

In addition, FDA conducts recall effectiveness checks to determine whether a recall is progressing satisfactorily, with the number of checks dependent on the degree of the hazard. For example, during the recent Castleberry's Chili recall in July 2007, FDA conducted more than 3,700 recall effectiveness checks. FDA will continue to explore new opportunities for optimizing recall communications to ensure our recall messages reach all of the necessary recipients.

QUESTIONS OF SENATOR BURR

Question 1. From my perspective, the largest gap in the FDA Food Protection Plan was the lack of discussion about FDA resources. The data comparing the resources of the FDA to that of the USDA is startling and very troubling, especially given that the FDA regulates 80 percent of the U.S. food supply. Are you requesting that OMB include more money for FDA food protection activities in the "2009 budget," if so, how much?

Answer 1. The activities recommended in the Import Safety Action Plan involve 12 different Departments and agencies and we are currently working on the implementation plans for the 14 broad recommendations and the 50 action steps. The requests for additional resources will be coordinated through the budget process for the affected Departments and agencies and result in requests for additional funding over a number of years. The President's fiscal year 2009 budget request will soon be presented to Congress and will include the first installment of funds to carry out these activities.

Question 2. Several witnesses will testify that the FDA Food Protection Plan limits the ability of the FDA to act in important food safety areas due to the proposed requirement that foods only come under process control programs if they have been linked to "repeated, serious adverse health consequences or death." Peanut butter and spinach could probably not reach that level, but I think everyone agrees that the processing plants for both food products need control programs. Do you agree that the "repeated, serious adverse health consequences or death" bar may be too high?

Answer 2. This is an important point. The proposed authority to require additional prevention controls for high-risk foods (unintentional contamination) is focused on those foods or categories of foods of greatest concern because of their known serious public health impact. Such authority would strengthen the FDA's ability to require manufacturers to implement risk-based HACCP or equivalent processes to reduce foodborne illness from these high-risk foods. It is appropriate to target prevention efforts where they can have the greatest public health impact.

However, we are not ignoring other foods that do not fall into this category. HHS and FDA will work to consider safety and defense risks associated with foods through their whole life cycle whether domestically produced or imported. This includes the following 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 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.

Question 3. Mr. Corby will testify about the unique and successful partnership the State of New York has developed with the FDA. Does the FDA have plans to replicate that partnership with other States?

Answer 3. Yes. FDA has posted the New York Department of Agriculture and Markets partnership agreement on the FDA Partnership Internet site and has made it available to all FDA Districts and the States. To the extent resources are available and States are willing to enter into these agreements, FDA has encouraged its District Offices to develop the appropriate partnerships to enhance the working relationships with the States within their districts.

Question 4. Mr. Corby's written testimony mentions North Carolina's use of an Incident Command System for the chili sauce recall. Due to that system, NC performed more recall audit checks than the rest of the country combined. Do HHS and FDA have any intention of pushing more States to adopt Incident Command Systems?

Answer 4. North Carolina demonstrated that its State infrastructure, the Incident Command System (ICS), functioned exceptionally well during a national recall. FDA has been working on the use of an Incident Command System process and recommended that basic ICS training include ICS–100 (Introduction to Incident Command System), ICS–200 (ICS for Single Resources and Initial Action Incidents), ICS–700 (National Incident Management System (NIMS), An Introduction), and

ICS–800 (National Response Plan (NRP), An Introduction) on-line training courses for FDA staff who may be called upon to respond and manage emergency incidents.

In 2007 and 2008, the FDA's Office of Crisis Management/Office of Emergency Operations and the Office of Regulatory Affairs began a series of ICS training classes to be held across the country in National Incident Management System (NIMS), ICS 300 (Intermediate ICS for Expanding Incidents) and ICS 400 (Advanced ICS). The target audiences for these classes are both FDA and State officials with a goal of integrating response operations across Federal, State, and local jurisdictions.

Question 5. I'm pleased the FDA Food Protection Plan includes strategies to protect the food supply from intentional contamination—known as food defense. In my view, it doesn't matter if food is contaminated unintentionally or intentionally—we should be prepared for both. As you know, the human health and economic consequences of a deliberate attack on our agriculture and food system could be massive. And we know from intelligence sources that some folks are interested in acquiring the ability to do so. Mr. Secretary, how are you working with DHS and USDA to ensure a coordinated approach to protecting the agriculture and food system from biological, chemical, or radiological contamination?

Answer 5. The National Strategy for Homeland Security and the Homeland Security Act of 2002 served to mobilize and organize our Nation to secure the homeland from terrorist attacks. The homeland security goals to prepare for, and respond to, such events are set forth in Homeland Security Presidential Directives (HSPDs) 5, 7, 8 and 9. HSPD–5 ensures that all levels of government responding to an incident of national significance have the capability to work efficiently and effectively together using a common national domestic incident management approach, and HSPD–8 provides guidance on how to prepare for such a response, including prevention activities. HSPD–7 focuses on issues concerning protection of all national critical infrastructures and key resources, the majority of which are owned and operated by the private sector. HSPD–9 represents a major step toward establishing a comprehensive national policy to defend the food and agriculture system against "terrorist attacks, major disasters and other emergencies."

Significant progress in the Food and Agriculture Sector, one of the identified Critical Infrastructures, on homeland security goals can only be accomplished through a partnership effort between all levels of government and those who own the Critical Infrastructure. The Food and Agriculture Sector Coordinating Council (SCC) was formed as part of the private sector response. The SCC is a self-governing body representing the food and agriculture industry. It provides a forum for the private sector to discuss infrastructure protection issues among themselves and to communicate with the government through the Government Coordinating Council (GCC). The GCC, with representation from Federal, State, Tribal and local governments, is the public sector component of the food and agriculture public-private partnership framework. The objective of the GCC is to provide effective coordination of food and agriculture security strategies and activities, policy, and communication across government and between the government and the Sector to support the Nation's homeland security mission. The GCC conducts monthly conference calls to discuss infrastructure protection issues. Also, monthly calls are held between the leadership for the GCC and SCC to discuss infrastructure protection issues. The Food and Agriculture Sector holds a joint face-to-face GCC/SCC meeting each quarter to discuss issues of concern. Finally, the Food and Agriculture Sector is also populating an electronic notification system with contact information for the GCC and SCC members so that we can convene a meeting of the sector members on short notice.

In July 2005, the Department of Homeland Security (DHS), the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Federal Bureau of Investigation (FBI) announced a new collaboration with private industry and the States in a joint initiative, the SPPA Initiative. The SPPA Initiative is a true partnership program, where an industry member, trade association or State may volunteer to participate in this vulnerability assessment program utilizing the "CARVER + Shock" method. The desired results of the SPPA Initiative include sharing:

- Unclassified reports that detail generally identified vulnerabilities, possible mitigation strategies, and warnings and indicators of an attack. The unclassified reports will be distributed to all site participants.
- Classified Reports that outline sector-wide vulnerabilities and lessons learned to effectively and appropriately prioritize national assets and resources. The classified reports will be distributed to DHS, USDA, FDA, and FBI.
- The "CARVER + Shock" assessment tool, and adapt, if necessary, to its unique production, processing, retail, warehousing, and transportation system for each subsector.

• Lessons learned.
• Assessment templates for each "system" by sub-sector that can be exported to other sites to identify vulnerabilities that incorporate existing tools.
• Sector-specific investigative templates and field guides for the food and agriculture/intelligence sector.
• R&D initiatives related to the food and agriculture sector.

Conducting face-to-face CARVER + Shock evaluations is resource-intensive and limiting in terms of the number of evaluations that can reasonably be conducted in any given timeframe. Therefore, the FDA has sponsored the development and delivery of a CARVER + Shock software tool that can be downloaded for free. In developing this software, FDA worked closely with USDA and beta tested the software with DHS in order to ensure maximum applicability. By having an on-line, free to use, CARVER + Shock software that produces results equivalent to those of a face-to-face session, any member of the food processing industry now has the ability to conduct a vulnerability assessment of their facilities and processes in a confidential manner. This CARVER + Shock software tool went live on our Web site in late June 2007 and has already been downloaded more than 2,000 times. The software tool is expected to be used by State and local food security agencies, industrial providers and any other parties interested in food defense. The tool is designed for use throughout the food processing industry.

In addition, FDA in cooperation with the Centers for Disease Control and Prevention, USDA, and State and local organizations representing food, public health, and agriculture interests announced a new food defense awareness initiative, ALERT. The ALERT initiative is designed to provide a uniform and consistent approach to food defense awareness at any point in the food supply chain, from farm to retail establishment. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination. The five key points are as follows:

A—How do you ASSURE that supplies and ingredients you use are from safe and secure sources?

L—How do you LOOK after security of the products and ingredients in your facility?

E—What do you know about your EMPLOYEES and people coming in and out of your facility?

R—Could you provide REPORTS about the security of your products while under your control?

T—What do you do and who do you notify if you have a THREAT of issue at your facility, including suspicious behavior?

We have prepared ALERT materials in several languages (English, Spanish, Chinese, Korean, and Vietnamese) and offer training on our Web site that is suitable for State, local, and industry stakeholders.

These are just a few of the many activities we have undertaken to protect against vulnerabilities and to coordinate and share information with our food defense partners.

Question 6. In November, FDA awarded grants to three Food Emergency Response Network (FERN) labs to improve the ability to detect radioactive material in food resulting from deliberate or accidental contamination. How will these new radiological screening and analysis capabilities fit into the overall food defense surveillance strategy supported by FERN?

Answer 6. The new radiological screening and analytical capabilities are targeted toward enhancing detection of radiological contamination and strengthening the Nation's overall capability to rapidly detect and respond to deliberate attacks on the food supply.

These enhanced capabilities further expand the FDA's advancement of the integrated strategy for protecting the Nation's food supply by their direct application in the three core elements of prevention, intervention, and response as outlined in the agency's Food Protection Plan. Laboratories with the established radiological capabilities will be involved in food defense surveillance testing and will bolster the FDA's emergency response efforts by increasing the capacity for testing of foods for radioactive contamination, whether intentional or accidental.

Question 7. Do you perceive the user-fee outlined in Chairman Dingell's bill to be a tax or a user-fee?

Answer 7. We would note that a user-fee relating to imports would need to be consistent with U.S. obligations under treaty. While deferring to the United States Trade Representative (USTR) in this area, we understand that under Article VIII of the General Agreement on Tariff and Trade (GATT), fees—other than import du-

ties and other taxes covered by another GATT provision—must be limited in amount to approximate the cost of services rendered and must not represent an indirect protection to domestic products or a taxation of imports for fiscal purposes.

Question 8. Do we need mandatory, enforceable, on-farm standards for safe produce production (as suggested by Mr. Taylor) or voluntary food protection plans as outlined by the FDA Food Protection Plan?

Answer 8. We believe that the development of written food protection guidelines to facilitate industry food protection plans for produce is an important step to ensuring produce safety. These guidelines would make a significant contribution to shifting the focus of produce safety from response to prevention, would call attention to corporate responsibility, and likely could be implemented significantly faster than a mandatory approach. In addition, FDA continues to explore additional actions it might take to improve produce safety. In 2007, FDA held two public hearings on produce safety which included the solicitation of all our stakeholders on ways to improve the safety of fresh produce. More specifically, FDA requested comments on what new Federal actions, if any, are needed to enhance the safety of fresh produce. FDA will continue to work with industry, consumer, and Federal, State, local, and international partners to comprehensively review food supply vulnerabilities and develop and implement risk reduction methods.

QUESTIONS OF SENATOR HATCH

Question 1. You have proposed a role for accredited third parties to evaluate compliance with FDA requirements. Ever since the Medicare program began, third parties have evaluated whether hospitals comply with Medicare requirements. Very little inspection is done by Federal workers. Can food safety follow the Medicare model?

Answer 1. The Import Safety Action Plan and the Food Protection Plan acknowledge that the ever-increasing volume of imported products and the complexity of food safety issues associated with them require an approach other than an exclusive reliance on examinations and analyses performed when products reach U.S. ports of entry. We have called for "pushing out the borders" by incorporating information about how the product was produced and the food safety controls and checks that were in place during its production into the import entry decision making process. This information can come from the processor, the government of the country in which it was produced, or reliable third-party, nongovernmental organizations. Such work is already done by these entities and information about those efforts could be used to inform the FDA entry review process. If the information that is obtained is sufficient to conclude that the risk of product adulteration or misbranding is significantly reduced, then the need for FDA examination or testing may be similarly reduced. That could enable FDA to shift those resources to riskier products, for which there is little or no information about its life cycle. FDA is working to develop these kinds of systems to improve the efficiency and effectiveness of U.S. control over imported foods. FDA does not envision that these systems will take the place of sampling and examination at the port of entry, but does envision that they will be an important component of the overall entry control system. Of course, third party information, whether it is derived from a governmental or nongovernmental source, is only as valuable as the accuracy and integrity of the information. For that reason, the Import Safety Action Plan and the Food Protection Plan both acknowledge the need for auditing and/or accreditation systems for third party certifiers.

A third party inspection system for food safety could have many similarities with the Medicare hospital model. However, one major third party in the United States is responsible for hospital inspections whereas we envision multiple third parties will be necessary to conduct food establishment inspections worldwide.

Question 2. What is the role of accredited third parties in other countries?

Answer 2. Official accreditation is the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services on its behalf. Depending on the program, an officially accredited third party may either: (1) carry out inspections and tests directly on the agency's behalf to ensure that a product is in conformance with requirements; or, (2) certify an entity (e.g., conformity assessment service/inspection service/laboratory) to carry out services according to specified criteria.

The role of accredited third parties is to ensure that products meet requirements. This is the case whether accredited third parties carry out their work in other countries with respect to imported food, or whether they carry out their work domestically on domestically-produced food. This is also the case whether such third parties

accomplish their objectives through direct product inspection and/or testing, or whether they accomplish the objective indirectly, e.g., certifying another body to actually inspect and/or test the product. For example, Australia permits the utilization of accredited foreign third parties to ensure that quality management systems are in place for a specific food producing firm/establishment to ensure that Australia's food safety requirements are met. Food produced by such firms/establishments is permitted to enter Australia at its lowest rate of inspection.

Question 3. What are the advantages and disadvantages of seeking agreements with other countries to recognize the same accredited third parties?

Answer 3. The principal advantage of having an agreement with another country which recognizes the same accredited third parties is the potential for enhancing information sharing. Since regulatory requirements for a food normally differ between countries, it would not be expected that an agreement with a country to mutually recognize an accredited body would result in accepting the other's country data for regulatory purposes. However, having in place an agreement to recognize the same accredited third party should increase confidence in the data gathered by the third party for either country and should enhance data sharing. This data sharing could provide significant industry as well as consumer health benefits and could result in better targeting of scarce resources.

There do not appear to be obvious disadvantages for two countries seeking an arrangement to recognize the same third party. Presumably the accredited third party treats each country as a separate and unique client. If confidentiality and conflict of interest requirements differ between the two countries, these two areas could become difficult obstacles to overcome, but would not necessarily be disadvantages.

Question 4. Could mutual recognition of accredited third parties speed harmonization of standards across countries?

Answer 4. Harmonization of standards can refer both to specific national standards for food products and to standards for assessing conformance by assessment bodies such as third party certifiers. It would not be expected that mutual recognition of accredited third parties would result in any harmonization of specific product standards. However, the mutual recognition of an accredited third party by two or more countries using an agreed upon specific set of criteria could speed the use of the criteria as an assessment standard, particularly if those countries were influential in world trade discussions.

QUESTIONS OF SENATOR ALLARD

Question 1. Can you describe how the recommendations by the working group, and FDA, would have avoided and/or more quickly addressed the issues that arose in relation to our domestic food supply over the past year? Please address, specifically those dealing with *E. coli* contaminated spinach and salmonella contaminated peanut butter?

In your opinion did the current system effectively address these issues in a timely manner?

What did your agency learn from these situations, and how were these concerns taken into account when making the recommendations that you have discussed today?

Answer 1. The investigation into the *E. coli* outbreak linked to bagged fresh spinach in 2006 determined that a number of the Good Agricultural Practices recommended by FDA were not being followed on or near the field implicated as the source of the contaminated spinach. As part of the Food Protection Plan announced by FDA in November, FDA will strive to ensure that Good Agricultural Practices are being implemented on produce farms in the United States and on farms in other countries that export produce to the United States.

FDA responded immediately to the outbreak upon learning that fresh bagged spinach had been implicated as the vehicle in the outbreak. FDA was told of the link to fresh bagged spinach late in the day on September 13, 2006. FDA and the California Department of Health Services had staff in the packing house on September 14, and FDA issued a warning to the public the same day. Your response to the outbreak could not have been any faster.

Similarly, FDA was informed that peanut butter had been implicated in the Salmonella Tennessee outbreak on February 13, 2007. FDA contacted ConAgra, the manufacturer, that same evening. FDA and the Georgia Department of Agriculture had staff in the manufacturing plant the next day, and FDA issued a press release alerting consumers not to eat peanut butter under the brands Peter Pan and Great Value. Subsequent press alerts were issued as greater knowledge of the scope of the contamination was determined over the course of the investigation.

FDA's response was timely and communications were consistent with the information we had about the scope of the problem. While we worked to ensure timely and coordinated communications with stakeholders, we are seeking to enhance communications and outreach with industry, State and local government partners. The Food Protection Plan has a component focused on improving communications.

Consistent with the Food Protection Plan's three main themes of Prevention, Intervention and Response, we are seeking to build safety into the production of produce and manufactured foods, verify prevention and intervene when risks are identified, and respond rapidly and appropriately when outbreaks occur.

Question 2. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc."

Answer 2. We currently engage in a large portfolio of activities related to educating the various stakeholder groups, many of these in partnership with other Federal agencies. There are additional activities that we could engage in to further educate the stakeholders listed above regarding food safety and recalls. To reach the broadest population of stakeholders, TV and alternative mass media campaigns need to be considered. Curriculum for elementary, middle, and high schools relative to food safety could also be considered. In some cases, the information provided to the children will serve to educate their parents. We are exploring a reinvigoration and associated marketing campaign of our branded Web site, *www.foodsafety.gov*, shared among USDA, CDC and FDA, where stakeholders can find food safety information and information on recalls. Routine public safety announcements and radio spots could be increased in frequency and content. In short, we need to use the media and our schools more broadly for food safety and recall educational purposes.

With regard to recalls, the recalling firm has the primary responsibility to effectively and rapidly remove problem products from the marketplace. FDA carefully monitors, advises or provides direction in the recall efforts, and often undertakes additional steps to enhance recall effectiveness by issuing press releases, posting information on the FDA Web site, disseminating information to our State regulatory partners, and by making Agency experts available for inquiries from media, industry, or consumers. We recently began posting photographs of recalled food items on the FDA Web site for significant recalls to enhance the public's ability to accurately identify the problem products. For the most significant ones, FDA establishes dedicated pages on the FDA Web site where all the most current information relative to a recall can be found. In addition, consumers and businesses can now subscribe to a Listserve available on FDA's Web site (*http://www.fda.gov/opacom/7alerts.html*) that will automatically provide information via e-mail on recalls, market withdrawals and safety alerts. This Web site also allows the public and private sectors to query the system for information on specific recalls. We plan to assess existing FDA consumer materials to determine if additional resources on where to find recall information is required for the consumer. We will continue to engage consumer groups for input on optimizing recall communications.

There are, however, additional activities FDA can pursue to ensure even greater public awareness of food-related recalls and we are exploring other options.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, HARKIN, ENZI, BURR AND ALLARD BY MICHAEL R. TAYLOR

QUESTIONS OF SENATOR KENNEDY

Question 1. There's a lot of real value in the Food Protection Plan, however, one thing that concerns me is that the plan proposes allowing the agency to require process controls for a food, but only after the food is associated with repeated instances of serious adverse health consequences or death. Why should the FDA have to wait for children or the elderly to die or be seriously injured by a food before companies making it are required to make it safely?

Answer 1. FDA should not have to wait until people are hurt before requiring that food producers and processors implement commonsense preventive-process controls. We should instead be taking a public health approach to food safety, which means focusing on preventing problems that can make people sick rather than merely reacting to problems after people are hurt. And the fact is that many companies already implement modern process control procedures to prevent food safety problems. My recommendation is that Congress should mandate preventive process control, flexibly adapted to a company's particular circumstances, as the proper standard of care for all food companies.

Question 2. A significant impediment to the FDA doing a better job on food safety is its serious lack of adequate resources. I believe the President should propose a

substantial increase in FDA's budget and the Congress should increase appropriated funds to the FDA. Assuming that won't happen, or that increases won't be sufficient, I'd like you to comment on some ways to leverage FDA resources:

- a third party program for inspection and laboratory testing;
- fees on the food industry, such as an annual registration fee;
- enhanced collaborations with States and localities.

Answer 2. I agree with the Chairman that, ideally, FDA's public health regulatory programs should be fully and adequately financed with appropriated funds. If that doesn't happen, however, I think all three of the suggested ideas have promise as ways to leverage or enhance FDA resources.

Many food companies already undergo third-party audits to verify they are operating state-of-the art preventive process control systems in response to the demands of their commercial customers, such as restaurant and grocery chains. Such audits could be a useful surrogate for FDA inspections if the auditors could be accredited by FDA or some other credible body to verify their independence and qualifications and if records of their audits were readily available to FDA. FDA could then focus its resources on companies that are not subject to such audits. I see somewhat less potential for leveraging private laboratory capacity. The network of commercial laboratories that already exists plays a useful role in performing testing to support the industry's process control needs, and efforts should continue to ensure that such labs are properly accredited and reliable. FDA should be able to consider data from demonstrably reliable private labs in the course of its regulatory decisionmaking. Such private testing capacity can never substitute, however, for FDA having substantial, first-tier lab capacity in-house for the testing needed to support its inspection and enforcement activities.

With respect to fees on the food industry, I think a well-structured annual registration fee system may be the most equitable way to generate a significant base of resources for FDA's food safety program. The very large number of domestic and foreign food establishments under FDA's jurisdiction would make it possible to raise significant sums while keeping the per establishment fees very modest, and this would avoid any sense that the agency was dependent on or beholden to any small group of companies for its resources. It would be important to make clear that, in its use of its food safety resources, FDA is properly accountable to the public and the Congress, not the food industry.

Finally, enhanced collaborations with State and local agencies should be an important element of a modernized national food safety system, regardless of concerns about resources, but I also agree that through more active partnerships with States and localities, FDA can achieve much more to improve food safety than it ever could on its own. There are over 3,000 State and local agencies, including health and agriculture departments, local sanitarians, and public health laboratories, working on some aspect of food safety. In addition to their traditional role as the front-line regulators and inspectors of retail food establishments and investigators of food-borne disease outbreaks, State and local agencies can play an important role in the enhanced food safety oversight that is needed on the farm. In the end, we need an integrated, national food safety system that takes full advantage of the expertise and resources available at all levels of government.

Question 3. You raised concerns about relying on voluntary efforts by the industry. Could you please expound on the problems with a voluntary approach to food safety?

Answer 3. First, I recognize and respect the fact that many leading companies are making efforts to implement modern, state-of-the-art food safety procedures that go well beyond any government requirement. Indeed, historically, and still today, much of the on-the-ground innovation in food safety has come from the food industry, including HAACP (Hazard Analysis and Critical Control Points), which represents a standard of care for preventive process control that is widely accepted among food safety experts and practitioners. Companies that implement these procedures know that it is in their best business interest to do so in light of the nature of the markets in which they operate and the demands of their customers. Many companies also are committed to food safety because it is the right thing to do.

Unfortunately, some companies operate in markets that are driven by low cost rather than high quality or high safety standards, and not all companies have the same level of internal corporate commitment to food safety. That is why we need regulation: to ensure that all participants in the commercial market for food observe a well-defined standard of care for food safety that meets reasonable public expectations. Efforts by government to "encourage" voluntary improvement in food safety practices by companies that are not otherwise committed to them for business or other reasons can easily be ignored and can have at best a transitory effect. In a

voluntary system, when the government efforts at encouragement flag, marketplace and business reality take over, and there is no mechanism in place for holding companies accountable for observing a standard of care based on prevention of food safety problems. The government is left in a reactive mode, able to seek correction only after a problem has been found with food in the marketplace or after someone has gotten sick. The public—and companies that already follow proper food safety procedures—expect and deserve better.

Question 4. You argue that every food company should have a plan to prevent food safety problems. Some would argue that such an approach is not risk-based, is overregulatory, and will require companies to spend money for little gain in food safety. How would you respond to these concerns?

Answer 4. This is an important point: modern preventive process control is inherently risk-based and flexible in the sense that it involves companies tailoring their preventive controls to the particular hazards that are likely to arise in their operations and to their own production or manufacturing system. Some plants are inherently low-risk and can have very simple food safety plans, while others may require more robust plans to deal with more significant potential hazards. I also think that, in crafting a legislative mandate in this area, Congress should recognize the need for flexibility in implementing a comprehensive requirement for food safety plans based on preventive controls. Small businesses should be given technical assistance and more time to comply; all firms should get clear guidance to facilitate the implementation of plans that add to the level of food safety assurance without being unduly burdensome. The point is not to a have a plan that exists just to satisfy a regulatory requirement but rather to have a plan that helps a company have confidence—and be able to assure customers—that proper steps have been taken to make the food safe.

Question 5. What can the HELP Committee, which is an authorizing committee and not the Appropriations Committee, do to increase the frequency with which food facilities are inspected?

Answer 5. One of the critical policy issues in considering reform of the food safety system is the role of inspection and the nature and frequency of inspection sufficient to be effective. This is very much an issue for the HELP Committee. In my view, inspection should be seen as part of an overall program to ensure a high level of compliance with food safety standards. Some minimum frequency of inspection is no doubt needed for this purpose, and one thing Congress could do is mandate a minimum frequency, while also recognizing that some food establishments pose a higher risk of non-compliance than others—and thus merit more frequent inspection—based on the inherent nature of their operations and their own performance over time. By establishing through authorizing legislation a modern, risk-based inspection mandate that includes measures of performance for FDA in terms of frequency of inspection and levels of compliance with food safety standards, Congress will have given the Appropriations Committees a benchmark against which to consider necessary funding levels.

Question 6. You talked about food safety from farm-to-table. Ms. Smith DeWaal talked about food safety on farms, and Mr. Dooley mentioned good agricultural practices for produce. Traditionally, the FDA doesn't play a huge role on farms or at retail establishments. Do you have some suggestions about how we could enhance FDA's role there without raising the obvious sensitivities? What role can the States play?

Answer 6. A true public health, preventive approach to food safety has to consider the full spectrum of the food system, from farm-to-table, because risks and opportunities to reduce risk exist all across that system. Both the production (on-farm) and retail ends of the spectrum present unique challenges for any food safety regulatory strategy, however, that are quite different from those that arise in food processing establishments. And I agree that these differences and some of the special sensitivities that exist, especially on the farm, need to be considered, and I think State and local agencies have important roles to play, both on the farm and at retail.

One of the challenges on the farm is that there are so many independent farming operations of enormous diversity in terms of the products they produce, the conditions under which they produce them, and, especially, their size. Moreover, historically, while animal producers have been subject to regulation with respect to their use of pesticides and animal drugs, they have been left largely out of the food safety system's efforts to reduce the burden of foodborne illness associated with pathogenic microorganisms. This is despite the fact that the basic concepts of preventive process control that can reduce risks in processing plants can be applied on the farm. Preventive controls on the farm need to be pursued, however, by recognizing the di-

versity of operations and working with agricultural producers to craft approaches that are flexible and adaptable to diverse conditions. It may be appropriate, for example, to focus the scope of any regulatory requirements on the farm where they can do the most good for food safety by exempting certain commodities, such as grains, and possibly small producers. The fact is that a large percentage of the Nation's supply of fresh produce that is vulnerable to dangerous contamination is produced by a relatively small number of large producers. In addition, government oversight on the farm should take full advantage of State and local agencies for inspection and other on-farm activities. In my view, standards should be set nationally, while on-farm verification that standards are being met could be done principally by State and local inspectors or accredited third-party inspectors.

At retail, State and local agencies already take the lead in inspection under a longstanding collaboration with FDA, which recommends through its model Food Code science-based standards and procedures for preventing food safety problems. At their discretion, States and localities adopt and enforce Food Code provisions or other standards and thus play the front-line role on retail food safety. This should continue. It is neither feasible nor desirable to have Federal inspectors inspecting every grocery store and restaurant in the country. Instead, the focus should be on strengthening the State and local roles by creating greater Federal incentives for adoption of the Food Code and greater Federal support for State and local compliance programs through technical assistance, training, and investment in local laboratory capacity.

Question 7. You testified about how important increased resources are for the FDA. How much does the FDA currently have for inspections? How much does it need? Do you have a sense of what the agency could do with another $10 million? Another $100 million?

Answer 7. FDA's total field budget for the food program in fiscal year 2007 was about $300, which supported a total field workforce of about 1,900, including inspectors and the laboratory personnel and compliance officers needed to test products and build cases based on the work of the inspectors. This workforce has to cover nearly 50,000 domestic processing establishments and nearly three times that number overseas, which account for millions of import shipments annually. FDA inspects most domestic plants rarely if at all, tries but fails to inspect all "high risk" seafood plants annually, visually inspects less than 1 percent of import shipments, and actually tests less than a fifth of those. I recite these facts to illustrate my view that a $10 million increase would be insignificant in relation to the challenges FDA faces and that even a $100 million increase, by itself, would not solve FDA's funding problem over the long haul.

I personally think that the budget for FDA's field force needs to double in real terms in order to keep up with the growing complexity of food safety problems and the flood of imports. But, to be effective, FDA's field force needs more than additional resources: it needs to be deployed in support of a new preventive strategy—one that empowers FDA's field force to hold companies accountable for implementing having appropriate preventive controls, rather than FDA being in the business of simply detecting and correcting problems. At any realistic funding level, FDA will never have enough inspectors to adequately protect food safety if they are working in their present, largely reactive mode.

Question 8. I understand FDA now inspects food facilities on average every 10 years. I think it's unlikely that appropriated money will increase enough, or that a user fee program could raise enough money, to allow FDA to inspect every food facility annually or even every 2 years. So there might be some value in a third party inspection program, if companies were to participate in it. Would you support such a program? Under what conditions?

Answer 8. I think a third-party inspection or "audit" program can add value to the food safety system by providing a credible, independent source of verification that a company has in place the right preventive controls and that the controls are working properly. Government inspection resources could then be deployed more toward companies that are not subject to such third-party inspections. To be relied on for any governmental purpose, however, at least the following conditions should apply: (1) the auditing firms must be accredited and the auditors certified as meeting prescribed standards of training and experience, (2) the records of their audits must be readily accessible to FDA; (3) adverse findings that suggest unsafe product might be in the market must be reported promptly to FDA; and (4) FDA would retain the discretion to inspect plants that had been subject to a third-party audit.

Question 9. Given finite resources and the many millions of imported food shipments from thousands of foreign sources, how can FDA provide sufficient oversight to assure American consumers that imported foods are safe?

Answer 9. As with domestically-produced food, Congress needs to provide FDA with a modern mandate for oversight of imports that is commensurate with the globalization of the food supply. Specifically, Congress should make the U.S.-based importer or other responsible entity accountable for ensuring that the imported food has been produced in accordance with U.S.-food safety standards, including applicable preventive process controls. This approach calls upon importers to manage their supply chains responsibly and, as a condition of entry of food into the United States, be able to document that imported food was produced under conditions that make it safe. Though this approach relies on the food industry meeting its food safety responsibilities, it requires meaningful government oversight to be effective and credible. Some of this could come by enhancing FDA's authority and resources to inspect overseas and to work with foreign governments to leverage their food safety oversight capacity. In addition, imports may be particularly amenable to third-party audits as a complement to government inspection. Importers with well-documented systems for ensuring the safety of their products that are verified regularly by independent, credible auditors could be given fast track entry into the United States.

QUESTIONS OF SENATOR HARKIN

Question 1. I agree with your emphasis on prevention of food-borne illness as presented in your testimony. However, to focus on prevention, we must act in a coordinated manner across all government agencies that play a role in ensuring the safety of our Nation's food supply.

Please describe the steps that FDA, USDA, and other agencies with responsibility over food safety can take to coordinate programs and, more importantly, integrate their missions, in order to focus on prevention, intervention, and response as called for in the FDA Food Protection Plan.

Answer 1. The Federal Government's many food safety agencies cannot effectively coordinate their programs, integrate their missions, and be more preventive under the current structure of the system, which is prescribed by law. Certainly, there has been coordination in certain focused areas, such as among CDC, FDA and USDA's Food Safety and Inspection Service on food-borne illness surveillance and outbreak investigations. With respect to integrating their core food safety programs, however, the agencies are hamstrung. This is most evident in the case of FSIS, which gets two-thirds of Federal food safety resources to carry out a statutorily required but obsolete form of inspection in the Nation's meat and poultry plants. FSIS is required by law to use nearly all of its resources for this purpose, rather than for collaborating with FDA on integrated preventive strategies, and FSIS is even precluded by law from working with FDA on the farm to address pathogens such as *E. coli* O157:H7 and Salmonella, which often originate on the farm but then affect meat and poultry and FDA-regulated products, such as fresh produce. The only substantial and lasting solution to the lack of integrated effort across the Nation's food safety system is legislative change. Congress should modernize the food safety laws to make prevention the central responsibility and to create a unified organizational structure with clear accountability for mounting integrated, prevention-oriented efforts to reduce foodborne illness.

QUESTIONS OF SENATOR ENZI

Question 1. You talk about performance standards, and I think this makes a lot of sense. One thing I worry about, though, is a proliferation of dozens or even hundreds of performance standards and how businesses, especially small businesses, can stay on top of it. We don't want to take all the innovation and flexibility out of the system. How do we make sure we have the standards we need, without getting too far down in the weeds?

Answer 1. Performance standards should focus on significant hazards where an objective measure of performance can make a clear contribution to food safety. The number of such hazards in any operation is typically small and thus any given business should have a fairly small number of standards to keep up with. In addition, proper performance standards are inherently flexible and should promote innovation. For example, rather than telling a company the exact time and temperature it should achieve in cooking a ready-to-eat food (a so-called "command and control" approach), it should specify the amount of pathogen kill required to produce a safe food and leave it to the innovation of the company to adopt the cooking process that works best for its products in its operation. In this way, the government sets the

food safety goal, on behalf of the public, and the company is free to choose how best to achieve the standard.

Question 2. You object to the standard in the Food Protection Plan for FDA imposing preventive controls of a food associated with "repeated serious adverse health consequences or death." Other than the use of the word "repeated" isn't that basically the standard for a Class I recall? We have to set priorities somehow—why isn't this standard good enough? What should the standard be?

Answer 2. My most fundamental objection to the approach in the FDA Food Protection Plan is that it relies on FDA rulemaking to establish requirements for preventive process control on a case-by-case basis. I think we need a comprehensive, congressionally mandated shift to preventive controls, with FDA charged to implement the mandate in a reasonable, flexible way, including possibly exempting some categories of companies from the requirement. In short, based on all that the food industry and the food safety agencies have learned about the value of preventive controls, Congress should shift the presumption from one that says such controls are not required to one that says they are.

While I do not think that the requirement of preventive controls should be left to case-by-case FDA rulemaking, if it is, the standard should be one that focuses on prevention, not the intensity of reaction. The classification of a recall as Class I determines not whether a product should be withdrawn but simply the intensiveness of the efforts a company must make to pull adulterated product from the market and confirm the effectiveness of the recall. It is appropriate that the most intensive efforts be reserved for cases in which there may be serious adverse health consequences. Products are also subject to a recall, however, if they "may cause temporary or medically reversible adverse health consequences." Somewhat less intensive efforts may be justified to complete the recall of such products from the market, but we should still be seeking to prevent products posing such risks from entering the market in the first place through preventive controls. Otherwise, we would be failing to address the great majority of foodborne illness cases through preventive controls, which I believe would be bad for public health and public confidence in the food supply. This is why the Class I standard for intensity of reaction in a recall situation is not a good model for deciding when preventive controls are needed.

Finally, I would note, as I did in my testimony, that the standard proposed in the Food Protection Plan is actually more restrictive of FDA's authority to require preventive controls than current law. Under current law, FDA has mandated HAACP (Hazard Analysis and Critical Control Points) based on the law's food adulteration provisions and the general authority the law gives FDA to issue regulations for "the efficient enforcement of the Act." Under this standard, FDA can issue preventive control regulations based on a showing that they will guard against a reasonable possibility of injury to consumers. The last thing Congress should do is make the standard for preventive controls more restrictive at a time when many in industry, as well as the expert community, are calling for a shift to prevention as the key to an effective, credible food safety system.

Question 3. You suggest unifying the food-related components of FDA into a single organization within HHS. I'm intrigued by this idea, as I think it avoids some of the pitfalls of "single food agency" proposals, but I think it falls short on dealing with the fact that there are still 20 different agencies that have a piece of food safety. Do you believe a new organization split off from FDA would be better off in terms of making sense out of the fragmented jurisdiction? Why?

Answer 3. I agree that bringing together all of the agencies that have a piece of food safety is the ideal solution and should remain a goal. I am convinced, however, that the right first step is to focus on FDA and on building within HHS a model food safety organization with the modern legislative mandate and other tools required to provide real leadership on food safety nationally and internationally. At some later time, if circumstances permit, the food safety functions of USDA could be folded into a fully unified Federal food safety agency.

The new organization within HHS would be better off in its ability to lead on food safety because, first, the four major components of FDA with food safety responsibilities would be unified into a cohesive unit with accountable leadership, and second, the food safety function in HHS would be elevated within the department, thus enhancing the ability of the food safety leader to be heard and be impactful in the executive branch and in the world. Right now, the food function at FDA is fragmented and submerged. That has to change for FDA and HHS to be effective on food safety.

QUESTIONS OF SENATOR BURR

Question 1. How can the current FDA retail food safety program be improved? What other actions can be taken to improve retail food safety?

Answer 1. The key for FDA on retail is to build on and enhance its partnership with the States and localities. Congress should recognize in law the critical role of State and local agencies on retail food safety, and it should provide FDA with the mandate and the resources to foster wider adoption and effective implementation of the Food Code. There is also much opportunity for FDA to leverage State and local interest in retail food safety by providing training and other technical assistance.

Question 2. Since you do not think FDA should be in charge of determining when preventive controls should be required, what does the new statutory prevention mandate for the FDA look like? What will the rules be for industry, both domestic and international, to follow?

Answer 2. I think that Congress should establish by law the principle (or presumption) that all those who produce and sell food should have in place the basic preventive controls to make it safe. This should be in the form of a flexible mandate that recognizes the diversity of the food system from farm to retail and that authorizes FDA to tailor the requirement to the circumstances of particular sectors. The basic elements for both domestic and international producers include demonstrated adherence to basic sanitation procedures, awareness of the potential hazards in their operations, and effective measures in place and working to minimize those hazards in accordance with applicable food safety performance standards. This is mostly common sense and good management of a food operation and should be implemented with reasonableness so that the system is making a real contribution to food safety, not just satisfying a legal mandate.

Question 3. Please explain in more detail your vision of FDA reorganization and what type of food safety position you want to be created.

Answer 3. I think FDA should be divided into two agencies. One would manage FDA's drug, medical device and biologics functions. The other would manage all of FDA's food-related functions and would include the current Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, the food-related field resources from the Office of Regulatory Affairs, and the National Center for Toxicological Research. The unification of these components in a single agency would put all of the food safety resources and expertise under one official, who could then be held accountable for the success of the overall program. It is particularly important that the field force at FDA become an integral part of the public health-oriented prevention effort on food safety, with clear accountability to the food safety leader. This bifurcated FDA should take advantage of synergies and shared services to the extent possible.

In addition to being unified, the food function should be elevated within HHS by making the leader of the food safety agency a presidential appointment, with a 7-year term, and reporting directly to the Secretary. The food safety leadership position should be accountable to the Secretary, the President and the Congress but be seen as a professional position that requires continuity to be successful.

Question 4. What do you think about the Grocery Manufacturers Association's idea of expedited entry of foods that meet FDA's standards and conditions for expedited entry?

Answer 4. I support the idea of expedited entry as an incentive for importers to more carefully manage their supply chains and to provide an extra measure of assurance that their products have been produced in accordance with U.S. standards.

Question 5. I noticed you used to run the USDA Food Safety and Inspection Service in the 1990s. I'm interested in your perspective on the best way for us to ensure any food safety and defense legislation we enact reflects a comprehensive "farm-to-fork" strategy. We cannot forget the farm portion of this equation—for both produce and animal agriculture. What is your advice to us in this regard?

Answer 5. The food safety challenges at the farm level are diverse and difficult. Approaches that work in processing plants may not work well on the farm. Nevertheless, production agriculture is properly just as much a part of the food safety system as any processor or retailer, and ways need to be found to set and enforce standards for preventive controls or other interventions on the farm where they can make a real contribution to food safety. One example is the fresh produce sector. Another is the control of pathogens in animal production. The implementation of any new standards on the farm should be done in partnership with State and local

agencies, including agriculture departments, that have working relationships with the farm sectors in their communities.

QUESTIONS OF SENATOR ALLARD

Question 1. It is my understanding that during recent issues with the domestic food supply, including issues with spinach and peanut butter, the industry was willing and cooperative in working with FDA to institute a recall. How would additional enforcement authority have changed this scenario?

Answer 1. Most recalls are conducted voluntarily, and any mandatory recall authority should be structured so that it does not undercut incentives for companies to cooperate on voluntary recalls. FDA and USDA should, however, have authority to mandate a recall when a company does not cooperate or when a mandatory recall is the best way to protect public health in an emergency situation. I do not know enough about the details of the spinach and peanut butter cases to comment on them specifically.

Question 2. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc."

Answer 2. I think the basics of food safety and how consumers can protect themselves should be built into every elementary school curriculum. With regard to broader public and industry education, no agency has a clear mandate or significant resources for this purpose. Without those tools, there is little the agencies can do. I think the collaborative efforts on food safety education going on between government and industry through the Partnership for Food Safety Education have the right idea but lack the resources to achieve the scale and reach needed to make a difference.

Question 3. Do you think that further education should play a role in addressing food safety? Do you have a single suggestion to further education and the distribution of informative resources regarding food safety?

Answer 3. I think food safety education has a critical role to play. Consumers have the right to expect that everyone involved in producing and marketing food has done everything reasonably possible to make it safe, but consumers still need to know and observe safe food handling practices. I think educating kids from a young age as part of their elementary education is the place to start.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, ENZI, BURR, AND ALLARD BY J. JOSEPH CORBY

QUESTIONS OF SENATOR KENNEDY

Question 1. A significant impediment to the FDA doing a better job on food safety is its serious lack of adequate resources. I believe the President should propose a substantial increase in FDA's budget and the Congress should increase appropriated funds to the FDA. Assuming that won't happen, or that increases won't be sufficient, I'd like you to comment on some ways to leverage FDA resources:

- a third party program for inspection and laboratory testing,
- fees on the food industry, such as an annual registration fee, and
- enhanced collaborations with States and localities.

Answer 1. Even if there were a substantial increase in resources and funding for FDA, the majority of food safety efforts in this country would still be performed by the States and local government agencies. What FDA must do, and do now, is adopt strategies for incorporating State and local government food safety efforts into a national food safety and defense plan. This is something FDA has recognized for years, but has failed to accomplish. FDA must leverage third parties and government entities for inspection and lab testing in order to meet today's food safety demands.

Third party inspection and lab testing at foreign manufacturing plants is a logical step for assisting FDA with imported products. State and local governments can very capably handle much of the domestic inspection and lab testing that is needed. FDA should not be eliminated from domestic food safety work, but a more collaborative and coordinated effort could be established with State and local agencies in a more strategic fashion. The Manufactured Foods Regulatory Program Standards [MFRPS], when fully implemented, will ensure State and local agencies are performing at a nationally recognized performance standard.

Most States and local agencies do assess fees to food establishments by way of licenses or permits. These can be used as an administrative enforcement mechanism, allowing State and local agencies to revoke a license or permit for firms that fail to follow food safety standards. Registration fees, on the other hand, are gen-

erally employed for raising income and do not carry the administrative clout a license or permit has. These fees, whether a license, permit, or registration, can provide necessary funding for government agencies to carry out needed food safety control functions.

Enhanced collaboration with State and local government agencies by FDA will never be accomplished until FDA begins to accept State and local inspection results and laboratory analytical work. Although FDA encourages States to enter their lab results into a data system called Elexnet, they do not use those laboratory results to initiate enforcement action. Some State laboratories, including New York's, are part of FDA's Food Emergency Response Network [FERN] and FDA will accept the test results of those laboratories for specific, FERN-related activities. However, the routine analytical work on foods performed by these same food labs is not accepted. If FDA were to accept analytical work from State and local government labs and act on that data, there would be an immediate impact on food safety. New York's recalls of imported foods is one example. A total of 1,469 recalls of imported products from 61 countries were coordinated by New York officials since 2002, and that information, including relevant lab analysis, was shared with FDA. FDA Import alerts were only issued on these products after FDA collected an additional sample of the recalled product for their own individual testing. To date, FDA has issued only 13 import alerts from the 1,469 imported food recalls coordinated by New York State.

Question 2. Mr. Taylor talked about food safety from farm-to-table. Ms. Smith DeWaal talked about food safety on farms, and Mr. Dooley mentioned good agricultural practices for produce. Traditionally, the FDA doesn't play a huge role on farms or at retail establishments. Do you have some suggestions about how we could enhance FDA's role there without raising the obvious sensitivities? What role can the States play?

Answer 2. States are already active at the producer level and FDA must begin to leverage this work. State officials in California have mandated a better practices program for leafy vegetable growers. State officials in Florida and Virginia are active in mandating similar efforts for tomato producers. Many other States, including New York, have developed their own Good Agricultural Practices [GAPs] certification programs and have made them available to fruit and vegetable growers. These GAPs certifications are conducted annually by States and have been used effectively by fruit and vegetable growers to enhance their markets. The private sector also has a number of GAPs certification entities.

Question 3. Mr. Corby, you describe how the FDA won't use test results or other information generated by the States. It makes sense to me that there could be considerable gains in efficiency if FDA were to accept such information. Would New York State, and, if you can answer, other States, be willing to work with the FDA to address any concerns it may have about information generated by the States, to make this happen?

Answer 3. The considerable gains you mention could be accomplished immediately. Consider that more than half of the inspections of food establishments reported annually by FDA were inspections performed by States under contract with FDA. Why FDA will not accept all the other inspections performed by the States in other food firms remains a mystery to State food safety program managers. Also, food firms that FDA may inspect once every 5 years or more are inspected annually by the States and, in many cases, multiple times each year. All of the States would likely be willing to work with FDA to develop a strategic inspection plan that would coordinate efforts and avoid duplication. Not all the collaborative efforts that could be accomplished would require additional funding. FDA should, however, consider a better funding system for the States than is currently utilized. USDA/FSIS is budgeted funds specifically for working with the States. FDA needs a similar line item in their budget for this purpose.

QUESTIONS OF SENATOR ENZI

Question 1. I like your idea of one food system. However, I don't think one food agency is the way to one food system. How do we get to one food safety system?

Answer 1. I believe a "single food safety policy" is what is needed. Whether there is one agency or a multitude of agencies at the Federal level, the States and local agencies will still perform the bulk of the work. In the later part of 1990, an effort called the National Food Safety System [NFSS] was put together and a number of collaborative Federal/State efforts were developed which are still in existence today. An alliance of food safety stakeholders should be organized to identify foundations for re-establishing an integrated food safety system for this country. There is cur-

rently an effort to do this through George Washington University, the Association of Food & Drug Officials [AFDO], and other organizations.

Question 2. How can we ensure that Federal food safety efforts effectively leverage State and local activities? Your State has done so through partnership agreements, but it seems that these have to be executed State by State. Is there any way to do it more efficiently, perhaps on a regional scale?

Answer 2. For inspection purposes, the Manufactured Food Regulatory Program Standards [MFRPS] is a great place to begin. Once State and local agencies verify that they meet the recognized program standards, FDA should begin to offer these States more inspection contract work. This added contract funding will provide States the motivation for complying with the MFRPS and thereby qualify for additional funds, to enhance the States' food safety programs. Most States will likely be very anxious to participate.

An effort to leverage laboratory analytical work conducted by States and local agencies is currently underway by FDA. This is a critical piece for FDA and may require lab certification and methods verification, all of which is currently supported by the States.

It is true that most collaborative Federal/State efforts today are produced on a State-by-State basis. There are, however, a number of successful existing partnership models that could be promoted and applied nationally or regionally. Two of the more popular ones are the Integrated Food Safety Partnership (model for State and FDA District) and the Import Collaborative Project (New York and Texas). These agreements are designed to produce a seamless system that is crucial for enhancing a food safety program.

Question 3. When you share information with FDA, where does it go? Do you think it just gets archived into a big database, or do you believe this vital intelligence is acted upon?

Answer 3. We share information with the FDA District Office in Jamaica, New York or the Upstate Import Office in Buffalo, New York. This data and information can be transmitted from there to any FDA office or Center. Unfortunately, the majority of this data is not utilized.

QUESTIONS OF SENATOR BURR

Question 1. How many States have similar food safety partnerships and/or import initiatives with the FDA offices in their States?

Answer 1. Texas has recently begun an imported food program modeled after what New York has been doing, while Michigan and Oregon have asked for our assistance in developing import programs there.

Question 2. What have been the biggest hurdles in working with the FDA on those initiatives?

Answer 2. The biggest hurdle has been the laboratory issue. As mentioned above, New York coordinated 1,469 food recalls of imported foods from 61 countries, providing FDA with the analytical evidence that the products were adulterated. FDA would only issue import alerts after they had completed their own lab testing. More frustrating was the fact that only 13 import alerts were accomplished for the 1,469 recalls because of FDA's lack of resources.

Question 3. I have heard about a new initiative, called FoodSHIELD, which the Association of Food and Drug Officials is supporting along with the DHS National Center for Food Protection and Defense and USDA. I understand this system is supposed to support Federal, State, and local government agencies, labs, and emergency responders in defending the food supply through web-based tools. What are the benefits of FoodSHIELD, and how can we support this innovative approach? In addition, what is the status of the FoodSHIELD databases that will profile the infrastructure responsible for protecting and defending the food supply?

Answer 3. FoodSHIELD is a sophisticated web-based platform that facilitates communication, coordination, education and training among the diverse communities that make up the Nation's food and agriculture sectors. It is sponsored by the National Center for Food Protection and Defense [NCFPD] in partnership with the Association of Food & Drug Officials. Two major components of FoodSHIELD are "LABDIR," a database that captures the national lab infrastructure, and "Food&AgDIR," the counterpart for Federal, State, and local food safety and defense programs. A few of the benefits of FoodSHIELD are as follows:

- Provides contact information for food protection and defense individuals across the Nation at the Federal, State, and local government levels;

• Profiles all agencies responsible for food protection and defense efforts from "farm to fork";
• Illustrates the enormity of food protection and defense efforts accomplished at the State and local levels by providing specific data on inspections and investigations conducted at that level;
• Collects information from food laboratories relative to accreditation, analytes, equipment, and expertise;
• Allows agencies to gauge their program performance against others through the use of Query tools;
• Allows individuals to quickly obtain emergency contact information for State and local governments; and
• Expansion of FoodSHIELD will include similar available information from industry.

There are currently about 28 States actively participating in FoodSHIELD and AFDO is obtaining commitments from the remaining States to get involved as well. Congress's support of FoodSHIELD would be most welcomed.

QUESTIONS OF SENATOR ALLARD

Question 1. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc."

Answer 1. We need a comprehensive education and risk communication system. Education should be a partnership between government, industry, and academia to provide consumers with instant food safety information concerning recalled products and illness issues. There have been a number of real successes associated with the formation of stakeholder alliances that were established to promote food safety education or to advance HACCP principles within a specific food industry (ie., Seafood HACCP Alliance). Stakeholders need to coordinate their education programs and messages, and this could be accomplished through a stakeholder's alliance. Product recalls must become better coordinated as well. State and local governments are much closer to industry and consumers than Federal agencies, and they can better provide information to small businesses, non-English speaking entities, and specialized food establishments such as food banks, food pantries, and institutions.

Question 2. Do you think that further education should play a role in addressing food safety? Do you have a single suggestion to further education and the distribution of informative resources regarding food safety?

Answer 2. Yes, education plays a very important role. Small businesses are in greatest need of education and State and local regulatory agencies have begun to target these establishments through food safety education requirements that include management certification and recertification. There is also food safety programs provided to small businesses specifically designed to assist them in gaining compliance with State requirements. We do this in New York and find that 75 percent of the firms provided specific educational guidance will gain compliance and pass their next inspection. We believe that education has become an effective enforcement and compliance tool. Multi-language materials and ethnic-specific programming is best coordinated at the State or local level for the reason mentioned in Question 1.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, ENZI, BURR AND ALLARD BY THE HON. CAL DOOLEY

QUESTIONS OF SENATOR KENNEDY

Question 1. There's a lot of real value in the Food Protection Plan, however, one thing that concerns me is that the plan proposes allowing the agency to require process controls for a food, but only after the food is associated with repeated instances of serious adverse health consequences or death. Why should the FDA have to wait for children or the elderly to die or be seriously injured by a food before companies making it are required to make it safely?

Answer 1. The responsibility to produce safe food must, in the first instance, rest with the food industry. Food companies are in the best position to understand and evaluate the potential risks associated with the production of different types of foods and to evaluate the preventive controls that might reasonably address those risks. The Secretary should thus have limited authority to require specific preventive controls when there is a risk of severe health consequences. The effectiveness and ongoing necessity of controls required under such emergency circumstances should be periodically reviewed by FDA.

Question 2. A significant impediment to the FDA doing a better job on food safety is its serious lack of adequate resources. I believe the President should propose a substantial increase in FDA's budget and the Congress should increase appropriated funds to the FDA. Assuming that won't happen, or that increases won't be sufficient, I'd like you to comment on some ways to leverage FDA resources:

- a third party program for inspection and laboratory testing;
- fees on the food industry, such as an annual registration fee; and
- enhanced collaborations with States and localities.

Answer 2. Greater consideration of how third party inspectors, auditors and laboratories can effectively supplement existing FDA resources should be the focus of the committee's deliberations, and greater collaboration between local, State and Federal agencies should be encouraged. However, food imports and facilities should not be taxed to provide benefits that accrue to the public, such as the cost of science and inspections. Fees are appropriate when the benefit of a fee flows to the food industry. The benefits of science and inspections flow to the public generally, not to the food industry.

Question 3. I understand that many in the food industry are implementing process controls to assure the safety of the foods they make, and they also expect their suppliers to have such controls in place. These sorts of voluntary programs are of course beneficial, but they don't help for those who don't voluntarily comply. Shouldn't every company have a plan to make its food safe, as Mr. Taylor and Ms. Smith DeWaal have testified?

Answer 3. Food companies are subject to a longstanding legal requirement to produce food that is not adulterated. All food companies are now required by regulation to implement a variety of preventive controls. What's more, food companies routinely identify and evaluate food safety hazards, implement additional preventive controls, and employ systems to ensure the effectiveness of preventive controls. FDA has ample current authority to intervene with food companies that do not adhere to these existing legal requirements.

Question 4. What can the HELP Committee, which is an authorizing committee and not the Appropriations Committee, do to increase the frequency with which food facilities are inspected?

Answer 4. Thanks to the leadership of Senator Kennedy, FDA food-related spending for fiscal year 2008 enjoyed an increase. What's more, Secretary Leavitt has pledged to seek a substantial increase for FDA food-related spending in the fiscal year 2009 budget request. We are eager to work with Senator Kennedy, other members of the HELP Committee, and with our partners in the Alliance for a Stronger FDA to ensure that appropriators recognize the critical importance of funding for FDA food-related activities. FDA should partner with other Federal agencies and with State and local officials to maximize the effectiveness and reach of various food facility inspections so that, using a risk-based system, facilities can be inspected at an appropriate frequency.

Question 5. Mr. Taylor talked about food safety from farm to table. Ms. Smith DeWaal talked about food safety on farms, and you mentioned good agricultural practices for produce. Traditionally, the FDA doesn't play a huge role on farms or at retail establishments. Do you have some suggestions about how we could enhance FDA's role there without raising the obvious sensitivities? What role can the States play?

Answer 5. We support the creation of scientifically based and enforceable produce safety standards. Although produce safety standards should be set nationally, FDA should be directed to partner with those State agencies designated by each governor (State agriculture commissioners, for example) to facilitate compliance and to ensure that unique local conditions are properly addressed.

Question 6. You testified against user fees. I believe that an inadequately resourced FDA is a liability for the food industry, and also for consumers and the public health. Do you agree, and if not, why not? If you do agree, and we assume for the sake of argument that FDA does not receive adequate increased appropriations, doesn't it become imperative for the food industry to support some form of user fees?

Answer 6. FDA is an essential and important partner for the food industry and needs additional resources to fulfill its mission of ensuring food safety. As I noted earlier, we are confident that Congress and the Administration share our desire to increase FDA spending and we oppose taxes or fee on food imports or facilities. As you know, a user fee is appropriate when the benefits of the government service

flow to an individual or to a particular business. In this case, the benefits of inspections, science-based standards, and enforcement activities flow to all Americans, not simply to food companies. What's more, food taxes or fees will fall unequally on some companies and some consumers. Increasing food taxes at a time when food prices are rising faster than inflation (due, in large measure, to the expansion of the Federal ethanol mandate) would negatively impact many Americans. The potential difficulties in obtaining sufficient appropriated funds should not be an excuse to impose a new tax on the food industry.

QUESTIONS OF SENATOR ENZI

Question 1. You support mandatory recall, but only when a company has refused to conduct a voluntary recall. What about where the company is conducting the recall, but dragging their feet about it? Should FDA be able to order them to conduct the recall on a certain timetable?

Answer 1. Yes. Foods that present the risk of serious adverse health consequences or death should be removed from the marketplace as fast as possible. We think that the recall system will work best when companies have the initial opportunity to conduct a recall. FDA should have the authority to order a recall if a company declines to undertake one and to monitor the effectiveness of recalls and to be able to intervene if a recall is undertaken but not implemented effectively.

Question 2. Prior to this year, no one would have thought that pet food was risky, but then there was a huge problem with melamine contamination. We can definitely do better on food safety, but we will someday be taken by surprise. How do you determine which products pose "no meaningful risk?"

Answer 2. Theoretically, any food can present a meaningful risk with respect to intentional contamination. But the vast majority of foodborne illness is due to inadequate controls over naturally occurring hazards, not to intentional contamination. By knowing the hazards associated with specific products, by using good food-borne illness attribution data, and by understanding the processes used in production of a food and the controls applied in addressing the hazards, it is possible to determine which products pose the greatest risk to consumers.

Question 3. FDA is woefully underfunded and understaffed. I am concerned that even with sufficient funds, there might not be sufficient personnel to fill the jobs, given the technical expertise required. You support capacity-building abroad, which is great, but what about capacity building here at home?

Answer 3. As a member of the Alliance for a Stronger FDA, we strongly support greater funding for FDA. In particular, we have urged Congress and the Administration to double FDA spending over 5 years.

QUESTIONS OF SENATOR BURR

Question 1. Mr. Taylor believes that the FDA should be given a new statutory prevention mandate that, through regulation, will outline specific standards the food industry needs to meet. It sounds like you agree with him. Is that correct?

Answer 1. We support making the prevention of contamination the primary focus of FDA's food-related activities. GMA believes the focus of our food safety efforts should be on the prevention of contamination. By constantly identifying and addressing the sources of contamination throughout each product's life cycle, we continually reduce the risk of food-borne illness to consumers. All food companies are now required by regulation to implement a variety of preventive controls. In addition, food companies routinely implement additional preventive controls to address additional risks posed by specific products.

Question 2. The drug and device industries pay FDA user fees for a set of FDA performance goals agreed to by industry and the FDA. If Congress changes FDA's statute on food safety and requires the FDA to be much more aggressive on the prevention side, I could envision a similar user fee and performance goal agreement being worked out between FDA and the food industry. Would you still consider that to be a tax?

Answer 2. Yes. FDA is an important and essential partner of the food industry, and we work with FDA to continually identify and prevent risks to public health. Expanding FDA's ability to develop science-based standards and new preventive controls benefits all consumers, not simply food companies. The performance goals in the drug and device context are fundamentally different from those that might be implemented on the food side. Drug and device companies are principal beneficiaries of the additional FDA staffing that the user fees provide while the public would be the principal beneficiaries of any fees imposed on the food side.

QUESTIONS OF SENATOR ALLARD

Question 1. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc."

Answer 1. Greater resources for FDA as well as greater collaboration between Federal, State, and local agencies are critically needed to improve food safety education.

Question 2. Do you think that further education should play a role in addressing food safety? Do you have a single suggestion to further education and the distribution of informative resources regarding food safety?

Answer 2. Public education is among the most effective tools available to address the threat of food-borne illness. Public agencies and the private sector are investing significant resources in efforts to promote food safety education. This begins with food safety education in elementary schools, but it requires reinforcement in later years as well. We need to be more innovative in how we approach this, with messages being delivered through print, broadcast, and electronic media.

RESPONSE TO QUESTIONS OF SENATORS KENNEDY, HARKIN, ENZI AND ALLARD BY CAROLINE SMITH DEWAAL

QUESTIONS OF SENATOR KENNEDY

Question 1. There's a lot of real value in the Food Action Plan, however, one thing that concerns me is that the plan proposes allowing the agency to require process controls for a food, but only after the food is associated with repeated instances of serious adverse health consequences or death. Why should the FDA have to wait for children or the elderly to die or be seriously injured by a food before companies making it are required to make it safely?

Answer 1. Process controls should be applied to all food production and not limited only to those foods with a history of causing "repeated instances of serious health problems or death to humans or animals," as called for in the Food Protection Plan. CSPI endorses legislation that would require all food establishments to implement process controls that meet performance standards designed to protect the public from foodborne illnesses.

I am especially concerned about the standard set forth in the Food Protection Plan, as neither peanut butter nor spinach production would be subject to process controls. Yet our experience of the last 2 years has shown that these products could clearly benefit from such a system. A single outbreak of *Salmonella* in Tennessee in peanut butter sickened 628 people in 47 States in 2007 and a single outbreak of *E. coli* 0157:H7 on spinach caused 205 illnesses and killed three in 2006. The peanut butter outbreak was linked to unsanitary conditions and a leaky roof, while the spinach outbreak was linked to inadequate controls to stop contamination from a nearby pasture. In both cases, simple process controls implemented and regularly monitored in the plant or on the farm may have prevented the outbreak. However, the standard in the Food Protection Plan could conceivably require FDA to wait for multiple or "repeated" instances of serious health problems or death before requiring process controls. Prior to the 2007 outbreak, peanut butter had been related to only three outbreaks since 1990 and prior to 2006, spinach to only two.[1]

Requiring a history of repeated outbreaks is also inconsistent with other instances where Congress has imposed safety requirements on the food industry based on the prospect of harm, rather than the proof of harm. For example, the Bioterrorism Act's traceability requirement at 21 U.S.C. 350c(b) is based on the need to identify whether a food "presents a threat of serious adverse health consequences or death to humans and pets" and uses a "reasonable belief" standard to trigger its record access provisions. 21 U.S.C. 350c(a).

It is likely a reactive standard will prove inadequate for preventing outbreaks and FDA would have to return to Congress for authority to require process controls based on more proactive criteria.

Question 2. A significant impediment to the FDA doing a better job on food safety is its serious lack of adequate resources. I believe the President should propose a substantial increase in FDA's budget and the Congress should increase appropriated funds to the FDA. Assuming that won't happen, or that increases won't be sufficient, I'd like you to comment on some ways to leverage FDA resources:

- a third party program for inspection and laboratory testing;
- fees on the food industry, such as an annual registration fee; and
- enhanced collaborations with States and localities.

Answer 2. The solution to inadequate resources at FDA is for the President to propose and Congress to enact a budget adequate to support FDA's responsibilities. Inadequate resources impose a significant risk to public safety.[2] The Coalition for a Stronger FDA estimated FDA needs for fiscal year 2008 at several hundred million dollars[3] above fiscal year 2007 funding just to carry out its current food safety mission. The FDA Science Board identifies a need for an additional $390 million at CFSAN and ORA to implement a new food import system, modernize and implement safety standards for fresh produce, and improve laboratories.[4] This does not include funds needed for CVM to modernize FDA's regulation of animal-derived products.[5] The Action Plan for Import Safety also highlights the need for additional resources to implement its recommendations.[6]

The FDA's Food Protection Plan attempts to sidestep the growing evidence of an agency that is underfunded by proposing leveraging third party inspections, imposing new fees and doing a better job of collaborating with State and local agencies. Fees proposed in the plan would raise about $26 million, which only offsets the costs of carrying out re-inspections of plants that fail an initial inspection and an export certificate program.

Each bulleted proposal above has merits, but none provides a panacea for FDA's budget problems. And each will require start up costs to ensure that activities done using other entities have the requisite reliability, including training, accrediting, compensating and auditing the external government or third party inspectors to ensure plants meet Federal standards.

Often these proposals are submitted as an alternative to increasing the funding for FDA. However, using third parties requires additional funding for certification and for State implementation. In fact, State and Federal agencies need compensation to conduct additional inspections, just as FDA would. Third party certification also would divert resources from FDA inspection to training, accrediting and auditing the third party organizations. Enhancing collaboration with State and local governments should be done. But it should be funded—otherwise FDA will have to divert scarce resources from their already anemic inspection program to an aggressive oversight program.

CSPI supports funding food safety through the annual appropriation process, but if direct revenue sources must be found, then applying a general fee on foreign and domestic registrations under the Bioterrorism Act could generate significant funds. We prefer this approach to a fee-for-service system for food inspections, where inspectors may believe that they are working for the companies rather than the public. More than 332,000 food establishments have registered with FDA under the Bioterrorism Act. A registration fee of $1,000 could generate $332 million for food safety activities. CSPI would be happy to provide additional analysis of this concept.

Question 3. Could you please your concerns, if any, with a voluntary approach to food safety?

Answer 3. Much of the current FDA food safety program is voluntary. FDA lacks authority to require producers to recall tainted products, and instead relies on a voluntary system to take unsafe food off the market. FDA's infrequent inspections mean that food safety is largely managed through an industry honor system for food processors. Farmers are not required to follow the agency's good agricultural practices. These voluntary systems are failing to protect the public and industry as evidenced by the fact that outbreaks linked to FDA-regulated products are much more common then those linked to meat and poultry regulated by USDA. In fact, food regulated by FDA account for 66 percent of all outbreaks of foodborne illness reported between 1990 and 2005[7]—more than twice the number of outbreaks attributed to food regulated by USDA.

Voluntary programs implemented through marketing orders administered by USDA suffer additional defects. The programs are controlled by the growers or processors who are subject to economic pressures and who can terminate the order by majority vote if compliance becomes too burdensome. Since the standards are set by the industry, they may not represent good science and are frequently developed without balanced input from the public health community or from the consumers they are intended to protect. This often results in programs that implement the least burdensome standards possible because the focus is more on minimizing the impact on processors or producers than on protecting consumers. The public is also at risk since participants may vote to end the marketing order at any time and thus terminate whatever protections it provides with little notice to consumers.

FDA's reliance on voluntary compliance with guidelines, education, and awareness proved ineffective in preventing foodborne illness from fresh produce. In 2006, CSPI called on FDA to enact a mandatory program, pointing out that the most important benefit of a mandatory program is that it would assure that both domestic and for-

eign growers and processors implement good agricultural practices. While many of the best growers and processors use HACCP-like systems and adhere to good agricultural practices, compliance is clearly not universal.[8] It was estimated that California spinach growers lost approximately $350 million in sales because of consumer reaction to the 2006 outbreak.[9]

Voluntary government guidelines like the ones called for in the Four Pillars recommendations from GMA may be useful in helping industry identify its responsibilities, but cannot substitute for enforceable standards. In a voluntary system one bad actor can negate the efforts of responsible growers and food processors.[10]

Question 4. You argued that every food company should have a plan to prevent food safety problems. Some would argue that such an approach is not risk-based, is over-regulatory, and will require companies to spend money for little gain in food safety. How would you respond to these concerns?

Answer 4. If a company wants to prepare food and sell it to the public, it has the responsibility to show that it has evaluated food safety hazards associated with the products and processes, and has implemented systems that will eliminate or control those hazards. Otherwise all the risk of production is being borne by the consumer of the product, and consumers are in fact being used as the "canaries in the coal mine." This is not acceptable, and many responsible companies have already implemented food safety plans throughout their productions systems.

These food safety plans should form the basis for government inspection and provide the road map for evaluating systems failures whenever an outbreak or recall occurs. Risk should certainly be used to determine inspection frequency, but it should not be the factor that determines what foods are subject to process controls.

Congress should enact food safety reform that places the primary responsibility for food safety on food establishments and gives the government sufficient authority to monitor and enforce this responsibility.[11] Written HAACP or HAACP-like plans are required of all meat, poultry, seafood and juice manufacturers, and have proven effective in helping to control hazards in those products. These plans are also widely used by many individual companies where they are not currently required today. Process control plans can be incorporated into food production systems at all levels. Inspections and audits of the plans would ensure all food establishments are meeting safety standards—such as limits on the incidence or levels of contamination. Monitoring and enforcement of safety standards is a key element of inspection in a successful food safety program.

The European Union has demonstrated that requiring process controls on all food establishments can be done without imposing too high a premium on individual companies. In the alternative, failing to implement process controls broadly will result in repeated instances of outbreaks imposing costs on the public and industry for healthcare services, litigation and lost confidence. These costs can be substantial. The Peter Pan peanut butter outbreak cost ConAgra more than $140 million, including $55 million in lost sales.[12] Meanwhile foodborne illnesses from all sources impose a cost on consumers of billions of dollars annually.[13]

Question 5. What can the HELP Committee, which is an authorizing committee and not the Appropriations Committee, do to increase the frequency with which food facilities are inspected?

Answer 5. The problems with inadequate inspections of food are not limited to a lack of funding. The United States lacks a modern food safety oversight system, like those currently in use in the European Union and many other countries around the world. The failure to modernize our system is having real impacts—consumers worry that we have a "third world" food supply, and other countries are reluctant to import poorly regulated food products.

The HELP Committee should develop and pass a modern food safety mandate for FDA-regulated food. It should contain the following elements:

1. A National Food Safety Program that incorporates:

- Update registration of food establishments and foreign food establishments.[14]
- Process controls (including on-farm process controls) to reduce the adulteration of food products.
- Performance standards enforced by inspections.
- Importer accountability supported by certification of foreign countries' food safety systems and exporters.
- Federal and State cooperation.
- Mandatory traceback.
- A resource plan that describes funding needed to implement the national program.

2. Research and Education

- Public health assessment system.
- Public education and advisory system.
- Research.

3. Enforcement

- Food detention, seizure and condemnation.
- Notification and mandatory recall.
- Civil and criminal penalties.
- Citizen civil actions.
- Whistleblower protections.
- Administration and enforcement.

4. Appropriations adequate to carry out these authorities

Question 6. Mr. Taylor talked about food safety from farm-to-table. You talked about food safety on farms, and Mr. Dooley mentioned good agricultural practices for produce. Traditionally, the FDA doesn't play a huge role on farms or at retail establishments. Do you have some suggestions about how we could enhance FDA's role there without raising the obvious sensitivities? What role can the States play?

Answer 6. The Fresh Produce Safety Act introduced by Senator Harkin offers a good starting point for improving safety on the farm. The bill establishes a national program for issuing good manufacturing practices for processors and good agricultural practices on the farm. Processors and growers would have to have written safety plans and keep records that can be inspected by the FDA. This is a good model for improving FDA oversight of on-farm safety.

Question 7. 1 understand FDA now inspects food facilities on average every 10 years. I think it's unlikely that appropriated money will increase enough, or that a user fee program could raise enough money, to allow FDA to inspect every food facility annually or even every 2 years. So there might be some value in a third party inspection program, if companies were to participate in it. Would you support such a program? Under what conditions?

Answer 7. As I noted above, FDA's Food Protection Plan attempts to sidestep the growing evidence of an agency that is underfunded by proposing leveraging third party inspections as a way of better allocating existing resources. The proposal has merits, but is not a panacea for FDA's budget problems. It will require start up costs to ensure that activities done using States or private entities have the requisite reliability. Mandating the use of third parties would also divert scarce agency resources from FDA inspection to training, accrediting and auditing the third party organizations. Therefore, the use of third parties should be seen as an alternative use of additional resources, not a substitute for new resources.

With respect to States acting in place of FDA inspection, that system is already in place. Many inspections of FDA-regulated facilities are already conducted by State inspectors. For example, of 17,730 FDA inspections conducted in 2006, more than half (9,164) were State contract or State partnership inspections.[15] The problem with this approach is that State inspection programs are not consistently funded, and are often the victim of cuts when the State is facing a budget shortfall. Therefore, FDA needs the ability to monitor State inspections year-to-year, and step up Federal oversight whenever State inspections are cut. Otherwise, the programs will be highly variable and therefore less valuable in protecting consumers.

With respect to third parties acting in place of FDA, this concept is controversial among many consumer organizations, who worry about the privatization of this important government service. At CSPI, we believe that there is a role for third party inspectors, so long as they have the same interests as the buying public in assuring the safety of the product. Thus, third party inspectors paid for by a retailer would be more trustworthy than one paid for by the company being inspected. It is also critical that these private entities are certified by FDA regularly, and that their inspections are regularly audited by FDA.

The concept of "nested audits" is very useful in this context. One country I have visited used this very effectively in its seafood inspection program. Seafood companies each utilize a HACCP-based safety assurance program. This program is audited by a private auditor certified by the government. The plants are then regularly inspected by the government agency, with the inspection frequency based on the plant's performance during previous inspections. The agency can audit the work of the private auditor at the same time that it looks at the plant during the inspection. The government program is also subject to audit by countries that import fisheries products, which in this case included the governments of the European Union, Japan, and the United States. This type of "nested audit" provides a high degree of certainty that the audits are high quality, and that the standards for the audits

are constantly being updated to meet international standards. It encompasses the concept of continuous improvement for all levels of the program.

Question 8. What can you tell us about the food safety approaches of the European Union or other countries, including both domestically produced food and imported food, with a focus on how those approaches compare to that of the United States?

Answer 8. The European Union (EU) has a much more modern system than the United States. Many of the national systems were modernized after the BSE ("mad cow") crisis in Europe, with a move toward unifying food safety responsibility under a single agency in many countries. In addition, the national programs must implement standards adopted by the European Commission. The EU has also centralized risk assessment under the European Food Safety Authority, which has the ability to independently evaluate risks and communicate to consumers and the national governments, though it has no regulatory (risk management) responsibilities.

The lessons learned in the EU can help guide our efforts to modernize food law in the United States. The EU's starting concept is that "food policy must be built around high food safety standards, which serve to protect, and promote, the health of the consumer." [16] The European Commission's White Paper on Food Safety identified the following principles[17]:

- Food safety policy must be based on a comprehensive, integrated approach that covers the food chain from "farm-to-fork."
- Stakeholders' roles in the food chain must be clearly defined.
  1. Food manufacturers and food operators have the primary responsibility for food safety;
  2. Competent authorities monitor and enforce this responsibility; and
  3. Consumers are responsible for proper storage, handling and cooking of food.
- Feed, food and their ingredients must be traceable through records kept by operators.
- The system needs to be flexible and reviewed to adapt to emerging risks and recognize new developments, while having a transparent approach to developing new policies.
- Risk analysis (which encompasses risk assessment, risk management and risk communication) should be the foundation for food safety policy.
- The science applied must meet the highest standards of independence, excellence and transparency. Where appropriate the precautionary principle should be applied in risk management decisions.

There are additional sources of information to guide the committee as well. CSPI, working with the World Health Organization and the Food and Agricultural Organization of the United Nations, formed the Safe Food International project. In 2004, Safe Food International published guidelines in consultation with consumer organizations in developed and developing countries to assist both consumer organizations and national governments in focusing on the basic requirements for national food safety programs in their countries. I have attached a copy of the Guidelines.

[Editor's Note: Due to the high cost of printing, previously published materials are not reprinted. For the Guidelines, please see http://www.safefoodinternational.org/guidelines_for_consumer_organizations.pdf.]

QUESTIONS OF SENATOR HARKIN

Question 1. I agree with your emphasis on prevention of foodborne illness as presented in your testimony. However, to focus on prevention, we must act in a coordinated manner across all government agencies that play a role in ensuring the safety of our Nation's food supply.

Please describe the steps that FDA, USDA, and other agencies with responsibility over food safety can take to coordinate programs and, more importantly, integrate their missions, in order to focus on prevention, intervention, and response as called for in the FDA Food Protection Plan.

Answer 1. FDA and USDA have had almost 100 years to coordinate their programs and integrate missions without making much progress. We still have USDA and FDA personnel inspecting imports side-by-side, and food plants that are subject to dual regulation. It would be a mistake to attempt to patch this system one more time by establishing an interagency authority or attempting to legislate cooperation between two separate food regulators.

We believe the best approach would be to form a unified food safety administration in the United States, a step already taken in many other countries. The agency

should be given a modern mandate, should be staffed from the existing food programs at FDA and USDA, and should use a budget that combines the resources of both these existing agencies. This approach has already been proposed by Senator Richard Durbin in the Safe Food Act of 2007, in response to a report of the National Academy of Sciences.

The United States can learn from experiences in many other countries that have already created a single authority to manage food safety. In 2005, GAO reviewed programs in seven countries that have consolidated food safety activities under one agency and reported that officials and stakeholders consistently stated that doing so "led to significant qualitative improvements in food safety operations that enhance effectiveness or efficiency." [18] Among the advantages cited in the report are "reduced overlap in inspections, more targeted inspections based on food safety risk, more consistent or timely enforcement of food safety laws and regulations, and greater clarity in responsibilities." [19]

Short of this, Congress could require both agencies with regulatory responsibility over the food supply to take responsibility for the entire food supply and provide them each with authority to act whenever they see a problem. This would permit inspectors to work across jurisdictions. This would address the problems that exist with imported foods where USDA and FDA jurisdictions sometimes overlap, but resources are not shared. If Congress is not willing to truly modernize food safety systems, it should consider some new "outside-of-the-box" approaches to improve the workings of the current system.

QUESTIONS OF SENATOR ENZI

Question 1. Like many of us, you are concerned about FDA getting the resources needed to implement the Food Protection Plan. Do you have any sense of what level of funding it would take to turn things around? Your testimony indicated hundreds of millions of dollars, but can you be more specific?

Answer 1. The FDA Alliance estimates FDA needs for fiscal year 2008 are $140 million above fiscal year 2007 funding levels, recommending a budget of $597 million for food safety programs.[20] The Coalition for a Stronger FDA last year began recommending an increase of $115 million for food safety programs at FDA but more recently raised its estimate to $250 million.[21] The FDA Science Board identifies an additional $390 million needed to implement a new food import system, modernize safety standards for fresh produce and upgrade existing laboratories. This does not include funds needed for CVM to modernize FDA's regulation of animal-derived products.[22] Based on these recommendations, anything short of $100 million in the fiscal year 2009 budget will not be adequate to see real improvement in FDA's food program and the actual need is more in the range of $200 to $400 million.

Question 2. You represent consumers. How do we get them—and by "them" I mean all of us, since we are all consumers—to be better players in food safety? We could change many things, and send consumers much safer food, but they could still contaminate it at home. Other panelists talked about the farm end of the "farm-to-fork" continuum—what about the fork end?

Answer 2. Educating consumers about safe food handling is a critical part of the food safety continuum. And it is not something that is done just once. Every year new scientific information is available, and consumers need to be reminded of the previous recommendations for keeping their food safe. CSPI joins with several of the government agencies that offer regular advice to the public on how to keep their food safe. We publish food safety advice in our Nutrition Action Health letter as well as on our Web site and in our media interviews. In fact, for over 5 years, the National Press Club invited me to hold a press conference right before Thanksgiving to remind consumers about safe handling, cooking and storage of holiday meals in their home kitchen.

Another important approach is the use of safe handling labels on meat, poultry, eggs, and other raw food products that reminds consumers of the basic handling messages for consuming these products, as well as warning labels on unavoidable unsafe products, like raw shellfish harvested from certain regions, unless treated to control the hazards.

In considering legislation, Congress should include a public education program, including labeling of raw and unsafe food products, and education of health professionals. Information provided to health professionals would improve diagnosis and treatment of foodborne illness. The Administration should be required to issue health advisories about foods that pose a threat to the public. However, this is not a substitute for improving the overall safety of the food consumers buy.

Another issue to consider in legislation is the importance of managing risks in the restaurant and retail food sector. More than twice as many food-borne illness outbreaks occur from food prepared outside the home. Restaurants and food establishments accounted for 46 percent of reported outbreaks between 1998 and 2004, according to data compiled by CSPI from CDC and State health department reports,[23] while home prepared foods accounted for 20 percent of outbreaks.

Question 3. Given the number and incredible variety of FDA-regulated foods, do you think pre-market approval of foods by FDA is advisable or even possible?

Answer 3. FDA has oversight of more than 136,000 registered domestic food facilities and there are approximately 189,000 registered foreign food facilities.[24] For comparison, USDA, which conducts pre-market inspections, has responsibility for just 6,282 plants nationally.[25] Pre-market approval for FDA-regulated foods would be costly and is not needed. Instead, Congress should enact laws to require food facilities to have in place industry specific food safety process control plans that are designed to meet federally established performance standards for safety. The plans should be subject to regular auditing by FDA during inspections, or using nested audits.

The concept of "nested audits" is very useful in understanding how FDA might improve oversight. One country I have visited used this very effectively in its seafood inspection program. Seafood companies each utilize a HACCP-based safety assurance program. This program is audited by a private auditor certified by the government. The plants are then regularly inspected by the government agency, with the inspection frequency based on the plant's performance during previous inspections. The agency can audit the work of the private auditor at the same time that it looks at the plant during the inspection. The government program is also subject to audit by countries that import fisheries products, which in this case included the governments of the European Union, Japan, and the United States. This type of "nested audit" provides a high degree of certainty that the audits are high quality, and that the standards for the audits are constantly being updated to meet international standards. It encompasses the concept of continuous improvement for all levels of the program.

QUESTIONS OF SENATOR ALLARD

Question 1. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc.

Answer 1. Educating consumers about safe food handling is a critical part of the food safety continuum. And it is not something that is done just once. Every year, new scientific information is available, and consumers need to be reminded of the previous recommendations for keeping their food safe.

CSPI joins with several of the government agencies that offer regular advice to the public on how to keep their food safe. We publish food safety advice in our *Nutrition Action Healthletter* as well as on our Web site and in our media interviews. In fact, for over 5 years, as a public service, the National Press Club invited me to hold a press conference right before Thanksgiving to remind consumers about safe handling, cooking and storage of holiday meals in their home kitchen.

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In considering legislation, Congress should include a public education program, including labeling of raw and unsafe food products, and education of health professionals. Information provided to health professionals would improve diagnosis and treatment of foodborne illness. The Administration should be required to issue health advisories about foods that pose a threat to the public. However, this is not a substitute for improving the overall safety of the food consumers buy.

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Question 2. Do you think that further education should play a role in addressing food safety? Do you have a single suggestion to further education and the distribution of informative resources regarding food safety?

Answer 2. The biggest single impact for food safety education would be through proactive programs in the schools. Early education on safe food handling is essential to breaking down bad habits in the home—like failing to take precautions like hand washing or properly cooking food. Food safety information can easily be added to the science curriculum at almost every level, explaining not only what consumers should do, but why it is effective. School-based curriculums have many crossover effects to the general public. Educating children helps to impact their parents' behavior. Educating teenagers before they begin working in restaurants can avoid many mistakes.

FDA has posted information specifically targeted for students and educators at *http://www.cfsan.fda.gov/~dms/educate.html*. Additionally, the National Science Teachers and FDA have collaborated on a food safety curriculum with materials and training available to help science teachers teach about food safety posted at *http://www.foodsafety.gov/~fsg/teach.html*. These are good efforts that should be sustained and expanded but they have not and cannot close the loop on food safety.

The home should be the final defense and not the front line in preventing foodborne disease. Our goal should be to provide safe and wholesome food to consumers, using preventive control programs at all levels. Private and public programs can then effectively arm consumers with information on how to recognize and avoid foodborne disease through safe food handling techniques.

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RESPONSE TO QUESTIONS OF SENATORS KENNEDY, ENZI, AND ALLARD BY PAUL YOUNG, PH.D.

QUESTIONS OF SENATOR KENNEDY

Question 1. You raised concerns about relying on voluntary efforts by the industry. Could you please expound on the problems with a voluntary approach to food safety?

Answer 1. Unsurprisingly, it is more expensive to produce food which is free of contaminants than otherwise. Pesticides and veterinary drugs are often used in crop and animal production, respectively, specifically to increase production gains. For example, it is well-documented that prophylactic use of antibiotics in animal production will not only prevent disease from occurring in the animals, but will also act as a growth promoter significantly improving feed conversion (i.e., more growth for the same amount of animal feed consumed). There is therefore a significant financial incentive for producers to use these chemicals to reduce costs and increasing profit margins.

FDA currently operates a voluntary approval scheme listing foreign producer establishments that importers are recommended to use when sourcing seafood for import into the United States. Due to the voluntary nature of this scheme, only four countries have submitted lists of establishments (Canada, Japan, New Zealand and Thailand), whereas 95 have done so to the European Union where approval is mandatory. Additionally, FDA recommends that "*Importers may consider purchasing from processors that are on such lists, and documenting that they are doing so, as one way of meeting their affirmative steps responsibility*. Despite this recommendation for voluntary action, many of the seafood import consignments refused entry by FDA during October 2007 originated from processing establishments not cited on the approved lists (even where those lists exist).

Clearly, the current voluntary approach carries little weight and given the price competitive nature of food production, a voluntary system does little to remove the incentive to use agricultural chemicals inappropriately.

It should also be noted that unlike pathogen contamination where acute disease conditions in consumers can act as indicators or "signals" of contamination, many of these agricultural chemicals, whilst being both genotoxic and carcinogenic may not give rise to acute conditions and left undetected could result in long-term effects.

Question 2. Mr. Taylor talked about food safety from farm-to-table. Ms. Smith DeWaal talked about food safety on farms, and Mr. Dooley mentioned good agricultural practices for produce. Traditionally, the FDA doesn't play a huge role on farms or at retail establishments. Do you have some suggestions about how we could enhance FDA's role there without raising the obvious sensitivities? What role can the States play? Do the authorities in the European Union and Japan have regulatory authority on farms and at retail?

Answer 2. As part of its farm-to-table approach, the European Union introduced legislation in 2004 (Regulation (EC) No. 852/2004) which requires all food business operators to implement and maintain a Hazard Analysis and Critical Control Point programme (HACCP). Whilst it is accepted that HACCP implementation is not yet feasible for primary production (although this is scheduled for review), it recommends that primary producers should implement these procedures as far as pos-

sible and additionally details specific hygiene measures and recordkeeping required by producers involved in both animal rearing and plant production. All of this inevitably increases the record-keeping burden of farmers and in Europe many farmers are increasingly turning to dedicated IT solutions, some of which can be managed from the field. I understand that Japanese authorities also strictly control the distribution of pesticides and veterinary drugs and enforce regulations mandating farmers to keep records regarding their use and withdrawal.

Question 3. You testified that Japan tests 10 percent of its imported food. Do you believe it is practical for the United States to test 10 percent of its imported food, and if not, is there a practical alternative?

Answer 3. Testing *per se* does not make the food safe, but serves to demonstrate compliance with required standards of production, thereby building consumer confidence. With regard to the practicality of 10 percent testing in the United States, FAO figures for the top 20 agricultural import commodities indicate that Japan imports significantly more than the United States, by volume. This would indicate that a 10 percent level of testing is achievable.

However, the figure of 10 percent cited in my testimony relates to the level of food imports undergoing laboratory analysis in Japan. The equivalent figure for the United States is currently quoted at around 0.2 percent. A shift to 10 percent testing would represent a 50-fold increase in the current level of laboratory analysis in the United States. Whilst employing the latest technological advances, such as the recent innovations from Waters, will help both in terms of cost effectiveness and throughput, clearly this would still require additional resources. Europe, for example, makes provision to allow testing to keep pace with import levels by funding imported food testing from a levy imposed on the importers, legislating to allow governments to recover up to the full cost of sampling and analysis.

QUESTIONS OF SENATOR ENZI

Question 1. You mention in your testimony a seafood export action plan whereby shipments in violation of the EU regulations could be sold into less stringent markets. Since a number of countries are overhauling their food safety systems, how do we get it right here at home while maintaining harmonization with other countries?

Answer 1. Situations like this arise because effective global harmonization of standards does not yet exist and because when import requirements are not either clearly stated or robustly enforced, they may be interpreted as being optional. When developing standards for U.S. domestic production, one must also bear in mind that the United States is the world's largest exporter of agricultural commodities and as you suggest, it is highly desirable to have standards acknowledged as offering equivalence with the requirements of export markets as described within the WTO SPS agreement. Implementing standards in line with the recommendations of Codex Alimentarius Commission will help, where these Codex standards exist. Otherwise, equivalence can only be assured through a comprehensive understanding of food safety requirements of each country or market. It is for precisely this reason that we in Waters Corporation are actively involved in discussions regarding food safety legislation with regulators in many countries, in order to facilitate this exchange of information.

Question 2. The EU and Japan have a food risk analysis body separate from the risk management side. I worry that these two sides would be too isolated from each other—I think risk assessment and risk management are iterative. You need those two functions to work together and learn from one another. Can you comment on how effective or not effective this separation is?

Answer 2. I can see both sides of this argument. I completely agree that close cooperation between risk assessment and management is absolutely essential, particularly with regard to ensuring effective and timely intervention. Indeed, exchange of scientific information is also key to ensuring that control measures are both necessary and appropriate. On the other hand, one vital role of food safety regulation involves maintaining consumer confidence. There is a risk, if both functions are covered by one organization that, either in reality or in the public's perception, the practicalities of risk management may influence the risk assessment and subsequent control measures. This separation ensures that regulations are based on science and the scale of control measures are appropriate to effectively manage the risk and are not dictated by the availability of resources. From my experience working in risk management in the UK, this system of separation works well, but only because of the very close collaboration and interaction that exists between both sides.

Question 3. We heard a lot about Radio-Frequency Identification (RFID) at last year's hearing, but it seemed that the conclusion was that this isn't ready for prime time, at least at the unit-of-sale package level. How is the EU implementing the requirement for full traceability?

Answer 3. Certainly, RFID is receiving a lot of attention for the traceability advantages it offers. However, food production is a very price conscious environment and reports indicate that early adopters of RFID appear to be struggling to justify the relatively high cost associated with this technology, which would agree with your assessment that it may not yet be appropriate for food traceability. There is a requirement for traceability in EU food law which it defines as "*the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution*." The EU has published guidelines which require food business operators to document the names and addresses of the supplier and customer in each case, as well as the nature of the product and date of delivery. In addition to the general requirements, sector-specific legislation applies to certain categories of food products (fruit and vegetables, beef, fish, honey, olive oil) so that consumers can identify their origin and authenticity. In the case of animals, producers must now "tag" every one with details of their origin and, when animals are taken for slaughter, stamp them with the traceability code of the abattoir. The tools used (ear tags, passports, bar codes) may vary from one country to another but must carry the same information.

Question 4. Whenever people talk about international standards, ISO comes up for discussion. I think they do a lot of great things, but when it comes to food safety, is ISO good enough?

Answer 4. There is no doubt that ISO standards play an important role in food safety. For example, the accreditation standard ISO 17025 is widely accepted as being highly desirable for laboratories involved in food safety analysis. However, ISO standards regarding safe food production are still evolving (such as the recent standards ISO 22000:2005 on hazard control and ISO 22005:2007 on traceability) and have yet to find widespread application. Many producers therefore choose to implement the Hazard Analysis and Critical Control Point (HACCP) recommendations to demonstrate due diligence. In Europe there is a legislative requirement for all food business operators to implement a HACCP programme. Indeed, some of the evolving ISO standards seek to standardize the implementation of HACCP.

QUESTIONS OF SENATOR ALLARD

Question 1. In your opinion what can be done to further educate the public, private sector and interested government agencies on food safety, recalls, etc."

Answer 1. This would appear to require considerable collaboration involving all interested parties. In a European survey, when asked who consumers most trust to inform them of a serious food risk, public authorities came fourth (behind consumer groups, physicians and scientists). Key elements appear to lie in maintaining the trust of the consumers and in providing them with accurate, easily understood information. In food recalls that I have been involved with in the past, the relevant agencies issued photographs of affected product, making it easy for consumers to establish whether they need to take action or not. I understand that this is currently being piloted by FDA and the consumer feedback should be most interesting.

Effective training for scientists involved in food safety analysis is also vital in ensuring that methods of analysis are appropriate and offer satisfactory assurances of product compliance. This necessity extends beyond U.S. borders, since imported food safety inevitably relies, to a large extent, on assurances provided by laboratories in those exporting countries. Waters Corporation has had discussions with a number of U.S. executive agencies who are regularly approached by scientists from foreign laboratories requesting training. It has been suggested that the establishment of a food safety institute capable of offering specialized scientific training to both domestic and foreign scientists would be of great benefit.

Question 2. Do you think that further education should play a role in addressing food safety? Do you have a single suggestion to further education and the distribution of informative resources regarding food safety?

Answer 2. In addition to the frequently discussed risk assessment and risk management strategies, risk communication also plays an extremely important role in food safety control. If consumers are presented only with the bald facts of potential hazards associated with a particular foodstuff, without the balanced view of the potential health benefits to be gained from wholesome product, it is likely to initiate complete avoidance which will, not only, damage the business of the vast majority

of responsible producers but may also limit the source of valuable nutrients for the consumers. In a recent European survey 53 percent of people surveyed claimed to have changed their eating habits as a result of hearing about a food hazard, with 16 percent stating that this change was permanent. The challenge then lies in building confidence for consumers that they are being both adequately protected and informed. If pressed to make a single suggestion regarding dissemination of information, it would be to create a single central repository for information relating to all aspects of food safety, ensuring that the message is consistent, comprehensive and, above all, easily understood by consumers.

[Whereupon, at 12:38 p.m. the hearing was adjourned.]

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