S. HRG. 111–1069

KEEPING AMERICA'S FAMILIES SAFE: REFORMING THE FOOD SAFETY SYSTEM

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

ON

EXAMINING KEEPING AMERICA'S FAMILIES SAFE, FOCUSING ON REFORMING THE FOOD SAFETY SYSTEM

OCTOBER 22, 2009

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C O N T E N T S

STATEMENTS

THURSDAY, OCTOBER 22, 2009

ADDITIONAL MATERIAL

KEEPING AMERICA'S FAMILIES SAFE: REFORMING THE FOOD SAFETY SYSTEM

THURSDAY, OCTOBER 22, 2009

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

The committee met, pursuant to notice, at 10:06 a.m. in Room SD–430, Dirksen Senate Office Building, Hon. Tom Harkin, Chairman of the committee, presiding.

Present: Senators Harkin, Dodd, Brown, Casey, Hagan, Merkley, Franken, Enzi, Gregg, and Isakson.

Also Present: Senator Durbin.

OPENING STATEMENT OF SENATOR HARKIN

The CHAIRMAN. The Committee on Health, Education, Labor, and Pensions will come to order.

Good morning, everyone. We meet today to discuss an issue of basic importance to all Americans: the safety of our Nation's food supply. There is perhaps no issue that affects Americans as universally as food safety. Part of our daily lives, and, for many in my State and elsewhere, the production, preparation, and sale of food is a source of livelihood.

Now, on the whole, Americans enjoy safe and wholesome food. But, to be honest about it, our food can be safer and it must be safer. Recent food outbreaks linked to spinach, peppers, peanut products, cookie dough dramatizes two important truths. First, our current regulatory system does not adequately protect Americans from serious, widespread food-borne illnesses. And second, the dangers associated with food-borne outbreaks are profound.

The Centers for Disease Control and Prevention estimates that food-borne diseases cause approximately 76 million illnesses each year, including approximately 325,000 hospitalizations and 5,000 deaths in the United States, each year. These are staggering numbers and totally intolerable. That's why, as we focus on a national healthcare reform, we can't afford to ignore food safety. Unsafe food is yet another strain on our healthcare system and it's a problem that we can and must address now.

I am heartened by the fact that the Obama administration has made food safety reform a major domestic policy initiative. In March, the President created the Food Safety Working Group to develop recommendations for bringing our food safety system into the 21st century.

Over the last 100 years, our meals have gotten more complex in this world. They include more varied ingredients, so they're subject to more diverse methods of processing and preparation. Today, raw agricultural products travel thousands of miles, from farms to processors to factories to the table. They're routinely processed and mixed along the way. In addition, we rely more and more on foods imported from abroad, often from countries with less rigorous regulation and different standards than our own. So, what do we need to do? Most of all, we need improved processes to prevent the contaminations of food in the first place.

Even though our Nation has 150,000 food processors, the FDA visits just 7,000 plants each year, and it visits even fewer of the foreign facilities that process food for shipment into the United States. That's why we need to allocate sufficient resources. If we really want to do this job, we'd better come up with the resources to cope with this different food distribution system that we've had to develop over the last 20 to 30 years to cope with the growing food industry and the inherent risks that threaten the safety of our food.

So, again, it's past time to modernize our laws. We need to act now. I am pleased that the President's Food Safety Working Group has begun a national dialogue on this issue. I'm also grateful to many Senators who have worked together in a bipartisan fashion. I know we're going to hear from the lead sponsor, Senator Durbin, and also Senator Gregg and others who have been working diligently on this. I thank them for that and for their strong bipartisan efforts to get this bill put together.

With that, I would yield to Senator Enzi.

OPENING STATEMENT OF SENATOR ENZI

Senator ENZI. Well, Mr. Chairman I'll just ask that my statement be included in the record so that Senator Isakson, who's a cosponsor on the bill, might have an opportunity to make a few comments.

The CHAIRMAN. Absolutely.

Senator ENZI. So, I would yield to Senator Gregg.

[The prepared statement of Senator Enzi follows:]

PREPARED STATEMENT OF SENATOR ENZI

Good morning. Food safety is not a partisan issue—we all want the safest food supply possible. The United States has one of the best food safety systems in the world. But even in the best of systems, there is always room for improvement.

The volume of food imports and the number of foreign producers and manufacturers are growing. At the same time, the supply chain is becoming more complex, due to innovations such as repackaging of fresh produce that mixes output from dozens of farms, or the potentially hundreds of ingredients in a ready-to-eat processed food.

FDA is the gold standard worldwide among public health agencies. After many years of inadequate resources, Congress has provided significant funding increases to FDA for food safety and related activities such as information technology. While it is impor-

tant to sustain these increases, FDA also needs a modernization of its authorities.

The powers the agency was given 100 years ago were appropriate for a world in which most of our food was grown and processed domestically. That is no longer the case, and FDA's tools need to keep pace with the challenges.

These outdated authorities coupled with a lack of resources have been made clear by recent outbreaks. For example, in the Peanut Corporation of America case last year, FDA did not know the facility was even making peanut butter, since the facility was initially registered as just roasting peanuts. There is currently no statutory requirement to update registration status when information changes. Last summer, during the *Salmonella* in tomato/peppers outbreak, FDA was not able to put enough "boots on the ground" to trace shipments back to the source of the contamination quickly.

Clearly, the complex nature of our food safety system requires all of the global partners—regulators, importers, manufacturers, academia—and other stakeholders to come together to propose meaningful, collaborative solutions.

I believe some of those solutions are contained in S. 510, the FDA Food Safety Modernization Act, which a number of members of this committee have cosponsored. I have a few concerns about the bill, particularly the provisions regarding FDA's relationship with farms as well as with State officials. While this bill is a good start, it is important that we go through regular order and do the hard work of making the bill even better. There is a lot of expertise on the HELP Committee about these issues, and we should bring that to bear on the legislation.

I look forward to the testimony today.

The CHAIRMAN. I recognize Senator Gregg.

STATEMENT OF SENATOR GREGG

Senator GREGG. Thank you, Mr. Chairman.

It's a pleasure, and I very much appreciate being at this hearing, and I very much appreciate your holding it.

It's a pleasure to be here, of course, with Senator Durbin, who is, with myself, the original sponsor of this bill, which we started working on in 2008. In an act of great clairvoyance, we both decided that eating was important. We probably did that over lunch somewhere.

[Laughter.]

It's very clear that the FDA needed more authorities and that we had to have a better regime for the purposes of protecting our food supply. This bill attempts to do that. It obviously isn't perfect, but it's a major step down the road in making sure that our food supplies are better protected and that the FDA has the authorities necessary to step in when it becomes clear that there is a problem. It does have mandatory recall, which is absolutely critical, in my opinion. It also sets up a regime where the food processors will be required to set up their own inspection systems and therefore, hopefully, be a step forward in the area of making sure that inspections are more comprehensive.

In addition, it addresses the international issue, which is a very serious issue, of foods coming into this country, because obviously a large percentage of our foods are imported.

So, I want to thank Senator Durbin for his extraordinary work on this. I want to thank everybody who has participated by cosponsoring it. I especially want to thank the Chairman and the Ranking Member for making time available on the calendar of this committee so that we can move it forward. And we hope it'll move promptly.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Gregg.

Senator Isakson.

STATEMENT OF SENATOR ISAKSON

Senator ISAKSON. Thank you, Mr. Chairman. I'll be very brief.

I just want to commend Senator Durbin on this legislation. As many of you know, the salmonella outbreak in peanut butter turned out to be borne in two plants, one of them in South Georgia. As it turns out, the evidence of salmonella contamination by a positive test for salmonella were lying in the files in the filing cabinet of the Peanut Corporation of America when Georgia ag agents, at the request of FDA, did an inspection based on a complaint, but, because of the existing law, those records were not available to the Georgia inspectors, and therefore, salmonella, which possibly could have been stopped, ended up spreading around the country.

So, I think Senator Durbin has done a great job in this legislation. I'm very proud to be a cosponsor, appreciate very much his being here. And it was a pleasure, yesterday, to meet Dr. Hamburg and get to know her better.

So, welcome to both of you.

The CHAIRMAN. Senator Brown.

STATEMENT OF SENATOR BROWN

Senator BROWN. Thank you, Mr. Chairman.

I particularly welcome to the committee Dr. Hamburg and Caroline Smith DeWaal, who's done such terrific work, and, of course, Senator Durbin for his leadership over the years.

I'll also be brief.

Each year, some 76 million people contract a food-borne illness in this country. The CDC estimates that 5,000 people die as a result. We've all heard these awful stories. In the last 2 years alone, our country has been faced with melamine in infant formula, harmful seafood from China, tainted peppers from Mexico, *E. coli* in spinach, salmonella in peanuts. And we wonder why our food safety system can't do a better job of preventing and detecting and minimizing the impact of food safety-related outbreaks.

We know that we import more fruits and vegetables—a good thing in this country, for sure—that people are eating fruits and vegetables all year round. Think of visiting a supermarket 25 years ago in February, versus today, and see what we have available. All wonderful things the Chairman's been so involved in, in dietary issues, preventive healthcare, encouraging people to eat better. But, we need to instill in people confidence that the fruits and

vegetables imported, and the food processed in this country or abroad—we need to, obviously, build trust much more in our food safety system.

Earlier this year, I introduced S. 425, the Food Safety and Tracing Improvement Act, to improve the ability of Federal agencies to trace the origins of contaminated food and provide the FDA and USDA with the authority to mandate recalls for adulterated and misbranded food products. So, we obviously need recalls. We also need these companies to do better traceability, if you will, so they know where these ingredients in foods came from.

We have a better process to recall malfunctioning toasters than we do contaminated meat. And that, clearly, is a place we've fallen short.

I'll just close with this, Mr. Chairman, that Nelly Napier, in Mentor, OH—it's a suburb just east of Cleveland—was an 80-year-old grandmother with a zest for life. She was an avid reader, a skilled puzzle solver, and an unwavering fan—a difficult task—of the Cleveland Indians. She was the mother of six children. She had 13 grandchildren, 11 great grandchildren. She became ill in January, after eating a peanut butter sandwich that was tainted with salmonella. When the doctors were called, they told the family they couldn't do anything, and she died shortly thereafter. That's deplorable. We can clearly do better that.

Senator Durbin's bill and the efforts of many on this committee, will be the major step we need to take.

Thank you.

The CHAIRMAN. Thank you very much.

Senator Casey.

STATEMENT OF SENATOR CASEY

Senator CASEY. Thank you Mr. Chairman.

I want to thank Senator Durbin for being here and for his work, for many years, on this issue, in introducing S. 510, the Food Safety Modernization Act legislation. We're grateful for Senator Durbin's presence here, in working with Senator Gregg.

Dr. Hamburg, we're very grateful to have you back in this room. We remember when you came here prior to your confirmation. We're grateful for your work.

Just fairly simply, I, like I think everyone here, believe that the American people have a reasonable—or should have a reasonable expectation of a safe food supply. There are a lot of ways to get there, but we know that we have countless examples of why that is not the case, why that reasonable expectation of safety is not there. And we're grateful that there's legislation in front of us to do that.

I just want to mention briefly the legislation Senator Grassley and I have, S. 429, the so-called Eat Safe Act. We introduced it in the last Congress. We have reintroduced it. It's really basic, in the sense that it's designed to address a critical aspect of this problem: food being smuggled into the United States of America. The greatest threat of smuggled food in agricultural products come from companies, importers, and individuals who circumvent U.S. inspection requirements or restrictions on imports of certain products from a particular country. Some examples of this are unpasteurized

raw cheeses from Mexico, strawberries from Mexico that are contaminated with hepatitis A. Other examples, as well. I'll include those in my statement for the record.

But, these smuggled food and agricultural products present a safety risk to our food, our plants, and animals, and pose a threat to our Nation's health, economy, and security.

So, the Eat Safe Act is one of the ways to positively impact this urgent challenge we have in the country, and Mr. Chairman, I'm grateful that you called this hearing so we can highlight these issues, and look forward to the hearing.

Thank you.

[The prepared statement of Senator Casey follows:]

PREPARED STATEMENT OF SENATOR CASEY

I want to thank the Chairman for calling today's hearing. It is an important step toward creating solutions to give Americans peace of mind that the foods they eat and give to their families is safe to consume. Americans have every right to expect a safe food supply. I am focused on food safety not only as a lawmaker but also as a consumer and a father. We all want food for our families that is nutritious and free from foodborne pathogens and contaminants.

Our government currently has no laws or regulations requiring a national system for traceability of U.S. foods. While many in the food industry do employ voluntary recordkeeping systems, there is no consistency from one system to the next. But implementation of a national traceability system is only half of the battle. There are still 76 million cases of foodborne illness in this country every year.

The United States Senate must look at ways to modernize the U.S. system of food inspection. We must provide the agencies that regulate food safety with additional authorities and resources to ensure the safety of our Nation's food supply. We must mandate science-based regulations to ensure the safety of food products that carry the most risk. Further, we must improve coordination between USDA, FDA, and the various other Federal and State agencies charged with regulating food safety.

We must ensure the safety of both domestic and foreign food products. That is why I introduced the EAT SAFE Act with Senator Grassley. The EAT SAFE Act is designed to address a critical aspect of the food and agricultural import system—food being smuggled into the United States. The greatest threat of smuggled food and agricultural products comes from the companies, importers, and individuals who circumvent U.S. inspection requirements or restrictions on imports of certain products from a particular country. Some examples of prohibited products discovered in U.S. commerce in recent years include unpasteurized raw cheeses from Mexico containing a bacterium that causes tuberculosis and strawberries from Mexico contaminated with Hepatitis A. These smuggled food and agriculture products present safety risks to our food, plants, and animals, and pose a threat to our Nation's health, economy, and security. The EAT SAFE Act addresses these serious risks by applying common-sense measures to protect our food and agricultural supply.

I understand that many Americans are concerned about food safety issues. So am I. Ensuring that our food supply, both domes-

tic and foreign food products, is safe is a high priority for me. As the Senate continues to address the issues we are discussing at this hearing, I will remain steadfast in my commitment.

The CHAIRMAN. Senator Franken.

STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Mr. Chairman. And thank you for holding this very important hearing.

I'd like to thank Senators Durbin and Gregg for putting forth this very important bill, S. 510.

We have heard, repeatedly and correctly, that our current food safety system is broken. The system relies heavily on reacting to outbreaks after they have occurred, instead of preventing their occurrence in the first place. Once an outbreak has been identified, it then takes far too long to track, contain, and remove the offending substances, or substance, within the food chain. We need Federal legislation now, so that we can bring our country's food safety system into the 21st century.

Right now, the FDA is unable to properly oversee our food safety system, because the agency lacks resources and authority in four key areas: No. 1, oversight of imported food products and ingredients; No. 2, access to food production records; No. 3, mandatory recall of contaminated food; and No. 4, the ability to trace the origin of food products.

I'm very pleased that S. 510 will move us forward in each of these areas and bring peace of mind to American families.

We simply have to be able to track where imported food is coming from and its safety. Fifteen percent of our food comes from overseas.

We must also ensure that FDA is equipped to address circumstances within the United States. For example, in late 2008, the Minnesota Department of Health noticed an elevated number of salmonella cases. After comprehensive investigations, the Department of Health identified the King Nut brand of peanut butter as the culprit, produced by the Peanut Corporation of America, as referenced by Senator Isakson. This contamination and the subsequent investigation led to the multiple recalls of more than 2,000 products from our shelves. But, if we were able to more immediately trace foods back to their producers, we would have withdrawn the contaminated foods far more quickly, and we would have saved lives and prevented illness.

Now, the recall is estimated to have cost the industry nearly a billion dollars, but the greatest cost was, of course, to American families. Over 700 became ill, and nine people died as a result of the PCA outbreak, including Shirley Almer, a Minnesota mother of three who had survived brain cancer and was in good health at the time of the outbreak.

To me, the most egregious part of the story is that PCA knew that the peanut products sent to our market were tainted. Third-party inspections in 2007 and 2008 had already found salmonella contamination in 12 different tests. PCA's inspection reports were glowing and showed no evidence of the problems present within the facility.

This is a clear indication that, while we need to increase the number of food inspections, it's equally important to strengthen the integrity of these inspections, like having a certification process for the inspectors.

We all agree that food safety is a top priority for our families and our country, and I support giving the FDA the resources it needs and the capability it needs to ensure that the food on our table is safe and reliable.

Mr. Chairman, I appreciate the opportunity to participate in this hearing today. I look forward to hearing from our witnesses to learn how we can work together to strengthen our Nation's food safety system and prevent senseless preventable deaths, like that of Shirley Almer.

[The prepared statement of Senator Franken follows:]

PREPARED STATEMENT OF SENATOR FRANKEN

Thank you Mr. Chairman. It is an honor to be here today, and I thank you for holding this hearing on such a critical and timely topic to the health of Minnesotans, and our Nation.

With the recent outbreaks like *E. coli* in spinach and *Salmonella* in peanut butter, we all understand how serious the threat of contamination is to our food supply. We have heard repeatedly and correctly that our current food safety system is *broken*. The system relies heavily on reacting to outbreaks *after* they have occurred, instead of *preventing* their occurrence in the *first place*.

Once an outbreak has been identified, it then takes far too long to track, contain, and remove the offending substance within the food chain. We *need* Federal legislation now so we can bring our country's food safety system into the 21st century.

I am proud to come from a State with a strong public health tradition. Minnesota is regarded as the leader in early detection of foodborne diseases, and we have a long record of working effectively with the FDA on food safety. Minnesota has been home to the *Homeland Security National Center for Food Protection and Defense* since its inception in 2004. The Minnesota Department of Health was recently awarded a 3-year cooperative agreement with the FDA to establish a Food Protection Rapid Response Team.

This award will help Minnesota adopt FDA's 10 "Manufactured Food Regulatory Program Standards," enabling better communication between agencies responsible for food safety, and quicker action in the event of a problem.

Right now, the FDA is unable to properly oversee our food safety system because the agency lacks resources and authority in four key areas: (1) oversight of imported food products and ingredients; (2) access to food production records; (3) mandatory recall of contaminated foods; and (4) the ability to trace the origin of food products. I'm very pleased that S. 510 will move us forward in each of these areas, and bring peace of mind to American families.

With regard to imported foods—we can do everything right with our food products here in the United States, but the reality is that about 15 percent of our food is imported from other countries. The FDA *must* be given the authority to verify that foods coming into this country are safe, so we can avoid situations like the 2007 melamine contamination in infant formula and pet food.

We must also ensure that FDA is equipped to address circumstances within the United States. For example, in late 2008, the Minnesota Department of Health noticed an elevated number of *Salmonella* cases. After comprehensive investigations, the Department of Health identified the King Nut brand of peanut butter as the culprit, produced by the Peanut Corporation of America (PCA). This contamination and the subsequent investigation led to the recall of more than 2,000 products from our shelves, and is estimated to have cost the industry nearly *$1 billion*. But if we were able to trace foods back to their producers, we would have withdrawn the contaminated foods much more quickly and saved lives and prevent illness.

But the greatest cost was to *American families*. Over 700 became ill and 9 died as a result of the PCA outbreak, including Shirley Almer, a Minnesota mother of three sons, who had survived brain cancer, and was in good health at the time of the outbreak.

To me, the most egregious part of this story is that PCA *knew* that the peanut products sent to our markets were tainted. Third-party inspections in 2007 and 2008 had already found *Salmonella* contamination in *12 different tests*. PCA's inspection reports were glowing, and showed no evidence of the problems present within the facility. This is a clear indication we need to increase the *number* of food inspections, it's equally important to strengthen the *integrity* of these inspections—like having a certification process for inspectors.

We all agree food safety is a top priority for our families and our country. And I support giving FDA the resources and capabilities it needs to ensure the food on our tables is safe and reliable. Mr. Chairman, I appreciate the opportunity to participate in this hearing today. I look forward to hearing from our witnesses to learn how we can work together to strengthen our Nation's food safety system, and prevent senseless, preventable deaths like Shirley Almer's.

The CHAIRMAN. Thank you very much, Senator.

Well, we're privileged to have with us the lead sponsor of S. 510, Senator Durbin. I first want to congratulate you and Senator Gregg, Senator Isakson, all of you that have worked on this bill. When I look at the supporters, the American Feed Industry Association, Frozen Food Institute, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food Marketing Institute, Grocery Manufacturers of America, National Fisheries Institute, National Restaurant Association, Trust for America's Health—that's pretty impressive. So, I thank you for all the great work you've done to lay the groundwork for this. And I might just say that we really do want to mark up this bill and get it through, Senator Durbin, because I'd like you to start calling me by my first name again, "Tom." What I mean by that is, every time I see Senator Durbin, all he says is, "Food safety."

[Laughter.]

I began to check my driver's license to see if my name had changed. So, that's just my obtuse way of saying that I know of no one who has been more persistent on this issue than Senator Durbin.

Welcome to the committee, Senator Durbin.

STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Mr. Chairman and Senator Enzi. Thank you both for allowing me to come before you, today.

I understand that this great committee has had two challenges, over the course of this Congress, with the illness of the great Ted Kennedy, our former chairman, and, of course, the focus rightly paid to healthcare reform. This committee did an extraordinary job in moving that issue forward. So, I was prepared to wait my turn, and I'm glad it's come today.

I thank Senator Gregg for being my cosponsor, Senator Isakson, Senator Burr, and so many others who have made this a strong bipartisan bill.

It's an honor to be here with Dr. Hamburg, from the FDA and Caroline Smith DeWaal. People who aren't here, and should be, include Nancy Donnelly, of Safe Tables Our Priority, who really raised my attention to this issue many, many years ago, when Nancy, living in Chicago, gave hamburger, bought at a local store, to her 6-year-old son Alex, who died within a matter of days from *E. coli* contamination. She's dedicated her life to food safety. I am here today because she hand-wrote a letter to me and told me this story. Though she didn't live in my congressional district, it touched my heart, and I decided I had to do something about it.

It's been a long time coming, to put together this coalition that you just enumerated. And I hope it's an indication of a lot of hard work that's gone into this. There's more to be done. We can make this a better bill. But, I think we should seize this opportunity, this once-in-a-political-lifetime opportunity, to do something significant on food safety.

The numbers are overwhelming. The fact is that every 5 minutes, three people in America are rushed to the hospital because of food illnesses. And sadly, at the end of the day, 13 of those people will die, every single day, because of food illness in America.

I have here a photograph of a lovely lady. Her name is Marianne Westerman, of Mendota, IL, a small town outside of Chicago. She's 80 years old. She's here with her grandson. She couldn't wait for the Labor Day weekend, to get together with her family. Marianne, a great cook, decided she'd make a salad before she drove up to Chicago to meet with the grandkids and all the members of the family. So, she reached in and took out a bag of spinach from her refrigerator. She thought this was a good, healthy food to give to her family. Hours after eating that spinach, Marianne Westerman was sprawled across her bathroom floor, vomiting violently and experiencing uncontrollable diarrhea. Then her kidneys failed. Marianne never made it to Chicago to see her family. Instead, she went straight to the hospital for 6 weeks. She was diagnosed with *E. coli*, and it was literally a life-and-death struggle as to whether she would survive. Thankfully, she did. But, the quality of her life will never be the same because of the bag of spinach that she used for that salad.

Americans ought to be able to trust the products they buy in the stores, spinach and so many others.

Our country has a good system, but we can make it better. There are far too many lives—and we've heard two other examples, here,

of people who innocently use food products and lives are changed forever.

FDA is a great agency. I really am a big fan. And they are working within the constraints of outdated laws, limited staff, and limited funding. They have been set up to react to outbreaks of contamination, and they do it well.

This bill, that we're considering today, would empower the FDA to prevent the outbreaks. Until we can prevent widespread contamination, businesses will take the hit every time consumers lose confidence.

Johnny Isakson, my colleague from Georgia, knows this story better than most. When it comes to the product, of course, of peanut butter. Americans love their peanut butter. But, the salmonella outbreak at Peanut Corporation of America led to one of the largest product recalls in history. This is the printout from the FDA, warning people not to buy the following products containing peanuts in America. There's a list of more than 3,900 products included in this FDA warning. Not surprisingly, Americans didn't stop at those 3,900; they stopped buying peanut butter. What impact did that have on this major food industry in America? It ended up costing them over $1 billion because of the contamination in one plant in Georgia.

Now, last summer—this is a show-and-tell—last summer, it was tomatoes. We remember that story, don't we? We were told, initially, tomatoes were responsible for a salmonella outbreak. So, retailers took tomatoes off shelves across America. Wholesalers destroyed their tomato supplies and tomato farmers were stuck with a product nobody wanted. We should have applauded this rapid response, but it turned out it was just plain wrong. The source of the contamination was not tomatoes. In the end, we found out, 6 weeks later, that the real source of the salmonella were jalapeño peppers imported from Mexico. Because of this mistake, tomato growers across America lost $150 million in product. Meanwhile, until the source was identified, more people got sick.

The FDA Food Safety Modernization Act will give the Food and Drug Administration the resources and authority to quickly trace food-borne illness back to the source, prevent millions of cases, like Marianne's, each year, save industries, save businesses, like spinach, peanuts, tomato, so many others. And I think it's something we need to seize right now and do.

This is our chance. I've been waiting for a long time for this moment, to have this kind of bipartisan support. And, Senator Harkin, I'm going to call you "Tom" again as soon as you report this bill.

[Laughter.]

But, until then, I'm going to work with you to make sure we get this to the floor. And I'm going to leave this, because I know, as a new chairman, you'd like to treat your committee to lunch——

[Laughter.]

Senator DURBIN [continuing]. And I trust that all of these products have been safely inspected.

I thank you for this opportunity to testify.

[The prepared statement of Senator Durbin follows:]

PREPARED STATEMENT OF SENATOR DURBIN

Thank you, Chairman Harkin and Senator Enzi. I also want to thank Senator Gregg and Burr, who worked closely with my staff and staff to the late Senator Kennedy to develop a strong, bipartisan bill.

I think what you will hear from today's witnesses is that there is growing consensus among consumer advocates, public health officials and the food industry that we need to update our food safety laws.

Every year, 76 million Americans suffer from a *preventable* food-borne illness, 325,000 are hospitalized, and 5,000 die. That means that every 5 minutes—3 people are rushed to the hospital because the food they ate made them sick. And at the end of each day—13 will die.

MARY ANN'S STORY

This is Mary Ann Westerman of Mendota, IL. Mary Ann is 80 years old. She's pictured here with her grandson.

On Labor Day weekend, Mary Ann made a salad before driving to Chicago to meet her family. She took some spinach out of the refrigerator—a food she knew was healthy and assumed was safe. Hours after eating the spinach, Mary Ann Westerman was sprawled across her bathroom floor—vomiting violently and experiencing uncontrollable diarrhea. Then her kidneys failed.

Mary Ann never made it to Chicago to see her family. Instead, she went to the hospital for 6 weeks, was diagnosed with *E. coli*, and received medical treatment through a hole in her neck.

Thankfully, Mary Ann is still alive, but the quality of her life will never be the same. Americans ought to be able to trust the spinach that is in their refrigerator.

This country has a good system, and *most* of our food is safe. But there are far too many lives—like Mary Ann's—that have been compromised by food-borne illness.

REFORM IS GOOD FOR BUSINESS

FDA is working within the constraints of outdated laws, inadequate staff, and not enough funding. FDA has been set up to react to outbreaks of contamination.

The bill this committee is considering today would empower FDA to *prevent* outbreaks. Until we can prevent widespread contamination, businesses will take the hit every time consumers lose confidence.

Peanut Butter

Take peanut butter for example. Americans love peanut butter. But the *salmonella* outbreak at Peanut Corporation of America, led to one of the largest product recalls in history.

Look at this list of the more than 3,900 peanut-related products that were recalled. Not surprisingly, Americans stopped buying food with peanuts in it. Because of the irresponsible conduct of one corporation, the entire peanut industry suffered. By some estimates, the industry lost almost $1 billion.

Tomatoes

Last summer we thought tomatoes were responsible for a *salmonella* outbreak. So retailers took tomatoes off shelves. Wholesalers destroyed tomato supplies. Tomato farmers couldn't sell. We would have applauded this rapid response if tomatoes were actually the source of the contamination. Turns out they were not!

It took almost 6 weeks before the real source of the *salmonella* contamination—Jalapeño peppers from Mexico—was discovered. Because of this mistake, tomato growers across the country lost almost $150 million. Meanwhile, until the source of the problem was identified, more people grew ill.

CONCLUSION

The *FDA Food Safety Modernization Act* will give FDA the resources and authority to quickly trace food borne illnesses back to their source. We can prevent millions of cases like Mary Ann's each year.

We can save industries—like spinach, peanuts and tomatoes—millions of dollars each year. I commend this committee for considering this bill to modernize our food safety system and urge your support for S. 510.

The CHAIRMAN. Senator Durbin, thank you again for your great leadership and your persistence in this effort. No pun intended, but it's coming to fruition. We intend to move ahead with a markup as soon as possible and get this to the floor. But, thank you for a very provocative statement—provocative in a good sense—provoking our thinking that we really have to do something on this, and we really have to do it very soon.

I recognize your leadership. And I know how busy you are. We thank you for appearing before the committee, and we'll do our darndest to get it done.

Thank you very much, Senator Durbin.

Before we turn to Dr. Hamburg, I would recognize Senator Dodd, who has been so wrapped up in healthcare reform. We're glad to see you here, at the committee——

Senator DODD. Nice to be with you.

The CHAIRMAN [continuing]. From the healthcare reform endeavors you've been involved in. We thank you, very much, on behalf of all the committee, for everything you've done in your leadership on healthcare reform. You're recognized.

STATEMENT OF SENATOR DODD

Senator DODD. Well, very, very briefly, Mr. Chairman, because we've got the commissioner here.

Let me commend Senator Durbin, on his way out, for his tireless efforts on this behalf, and all of those who are gathered in the room here today who have such a strong interest in the subject matter, and Mike Enzi, who I've enjoyed working with, as well, on this matter, and the fact you've been able to pull this together. Hopefully, we can move forward with it.

Obviously the information you've heard—I was stunned to—you read these numbers, and it's hard to believe that they're as dramatic as they are, but here we lose—there are 76 million illnesses

every year—325,000 hospitalizations, 5,000 deaths each year—at a cost of almost $7 billion, but all related to this subject matter.

All of us know of stories in our own States. Haley Bernstein, of Wilton, CT, 3 years old, became ill, eating lettuce contaminated with *E. coli*. It has been quite an ordeal. She spent 14 weeks in the hospital, suffered kidney failure, had a seizure that led to bleeding in the brain, and temporary blindness. As a result of her illness she developed diabetes. Her food-borne illness occurred more than a decade ago, and she lives with the effects every single day of her life since then. She also has a vision deficit, weakness in her right side, and suffers from reduced kidney function. She's been on insulin pump for 7 years. She's one of the lucky ones. She survived.

These stories get repeated day after day in every jurisdiction across the country. And so, this legislation has a sense of urgency to it that I hope all of us can appreciate.

I just want to express my gratitude to the committee, and to others as well, to include the legislation we've offered dealing with food allergies. Again, this is—watching the peanut butter being held up, here—obviously it's a great source—I look at my friend from Georgia, here, knowing the importance of peanut butter in Georgia.

For my little girl, Grace, it's a lethal product for her, until we come up with a non-allergic alternative. She's been in anaphylactic shock four times. She's 8 years old. And she's been near death on four occasions with airborne allergies; she doesn't have to ingest them, she just has to be in the presence of them, with things like cashews and others, things like citrus and shellfish and other items. So, the fact that we've got some provisions in here—by the way, my interest in it predates the birth of my child—going back to food labeling issues, as well as dealing with EpiPens and the safety of them, where there were recalls involved, and then becomes very personal when you have a child affected by it. Twelve million people in our country are affected by food allergies. Thank God, most of them are not as seriously affected as my daughter is, but many are. And, the fact that we're including something here dealing with that—the guidelines in grants to States, so they can develop some guidelines in developing the safety standards for people across the country—has great value, as well.

I thank you, Mr. Chairman, for the bill and the efforts and the fact that everyone's so deeply involved in these questions. It means a great deal. And I thank you for that.

I apologize to you, Madam Commissioner, if I can't stay for all of the hearing, but to hear your comments, as well. We're so pleased you are where you are. You bring a wonderful set of credentials to this. I had a wonderful chance to meet earlier and talk, and so forth, so I thank you.

And thank you, Mr. Chairman, for your leadership on this, as well.

The CHAIRMAN. Thank you, Senator Dodd.

Dr. Margaret Hamburg was confirmed on May 18, 2009, by unanimous Senate vote, to become the 21st Food and Drug Commissioner. The second woman to be nominated for that demanding position, Dr. Hamburg is exceptionally qualified for her new job by her training and her experience as medical doctor, scientist, and

public health executive. In 1990, Dr. Hamburg joined the New York City Department of Health and Mental Hygiene as Deputy Health Commissioner and, within a year, was promoted to commissioner, a position she held until 1997. In 1994, Dr. Hamburg was elected to the membership of the Institute of Medicine, and one of the youngest persons to be so honored. Three years later, President Clinton appointed her to the position of Assistant Secretary for Policy and Evaluation in U.S. Department of Health and Human Services. And, of course, President Barack Obama nominated her for the FDA Commissioner on March 25, 2009.

So, Dr. Hamburg, again, congratulations on your assuming this position. We welcome you to the committee. Without any objection, your statement will be made a part of the record in its entirety. And we ask you to please proceed as you so desire.

STATEMENT OF MARGARET HAMBURG, M.D., COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, WHITE OAK, MD

Dr. HAMBURG. Thank you very much, and good morning, Chairman Harkin, Ranking Member Enzi, and members of the committee.

I am Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration. Thank you, for this opportunity to discuss issues in food safety, especially the pending food safety legislation.

Let me first commend you, Mr. Chairman, for your leadership and longstanding commitment to improving food safety. I also would like to thank the members of this committee and their staffs who worked hard on this important legislation, as well as Senator Durbin, the lead sponsor.

Food safety is a core public health issue. Every year, millions of people in our country suffer from food-borne illness, hundreds of thousands are hospitalized, and thousands die. This does not need to happen. And we have a historic opportunity to see that it doesn't.

We are joined by a coalition of consumer groups fighting for improvements in our food safety system and by major sectors of the food industry, who are advocating as well, for fundamental change.

FDA is the Federal agency responsible for overseeing the safety of the food supply, except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture. Ensuring that foods are safe and secure is a vital part of the FDA's mission. And FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

President Obama has made a strong commitment, as well, calling food safety one of the most fundamental responsibilities of government. On July 7th, a Food Safety Working Group established by the President issued its key findings on how to strengthen and modernize the food safety system for the 21st century, based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The comprehensive food safety bill that you're considering, the FDA Food Safety Modernization Act, sponsored by a number of members of this committee, includes many of the authorities identified as vital by the Working Group.

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From FDA's perspective, there are three key questions that must be asked about food safety legislation: Does the legislation refocus the system to place a greater emphasis on prevention? Does the legislation provide FDA the legal tools necessary to carry out its existing and new food safety responsibilities? And does the legislation provide or anticipate resources for the agency to match its responsibilities? I'd like to address each of these questions in turn.

First, Does the legislation refocus the system toward prevention? The legislation would, indeed, shift FDA's approach to food safety from one that reacts to outbreaks to one that seeks to prevent them in the first place. Key provisions in the legislation relevant to the goal of prevention include section 103, which requires facilities to conduct hazard analyses and implement preventive control plans. Section 105 requires adherence to science-based safety standards for fresh produce to minimize the risks of serious adverse health consequences. These and other provisions are critical to modernizing our food safety system and improving health outcomes.

Second, Does the legislation provide FDA the legal tools necessary to carry out its existing and new responsibilities? S. 510 represents a comprehensive and significant modernization of the food safety system and provides FDA with some essential legal tools. For example, section 301, the Foreign Supplier Verification Program, will provide FDA with important information about importers and require that importers verify the safety of the food they are bringing in. These requirements are enforced by a prohibitive act and the ability to refuse entry of the food into U.S. commerce. Section 207 provides important revisions to the existing standard for the administrative detention of foods that could help us prevent unsafe food from reaching consumers.

Other provisions of the bill could be strengthened by including effective enforcement mechanisms and other legal tools. For example, S. 510 does not provide FDA with explicit authority to access food records during routine inspections. Such access is critical to our ability to assure the ongoing implementation of appropriate preventive measures and safety standards. This is one of the most significant gaps in FDA's existing authority.

Section 103 outlines requirements for hazard analysis and risk-based preventive controls. However, the effectiveness of this provision would be greatly strengthened if it deemed food that violates this section as "adulterated," rather than simply creating a prohibited act. That would allow FDA to seize foods in domestic commerce or refuse imports of products if not in compliance.

Third, Does the legislation provide or anticipate resources for the agency to match its new responsibilities? Section 201 provides a mandate for FDA to achieve specified frequencies of inspection based on risk. Inspections are a critical element to ensuring high rates of compliance with the preventive control standards. And that is essential to improvements in food safety. We embrace the intent of section 201, but our concern is that the bill does not provide a guaranteed, consistent funding source to help FDA fulfill its new responsibilities. The Administration supports inclusion of a registration fee, as provided in the President's budget, which could be used, in part, to fund this inspection mandate.

We also suggest the inclusion of language that provides FDA flexibility to adjust the inspection frequencies, as appropriate, and language authorizing FDA to use accredited third parties to meet the inspection frequency for foreign facilities.

Mr. Chairman, this is a historic moment for food safety in the United States, a moment for FDA, with our important partners at the State and local level, as well as internationally, to rise to the challenges of the 21st century. The legislation is a major step in the right direction. I look forward to working with you on this legislation.

Thank you, again, for the opportunity to discuss this important legislation with you this morning. I'd be happy to answer any questions you may have.

[The prepared statement of Dr. Hamburg follows:]

PREPARED STATEMENT OF MARGARET A. HAMBURG, M.D.

INTRODUCTION

Good morning, Chairman Harkin and members of the committee. I am Dr. Margaret Hamburg, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to review current issues in food safety, especially pending food safety legislation that is of great interest to this Administration. I would first like to commend you, Mr. Chairman, for your leadership and your long-standing commitment to improving food safety. I also would like to commend many members of this committee and their staffs for their work on this important legislation, as well as Senator Durbin, the initial sponsor.

By way of background, FDA is the Federal agency that is responsible for overseeing the safety of the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at the U.S. Department of Agriculture (USDA). Ensuring that foods are safe and secure is a vital part of FDA's mission, and FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

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

Food can become contaminated at many different steps—on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. Over the years, we have made progress to prevent both intentional and unintentional contamination of food at each of these steps. However, changes in consumer dietary patterns, changes in industry practices, changes in the U.S. population demographics, evolving pathogens, and an increasingly globalized food supply chain pose challenges that are requiring us to adapt our current food protection strategies.

President Obama has made a personal commitment to improving food safety. In March 2009, President Obama stated that protecting the safety of our food and drugs is one of the most fundamental responsibilities our government has, and established the President's Food Safety Working Group. On July 7, the Working Group issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The Working Group noted the need to modernize the food safety statutes to provide key tools for FDA, the Food Safety and Inspection Service at USDA, and other components of the Federal Government to keep food safe. Some of the necessary legislative authorities highlighted in the findings include:

- enhanced ability to require sanitation and preventive controls at food facilities, based on a scientific hazard analysis;
- the ability to access basic food safety records at facilities;
- enhanced ability to use resources flexibly to target food at the highest risk and achieve the maximum gain for public health;

• enhanced ability to establish performance standards to measure the implementation of proper food safety procedures; and
• the ability to require mandatory recalls.

A food safety bill recently passed by the House of Representatives, H.R. 2749, the "Food Safety Enhancement Act of 2009," addresses all of the above authorities and includes many of the other key recommendations of the Working Group.

The comprehensive food safety bill under consideration in the Senate is S. 510, the "FDA Food Safety Modernization Act." Its sponsors include many members of this committee. It also includes many of the authorities identified as important by the Working Group, such as preventive controls and mandatory recall authority.

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

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

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

FOOD SAFETY LEGISLATION

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

• First, does the legislation refocus the system to place greater emphasis on prevention?
• Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities?
• Third, does the legislation provide or anticipate resources for the Agency to match its responsibilities?

I will focus on S. 510 for a discussion of these questions. I will address each of these three questions in turn and highlight a few of the many important authorities in this bill.

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

The legislation would indeed transform FDA's approach to food safety from a system that far too often responds to outbreaks rather than prevents them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

FDA is eager to further the development of this modern system. Working with the Centers for Disease Control and Prevention and our partners at USDA, as well as with industry, consumers, States, localities, and other key stakeholders, we are working to establish basic standards for preventive controls. This system will make our overall approach and philosophy to food safety more consistent across government.

Key provisions in the legislation relevant to this goal include section 103, which requires facilities to conduct hazard analyses and write and implement a preventive controls plan. Section 105 requires adherence to science-based safety standards for fresh produce to minimize the risk of serious adverse health consequences or death. These, and other provisions, are critical to modernizing our Nation's food safety system.

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

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

The Senate bill, S. 510, represents a comprehensive and significant modernization of the food safety system and provides FDA with some essential legal tools. For example, section 301 (Foreign Supplier Verification Program) will provide FDA with important information about importers and require that they verify for each sup-

plier that food is not adulterated and is in compliance with allergen labeling requirements, preventive control requirements, and safety standards for produce. These requirements are enforced by a prohibited act and refusal of entry. These new requirements will help reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety.

Section 207 provides important revisions to the existing standard for the administrative detention of foods. The current standard of "credible evidence or information" of "a threat of serious adverse health consequences or death to humans or animals" is too high given that a key purpose of the provision is to provide time to gather information regarding the product's potential to cause significant harm. As a result, the existing authority is often not useful in situations where it otherwise could help us prevent or minimize the harmful effects of an adulterated or misbranded food.

Other provisions of the bill, however, need to be strengthened by including effective enforcement mechanisms and other legal tools. For example, S. 510 does not provide FDA with explicit authority to access food records during routine inspections, one of the key authorities identified by the Working Group. Routine records access is a critical component of a food safety regulatory framework and is one of the most significant gaps in FDA's existing authority. Although FDA has routine records access for certain other FDA-regulated products, and USDA has routine records access for USDA-regulated products, FDA does not have explicit authority for routine access to records for the vast majority of foods under its jurisdiction. This authority is essential to enable FDA to identify problems and require corrections before people become ill. Under current limited authority, FDA generally only has access to required records during an emergency situation involving serious threats to health or life. Routine records access also enables the Agency to verify during routine inspections that firms are maintaining the required records. An investigation this year by the HHS Office of Inspector General found significant lapses in compliance with recordkeeping requirements.

Another key legal tool that is not included in S. 510 involves information sharing. Enhancing FDA's information sharing authority is a critical element of an integrated Federal/State system and is also essential for effective public health communications with FDA's international regulatory partners. The Working Group highlighted the need to improve information sharing during a foodborne illness outbreak to speed the epidemiological investigation and traceback of the source of the illnesses to protect consumers and help industry recover faster. FDA recommends that language be included similar to that in section 112(b) of H.R. 2749. Under that provision, FDA may provide Federal agencies, State and local government agencies, foreign government agencies, and certain international organizations both confidential commercial and trade secret information relating to food with provisions to ensure its confidentiality, consistent with international obligations. FDA may also receive such information from such agencies and organizations and maintain its confidentiality. When necessary to protect public health, FDA may also disclose to other persons confidential commercial information relating to food, provided those persons maintain the information's confidentiality. Such information sharing is critical for building an integrated food safety system partnership.

Section 103 of S. 510 outlines requirements for conducting a hazard analysis and implementing risk-based controls. This authority is an essential component of a modern food safety system. However, the effectiveness of this provision would be greatly strengthened if it deemed food that is in violation of this section as "adulterated," as in the House bill. As currently drafted, S. 510 addresses enforcement via the creation of a prohibited act. Creation of a prohibited act would support an injunction but would not provide a legal basis, for example, for a seizure, administrative detention (as amended by the legislation), or refusal of admission of imported food from a facility that is not in compliance with the requirements. We encourage this committee to include an effective enforcement mechanism, as provided in the comparable section of H.R. 2749. That would make this section consistent with most other enforcement mechanisms in the Federal Food, Drug, and Cosmetic Act.

Similarly, section 105, which authorizes mandatory safety standards for fresh produce, addresses enforcement via the creation of a prohibited act. As explained above, this means that FDA may not seize or refuse admission of fresh produce because it is not in compliance with the requirements. Section 105 provides important authorities that will help prevent foodborne illnesses only if the standards are effectively implemented and enforced; therefore, it is essential to have effective tools for enforcing these requirements.

Section 204 (Enhanced Traceback and Recordkeeping) does not include any type of enforcement mechanism. To encourage compliance and to have consequences for lack of compliance with these important requirements, it is necessary to include an effective enforcement mechanism.

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

An important element of S. 510 is that it provides FDA a mandate to achieve specified frequencies of inspection based on risk. Inspections are a critical element to ensuring high rates of compliance with the preventive control standards and other food safety performance standards that will help drive improvement in food safety and reduced rates of foodborne illness.

FDA supports the intent of section 201 to require a minimum inspection frequency based on risk. However, we are concerned that the bill does not provide a guaranteed consistent funding source to help FDA fulfill its new responsibilities. The Administration supports inclusion of a registration fee, as provided in the President's Budget for fiscal year 2010, which could be used, in part, to fund this inspection mandate. We also suggest the inclusion of language that provides FDA flexibility to adjust the inspection frequencies. Further, we suggest adding language to authorize FDA to use accredited third parties, such as foreign regulatory agencies, to meet the inspection frequency for foreign facilities.

FDA supports the bill's inspection goals for domestic food facilities. However, food imports present a significant resource challenge. It is important that food imports meet the same requirements as domestic products, and we are pleased that the bill provides FDA with new tools to help ensure they do, including the requirement that importers verify that their foreign suppliers are in compliance and the authorization to require certification of compliance for imported food under certain circumstances.

FDA plans to increase inspection of foreign food facilities, but we are concerned that the bill's foreign inspection mandate may not result in the best use of FDA's resources, in light of the approximately 230,000 registered foreign facilities (as of the beginning of this month) and the high cost of overseas inspections. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting a strong accredited third-party inspection program, and increasing targeted, risk-based foreign inspections, consistent with the United States' international trade obligations.

We are committed to working with Congress to ensure that FDA has sufficient resources, including fees, to carry out its inspection mandate. This will be essential to our success. We note that the current inspection mandate in the bill will far outstrip our current resources.

It is also of critical importance to provide resources to help build the capacity of our State and local food safety partners. FDA supports section 205(d) of S. 510, which reauthorizes appropriations for food safety capacity-building grants. Grants that could be extended over multiple years, if the State meets FDA performance standards, would be especially helpful by providing greater certainty and continuity for the grant recipients, thus encouraging their participation in the food safety program.

CONCLUSION

This is a historic moment for food safety in the United States—a moment for FDA and its sister agencies in the Federal Government to rise to the challenges of the 21st century. Success means fewer hospitalizations and deaths, fewer economically devastating recalls, and greater health for the American people.

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

Thank you again for the opportunity to discuss FDA's perspective on pending food safety legislation and the Administration's interest in improving food safety. We understand that the Administration may have additional views on this legislation. I would be happy to answer any questions.

The CHAIRMAN. Dr. Hamburg, thank you very much for your statement. As I said, your total statement will be a part of the record in its entirety.

You mentioned section 103 and HACCP. Let me just start there, if I might.

Dr. HAMBURG. OK.

The CHAIRMAN. The FDA already makes use of preventative control programs for food safety. You have the Hazard Analysis and Critical Control Points in juice and seafood, but not in other foods. In 1996, FDA conducted a pilot program to consider expanding

HACCP requirements to other foods, yet this expansion has not occurred. Can you tell us, either now or provide for us, what was learned from the 1996 pilot study and these HACCP programs to indicate the effectiveness of preventative control programs in food safety?

I might just add to that issue, from my years of service on the Agriculture Committee, we fought long and hard, over many years, to get the HACCP program in agriculture, and for meat and meat products and it's worked quite well, quite frankly. So, I'm just wondering, What's happened with FDA? Has it worked all right with juice and seafood? Has it not been expanded? And you said 103 does do that, I guess——

Dr. HAMBURG. Yes.

The CHAIRMAN [continuing]. In 510.

Dr. HAMBURG. I think we have seen, in a number of domains, that the HACCP approach and the implementation of a risk-based hazard-control approach is extremely beneficial to strengthening food safety and reducing risks. I do believe that this legislation is an opportunity for FDA to move forward in important ways to really refocus on the importance of prevention on the opportunity to put in this kind of a risk-based approach, not just in the areas of seafood and juice, where we are currently employing that approach, but in the broader array of areas, so that, no matter what the food product, we can, in a systematic way, working with the producer, identify: Where are the points of vulnerability? How can those points of vulnerability be shored up? And how can FDA, working in partnership with producers, make sure that those points of potential risk are eliminated to the greatest degree possible?

The CHAIRMAN. Do you know if you or your staff have looked at the pilot programs that they did in the late 1990s to see what——

Dr. HAMBURG. You know, I can't speak to the details of that pilot program, but I'd be happy to provide you with additional information.

But, we do have ongoing real-world experience with this risk-based approach, and I think that certainly we in the FDA—and I think you'll hear from the coalition of others supporting this bill—we all feel that the risk-based preventive approach reflected in the legislation is the direction that we must go.

The CHAIRMAN. In reading over the testimonies last night, I noted that Ms. DeWaal's written testimony advocated requiring testing as a part of preventative controls. Now, I just wanted to know, do you agree that testing is a necessary component of a meaningful preventative control system?

Dr. HAMBURG. Testing is a very important part of a preventive control approach. I think that, again, we have real opportunities to put in place a more systematic and science-based approach to testing through this legislation. Also, looking forward, we have opportunities to leverage remarkable advances in science to improve testing capacity so that we can do more onsite, in a real-time way, in order to provide the best possible protections to consumers.

The CHAIRMAN. The last point that you brought up was on whether the bill provide resources, or anticipate that there would be resources, adequate to do the job we're now going to require the FDA to do? This has been a continuing battle for years. We keep

asking the FDA to do more and more, and without the resources to do it. So, as we proceed on this, I just want you to know that I'm going to be asking for some pretty hard figures on what it would require, in terms of appropriations, to adequately carry out this food safety system that we are now, hopefully, anticipating getting. What will it require? As an appropriator, I need to know some pretty hard figures on that. Again, I don't want to be in the position of having passed a bill that purports to do all these wonderful things, and we don't provide the money for it, and we give false hope to people that now their food is going to be safer, when we don't give you the resources with which to carry it out. So, I'm not asking that question now, but I'm just telling you to anticipate that I'm going to be coming to you to ask you for some pretty hard figures on this, on what it's going to require.

Dr. HAMBURG. Mr. Chairman, I appreciate that enormously, because it is the case that our mandates and responsibilities have far outstripped our resources. We need to be able to have in place a comprehensive and effective program with sustained funding support, and we will work closely with you, as you move forward with this legislation, so that you understand, as explicitly as possible, what we think are the needs associated with the elements of this legislation.

The CHAIRMAN. Thank you very much.

My time has expired.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman.

I, too, am interested in those cost factors, and I know that the FDA has made significant advances in expanding its workforce, but I think it's still understaffed in a number of areas. The new authorities and requirements in this food safety bill would necessitate adding even more staff. What's being done to ensure sufficient recruitment, training, and retention of food safety employees?

Dr. HAMBURG. This is a very important priority for me, as the new commissioner, of course. And we are working hard to, No. 1, strengthen and restructure our food safety activities within the agency. I've created a new deputy commissioner for food safety, and we're aligning the different components of food safety, that have been spread throughout the agency, into a more integrated organizational structure with more accountability, as well as, hopefully, important synergies.

We have been expanding, in terms of our workforce, over the last couple of years, although, to be honest, it's been a bit of a roller-coaster ride, in that we had had declining resources following the tragedies of 9/11 and the anthrax letters, there was a burst of renewed interest in food safety and new resources, and then those resources started to decline again, so in terms of inspectors and key staff, our numbers have been declining. Over the last couple years, we've had a new investment in this important area. So, we're rebuilding again, training, getting more inspectors out into the field. We're also, as this bill suggests, trying to put in place a new paradigm, which is this focus on prevention, rather than responding to outbreaks. That has also been a major focus of effort, to think about how to best approach that.

And we're spending, also, a lot of time in the field, trying to learn more about the concerns of farmers, big and small, manufacturers, producers, distributors, so that we can shape a program that's truly responsive, and also working with partners at the State and local level and internationally.

Senator ENZI. I'm the accountant, though, so I'm always looking for a little more specificity. I'm curious as to how many people you're short, at the present time, and how many additional people you think will be necessary to do something like this bill.

Dr. HAMBURG. As I said, we will work closely with you, in terms of providing you with the numbers. We are, over the next year or so, expecting to be adding some 350 new people into the food safety program, and about 125-plus of those will be in the field. We expect, with that, to be able to expand the numbers of domestic inspections by about 2,000. Internationally, it will be less, because those are more time-consuming and costly inspections. Also, ramping up our activities at the border will be part of our expanded activities, as well.

Senator ENZI. And that's what you anticipate even before this bill is passed.

Dr. HAMBURG. Yes.

Senator ENZI. OK. Thank you.

You mentioned something about a registration fee. How many total dollars are you trying to raise? And how would you see that broken down among the people that are registering now?

Dr. HAMBURG. All of this does depend on the shape of the legislation that emerges, but we do know that, already, the demands, in terms of the food safety program, far outstrip the resources that we have. And moving forward to take on new responsibilities, it will be essential to have that supported with adequate resources and sustained, predictable funding. So, as I told Chairman Harkin, we will work closely with you and provide, our best numbers and statistics with respect to key personnel, support systems that are needed. We, along with other people, have important investments in IT and other areas, in order to put in place the comprehensive program that's needed. But, we are really eager to work with you. I understand that, actually, our staffs have already been providing considerable technical assistance, and we want to continue that.

Senator ENZI. I'm sure that CBO will need some help along those lines.

Dr. HAMBURG. CBO has the ultimate expertise in costing out a bill. That's not our expertise, that's for sure.

Senator ENZI. I see that my time is expired.

I have a whole lot of other questions. I'll submit those in writing.

Dr. HAMBURG. I apologize for my lengthy answers.

Senator ENZI. Lengthy is not a problem, but I'll have to get lengthy answers on the other questions from you in writing.

Dr. HAMBURG. All right.

The CHAIRMAN. Senator Merkley.

STATEMENT OF SENATOR MERKLEY

Senator MERKLEY. Thank you very much, Mr. Chair.

And thank you for your testimony. I wanted to ask you a little bit about how we can make sure that small farms and organic

farms do not find that they're getting directions from numerous organizations, if you will, as they work to comply with food safety and also comply with organic standards.

Dr. HAMBURG. This is a very important concern, and one that I certainly have heard, and we are trying to be as responsive as possible. You know, farms differ in size. Areas of farming differ in conditions. Strategies of farming differ, as well. We want to be able to produce a system that's responsive to the unique needs and circumstances that are reflected in the diverse array of agricultural types and conditions that exist in our country. We believe that that can be achieved within the approach that's outlined in this legislation.

I have to tell you that I would have been, actually, visiting a farm today, out in California, and my colleague Mike Taylor, who's my senior foods advisor, would have been down in Florida on a farm, as well, but for this hearing. We thought it was important to be here, and we'll reschedule those visits. But, we are trying to work with those communities, understand their issues and concerns, and work flexibility into any guidance and rulemaking that we would pursue, so that we can have a system that works for everyone and ultimately works for the consumers. Because whether you are big or small, organic or not, food safety still has to be the top priority. That's what we're focused on. And we're focused on preventing contamination in the first place, to the greatest degree possible.

Senator MERKLEY. Yes. Thank you.

I'll tell you, as I was doing town halls, through the summer—while healthcare was the dominant issue, in almost every town hall—someone came to me, really concerned about the impact on small farms or on organic farms. There were also a lot of comments—and I've been assured that these are based on misunderstandings of the bill—but, a lot of concerns that roadside stands would be put out of business, farmers' markets would be put out of business, backyard gardens would be put out of business. I just want to give you a chance to put on the record that if, indeed, these are exempted, as I'm sure they are, to hear it from you, and to have it clearly stated.

Dr. HAMBURG. Well, I think that we would be striving, as I said, in our guidance and rulemaking, in all of our activities, to build in flexibility to address those very legitimate questions and concerns. There's a growing interest, as I'm sure you know, in this country, in having access to local foods and the produce from local farms. We want to support people's desire to do so, not hinder it. But, we want to make sure that wherever the food is grown, however it's produced, it meets important standards for safety.

Senator MERKLEY. But, isn't there a specific exemption for direct farm-to-market, where it doesn't go through a food processor, that would take away the concerns of most of the folks who have roadside stands and farmers' markets?

Dr. HAMBURG. I'm getting expert consults, here. I think it's just that this legislation—correct me, if I'm wrong—applies just when food is entered into interstate commerce. So, yes.

Senator MERKLEY. Yes. OK. Folks back home will be glad to hear that.

Thank you very much.

Dr. HAMBURG. Thank you.

The CHAIRMAN. That's an area I've also been interested in. And it is true that the farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment, for whatever that's worth.

Senator Gregg.

Senator GREGG. Thank you, Mr. Chairman.

Doctor, just so it's clarified in my mind, you support this bill, as presented by myself and Senator Durbin, is that correct?

Dr. HAMBURG. Yes. You know, as I indicated in my remarks, there are some areas that I would like to see some strengthening. But, I think it's a terrific and comprehensive approach to a problem that is very pressing and where FDA currently lacks critical authority.

Senator GREGG. Thank you. "Terrific and comprehensive," I like that.

One of the issues that you mentioned and you raise and you redflag for us is this question of the distribution of the trade secrets and commercial processes that are involved. And this is one of those issues where there's just not a good, clear answer, because you've got to balance the importance of getting the information, and using it effectively, with the importance of protecting the information to the entity that has that sort of information, and their view that it may actually affect their capacity to survive in the enterprise. You appreciate that subtlety, I'm sure——

Dr. HAMBURG. Absolutely.

Senator GREGG [continuing]. Or that debate.

I guess my concern is that the House bill, in this area, probably will drive a lot of people to simply not maintain the information, because they'll say, "Oh, we don't want to have that information broadly distributed by the FDA, if they have access to it." So, I do think we have to be careful in that area. Do you understand our concern there?

Dr. HAMBURG. Yes. Of course, the protection of commercial confidential information is very vital to FDA, across a whole range of activities in the drug and medical product area, as well as in the food area. But, we do want to make sure that we can share information with key partners at the State and local level, or at the international level, when we need to respond to an ongoing outbreak in order to rapidly identify a problem——

Senator GREGG. That is critical.

Dr. HAMBURG [continuing]. And contain and control it.

Senator GREGG. I think if we had that sort conditionality on it, that it was an outbreak-related event that was some sort of—so, I would like to suggest that we work on that, because I see that as a tension between the House bill and our bill——

Dr. HAMBURG. Terrific.

Senator GREGG [continuing]. And that we should be able, hopefully—it will be difficult, but I should hope we can get some resolution on it.

Another area where you folks have some concerns, and which raises the issue, is when you can seize. It seems to me, you

shouldn't be able to seize if it's a paper event. You know, in other words, if they fail to have their plan, or they fail to have it appropriately structured, I don't think that should be a seizure event. I think seizure has to be related to—there's a product that's failed, there's a product that's a risk.

Dr. HAMBURG. I think, clearly, we want to target the high public-health impact events. I think the greatest concern with respect to this somewhat arcane distinction between prohibited act and an adulterated product is that we oftentimes do have a real public health obligation to move as swiftly as possible, because a product is in commerce and may be harmful to health. And, in that case, we do not want to have to pursue, through the legal system, permission to act. We feel that we need to swiftly act.

Senator GREGG. I hate to interfere, but my time's limited—I mean, I don't think there's any disagreement there. I mean, if you folks have come to the conclusion there's a risk, obviously there's an event. The question is, if it's just a paper event—you know, if you find they don't have the right paper, we shouldn't have that.

Dr. HAMBURG. I don't think we would be seizing products based on that.

Senator GREGG. If that's your view, then I think we're probably on the same wavelength.

Dr. HAMBURG. Yes.

Senator GREGG. Well, I appreciate your support of the effort here, and I appreciate the great job you folks are doing. Hopefully, we can get this bill passed.

Dr. HAMBURG. Thank you. We certainly appreciate your leadership.

Senator GREGG. Thank you.

The CHAIRMAN. Thank you, Senator Gregg.

Senator Franken.

Senator FRANKEN. Dr. Hamburg, thank you for your work.

What is the cost, in dollars, of unsafe food in this country if you put together all the recalls of food and—which are necessary—the $100 million that was lost by the tomato industry, when it wasn't tomatoes, after all; it was jalapeno peppers; I guess, the billion dollars for the peanut industry; and then, on top of that, all the illness, all the hospitalizations, all the permanent injury that people sustain in illness, and the deaths? Is there a dollar figure for all of that?

Dr. HAMBURG. You know, someone may well have added that all up. I can't give you that number now, but the cost is very high. In some ways, it maybe is almost incalculable, in terms of the preventable deaths and illnesses that have occurred.

But, your point is so important to underscore, in that this is more than just about people getting sick. While that is a huge and overriding concern, it also is about the health of our healthcare system, in terms of preventable costs, and the health of our economy, in terms of important industries that are badly damaged by these unnecessary food outbreaks. And so, there's a compelling reason to act, and act now, in terms of putting in place a program that is sensible and doable, that will, I think, dramatically modernize and transform our food safety system and bring down all of those human and economic costs.

Senator FRANKEN. Because the Chairman brought up the cost of this, in terms of enforcement and all the kinds of things we need to do, and I just hope that people are aware of the cost-benefit analysis of doing the kind of measures that we need to do, in order to ensure food safety, that there is really an economic benefit to it.

Dr. HAMBURG. Absolutely.

Senator FRANKEN. Let me ask you about prosecution of the folks at the Peanut Corporation of America. What happened to them? They just went bankrupt? Is that what they did?

Dr. HAMBURG. Well, I think they did declare bankruptcy, and there is a criminal case that's ongoing.

Senator FRANKEN. Is it a Federal one or a State one?

Dr. HAMBURG. I believe it's both. Thankfully, they are the exception to the rule. Most companies are not at the extreme end that PCA was. We have had a lot of terrific cooperation working with industry when problems emerge. But, PCA was an extraordinarily——

Senator FRANKEN. I just want to make sure that people in this industry know that there is a criminal price to be paid if they withhold information and—the result is, people die—and that they should know—I just want to incentivize good behavior.

Dr. HAMBURG. Right.

Senator FRANKEN. You know what I mean?

Dr. HAMBURG. Indeed.

Senator FRANKEN. And it's important to me that we improve communications between the State and the Federal Government on this and—as well as between, say, the FDA and the CDC. Could you comment on how we can best get all these players to work together to make the most of our investment that we're going to make in this?

Dr. HAMBURG. It is absolutely essential that we have a coordinated, integrated strategy that uses all of the assets and strengths of local and State authorities, along with the FDA and FDA's critical partners at the Federal level, USDA and CDC. I would say that we are experiencing extraordinary cooperation at the present time. I think the President's Food Safety Working Group has been very helpful in bringing together the agencies at the Federal level that have responsibilities for food safety, and coming up with a sort of a coordinated vision and strategy. We are working extremely closely with CDC. Perhaps it helps that the director of the CDC used to work for me. So, we have a good line of communication. But, at every level, we are really embracing this new approach and working very well together.

You'll hear, in the next panel, from a State health authority. But, that partnership is absolutely key, and in terms of our ability to actually fulfill our mandates across the Nation to engage State and local health authorities in doing inspections and providing oversight, in working to assure appropriate safety standards and preventive controls, is vital. So, we——

Senator FRANKEN. Thank you.

Dr. HAMBURG [continuing]. Are working hard. Then, it's a whole other discussion about the needs, in terms of the global world we live in and working with international partners, as well.

Senator FRANKEN. We'll have to have that whole other discussion with some other Senator.

Thank you, Mr. Chairman. My time has run out.

The CHAIRMAN. Thank you, Senator Franken.

Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman.

I want to reiterate both Senator Gregg's point, in terms of seizure, as well as Senator Merkley's point on direct farm to consumer sales. As I understand it, the exemption is if it's within the State. But, if it were interstate transferred from farm to consumer, it would be regulated. Is that correct?

Dr. HAMBURG. Yes.

Senator ISAKSON. OK. Thank you. That's very important in Iowa, when you buy roadside corn when the crop comes in. The same thing in Georgia, when the farmer sells his peanuts or his tomatoes.

On Senator Franken's question—and correct me if I'm wrong, because I may be—but, in the enforcement of FDA violations, the primary enforcement is criminal action, isn't it, like in the PCA's case?

Dr. HAMBURG. There is a continuum. And I would say PCA, was at the extreme end and hardly typical. Criminal actions are not required. In the majority of cases, we work with the companies, after identifying the problem, to get them fixed. There are areas where we need to work with other partners, in terms of enforcement actions. In fact, sometimes State and local authorities actually have stronger enforcement tools than the FDA does. And that's another important part of the partnership, although this legislation would enable us to take on some of those key additional authorities, such as mandatory recall.

Senator ISAKSON. It's also my understanding that, currently and in the past, inspections have generally been made—you'll subcontract with the Department of Agriculture, for example, in Georgia, if you get a complaint on a potential violation at a facility. Is that correct?

Dr. HAMBURG. That's correct.

Senator ISAKSON. I think most of the enforcement is complaint-based, not proactive. One thing this bill will do is expand your ability to be proactive. Is that correct?

Dr. HAMBURG. It will expand our ability to be proactive. It will expand our ability to work with farmers, producers, and manufacturers to prevent problems from occurring in the first place by identifying where are the hazards and how they can best be addressed. And that is very, very important, when you think about the system overall.

Senator ISAKSON. And then, the lesson learned from PCA, there were 12 tests in their files proving positive for salmonella during times in which inspections by the Georgia Department of Agriculture were made, at your request, but because they didn't have access to those files, they couldn't see them. This legislation broadens the ability for that information to be made available, upon request, as long as it doesn't violate the proprietary interest. Is that correct?

Dr. HAMBURG. Yes. And your description of the situation with PCA underscores just why that is so vital.

Senator ISAKSON. Well, thank you very much. I appreciate and look forward to working with you on this legislation.

Dr. HAMBURG. Thank you.

The CHAIRMAN. Senator Hagan.

Senator HAGAN. I will pass on questions, at this time.

The CHAIRMAN. Thank you very much, Senator Hagan.

Dr. Hamburg, thank you very much for being here. We may follow up with some other written questions.

Dr. HAMBURG. Thank you.

The CHAIRMAN. Thank you, Dr. Hamburg.

Dr. HAMBURG. Thank you. I look forward to working with you.

The CHAIRMAN. Same here. Thanks, Dr. Hamburg.

I've just been notified that a vote is likely to begin at 11:50, so we'd like to proceed on to our next panel.

So, we'll call our next panel: Caroline Smith DeWaal, director of the Food Safety Program at the Center for Science and the Public Interest, the leading consumer analyst on food safety reform. In 2002, she coauthored "Is Our Food Safe? A Consumer's Guide to Protecting Your Health and Environment." Also, Tom Stenzel, president and CEO of the United Fresh Produce Association, a leading trade association for the produce industry. Mr. Stenzel has served in several government and industry leadership positions, including as a member of the U.S. Department of Agriculture Fruit and Vegetable Advisory Committee.

Now, I will turn to Senator Isakson for purposes of an introduction.

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

I'm pleased to be able to introduce Michael Roberson of Publix Grocery Stores. I had the privilege, when I served in the Georgia legislature many years ago, of welcoming Publix when they came to Georgia. They're a Southeastern supermarket of outstanding reputation, 12 successive years chosen one of the 100 best companies in America to work for. They employ 20,000 Georgians, have 180 grocery stores, and one them is in my neighborhood, and I shop there every Sunday, when I'm home, with my wife. Dr. Roberson is a graduate of Mississippi State, with a bachelor's degree in microbiology, but a master's degree from the College of Veterinary Medicine in Michigan State University in food safety and food products. He's on every possible national and international board on food safety that you could want. He'll be an outstanding person to testify. And if anything, we always need an Eagle Scout, and he's an Eagle Scout. So, when it comes to food safety, we need all the Eagle Scouts we can get.

I want to welcome Mr. Roberson and praise the Publix company for the great work they do in the Southeast, and particularly in my State of Georgia.

The CHAIRMAN. Thank you very much, Senator Isakson.

Now I'll turn to Senator Hagan also for the purposes of an introduction.

Senator HAGAN. Thank you, Mr. Chairman.

Before I introduce Mr. Ragan, I want to also welcome Mr. Roberson. My family lives in Lakeland, FL. Publix is a wonderful corporate entity in that community. So, thank you.

But, I do want to introduce Dan Ragan—Mr. Ragan. It's my pleasure to introduce him, today. Dan is the director of the North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division. Dan is a registered pharmacist who has worked for the Department for almost 10 years. Since January, he has served as an assistant director of the Food and Drug Protection Division, and prior to that, he was an administrator of North Carolina's Drug Protection Program. He grew up in Raleigh, NC, and received his undergraduate degree in animal science from one of our fabulous universities, NC State, in 1978. He graduated from pharmacy school in 1982, from another great university, the University of North Carolina at Chapel Hill, before opening his own practice in 1987. He has run multiple retail pharmacy operations, as well as worked as a consultant in long-term care pharmacy operations.

Dan, welcome, and we certainly do look forward to hearing from you and having you here, today. Thank you for coming.

The CHAIRMAN. Well, thank you very much, Senator Hagan.

We'll just proceed now. Again, your statements will all be made a part of the record in their entirety.

What we'd like to do is, I'll just go from left to right, start with Ms. DeWaal and we'll go through. And if you could summarize in 5 minutes or so, I would be deeply appreciative.

Ms. DeWaal, welcome. I was going to say welcome back to this committee, but I guess the last time you testified before me was on the Agriculture Committee, on the same subject, earlier this year. Welcome to this committee, Ms. DeWaal, and please proceed.

STATEMENT OF CAROLINE SMITH DeWAAL, DIRECTOR OF FOOD POLICY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, WASHINGTON, DC

Ms. DEWAAL. Thank you very much, Senator Harkin. And thank you and Senator Enzi for holding this hearing. I think it's a very important morning for food safety in the beginning of a modern system.

I also want to thank Senators Durbin and Gregg, and many others, for cosponsoring the legislation, and also Commissioner Hamburg, for her leadership in this area.

CSPI represents over 900,000 consumers, but I'm here today on behalf of a larger coalition of consumer organizations. And we want to explain to you that, in fact, the people who really pay for an unsafe food supply are the consumers who must rely on it every day.

Let me tell you about one consumer. Michael Thomas was 50 years old when he became a victim of tainted peanut butter. Michael loved peanut butter and had a spotless health history. Unfortunately, he ate some of the salmonella-contaminated peanut butter, and the consequences for him and his whole life and his family were very severe. Michael spent weeks in and out of emergency rooms. He suffered from dehydration, stomach pains, and high blood pressure. His right eye hemorrhaged. And harm extended to his heart, his nervous system, and intestines. This previously

healthy man spent over 5 months bedridden. He lost his job. He lacked insurance at the time, so he paid out-of-pocket for the medical bills. He ended up losing his house. He now lives with his family, his grown children. But, Michael was lucky enough to survive.

I noticed many of the Senators today mentioned the Almer family and the Donnelly family and other families who haven't been so lucky. But, Michael was truly shocked when the peanut butter outbreak happened all over again to a new group of consumers. He was a victim of the 2007 peanut butter outbreak, an outbreak which, if it had been listened to—and acted on—could have prevented the 2009 outbreak which, as you know, Senator, killed nine people.

Consumers will continue to be the unwilling victims of our Nation's food safety system until Congress acts to fix it. Successive outbreaks caused by numerous healthy foods, things like spinach, lettuce, tomatoes, peppers, alfalfa sprouts, things we all should be eating every day, and even such treats as ice creams and cookie dough, have caused a steep decline in consumer confidence in the food supply.

Reform of the food system is long overdue. We've already talked about the estimates of illnesses—76 million cases of illness, 325,000 hospitalizations—but, these are all preventable. Economists—Senator Franken asked already about what is the true cost—well, economists estimate that with the emergency room visits, the hospitalizations, and the lost work, the costs can be $40 billion to over $100 billion. Even if these numbers were cut in half, Senator, they're still too large. These can be prevented.

While each story is tragic, there is good news, too. This is an area where the public really understands that the government plays a vital role in protecting them and their families. In a recent poll, 9 out of 10 American voters said that they support the Federal Government adopting new safety measures, including individual measures that are included in Senate 510. Things like requiring foreign countries to certify that their food safety systems are as strong as ours, requiring tracing systems to trace food back to the source, mandating government inspections of high-risk food plants, requiring food companies to test for contamination and to report those tests to the government, requiring produce standard—growers to meet standards, and also mandatory food recalls.

Overall, we believe S. 510 is a strong food safety bill. But, we do recommend a few minor changes to the bill in the areas of the risk-based inspections system, mandating testing, making that a more clear part of the bill, and also strengthening the import provisions.

I'd like to thank you for inviting me here today to discuss S. 510 and for the movement in your committee of addressing this important issue. We believe that food safety, as demonstrated here today, is truly a bipartisan measure and one that is supported by the interests here today before you, as well as voters all over the country. Though the year is fast drawing to a close, we believe that you do have time and you can make the time to address this.

And truly, as Mike Thomas' story reminds us, failing to pass meaningful food safety legislation now is like setting the table for the next outbreak.

Thank you, Senator Harkin.

[The prepared statement of Ms. DeWaal follows:]

PREPARED STATEMENT OF CAROLINE SMITH DEWAAL[1]

Good morning Mr. Chairman, Ranking Member Enzi and members of the committee. My name is Caroline Smith DeWaal. I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 950,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

CSPI works closely with the Make Our Food Safe Coalition that supports passage of food safety reform legislation in Congress. The coalition includes groups formed by and representing the victims of food borne illness, like Safe Tables Our Priority and the Center for Foodborne Illness Research and Prevention; broad-based consumer organizations, like Consumers Union and the National Consumers League; public health groups like the American Public Health Association and the Trust for America's Health; and it is coordinated by The Pew Charitable Trusts and the Consumer Federation of America.

NOW IS THE TIME TO REPAIR OUR FOOD SAFETY SYSTEM

Thank you for asking me here today to discuss S. 510, the FDA Food Safety Modernization Act. The American public cannot wait any longer for solutions to address a seriously broken food safety system. Successive outbreaks caused by numerous healthy foods like spinach, lettuce, tomatoes, peppers, alfalfa sprouts, and even such treats as ice cream and cookie dough[2] have demonstrated that our 100-year-old legal foundation and outdated strategies are inadequate to protect our citizens.

Reform of the food safety system is overdue. CDC estimates that foodborne diseases cause 76 million illnesses, 325,000 hospitalizations and 5,000 deaths annually. Economists believe that these illnesses pose a huge burden to society, with estimates for emergency room visits, hospitalizations, and lost work ranging from $40 billion to well over $100 billion annually.[3] [4] Even if these numbers were cut in half, they are still too high. These are illnesses and deaths that are largely preventable.

Foodborne illnesses are most severe for the elderly, the very young, pregnant women, and immunocompromised people, and some illnesses lead to chronic medical conditions. Unfortunately, some outbreaks cause consumers to stop buying healthy foods, a fact demonstrated by depressed spinach sales after the 2006 outbreak.[5] Consumer confidence in the safety of food has declined in recent years due to the steady parade of outbreaks.[6]

Outbreaks are the result of an antiquated legal system that ties the hands of FDA when seeking food safety information from plants and limits the effectiveness of the agency to enforce the laws. The FDA operates under a number of laws that are 50 to 100 years old: the Federal Food and Drug Act of 1906,[7] which focused on dangerous chemical preservatives; the Federal Food, Drug, and Cosmetic Act of 1938,[8] which addressed economic adulteration of food and provided authority to set food standards and inspect factories; and the Public Health Service Act of 1944, which gave the agency authority to prevent communicable diseases transmitted in food.[9] Food additive and pesticides laws gave FDA additional authorities in the 1950s.[10] None of these was designed to address microbial hazards or emerging technologies.

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[1] The following members of the Safe Food Coalition and the MakeOurFoodSafe.org Campaign join in supporting this testimony: Center for Foodborne Illness Research and Prevention, Consumer Federation of America, Consumers Union, Food and Water Watch, National Consumers League, S.T.O.P.—Safe Tables Our Priority, and Trust for America's Health.

[2] Details of these outbreaks are listed on the Center for Science in the Public Interest *Outbreaks & Recalls* Web site at *http://www.cspinet.org/foodsafety/outbreak_report.html*.

[3] Trust for America's Health, *Fixing Food Safety: Supply from Farm-to-Fork*, Apr 30, 2008, at *http://healthyamericans.org/reports/foodsafety08/FoodSafety08.pdf*.

[4] Roberts, Tanya (2007) "The Economic Costs of Long-term Sequellae of Selected Foodborne Pathogens," Invited Speech, International Association of Food Protection, Orlando, FL.

[5] 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*m.

[6] Thompson West Research, *Consumers Worried About Product Safety*, Dec. 18, 2007, at *http://west.thomson.com/news/releases/productsafety.aspx*.

[7] Federal Food and Drugs Act of 1906, Pub. L. 59–384 § 34 Stat. 768 (1906).

[8] Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 301.

[9] Public Health Service Act 42 U.S.C. § 264.

[10] E.g. Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 409, "The Delaney Clause".

Within this legal structure, the agency has developed regulations to cope with the need for new oversight for modern hazards. In the 1990s, the agency adopted regulations that put seafood and juice industries under mandatory Hazard Analysis and Critical Control Point (HACCP) programs. After a long hiatus, the agency recently adopted a new regulation covering egg safety at the production level.[11] But the agency's approach of developing regulations food-by-food is proving brutally inefficient to protect the public. By the time one food is covered, the next problem has already emerged.

CONSEQUENCES OF BROKEN FOOD SAFETY SYSTEM FALL ON THE CONSUMER

Those who pay the price for the antiquated legal and regulatory system are the consumers who must rely on it daily. Let me tell you about one consumer, a member of Safe Tables Our Priority. Michael Thomas was 50 years old when he became a victim of tainted peanut butter. Michael loved peanut butter and had a spotless health history. A father of four and grandfather of 20, Michael was known for his love of peanut butter. It was so well known that his own father called to warn him when he heard media reports about a peanut butter recall. Unfortunately, Michael had already eaten some of the *Salmonella*-contaminated product—and the consequences were severe, leading to reactive arthritis.

Michael spent weeks in and out of emergency rooms, suffering from dehydration, stomach pains, and high blood pressure. His right eye hemorrhaged. He was treated for nervous system damage, and damage to his heart, eyes, intestines, shoulders, and arms. This previously healthy man spent over 5 months bedridden. And because he lacked insurance at the time, he spent thousands on medical bills and lost his house due to the financial toll of his illness.

But Michael was lucky enough to survive, only to be shocked and outraged when it happened all over again this year. Michael was a victim of the *2007*-tainted peanut butter outbreak, but when he heard of the 2009 outbreak—which sickened hundreds and killed at least nine people—he couldn't believe it. In a 2009 letter describing his experience with foodborne illness, Michael says,

> "I did take some comfort in the belief after it happened to me that the system was fixed and would not happen to any more families . . . but here we are once again, literally right down the road from that very same plant I was poisoned from, with exactly the same situation, but even more widespread than it was before."

Just as Michael's 2007 experience was revisited in 2009, there is no question it will happen again—this year or next, from this product or another. Consumers will continue to be unwilling victims, until the system is fixed.

THE PUBLIC IS READY FOR CONGRESS TO ADDRESS FOOD SAFETY

The stories of outbreaks and recalls over the last few years are tragic, and they have had a huge impact on consumer confidence in the safety of the food supply. But there is good news too. This is an area where the public understands that government plays a vital role in protecting them and their families.

In a poll on Americans' Attitudes on Food Safety,[12] commissioned by The Pew Charitable Trusts and conducted by Hart Research/Public Opinion Strategies, 9 out of 10 American voters support the Federal Government adopting new safety measures,[13] including the following individual measures:

- 92 percent support requiring **foreign countries** that export to the United States to certify that their food safety systems are as strong as ours;
- 94 percent support requiring **tracing systems** that enable the FDA to trace food back to its source;

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[11] Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule. 74 Fed. Reg. 33,030 (July 9, 2009).

[12] These findings are derived from a nationwide survey of 1,005 registered voters, conducted June 29 through July 3, 2009, by Hart Research Associates (D) and Public Opinion Strategies (R) on behalf of the Pew Charitable Trusts and the Produce Safety Project. Respondents were reached by telephone through a random-digit dial method of sampling. The results of the poll are statistically representative of the opinions of voters across the country, and carry a margin of error of ±3.1 percentage points for the full sample, and higher margins of error for subgroups of the sample.

[13] According to the polling firms, support crossed gender, age, economic, and even partisan lines—96 percent of Democrats, 88 percent of independents, and 83 percent of Republicans said they supported the need for food safety legislation.

• 91 percent support annual or semi-annual government **inspections of facilities** that process food that is at a high risk of contamination, including 75 percent who strongly favor this;
• 92 percent support requiring food companies to **test for contamination and report** results to the government;
• 90 percent support requiring **produce growers to meet standards** for water quality, manure use, and worker sanitation; and
• 89 percent support giving the FDA authority to issue **mandatory food recalls**.

Since 2007, Congress has conducted 28 oversight and legislative hearings on food safety. These hearings often discussed the painstaking investigations by Members of Congress and their staff of diverse outbreaks such as spinach tainted with *E. coli O15*7:H7, peanut butter contaminated with *Salmonella*, and pet food adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers' processes and in the Food and Drug Administration's oversight. With evidence of both unintentional and intentional contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has highlighted the inadequate state of our food regulatory system and placed food safety in its high risk category 3 years in a row.[14]

The evidence that FDA reform is needed has been made crystal clear in congressional hearings, victims' stories, and voter polling. In addition, I think you will hear today that there is widespread consensus among a broad range of stakeholders that the time for passing this reform is now.

SAFETY MUST BE BUILT INTO THE FOOD SUPPLY SYSTEM

The heart of any effective reform effort lies in prevention, not reaction. Congress should require every food processor regulated by FDA to have a food safety plan detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. These hazard analysis and preventive control plans are already required for all meat and poultry plants,[15] and such plans should be a prerequisite for all food processors that want to sell food in the United States.

Prevention is our first line of defense when it comes to food safety. The Senate legislation establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for government inspections. However, the history of these programs where they have been implemented by FDA, such as in the seafood area, demonstrates that Congress must also give FDA the authority and funding to enforce compliance through regular inspections and access to company records.

Additionally, FDA needs the authority to set performance standards for the most hazardous pathogens and to require food processors to meet those standards. The standards are used to ensure that food is produced in a manner that limits the likelihood of contamination by pathogens, chemicals, or physical hazards. Most importantly, performance standards set a level-playing field for the industry. Companies know in advance what standards will be enforced for their industry and products.

With mandatory food-safety planning combined with performance standards, the government can focus on more effective government oversight through frequent inspections, with analysis of records and laboratory test results.

S. 510, the FDA Food Safety Modernization Act, contains these essential elements. But a few elements should be strengthened to ensure that FDA can prevent many future outbreaks and address the other hazards that can impact so many consumers.

EFFECTIVE FEDERAL OVERSIGHT IS NEEDED TO ENSURE COMPLIANCE

S. 510 is built on the framework of existing HACCP regulations adopted by the Food and Drug Administration. While this foundation mandates the actions that the industry itself is responsible for, it lacks similar specifics in describing the government's oversight and responsibilities. On behalf of the Make Our Food Safe Coalition, we would like to propose three changes that would strengthen S. 510:

Recommendation 1: Risk-Based Inspection and Inspection Frequency

We believe it is critical to establish categories of risk to ensure that FDA will establish meaningful schedules of inspection. To be adequate, the statutory provisions on Federal inspection should do three things:

[14] Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO–09–271, Jan. 2009.
[15] Hazard Analysis and Critical Control Point (HACCP) Systems, 9 CFR § 417 (2009).

• Establish a minimum of three risk categories;
• Set inspection frequencies based on these categories, with the minimum frequency of once every 6 to 12 months for high-risk facilities; and
• Prohibit FDA from using certification by a private entity as a factor in setting the frequency of Federal inspection for a domestic facility.

Recommendation 2: Testing and Reporting Requirements, Affirmative Reporting of Positive Test Results

In order for a system based on preventive controls to be truly effective, food companies must be required to test for the types of contamination most common in their (or similar) products to determine whether their systems are actually working. We recommend that you strengthen the testing and reporting requirements of S. 510 by adopting requirements that:

• A facility conduct testing as a verification step in its preventive control plan; and
• Facilities report promptly to FDA any positive results from its testing program.

Recommendation 3: Imports and Imported Produce

Imports of FDA-regulated foods present many difficulties for the agency, simply because of the current number of suppliers and the volume of imports. We generally support the language in S. 510 on imports, which provides for certification of food facilities that import food products. The language should be strengthened by:

• Requiring government-to-government certification for high-risk foods;
• Clarifying that FDA has the principle responsibility for accrediting the import programs of foreign governments;
• Clarifying that private accrediting bodies must be under strict FDA oversight, and FDA should be notified of all actions they take regarding the agents they accredit; and
• Adding language requiring FDA to set up a system for determining whether standards for imported produce are at least equal to standards applicable to such commodities produced in the United States.

Finally, I would like to highlight that FDA and State inspectors are also hampered in conducting inspections by restricted access to plant records that could help identify problems before they erupt into an outbreak. As the committee may recall, FDA had to invoke the Bioterrorism Act to obtain records from Peanut Corporation of America of 12 tests that were positive for *Salmonella* in the year and a half leading up to the outbreak.[16] Food companies can refuse to disclose records to inspectors unless the FDA has a reasonable belief the food is adulterated, presents a risk of serious adverse health consequences or death, and the inspector presents a written demand.[17] We saw this same situation play out in the 2007 Peter Pan peanut butter outbreak where, had inspectors been given access to test records, they would have been alerted to the plant's test results for Salmonella.[18] To fix this, the law needs to be changed so that inspectors can access records that may allow them to prevent outbreaks. Meanwhile, the ability to access all food safety documentation during inspections is an essential tool to verify that control systems are present, maintained and operating properly.

S. 510, THE FDA FOOD SAFETY MODERNIZATION ACT

Both the House-passed bill and the one under consideration in this committee share many similarities: processors must re-register periodically, implement food safety plans, meet performance standards, and administer programs to verify the food they import complies with U.S. law. In addition, FDA must conduct risk-based inspections and can require high-risk imported food to be certified as complying with U.S. law. Lastly, FDA can order a recall of food likely to cause serious illness or death.

There are numerous points of agreement when it comes to food safety reform packages being considered in Congress. We were very pleased to see the bipartisan consensus that emerged for H.R. 2749, which passed the House on July 30, 2009, with a vote of 283–142. We believe that food safety is truly a bipartisan measure

[16] See, *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply:* Hearing before the House Subcommittee on Oversight and Investigations, 111th Cong. (2009) (October 6, 2008 e-mail from Stewart Parnell to Sammy Lightsey).
[17] 21 U.S.C. § 374(a)(1)(B); FDA, Regulatory Procedures Manual 2008, § 10–4–3.
[18] Two years before the outbreak, the plant manager refused an oral request from FDA inspectors to see company records of a positive *Salmonella* test telling them they would need a written request. 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*.

that can be passed this year. It is strongly supported by voters all over the country. And truly, as Mike Thomas' story reminds us, if we don't act now, the next outbreak may be even more serious.

CONCLUSION

Now is the time for Congress to fundamentally reform our food safety system. The year is fast drawing to a close, but enactment by the end of this year should be the goal. Two years ago, Congress expressed its commitment to adopt a modern regulatory oversight program at FDA and fund it adequately to fulfill its mission.[19] Congress has increased the FDA food budget by 50 percent in that period, which lays the ground work for this legislation. Bipartisan legislation has already passed the House of Representatives.[20] That spirit of compromise has also infected the groups you see before you who have formed make-shift alliances to help deliver the message that reform is urgently needed. It is rare to see the level of consensus reflected among such diverse consumer and industry organizations on the need to fix our national food safety system. The public debate has defined the issues and we have a consensus for action. Congress can, with simple changes, take action this year to make food safer for American consumers. I urge you to act. There is no reason to delay.

The CHAIRMAN. Thank you, again, Ms. DeWaal, for your statement.

Mr. Roberson, welcome. Again, if you could summarize in 5 minutes we'd sure appreciate it.

Thank you.

STATEMENT OF MICHAEL ROBERSON, FOOD MARKETING INSTITUTE, ARLINGTON, VA

Mr. ROBERSON. Thank you. Chairman Harkin, Ranking Member Enzi, and Members of the HELP Committee, I'm honored to represent the Food Marketing Institute to present testimony on S. 510, the FDA Food Safety Modernization Act.

I ask that my written testimony be submitted for the record.

My name is Michael Roberson, director of corporate quality assurance with Publix supermarkets of Lakeland, FL. I hold a bachelor's of science degree in microbiology from Mississippi State University and a master's in food safety from the College of Veterinary Medicine at Michigan State University. This provides me with the understanding of the microbial hazards associated with food.

Publix is owned and operated by 140,000 associates, with 2008 sales of $23.9 billion. Currently, Publix has 1,014 stores in Florida, Georgia, South Carolina, Alabama, and Tennessee, with multiple food manufacturing facilities. FMI is a national trade association that has 1,500 member companies made up of food retailers, wholesalers in the United States, accounting for three-quarters of all retail food store sales.

The most important goal of all food retailers and wholesalers is to ensure that the food we sell is as safe as possible. To achieve this goal, supermarkets have many prevention programs in place to protect our customers. These include employee food safety training, extensive sanitation programs, food safety management systems, consumer education, and supplier control programs.

Regrettably, recent food safety system failures have revealed weaknesses that highlight the need to update our food safety laws.

[19] Food and Drug Administration Amendments Act of 2007, Pub. L. 110–85 § 1005, 121 Stat. 823, (2007).

[20] H.R. 2749, the Food Safety Enhancement Act, passed July 30, 2009, by a vote of 283–142.

As the purchasing agent for the consumer, and the final link in the supply chain, our industry understands, it is vital that the FDA has the necessary authority, credibility, and resources to meet the challenges of today's global marketplace.

Mr. Chairman, I applaud you, Mr. Enzi, and all the members of the committee, for your commitment to improve food safety.

I'd like to turn to S. 510, a bipartisan bill, introduced by Senator Durbin and cosponsored by your HELP Committee colleagues, Senators Dodd, Gregg, Alexander, and Burr, and Isakson.

Food safety is a shared responsibility. We must improve the collaboration among all stakeholders, including government and industry. Many of the proposals in S. 510 are consistent with our approach by enhancing prevention and the tools available for intervention and response.

We support the requirement that every registered facility have a hazard analysis and risk-based preventive control plan. The appropriate development and the use of a food safety plan goes a long way toward developing a culture within a company that is critical to ensuring food safety.

We support the development of standards for produce safety. We believe that standards can be designed to accommodate any size farm. Publix expects all suppliers of fresh produce to maintain a food safety compliance program to address the management of good agricultural practices and minimize the microbial hazards associated with produce.

We support the targeting of inspection records based on risk. We would encourage FDA to partner with State and local officials. We would also encourage that the FDA develop a separate classification for warehouse facilities that only holds foods that are not exposed to the environment, as is allowed in section 103.

We support enhancing trace-back requirements—specifically, the legislation's establishment of pilot projects. Our industry recognizes that current traceability systems are not uniformly meeting the needs of the industry, the consumer, and the government. We understand that there will be technical challenges and significant costs associated with the implementation of traceability throughout the supply chain's infrastructure. That is why we see the pilot project approach as being critical.

We support the mandatory recall provisions and the procedural limits in the bill. In 2007, the FMI board of directors adopted a policy urging Congress to grant FDA mandatory recall authority. We support the requirement for FDA to notify the public about a recall, but recommend that Congress direct FDA to use the most specific information available.

We support the legislation's recognition of voluntary certification by accredited third-party auditors. Properly constructed third-party certification program can offer rigorous, objective evaluations of a manufacturer's food safety programs.

Certification audits often exceed the legal requirements for food safety standards. These programs should not replace government oversight or attempt to deputize the private sector auditors as an enforcement arm of FDA. Certification audits are different than both a governmental inspection and noncertification audit. During

a third-party certification audit, the auditor is measuring how the company manages food safety as part of its regular operations.

We would also encourage that the committee further amend this section to ensure that all terminology is consistent with internationally recognized language and terms, such as those used by the Global Food Safety Initiative.

Together, we believe that these provisions, along with those highlighted in my written statement, will help restore confidence in our Nation's food supply.

Mr. Chairman, we appreciate the opportunity to testify, and the efforts of this committee.

I look forward to your questions and will remain available for further discussion and information, should you need it.

[The prepared statement of Mr. Roberson follows:]

PREPARED STATEMENT OF MICHAEL ROBERSON

Chairman Harkin, Ranking Member Enzi and Members of the HELP Committee, I am honored to appear before you today on behalf of the Food Marketing Institute (FMI) to present our views and suggestions on helping protect our food supply and on S. 510, the FDA Food Safety Modernization Act. FMI and its member companies share the common goal of enacting legislation this year that will have a genuine and positive impact on our food safety system.

I am Michael Roberson, the Director of Corporate Quality Assurance with Publix Super Markets, Inc. of Lakeland, FL. I lead a team of dedicated professionals responsible for food safety and quality assurance systems throughout Publix and our integrated chain of manufacturing, distribution, and retail food stores. With a B.S. degree in Microbiology from Mississippi State University, and a M.S. in Food Safety from the College of Veterinary Medicine at Michigan State University, I possess a technical background and a thorough understanding of the microbial hazards associated with food and factors most frequently implicated in food-borne disease.

Publix is privately owned and operated by its 140,000 employees, with 2008 sales of $23.9 billion. Currently, Publix has 1,013 stores in Florida, Georgia, South Carolina, Alabama and Tennessee and five separate food manufacturing facilities. The company has been named one of FORTUNE's "100 Best Companies to Work for in America" for 12 consecutive years. In addition, Publix's dedication to superior quality and customer service is recognized as tops in the grocery business, most recently by an American Customer Satisfaction Index survey.

Today I am representing FMI, a national trade association that has 1,500 member companies made up of food retailers and wholesalers in the United States and around the world. FMI members operate approximately 26,000 retail food stores with combined annual sales of roughly $400 billion, representing three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of national and regional chains as well as independent grocery stores.

The American consumer has access to a selection of products in the grocery store that is unmatched. Our customers have products available to them everyday that are grown and made not only in the United States, but throughout the world. As a result, fresh fruits and vegetables are available for purchase year round and fresh seafood can be found in the middle of our country far from any ocean. The average grocery store has about 47,000 individual items on its shelves, with large supermarkets having over 100,000 items for sale. Regardless of the number of items in a store though, the most important goal of food retailers and wholesalers is to ensure that the food we sell is as safe as possible and of the highest quality possible.

Regrettably, high profile food safety outbreaks and recalls involving tomatoes, jalapeños, peanuts and pistachios have not only made headlines, but have caused illness and in some cases even death. While the causes of these problems were the result of poor food safety practices—and in some cases possibly criminal actions—they did reveal weaknesses in the existing food safety system and highlighted the need to update the laws and culture necessary to adequately protect our food supply. As the purchasing agent for the consumer and the final link in the supply chain, our industry understands that it is vital to ensure that the FDA has the necessary authority, credibility and resources to meet the challenges of today's global marketplace.

As this process moves forward, consumer confidence is an essential factor in this debate. Food safety issues can be extremely complex and consumers vary greatly in

their knowledge of the science and other issues affecting the safety of our food supply. However, as food safety issues draw national headlines, consumer awareness as well as concern about the safety of commercially prepared foods and products purchased at the supermarket heightens. As a result, shoppers may quickly alter purchasing decisions and will even go as far as avoiding an entire product category if they are not confident of its safety.

In FMI's annual survey of consumers, U.S. Grocery Shopper Trends report (Trends), 83 percent of shoppers say that they are either somewhat or very confident in the safety of food in the supermarket. However, the vulnerability of consumer confidence is illustrated by the high percentage of shoppers who are only "somewhat" confident at 72 percent compared to those that are "very" confident at 11 percent. We believe that strengthening consumer confidence is the responsibility of both private industry and the government working together.

At the retail level, supermarkets have many prevention programs currently in place to protect our customers, including consumer education campaigns, employee food safety training, extensive sanitation programs, food safety management systems, and programs that involve working closely with our suppliers, especially those beyond our borders. I would like to share with the committee some programs utilized by Publix and by many other companies in the food industry at both the retail and manufacturing levels to help ensure the safety of the products on our shelves.

Publix is committed to working with the supplier community, including our own manufacturing plants, to constantly improve the safety of the food they manufacture and process, and to this end participates in the Safe Quality Food (SQF) Program. SQF provides independent certification that Publix's suppliers' food safety and quality management systems comply with domestic and international food safety regulations. Recognized by the Global Food Safety Initiative (GFSI), accredited third party certification programs, such as SQF, are objective, independent bodies that are highly qualified to help enable suppliers to assure their customers that food has been produced, processed, prepared and handled according to the highest possible standards, which meet or exceed the standards set by the U.S. Government. Publix has chosen to use GFSI recognized accredited third party certification programs like SQF because they represent the cultural change that is needed in our food safety system. It provides an additional layer of review above anything that is required by local, State or Federal Government and helps ensure our brand of integrity and the protection of our consumer.

Within the domestic retail setting, training store managers and workers in food safety is an important tool for protecting public health. Currently, Publix makes extensive use of the SuperSafeMark program to train and certify our retail management associates on the importance of food safety. SuperSafeMark is the most comprehensive food safety and sanitation instruction and certification program ever offered to food retail employees. This program includes methods for combating foodborne illness with time and temperature controls, measures to prevent cross contamination, and programs for personal hygiene, and cleaning and sanitizing best practices.

When a problem is identified, we take immediate action and remove the recalled product from the distribution chain and retail shelves as quickly as possible. To help assist in the process, the food retail and manufacturing community collaborated and developed the *Rapid Recall Exchange*, an online resource that includes a secure and automated alert system allowing suppliers to send information to retailers and wholesalers about products that must be recalled and to do so rapidly and accurately in a standardized form 24 hours a day, 7 days a week. The *Exchange* has recently been introduced and we are encouraged that it will prove to be a useful tool to our industry.

The final link in the supply chain is the consumer. Publix has long provided our customers with practical, science-based guidance on safe food handling at home through the Partnership for Food Safety Education. The Partnership brings together consumer advocacy groups, the FDA, U.S. Department of Agriculture, Centers for Disease Control and Prevention, national industry associations and health and scientific groups. FMI President and CEO Leslie Sarasin is the current chairman of the Partnership's Board.

The Partnership created the award-winning "Fight BAC!" education program to teach children about food safety as part of their school curriculum. The Partnership's "BAC Down!" program urges consumers to use thermometers to ensure their refrigerators remain at safe temperature levels—no higher than 40 degrees F. Most recently, the Partnership launched the "Be Food Safe" campaign in cooperation with USDA to provide retailers with a wide range of resources to educate their customers about safe food practices. The campaign encourages the use of colorful, modular

icons and photography to illustrate the basic and most important safe food-handling practices:

- Clean—Wash hands and surfaces often.
- Separate—Do not cross-contaminate foods.
- Cook—Heat foods to proper temperatures.
- Chill—Refrigerate foods promptly.

All of these prevention programs at the retail level cannot ensure that we deliver safe food to our customers if the food coming into our stores isn't already produced and processed to the highest standards. While the entire food industry continues to work together in developing stronger and innovative food safety programs, FMI and its members recognize the crucial and evolving role for government to play in assuring the safety of our food supply.

Mr. Chairman, I applaud you, Mr. Enzi and all the members of the committee for your commitment to improving our food safety system by holding this hearing and exploring the ways to achieve this common goal. I would like to specifically comment on S. 510, the FDA Food Safety Modernization Act introduced by Senator Durbin and cosponsored by a diverse bipartisan group, including your HELP Committee colleagues, Senators Dodd, Gregg, Alexander, Burr, and Isakson. Upon its introduction FMI sent a letter to Senator Durbin expressing support [1] for his bipartisan effort and the legislation's recognition that all points in the supply chain play an important role in food safety which we would like to include in the record.

Many of the proposals in S. 510 are consistent with our approach to improving the food safety system by emphasizing the need to have preventive measures as the foundation on which any food safety system should be built. The bill also recognizes that we need to focus the majority of our resources on facilities and products that pose the greatest risk of contamination that could result in food-borne illness or injury. We must continue to be sure that any changes meet certain criteria:

- Be supported by science;
- Have measurable benefits;
- Be affordable;
- Be realistic; and
- Be implemented without unintended consequences.

It is also imperative that mitigating risk is the guiding principle for changes and that our focus is on actions that will have the greatest impact in reducing food-borne illness. There are many policy initiatives in the legislation that we support because of their clear focus on preventive measures.

TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

Sec. 103. Hazard Analysis and Risk-Based Preventive Controls

We support the requirement that every registered food facility design, conduct and maintain an evaluation of food safety risks in their business that identifies potential sources of contamination, identifies appropriate food safety controls, and documents those controls in a food safety plan. The correct development and use of a food safety plan goes a long way toward developing a culture within the company that is critical to ensuring food safety. We commend the legislation for recognizing the low-risk nature of warehouse facilities that store packaged food that is not exposed to the environment by allowing the Secretary to modify the requirements for these facilities.

At Publix, the food safety systems designed in our manufacturing operations have redundant food safety control processes. This begins with ingredient suppliers. Prior to producing new product, the food safety requirements and ingredient controls are verified. Pre-requisite food safety programs along with cleaning and sanitation elements lead into the Hazard Analysis and Critical Control Points (HACCP) food safety system. We recognize the importance of a quality-first food safety system and understand that food safety is everyone's mutual responsibility.

Sec. 105. Standards for Produce Safety

We support directing FDA, in consultation with USDA and State departments of agriculture, to establish science-based standards for the safe production and harvesting of fruits and vegetables. Publix expects all suppliers of fresh produce to maintain strong food safety compliance programs to address the management of Good Agricultural Practices (GAPs) and minimize the microbial hazards associated with fruits and vegetables. Recent industry best practices guidance has been developed for fresh leafy greens, melons, and tomatoes. We support these collaborative

[1] FMI Letter to Senator Durbin March 2, 2009.

efforts to improve food safety associated with fresh produce and believe standards can be designed that can be implemented on any size farm.

TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

Sec. 201. Targeting Inspection Resources

We support directing FDA to allocate limited inspection resources depending on the "risk profile of the facility." The risk of food-borne illness and contamination varies greatly depending on the type of product that the facility produces. For example, at Publix one manufacturing facility may produce bottled water while a different facility produces spinach and artichoke dip. Understandably, the spinach and artichoke dip is comprised of many additional ingredients, requires refrigeration control, and would be considered a food with greater risks than bottled water. We would also encourage that FDA be allowed to develop a separate classification for warehouse facilities that only hold foods that are not exposed to the environment as is allowed in Section 103.

In addition, we would encourage FDA be directed to consider the inspections performed by State and local officials. Our retail stores are inspected by State departments of agriculture and local health departments. Our manufacturing facilities and distribution centers are inspected by the USDA, FDA, and State departments of agriculture. With proper training and coordination, we believe that State and local inspections should assist FDA with its responsibilities in a cost-effective and efficient manner.

Sec. 204. Enhancing Traceback and Recordkeeping

We support the legislation's establishment of pilot projects to test and evaluate new methods for rapidly and effectively tracking fruits and vegetables. Our industry recognizes that current traceability systems are not uniformly meeting the needs of industry, the consumer, and government. Enhancing systems that will help minimize the time required to identify, isolate and remove product that may cause injury, illness or adverse health consequences is the most important goal of a traceability system.

Moving forward, this is not a static process as technology improvements that may revise procedures both on the information side and the food processing side are constantly being updated. Improving traceability is a long term commitment among all commodity groups. The food industry has proactively undertaken a number of strong pilot projects addressing the unique needs of a particular product or industry that are already resulting in improvements in best practices. We understand there will be technical challenges and significant costs associated with the implementation of traceability throughout the supply chain's infrastructure and that is why we see the pilot approach as being critical to developing best practices. Collaboration with FDA is necessary to ensure that industry initiatives will better assist in the event of a food safety outbreak.

Sec. 205. Surveillance

We support the enhancement of food-borne illness surveillance systems to improve the collection, analysis and reporting of data. Federal, State, and local food safety and health officials must be able to work together in an effective manner in order to quickly recognize a pattern of food-borne illness and identify the cause.

The tomato scare in the spring and summer of 2008 exemplifies the importance of surveillance. When tomatoes were targeted as the cause of the salmonella outbreak, the food retail industry reacted to ensure our customer was protected. At Publix, this resulted in over 350,000 tomatoes being removed from sale within a 3-hour timeframe. After millions of dollars of losses across the food industry, tomatoes were still in question until a team of experts at the University of Minnesota identified jalapeños as the culprit.

Based on previous success, FMI has endorsed legislation introduced by Senator Klobuchar and Senator Chambliss that would establish regional food safety centers of excellence modeled on the system at the University of Minnesota. We believe S. 1269, the Food Safety Rapid Response Act, will enable the Centers for Disease Control and Prevention to:

- Better coordinate food-borne illness surveillance systems, and
- Better support State laboratories in outbreak investigations with needed expertise. We would encourage its inclusion in S. 510.

Sec. 206. Mandatory Recall

In 2007, FMI's Board of Directors adopted a policy urging Congress to grant the Food and Drug Administration the authority to require a recall of seriously adulterated food when the entity responsible for its adulteration refuses to or delays in re-

calling the food. The provision in S. 510 requires FDA to give a responsible party the opportunity to cease distribution of an adulterated or misbranded food product while authorizing the Agency to issue a cease distribution order and a mandatory recall order if necessary.

We support the mandatory recall provision and the procedural limits in the bill, including the direction to FDA to work with State and local public health officials, who are often valuable resources, and the limitation that the authority may only be exercised by the Commissioner. Mandatory recall is a significant action and should only be directed by the highest knowledgeable authority within the Agency and the Agency should be accountable for executing that authority.

We support the requirement for FDA to notify the public about a recall, but would recommend that Congress direct FDA to notify the public with the most specific information available. General alerts can sometimes be misleading to consumers and do not provide sufficient direction for retailers to execute a recall. In order to recall foods effectively retailers need the greatest amount of specific information as possible.

TITLE III—IMPROVING THE SAFETY OF IMPORTED FOOD

Sec. 301. Foreign Supplier Verification Program

Food retailers are extremely reliant on imports as our customers demand a wide range of products—such as fresh produce—regardless of the season. However, importers play a mutually important role to import product into our country with the assurance that it is safe. At Publix, we only source food from suppliers that are able to meet our strict requirements for food safety and product quality. For Publix-branded products, this includes an in-depth review of total quality systems through audits and evaluations. We believe that food safety supplier verification activities will further assist to mitigate food safety risks associated with imported foods.

Sec. 302. Voluntary Qualified Importer Program

We believe it is appropriate to establish systems to encourage the use of additional measures of assurance by importers and foreign producers. We support the use of incentives to encourage food producers to take steps beyond those that are required by law to ensure the safety of the food supply and the use of a variety of factors to determine the risk posed by different foods.

Sec. 306. Building Capacity of Foreign Governments With Respect to Food

All food in the United States must meet the same high standards for safety, regardless of where the food was produced. Nonetheless, not all countries have the same standards for food production as exist in the United States. Accordingly, we commend S. 510 for including a provision that requires FDA to develop a plan within 2 years of the bill's enactment to assist foreign governments in building their technical, scientific and regulatory capacity.

Sec. 308. Accreditation of Third-Auditors and Audit Agents

Properly constructed accredited third party certification programs provide rigorous, objective evaluations of a food producer's safety programs. Although these programs cannot replace government oversight, certification from an accredited third party can provide some assurance that the certified company has received extensive and objective scrutiny for compliance with food safety standards that often exceed the legal requirements.

We support the legislation's recognition of certification by accredited third party auditors, but we would encourage that the committee further amend this section to ensure that all terminology is consistent with internationally, recognized language and terms. We also support the use of certification programs in the assessment of risk that FDA must perform in allocating its enforcement resources. Specifically, accredited third party certification programs are appropriate tools for use in both the Voluntary Qualified Importer Program (Section 306) and in the Import Certification Program (Section 303).

However, these programs should not replace government oversight or attempt to deputize private-sector auditors as an enforcement arm of the Federal Government. As an example, we are concerned with the provision that audits be "unannounced"—the same manner that a government inspection is conducted. Audits performed under an accredited third party certification program are different than a "snapshot-in-time" governmental inspection. During a third party certification audit, the auditor is watching and observing how the company manages safety as a part of its regular operations. It is a thorough rigorous assessment of the systems that are in place. Even announced, a company cannot just "cover up" fundamental procedural flaws.

Most audits involve two parts: (1) a "desk" audit which is a review of all of the plant's documentation, written food safety plans, risk and hazard assessments, etc. and (2) an on-site evaluation. These two audits, together help, to verify compliance with Federal food safety standards and internationally recognized best practices. Announcing the audit ensures that the necessary people and documents will be available to the auditing company's auditors at the appropriate time and place.

Mr Chairman, thank you for the opportunity to testify. We appreciate the efforts of this committee to help restore confidence in the food safety system and reduce food-borne illness. I look forward to your questions and remain available for further discussion and information should you need it.

The CHAIRMAN. Mr. Roberson, thank you very much for a very succinct and forward statement.

Mr. Ragan, please proceed.

STATEMENT OF DANIEL L. RAGAN, DIRECTOR, NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES, FOOD AND DRUG PROTECTION DIVISION, RALEIGH, NC

Mr. RAGAN. Thank you. Thank you, for the opportunity to be here today.

I've been invited today to offer input as the director of the North Carolina's principal food protection agency, the North Carolina Department of Agriculture and Consumer Services. We are the State inspection program within North Carolina. And I'm proud to represent the Department of North Carolina and our commissioner, Steve Troxler.

Statistically, as a State employee, you have to realize that we perform approximately 90 percent of all food safety inspections conducted annually in U.S. food manufacturing and distribution establishments. This past year, North Carolina had 31 inspectors complete over 5,000 inspections.

But, I want to draw your attention to three provisions that I think would make our food system more effective, stronger, and would be proactive.

The first is the development of a national standard. We need to establish one set of nationally accepted food safety inspection program standards to create a system that assures that regulatory programs across the country are uniform in how they work and how they prevent and respond to food-borne illnesses. The model for this presently is the current Manufactured Food Regulatory Program Standards, the MFRPS, drafted by FDA with the input from the States. The program promotes equivalency between State programs and requires continuous evaluation and improvement, as well as auditing by FDA. It requires that inspections are conducted on a risk basis considering the nature of the product, the process, the firm history, and product distribution.

Another aspect of the MFRPS involves the universal laboratory standards. Presently our laboratory is undergoing ISO 17025. It's an accreditation program that would allow our laboratory to produce defensible, accurate, reproducible, precise, and credible information. And it would be accepted by all State and Federal agencies.

The second area that we need is coordinated training. Training is another key aspect of the MFRPS. The establishment of a nationally recognized standard is a futile endeavor if there is no coordinated effort to train the regulators in industry to meet and ex-

ceed those standards. The Association of Food and Drug Officials and the International Food Protection Training Institute are currently collaborating in the development of a certified training program for food regulatory specialists. This kind of work should be commended and encouraged.

Training of our industry partners is also critical. If we work together, industry can proactively conduct hazard analysis so that effective preventive controls can be identified and implemented. In turn, regulatory agencies can verify through testing that quality control plans are effective and preventive controls are in place. We can never just test our way into food safety.

The final area that we'd like to discuss is a rapid response to food-borne illness outbreaks. When food-borne outbreaks do occur, the response is tedious, it's time-consuming, and it's expensive. It is however, a proactive desire to contain an outbreak. We have activated our rapid-response team several times and engaged the assistance of our partners at the North Carolina Department of Environmental and Natural Resources and Public Health under the ICS structure. We've put a lot of feet on the ground in a hurry and we've utilized our partners' assistance in getting information out to the public.

Recently, we utilized North Carolina's 86 local health directors to release information of a sandwich recall that was initiated for listeria.

We also have developed technology to provide situational awareness under our rapid-response program. We use a Web-based information system to—during these recalls—collect and report information on a real-time basis. This is unique to North Carolina, but it's also something the Federal Government needs to encompass.

We tried something new in one of our recalls recently, and that was the use of a reverse-911 capability. In a manner of minutes, by collecting information, we were able to transmit to 2,200 firms, the information of a recall.

Again, traceability has been mentioned here earlier. During a time of recall or rapid response, traceability is a huge issue to us. It becomes important for us to determine where is the contamination. Is it at the manufacturing? Is it as the storage? Is it shipping? Or, potentially, is it an act of terrorism?

Restoration is also an issue for us in North Carolina. Our goal is to restore facilities to production so that businesses prosper and so North Carolinians can keep their jobs. But, it's been an unexpected encounter of additional expenses. During the peanut industry, as we've all discussed today, we spent 4 months with one of our firms that was contaminated, working with them on a daily basis. The cost to us was in excess of $250,000 to get them back up and running. They made the commitment, we made the commitment. And I'm proud to say today, they're back up and running.

Also, last year the tomato industry was damaged when a consumer advisory was issued that tomatoes were likely the source of the salmonella, when, in fact, it was the peppers from Mexico. While food safety standards must be uniform, they must also be scalable, particularly those that are imposed at the farm level. One-size simply does-not-fit-all.

In summary, my message to you is clear. No. 1, impose a system that allows for national standards. No. 2, support intensive and appropriate training to those standards. And, No. 3, prepare the regulators in the industry to quickly respond to potential food-borne illness and outbreak.

Keep in mind, however, that while all these things are being discussed and need to be put in place, the issue is still money and still finances. For States to improve the food safety system and meet the expectations of these programs, as well as of the American public, they must be funded appropriately. More feet on the ground, more staff in the lab will require recurring multiyear funding.

Thank you.

[The prepared statement of Mr. Ragan follows:]

PREPARED STATEMENT OF DANIEL L. RAGAN

I. INTRODUCTION—INTEGRATED PROACTIVE SYSTEM

I would like to thank Chairman Tom Harkin, Ranking Member Michael Enzi, and distinguished members of the committee for the opportunity to offer this testimony. We are faced with the challenging task of protecting the safety and economic viability of our Nation's food supply system. Americans are fortunate to enjoy one of the safest food supplies in the world. However, we are still faced with multi-state foodborne illness outbreaks that result in deaths and life-changing illnesses. Americans are beginning to question the safety of our food supply and are calling upon all of us to implement stronger food safety measures.

We can achieve our shared vision for a safer food supply only if we concentrate on true integration and collaboration. Over 3,000 Federal, State, and local regulatory and public health agencies have a role in protecting the food supply. FDA provides guidance, model codes and other technical assistance to State, territorial, tribal and local regulatory partners to assist them in carrying-out their regulatory responsibilities. Since 1972, FDA has also contracted or entered into partnership agreements with many State regulatory agencies to perform inspections and investigations. In fact, more than half of all FDA inspections are performed under contract by States. As a result States perform approximately 90 percent of all food safety inspections conducted at food manufacturing and distribution establishments.

Within the last 2 weeks the NC Department of Agriculture & Consumer Services initiated a recall of sandwiches due to the potential for the contamination of *Listeria monocytogenes*. Listeriosis is a bacterial infection that can result in stillbirths or miscarriages in pregnant women or cause serious illness in elderly or immunocompromised populations. This year FDA began funding environmental sampling as part of the contract with State regulatory programs. Our in-depth inspection of the subject food manufacturer was a firm under contract inspection with the FDA. Our laboratory testing initially identified *Listeria monocytogenes* only in the processing environment, which led us to conduct additional finished product testing. Testing determined sandwiches distributed by the firm may also be contaminated and a voluntary recall by the firm was initiated.

An effective response to any food incident requires the collaboration of Federal, State, and local agencies. Our partnership with FDA allowed us to initiate a voluntary recall of a potentially hazardous food and prevent future illnesses in multiple States. We collaborated with the NC Department of Environment and Natural Resources and our 86 local health departments to notify the public and firms not under our regulatory jurisdiction, such as schools and other institutions, of the recall. In addition, we used technology referred to as reverse 911 to call thousands of firms in less than 1 hour that had received the recalled product.

North Carolina hosted a listening session for FDA and USDA to allow the concerns of small and medium farmers to be expressed concerning upcoming food safety legislation. The farmers were committed to ensuring the safety of their produce. However, two themes that were clearly heard were scalability and there needs to be indemnification for farmers damaged by fresh produce-linked outbreaks. For example, the Salmonella St. Paul outbreak was initially linked to tomatoes. Further investigation linked the outbreak to a farm in Mexico. Unfortunately, for tomato farmers in the United States the economic damage was irreversible.

We must continue to implement sensible measures which lead to the early identification of food safety issues and prevent foodborne illnesses from occurring. Food

safety must be built into the entire lifecycle of a food, from production to consumption. We must not rely only upon epidemiological data alone, after illnesses and deaths have occurred, to alert us to food safety issues. Similarly, we will never be able to realistically maintain a system which relies solely upon testing to verify the safety of the American food supply.

The food supply system is extremely complex. It includes more than 150,000 registered domestic food manufacturers, over 1 million supermarkets, restaurants, and other food service establishments, and more than 2 million farms.

Regulators must promote corporate responsibility for food safety. Firms should identify and evaluate hazards, implement preventive measures, and monitor the effectiveness of risk-based preventive controls. As new risks are identified or controls are found to be ineffective, industry must establish corrective actions. Regulatory agencies can then conduct risk-based inspections and testing to verify preventive controls were effective.

Establishing the metrics for measuring our success will allow us to direct our resources most effectively. Of equal importance, regulatory agencies must have the authority and resources to protect the consumers when preventive measures fail.

Trust must also be built between the regulatory agencies and the food industry. Last week, the NC Department of Agriculture & Consumer Services was notified by one of our firms of a positive Salmonella testing result. The firm had not shipped the product and had no mandatory requirement to report the positive finding to a regulatory agency. However, our relationship with the firm prompted them to immediately notify us of the issue. The Department, in collaboration with the FDA, is now verifying the firm's restoration plan through systematic inspections including environmental and finished product sampling. Like other States, North Carolina is committed to helping our firms quickly identify and respond to a food safety issue so they can safely resume production.

II. STANDARDS

Legislation under review by Congress will undoubtedly give the FDA new authority and tools and resources to comprehensively reform the Nation's food safety systems. Some proposals specifically address issues surrounding the recall of unsafe product by increasing the frequency of inspections at all food facilities, giving the FDA expanded access to records and testing results, and allowing the FDA to recall dangerous food products in the event a company fails to recall a product at the FDA's request. Increased inspection frequencies and mandatory recalls can only be achieved by leveraging the resources of State regulatory programs. Also, many State and local agencies currently have broader regulatory authorities than the FDA. The collaboration of all agencies allows us to rapidly and effectively minimize the public health impact of a food incident.

Furthermore, rapid containment is necessary to minimize the economic impact of a food incident and to maintain consumer confidence.

Leveraging Existing Resources

Current leveraging efforts have not been sufficient to ensure adequate oversight of the entire food supply chain. Throughout the years, numerous reports point out that the FDA does not take full advantage of the inspectional and surveillance capabilities of our State, territorial, tribal and local regulatory and public health partners. This situation is due in large part to the varied standards and laws in each State as compared with the Federal system, as well as to the lack of interoperable data systems and legal impediments to sharing data among partners.

Equivalency

A fundamental concept to be found in a nationally integrated plan is the development of uniform standards and programs with demonstrated equivalency. The concept of equivalency allows States to use different approaches yet achieve the same level of public health protection. The demonstration of equivalency will allow the FDA and States to make greater use of each other's laboratory analytical and inspection data in pursing advisory, administrative, or judicial actions. North Carolina was one of the first pilot States for the Manufactured Food Regulatory Program Standards (MFRPS). MFRPS is a continuous improvement program developed by FDA for State and local food regulatory agencies to ensure equivalency in regulatory programs including inspections, sample analysis, compliance, training, and emergency response. While originally designed for food programs, North Carolina is now piloting MFRPS in our animal feed regulatory program. The interconnectivity of the food supply makes it necessary for us to demonstrate equivalency in both food and animal feed programs. In addition, the Retail Food Standards are another important

tool in the standardization and continuous improvement of retail food regulatory programs.

Oversight and Accountability

System integrity and credibility should be maintained through regular program oversight and accountability at all levels. The FDA conducts audits of State inspectors who perform inspections under contract. Also, many States have trained auditors to ensure inspections conducted under the authority of the FDA and State meet the same high standards. Maintaining the credibility of the regulatory program is a key feature of the MFRPS program through auditing all aspects of the inspection.

National Risk-based Planning

Federal and State inspections should be conducted in accordance with a public health risk-driven national work plan. Multiple risk factors should drive the inspection frequency including the type of food being produced, population being served, and the compliance history of the firm. An integrated system will result in more coordinated response efforts to prevent food incidents from occurring and enhance our response to multi-state outbreaks when they do occur.

Laboratory Accreditation

Regulatory programs must be supported by accurate and defensible laboratory results. Many States such as North Carolina are either ISO 17025 accredited or in the process of receiving accreditation. ISO 17025 accreditation allows for laboratory data to be accepted by Federal, State, and even international partners. Currently, the lack of laboratory accreditation hinders the capability of FDA to accept data from State regulatory partners. By providing the FDA the confidence to initiate regulatory actions based on State results can exponentially increase the Nation's capacity to detect and respond to food safety problems.

III. TRAINING

Uniform standards are worthless if regulatory officials and industry partners do not know how to implement, meet, and exceed them. An integrated food safety system can only be accomplished through an integrated and standardized training program for both regulatory officials and industry.

International Training Food Protection Training Institute

The International Food Protection Training Institute in Battle Creek, MI provides the foundation for the certification of food regulatory specialists. In partnership with the Association of Food and Drug Officials (AFDO) and FDA, the Institute is committed to providing food regulatory specialists with continuous training through a network of university-affiliated centers and the use of multiple innovative instructional methods. The training of food regulatory specialists should be career-spanning as new food safety challenges emerge, inspection and investigation strategies evolve, and regulatory authorities change. The training provided by the Institute will complement the courses offered by FDA.

North Carolina has demonstrated our commitment to training our staff by being the first State to modify and teach the ADFO-developed "Applications of Basics of Inspection and Investigation" to our food regulatory specialists. Just last week we provided our modified course and sent our training coordinator to Battle Creek to teach inspectors from other agencies from around the country.

Industry Training

The U.S. food industry will have greater responsibility for complying with increasing food safety regulations. State and Federal regulatory agencies have traditionally relied upon land-grant colleges and universities to deliver education and training programs that address the food industry's needs. Food safety experts agree the time has come to establish a measurable matrix to evaluate our industry partners. Without a concerted effort to educate, train and re-tool industry partners, legislation which is intended to improve the safety of our Nation's food supply will not meet that objective. An urgent need exists to increase both the regulatory community and industry's capacity to prevent food safety problems, detect and respond to food-borne illness outbreaks, and protect our food supply from natural and deliberate contamination.

IV. RESPONSE AND RECOVERY

Traceability

An integrated, proactive system should decrease the number of major foodborne illness events. However, when an event occurs, States need the tools to provide

timely traceability, rapid recall and to facilitate market recovery. Recent multi-state outbreaks linked to fresh produce and ingredients, such as the peanut recall earlier this year, have magnified our inability to rapidly trace and remove potentially contaminated foods from the market. Delays in market removal result in additional illnesses, deaths, and economic loss. "Rolling" recalls only serve to undermine consumer confidence in the food supply and government. While the Bioterrorism Act of 2002 requires one step trace back and trace forward, current recordkeeping systems often do not provide investigators the information necessary to rapidly identify the source of a foodborne illness outbreak. FDA should provide guidance for uniform traceability requirements and systems for food manufacturers and distributors. Such guidance should be scalable and meet the needs of the entire industry.

Market Recovery

National food safety scares, food illness outbreaks, and recalls have a direct economic impact on the specific entity at the center of the action, but they also have an economic impact that ripples throughout industries, into processing facilities, farms, and communities across the country. Put differently, when a foodborne illness outbreak occurs, that outbreak and any accompanying recall efforts, media notifications, and regulatory actions can devastate entire commodity markets and the farmers and processors involved with that particular market. For example, many North Carolina farmers who grow peanuts were just coming off their best crop year ever when the Peanut Corporation of America-based salmonella outbreak occurred. Many of those farmers were not able to secure contracts for the peanuts they harvested and many have lowered their planting projections as a result of weak demand in the market.

Securing the safety of America's food supply simply cannot occur if some system is not put into place to "re-establish" markets damaged by a food-illness or outbreak and offer indemnification for the farmers, lest we limit the number of individuals involved in food production and become even more dependent on foreign sources for our food. Comprehensive food safety legislation must include market recovery assistance for industries battered by food safety scares, consumer advisories, recalls, and peripheral events. Such assistance may include provisions for State Departments of Agriculture, commodity associations, or others to access funds for market recovery efforts which can be narrowly tailored to the scale of the market disruption and which are targeted to audiences who can take actions to minimize that disruption.

Unified Rapid Response

The use of the Incident Command System (ICS) has allowed North Carolina to engage all of our partners for a unified and rapid response to a food incident. During the Castleberry recall, the use of ICS allowed us to coordinate the efforts of over 700 regulatory officials to conduct more than 16,000 recall effectiveness checks. We continue to implement ICS and utilize rapid response teams to respond to any significant food safety event. As noted earlier, the PCA-based salmonella outbreak affected the entire food industry, including one major snack manufacturer in North Carolina. The use of ICS allowed us to efficiently coordinate recall effectiveness checks with our Federal, State, and local partners in addition to overseeing the restoration of a major snack manufacturer and conducting in-depth inspections of our peanut processors to restore consumer confidence.

V. INFORMATION SHARING

As the Nation moves towards integration of the food safety system, real-time sharing of information must occur. Multiple surveillance activities for early detection of food safety issues and illnesses are in place yet the information is not systematically mined. Surveillance activities include conducting risk-based inspections, risk-based retail survey programs, recall effectiveness checks, and responding to consumer complaints.

Real-time Information Sharing

Accurate and standardized data should be collected from all levels of government and systematically mined for early detection of food incidents. Real-time data sharing systems must be in place and accessible to all Federal, State, and local food protection agencies to provide for seamless sharing of all data. By combining the multiple layers of data we are collecting, we can begin to detect food safety issues before multi-state outbreaks occur and thousands of consumers become ill.

North Carolina and other States are now piloting a project to share all manufactured foods inspection data with the FDA by interfacing with eSAF. We have also developed a real-time system for collecting recall effectiveness data that we have shared with all of our State and local regulatory partners. During the cookie dough

recall initiated for *E. coli O15*7:H7, we piloted the system with other States. The result was the ability to determine nationally the effectiveness of the recall and provide a platform for targeting resources during a response. Also, many States participate in eLEXNET, an electronic system of the Food Emergency Response Network (FERN) to store sample data results and allow users to identify trends.

Removal of Legal Barriers

Currently, only a fraction of the data being collected is accessible to all food protection agencies. The legal barriers to sharing information must also be eliminated. The FDA currently requires all firms subject to their regulation to be registered underneath the Bioterrorism Act of 2002. However, States do not have access to this database. Conversely, many States are aware of firms that are not registered with FDA. The result is not one agency contains a complete and accurate inventory of food manufacturers, distributors, and retailers. The same is also true of the newest initiative of FDA, the Reportable Food Registry. While the FDA has committed to share information with the States as appropriate, having real-time access to all of the information collected can help all regulatory partners develop appropriate risk-based responses and implement preventive measures.

VI. FUNDING

A commitment from both the FDA and the States is necessary for the successful integration of a proactive and prevention-based food safety system. The States have demonstrated their commitment through the participation of multiple initiatives to build equivalent regulatory, laboratory, and emergency response programs. We have also demonstrated our commitment to share our data in real-time. An equal commitment from the Federal Government is necessary for full integration of the Nation's food safety system. Funding to State agencies must hinge upon measurable objectives and deliverables.

The FDA contracts with State regulatory programs to conduct inspections and sample analysis, which contracts are generally renegotiated annually. The annual renewal of Federal funding prevents States from building the foundation for long-term success. However, to be fully successful, the national food safety system must be built with continuous input from FDA's regulatory and public health partners. It must be sustained through multi-year funding that will be provided to State and local regulatory and public health partners to build the necessary State and local infrastructures, contain adequate legislative authorities to facilitate information sharing and communication among all partners, and include infrastructure for a national electronic information-sharing mechanism. These actions will result in a national food safety system that reduces foodborne illness, identifies sources of risk throughout the system, and reduces time to detect and respond to outbreaks. A public health driven, collaborative, and leveraged approach to food safety activities and responsibilities will be reflected in improved public sector resource utilization at a national level, which provides additional capacity for ensuring a safe and secure food supply.

Congress should provide dedicated, line-item funding from the Federal level to State and local programs. A current model for assessment and funding may be the USDA Talmadge-Aiken meat inspection program. Pursuant to the Talmadge-Aiken Act, States may enter a cooperative agreement with USDA, pursuant to which State plants receive "Federal inspection" performed by federally licensed State employees. The T/A program provides funding to State programs that are uniform and consistent with USDA-FSIS standards based on the regulatory responsibilities (e.g., number and size of firms) of the State agency.

Direction should be given for the Secretary of HHS to develop timelines for all States to be compliant with MFRPS and to demonstrate, at minimum, equivalency to FDA. Full implementation of MFRPS in all States will require greater funding to acquire the staff, training, and data management systems necessary. Funding should be based on regulatory responsibilities and meeting benchmarks for full compliance with MFRPS. While $5,000 was provided for pilot States to conduct a self-assessment and to create an operational plan for self improvement, this amount of limited financial support does not provide the States the capability to fully meet the requirements of MFRPS. Furthermore, funding for the International Training Institute for Food Protection and its affiliated universities is another key component for States to be in compliance with MFRPS.

Congress should also increase funding for the food protection training institutes affiliated with land-grant colleges and universities for the development and delivery of a measurable comprehensive food safety education and training program that addresses the needs of industry in meeting the new food safety modernization act re-

forms. Similar to the training program for food regulators, the training program for industry should include a certification component.

Funding is not only necessary to identify food safety issues, but to facilitate the recovery of the food industry following a major food incident. The restoration of a major food manufacturer is costly to both the government and industry. State regulatory agencies are committed to assisting our industry in recovering from a major food incident, however, the financial resources must be provided. Also, through no fault of their own, the entire farm to fork food continuum suffers when a significant food incident occurs. We must build a food safety system which promotes prevention, early identification, rapid response, and swift recovery to any type of food incident.

VII. CONCLUSION

I would like to thank the committee for this opportunity for North Carolina to present our perspective on the resources and commitment required for an integrated food safety system to be successful. Nothing is more important to the quality of our lives than the food we eat. We can no longer take the safety of our food supply for granted. State and local regulatory agencies are currently conducting 80 percent of the food safety and defense work in the United States including inspections, emergency response, consumer complaints, and laboratory testing. By investing in State and local regulatory program we can build the capacity necessary to protect the food supply and fulfill our obligation to the American public. I will be happy to answer any questions the committee may have.

The CHAIRMAN. Thank you very much, Mr. Ragan.

Mr. Stenzel, welcome, again, to the committee. Please proceed.

STATEMENT OF THOMAS E. STENZEL, PRESIDENT AND CFO, UNITED FRESH PRODUCE ASSOCIATION, WASHINGTON, DC

Mr. STENZEL. Thank you, Chairman Harkin, Ranking Member Enzi, and members of the committee.

United Fresh Produce Association represents the growers, shippers, fresh-cut processors, and marketers of fresh fruits and vegetables who account for the vast majority of produce sold in the United States today. These include family businesses—small and large producers in both conventional and organic production.

Mr. Chairman, we've worked together for many years now to promote increased consumption of fresh fruits and vegetables for America's children. And you know of our industry's commitment to safety. We're committed to doing everything we possibly can to ensure the safety of the products we grow, package, and deliver to consumers. Our association published the first food safety guidelines for the fresh-cut produce industry 17 years ago, and we developed the first industry guidelines, in the mid-1990's, to minimize on-farm microbiological food safety risks.

Following the *E. coli* outbreak associated with one brand of spinach in September 2006, the industry undertook a comprehensive reevaluation of leafy-greens production, handling, and processing to ensure compliance with best practices in assuring safety. Other commodity groups have done likewise, with the tomato industry implementing rigorous standards and metrics that are now incorporated in State law in Florida.

The industry is well along in a multiyear produce traceability initiative committed to driving a standardized system of case coding for total supply-chain traceability. And the industry is now working hard to drive harmonization of global good agricultural practices for all fruit and vegetable growers. With this unprecedented commitment to food safety from field to table, the public can be con-

fident in the safety of the over 1 billion servings of fresh fruits and vegetables consumed in America every day.

Yet, we, too, know that there must be changes in our Federal system of food safety oversight. We've seen the failures in our system up close; first, in failing to focus on the risk, where they're most likely to occur, and second, in misguided management of outbreak investigations that confuse the public and cast entire industry sectors into doubt.

Our board of directors took the bold step, 3 years ago, to adopt a series of public policy principles calling for mandatory science-based regulation by the Federal Government. Let me explain the importance of these three principles.

We believe, first, that produce safety standards must allow for commodity-specific food safety practices based on the best available science. In a highly diverse industry that is more aptly described as hundreds of different commodities, one-size clearly does-not-fit-all. The large majority of produce commodities have never been linked to a food-borne disease. FDA states that only five produce commodities have been associated with 80 percent of food-borne disease outbreaks in the past 10 years.

We believe produce safety standards must be consistent for any individual commodity grown anywhere in the United States or imported into this country. Consumers must have confidence that safety standards are met, no matter where the commodity is grown, nor whether it was grown by a small or large farmer, nor conventionally or organically.

Last, we believe that this will require strong Federal Government oversight and compliance in order to be credible. We believe that FDA must determine appropriate nationwide safety standards with full input from the States, industry, academia, and consumers. In turn, it is then important for FDA to work with its partners at the USDA and State departments of agriculture to ensure compliance with produce safety standards.

We're pleased that the consensus in Congress has grown in support of these principles, as embodied in S. 510 introduced by Senators Durbin, Burr, and many colleagues here.

While most of my testimony today is about prevention of illness, and properly so, I also want to call your attention to the failures evident in outbreak management. Already discussed today, the tomato industry's impact, where for 6 weeks the industry was basically shut down in pursuit of the wrong product.

The current system offers diffuse responsibility, which creates a lack of accountability. The current system doesn't use valuable industry expertise. And the risk communication and outbreak management is unacceptably broad and can actually be harmful to public health.

Just consider this one fact. The 2006 *E. coli* outbreak linked to spinach is now known to have been limited to one farm, one packing plant, on only 1 day's production. The only contaminated spinach ever marketed was packaged on August 15, 2006, 3 years ago; yet consumption of this nutritionally dense vegetable is still down from where it was 3 years ago. Public health is not well served by such misplaced fears.

I also urge the committee to reject calls to water down the food safety requirements in this bill as a way to satisfy some who say that small farms or organic farms should not have to comply. Mr. Chairman, we have a number of small farms and organic farms in our membership, and they are committed to complying with whatever safety rules that FDA sets. Our industry has learned the painful lesson that we are only as strong as our weakest link.

We believe a better plan is to offer technical assistance, training, and financial support, perhaps including reduced fees for small businesses, to assist small resource farmers to comply with the important food safety and traceability standards.

Thank you very much.

[The prepared statement of Mr. Stenzel follows:]

PREPARED STATEMENT OF THOMAS E. STENZEL

INTRODUCTION

Good morning Chairman Harkin, Ranking Member Enzi, and members of the committee. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,500 growers, packers, shippers, fresh-cut processors, distributors and marketers of fresh fruits and vegetables accounting for the vast majority of produce sold in the United States. We bring together companies across the produce supply chain from farm to retail, including all produce commodities, both raw agricultural products and fresh ready-to-eat fruits and vegetables, and from all regions of production.

I mention these characteristics because our organization's views on food safety are shaped by this broad and diverse membership across the entire produce industry, not any one sector or region. In the area of science and food safety, our association works to develop industrywide consensus on the best overall policies and practices to serve the American consumer.

Let me begin by repeating something you've heard many times before, and will hear many times in the future. Food safety is our industry's top priority. The men and women who grow, pack, prepare and deliver fresh produce are committed to providing consumers with safe and wholesome foods.

That is what drives food safety to be a process of continuous improvement, not a static achievement. We are on a continuum constantly striving to improve, while understanding scientifically that perfection—or zero risk—is not possible. Because our products are enjoyed by consumers in their fresh and natural state without cooking, we have to be right every single time—not one in a million, or even one in a billion.

Now, I personally am confident in my produce choices today. I know the personal care and commitment of people I meet who are growing and processing fresh produce, and I trust them to be doing their very best to market safe products. And I know that their results are overwhelmingly successful, with the actual incidence of illness extremely low. Just look at the numbers.

- Over a billion servings of fresh produce are eaten every day.
- More than 5 million bags of fresh salads are sold every day.
- And, out of the hundreds of fruits and vegetables offered in a typical supermarket, only a very few have been implicated in illness outbreaks, and then rarely as compared with their volume of consumption.

But, we also know that consumers today are walking into grocery stores and restaurants with concerns, doubts, and sometimes fears about produce. They don't understand those statistics; they don't know what farmers and processors are doing to protect the safety of their produce; and equally important, they do not have complete confidence that government is doing all it should to protect their health.

Most importantly, we cannot lose sight that health experts are unanimous that Americans must increase our consumption of fruits and vegetables for better health. That's the juxtaposition we face today on food safety—it is simply unacceptable for Americans to fear consuming fresh fruits and vegetables that are essential to their good health.

PRINCIPLES FOR PRODUCE SAFETY

Mr. Chairman, we have worked together to promote increased consumption of fresh fruits and vegetables for the health for America's children for many years, and you know that our industry's commitment to safety is the bedrock of that effort. Our commitment to produce safety is twofold.

First, we will do everything we possibly can as an industry to ensure the safety of the products we grow, package and deliver to consumers. Our association published the first *Food Safety Guidelines for the Fresh-Cut Produce Industry* 17 years ago, and we are now on our 4th edition. We developed the first industry guidelines in the mid-1990s to minimize on-farm microbiological food safety risks for fruits and vegetables, and worked closely with the FDA to publish Federal guidelines soon thereafter. Food safety has been at the forefront of our mission to serve the American public for many years.

Following the *E. coli* outbreak associated with one brand of spinach in September 2006, we undertook a comprehensive reevaluation of leafy greens production, handling and processing to enhance every possible step we could take in assuring safety. Even though that problem was isolated to one small farm, the entire leafy greens industry has adopted the most rigorous scientific principles to minimize risk, and developed compliance protocols and audits that are now conducted by State government officials.

Other commodity groups have done likewise, with the tomato industry implementing rigorous standards and metrics that have been incorporated in State law in Florida.

Earlier this year, our association brought together worldwide leaders in produce safety standards and auditing, launching an ongoing initiative to drive harmonization around the most rigorous set of good agricultural practices known as GAPs, applicable to all produce operations.

The committee should be familiar with our Produce Traceability Initiative (PTI), an industrywide commitment launched by three major trade associations in 2008 to drive a standardized, total supply chain traceability system with case coding to allow rapid traceback and isolation of any potential problems.

I can tell you with certainty today, that produce is safer today than ever before, with an unprecedented commitment from food safety from field to table.

Yet, we too know that there must be changes in our Federal system of food safety oversight to restore public confidence in what too often appears to be a broken system. We have seen the failures of food safety oversight up close, first in failing to provide the resources and focus on prevention of contamination where most likely to occur, and second in misguided management of outbreak investigations that confuse the public about true risk and cast entire industry sectors into doubt.

In order to address these issues, our Board of Directors took the bold step 3 years ago to adopt a series of policy principles calling for mandatory, science-based regulation by the Federal Government. Let me repeat those principles once more:

- To protect public health and ensure consumer confidence, produce safety standards:
  - Must allow for a commodity-specific approach, based on the best available science.
  - Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country.
  - Must be federally mandated with sufficient Federal oversight of compliance in order to be most credible to consumers.

Since that time, our industry has been a leading proponent of strong Federal Government oversight of food safety, testifying before the House or Senate more than 10 times, working extensively with FDA and USDA, and sharing perspectives with other stakeholders and the consumer community.

We are pleased that the consensus in Congress has grown in support of these principles, which have largely been incorporated into H.R. 2749 the Food Safety Enhancement Act passed by the House, and S. 510 the Food Safety Modernization Act of 2009 introduced by Senators Durbin and Burr and colleagues.

As this committee and the Senate consider changes to our food safety laws, let me explain the importance of each of these principles.

• *Must allow for a commodity-specific approach, based on the best available science.* We believe produce safety standards must allow for commodity-specific food safety practices based on the best available science. In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one-size clearly does-not-fit-all. For example, the food safety requirements of products grown

close to the ground in contact with soil are far different from those grown on vines or trees. The large majority of produce commodities have never been linked to a foodborne disease. In fact, a recent FDA Federal register notice confirms that five produce commodities have been associated with 80 percent of all foodborne disease outbreaks in the past 10 years, and that is where we must direct our resources.

In addition, government and industry alike must be careful that broad strokes do not result in requirements that should not apply to specific commodities, and do nothing to enhance safety. Taking a general approach would be far too easy to add regulatory costs and burdens to sectors where those requirements are unneeded, without doing anything to enhance safety where most critical. Finally, as part of this commodity specific approach, FDA must develop a rulemaking procedure that establishes risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary determines such standards are necessary to minimize the risk of microbial illness.

• *Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country.* We believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed. Because of the variation in our industry's growing and harvesting practices in different climates and regions, flexibility is very appropriate and necessary. For example, some production areas use deep wells for irrigation while others use river water supplied from dams. Some farms use sprinkler irrigation, others use a drip system laid along the ground, and still others use water in the furrows between rows of produce. But the common factor must be that all uses of water for irrigation must meet safety standards that protect the product. That must be true whether the produce is grown in California, Florida, Wisconsin or Mexico.

• *Must be federally mandated with sufficient Federal oversight of compliance in order to be most credible to consumers.* We believe achieving consistent produce safety standards across the industry requires strong Federal Government oversight and responsibility in order to be most credible to consumers and equitable to producers. We believe that the U.S. Food and Drug Administration, which is the public health agency charged by law with ensuring the safety of the Nation's produce supply, must determine appropriate nationwide safety standards in an open and transparent process, with full input from the States, industry, academia, consumers and all stakeholders. We are strong advocates for food safety standards based on sound science and a clear consensus of expert stakeholders.

In turn, it is important for FDA to work with its partners at the USDA and State departments of agriculture to ensure compliance with produce safety standards. We do not see a need for thousands of new FDA inspectors moved from processing plants to farms and fields, but rather a close working relationship with the USDA that understand agricultural production and can better monitor and assure compliance with FDA rules.

Together, these three policy principles provide a direction for a food safety regulatory policy that we believe would most help our industry enhance produce safety, concurrent with establishing the highest level of public trust in our industry and in our fresh produce offerings. It is our goal to support a U.S. regulatory framework for the fresh produce industry that incorporates these principles.

OUTBREAK INVESTIGATIONS

While most of my testimony today is rightly focused on what we can do to prevent illness associated with our products, I must also include comments about the current management of outbreak investigations by Federal, State and local Government.

In testimony I presented last summer to the House Energy and Commerce Committee, I discussed the multitude of failures evident in the *Salmonella* Saintpaul outbreak in 2008 that was eventually linked to jalapeño peppers, but only after shutting down the tomato industry. In that testimony, I highlighted several fundamental flaws in outbreak management that I believe should also be addressed in reform of food safety laws.

1. Diffuse Responsibility Creates Lack of Accountability

The diffuse responsibility for public health in outbreak investigations results in no one agency or individual in charge, leaving local, State, and Federal officials vying for leadership; various agencies pursuing different priorities; and well-meaning individuals reacting independently to events rather than as part of a coordi-

nated investigation moving forward in a logical and expeditious direction. Another indicator of this problem is the lack of a coordinated national training program for investigators at the Federal, State and local level. The resulting inconsistency of field work in these investigations is a major impediment to accurate and timely results.

We suggest Congress direct the Administration to put in place an outbreak investigation structure with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. We suggest examining the system for National Transportation and Safety Board investigations, which from afar, seems designed for a 24–7 immediate response, with clear authority and command leadership, supported by a team of well-prepared experts. Simultaneously, HHS should mandate and provide the resources for nationally consistent training for all local, State and Federal employees involved in food safety investigations and inspections.

2. The Current System Doesn't Use Industry Expertise

The government's failure to use industry's expertise in outbreak investigations is one of our most important lessons. Let me first say that this needs to be a transparent process in order to have public credibility. But there is an abundance of knowledge in the industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. Based on geographic distribution patterns of illnesses alone, industry representative advised FDA quickly that tomatoes were extremely unlikely to be the source of contamination, yet such input was ignored until proved correct 6 weeks later when jalapeños chopped up in salsa were linked to the outbreak.

Congress and the agencies should find a proper and transparent way to bring industry expertise into its investigations. We specifically recommend that a group of experts in major produce commodities be selected and vetted by government well ahead of time, perhaps through a process similar to gaining a security clearance. Then, at a moment's notice, these pre-cleared experts could be assembled with government investigators to provide counsel in their areas of expertise.

3. Today's Risk Communication Is Unacceptably Broad

These are complex issues indeed, and tough to explain. The principle of timely and candid communication with the press and public cannot be compromised. Yet, the public is not well-served by stoking fear of all spinach, or all tomatoes, or any other commodity when the actual risk is very limited. Consider this fact—the 2006 *E. coli* outbreak linked to spinach is now known to have been limited to one farm, one processing plant, on only one day's production run. There have been no further illnesses since that time reportedly linked to spinach. Yet, consumption of this nutritionally packed vegetable is still down from where it was 3 years ago. Public health is not well-served by such misplaced fears.

CONGRESSIONAL FOOD SAFETY LEGISLATION

Let me now discuss our thoughts on S. 510 the Food Safety Modernization Act now before the Senate. We support this bill as an aggressive and comprehensive approach to reforming food safety law. While we would like to see further direction to HHS for improving outbreak investigations, we believe many of the tough issues have been addressed in this legislation, leading to the bipartisan nature of its cosponsors.

Specifically, we applaud the bill's commodity-specific approach to produce, which necessarily focuses resources where most needed. We applaud the bill's requirement that FDA work with USDA and the States in implementation and compliance measures. And, we applaud the bill's mandate for an expedited entry program for imports that can demonstrate compliance with U.S. food safety standards.

I also want to urge the committee to reject calls to "water down" the food safety requirements in the bill as a way to satisfy some who say that small farms, organic farms, or others should not have to comply. Mr. Chairman, I have a number of small farms and organic farms in our membership, and all are committed to following whatever food safety rules that FDA deems to be important to protect public health. Size does not determine whether food safety is important—every consumer's health is just as important whether purchasing vegetables at a farmers market or a grocery store. Our industry has learned the painful lesson that we are only as strong as our weakest link. If Congress truly wants to build public confidence in our food safety system, all fruits and vegetables must comply with basic safety rules no matter where or how grown.

Rather than seek exemptions from basic food safety requirements, we believe technical assistance, training and financial support—including reduced fees for all

small businesses—are more appropriate ways to assist small resource farmers and produce distributors to comply with important food safety and traceability standards. We are confident that every produce grower—in this country or abroad—should be able to comply with the commodity-specific standards and guidance anticipated from FDA for the safe production and handling of fruits and vegetables.

We urge the committee to move swiftly in deliberations on S. 510 in order to allow Senate consideration this year. With H.R. 2749 pending, passage of S. 510 would provide strong Senate leadership in conference to formulate final bipartisan legislation that can be broadly supported by both chambers, industry and consumers.

CONCLUSION

In conclusion, let me return to the important role fresh fruits and vegetables play in public health. Of course any reasonable person in the food industry would want to produce only the safest possible product. But for us, somehow it seems even more important because of the healthfulness of fresh produce. The very Department of Health and Human Services that regulates our safety has the dual responsibility to promote the importance of eating more fruits and vegetables to prevent chronic diseases such as cancer, heart disease, stroke, and more. Now, our Nation is faced with an obesity crisis that threatens the long-term health of our children and out-of-control escalation in health care costs unless we radically change eating habits to consume more fruits and vegetables.

With that public health imperative, fears of food safety have no place in the fresh produce department. We, as an industry, must do all we can to prevent illnesses from ever occurring, and we will.

But because science tells us there is no such thing as zero risk, government must also be able to assure the public that even if something does go horribly wrong in an isolated case, consumers can continue to have confidence in fresh produce. We must all be able to trust the overall system of government oversight and industry responsibility, working together to produce the safest possible supply of fresh, healthy and nutritious fruits and vegetables.

The CHAIRMAN. Thank you again, Mr. Stenzel.

And you're right, we've worked together, going back to the early 1990s, if I'm not mistaken. So, it's been a long and very enjoyable working relationship to get more fresh produce and vegetables, in our diets.

Ms. DeWaal, there are a lot of things I'd like to cover with you, but just one, on the issue of food imports. Your testimony advocates requiring government-to-government certification for high-risk foods. Well, what if the FDA concludes that it cannot certify a particular foreign government's oversight program? Does that mean that no facility in that country should be allowed to sell high-risk foods into the United States? Or could the FDA certify facilities in such countries on a facility-by-facility basis?

Ms. DEWAAL. Thank you, Senator Harkin. The bill provides for that situation. First of all, S. 510 contains something, which isn't in the House bill, which complicates the imports section, a little bit. It's got what's called an "accrediting body." And that body actually—I think you may want to look at that provision in the bill closely, because that body actually would get between two governments, the U.S. Government and a foreign government, in assuring that that foreign government can certify. I don't think that was the intent of the drafters. So, I think that this accreditation body is something you're going to want to take a close look at.

Now, the bill does provide for the situation where you don't have the government-to-government certification, which, as you know, is critical to the meat safety area; it's what is actually used in the meat safety area to ensure the safety of imported products.

In the FDA bill, it's a lot more complicated, because of the number of products and the number of countries involved. So, in that case, there are independent certifying agents. These may be third

parties that just serve the role of certifying an entity in a foreign country to ship FDA-regulated food. This is a new concept. It's an important concept. It's one, I know, that FMI uses a lot and actually plays a role in. But, it's an important new concept in food safety that would be brought to bear. It's like the FDA would be adopting something that's already working in the private sector to help them in this area of imports.

The CHAIRMAN. Anybody else have any views on this at all, or thoughts on the question I just asked on that, about foreign imports?

Mr. STENZEL. Mr. Chairman, I think they're clearly going to be cases where FDA is not able to certify a foreign government having the exact same standards. So, there does need to be that system to allow for a high-risk product, independent certification that FDA accredits. They have to make sure that it's a reliable inspection, but there needs to be a way. That's only on the high-risk products. One of the important provisions of the bill is that it requires the importers to certify that the product, in our case, has been grown in accordance with U.S. safety standards. And we think that essentially is the right approach.

The CHAIRMAN. Very good. Thank you, Tom.

Mr. Roberson, did you have something on this?

Mr. ROBERSON. Senator Harkin, my colleague Ms. DeWaal referred to the program that FMI has, and that is the Safe Quality Food Program. That program has been benchmarked through the Global Food Safety Initiative, and as part of that accreditation process, the SQF program has to go through an ANSI certification, so it does provide a very high level of accreditation to that third-party accredited certification audit.

The CHAIRMAN. Right. Exactly.

One thing I just wanted to ask all of you, and that is in S. 510, we're trying to set up regimes in which consumers would be very confident that their food would be risk-free. But, isn't there also an element that we need more education of the general populace on what their responsibilities are once they get this food?

Mr. Roberson, in terms of grocery stores, in terms of information that grocery stores could put out, if you buy fresh produce and stuff that's not triple-washed and bagged, this needs to be washed, this needs to be cleaned. Your fruit that you buy, your apples, your pears and things, please wash them thoroughly before you give them to your children or eat them. I don't know if Publix does that. I don't know that, or if other stores do that. But, it seems to me that there's got to be an element in this also of informing consumers of what they should do.

Mr. ROBERSON. Senator Harkin, thank you for the opportunity to respond. You're absolutely right, consumers do play a role in the link of the food supply continuum, that farm-to-fork discussion that we've all spoken about for years. Publix and other member companies of FMI have, for many years, partnered with the Partnership for Food Safety Education, the development of the Fight Back Campaign, over 10 years ago, and most recently, in partnership with the USDA and FDA, the development of the new Be Food Safe Campaign. There are excellent consumer education programs that

are out there, and we do partner with the Partnership for Food Safety Education to make that available to consumers.

The CHAIRMAN. Ms. DeWaal, you obviously are a big consumer representative.

Ms. DEWAAL. Yes, Senator. We strongly support consumer education. In fact, we send it out in our magazine, which goes out about 10 times a year.

The key issue, I think, though, is the—I think consumers are very willing to do their part, but they should be the last line of defense and not the first line of defense for unsafe food. And I think we would all agree on that.

The CHAIRMAN. We all agree with that.

Ms. DEWAAL. Thank you.

The CHAIRMAN. The other thing is that it's got to be part of a school curriculum, maybe even in elementary education, kids ought to be taught about this. I'll think about that with my fresh fruit and vegetable program.

Mr. Ragan, my time is out, but if you had a view on this—

Mr. RAGAN. The only addition that I'd like to make from North Carolina is that we've actually got a bilingual specialist who's putting out these programs in both English and Spanish.

The CHAIRMAN. Very good. You're ahead of the curve.

Thank you very much.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman.

Ms. DeWaal, I need a little clarification about your recommendation to require that every positive test be sent to the FDA. Some of the products can be remediated after they do the test and others may be destroyed on a positive test and never endanger anybody. So, I don't want to discourage companies from doing testing, but I also don't want to overwhelm the FDA with information that might no longer be useful. Are you worried that this reporting might result in the FDA looking for a smaller needle in a bigger haystack?

Ms. DEWAAL. Senator Enzi, I think that's an excellent question. The key to mandatory reporting is that, first of all, there be efficient IT systems at the Food and Drug Administration. These are computer-based systems that would allow the information to be transmitted to the agency, but the agency would necessarily be looking at every positive test result. Similar systems are actually being used at the Environmental Protection Agency, where they actually get a volume of data from water—the water processors, people who are responsible for ensuring the safety of water. That's the model we've been looking at. But, again, it does rely not on an individual at FDA who's responsible for looking at every one of these positive test results, but to have efficient systems that kick out the things that are abnormal or where the agency can identify, for example, that a company is not taking a critical step to control it.

This is very important, though, because of the issue with the peanut butter outbreak earlier this year, where that company had almost a dozen positive test results that they'd never shared. In fact, they were hiding them and sending the products out anyway.

Senator ENZI. I'm still trying to figure out what to do with the dilemma of people who know they're doing something wrong, but

they don't do anything about it, regardless of how many tests we impose on everybody else. So, I appreciate that answer.

Mr. Roberson, Publix seems to be able to respond very quickly to recalls. In your testimony, you mentioned the Rapid Recall Exchange, which is an alert system regarding recalls. Can you tell me how this voluntary program works with the Mandatory Reportable Food Registry that just got underway earlier this year?

Mr. ROBERSON. Absolutely, Senator Enzi. Thank you, for the question.

The Rapid Recall Exchange is a system that was built collaboratively through different levels of the industry. Both the retail industry, the restaurant industry, working in collaboration with the manufacturing industries, realized that it was important to put together a one-stop shop, you might say, of a system that would communicate recalls immediately and instantaneously with everybody throughout the purchasing side of the food industry. In doing such, when we receive that information, we can quickly communicate recalls. In Publix's case, we have 1,014 stores over five States. We can communicate that quickly from our corporate office to all of our stores. And within just a matter of minutes, we can remove suspect recalled product from the marketplace.

There is a link that this Rapid Recall Exchange is—in a future addition, I believe—it's going to have the capabilities of linking into the new FDA Reportable Food Registry. I don't have enough details on that to answer it in full but, I understand there will be a future linkage between the two.

Senator ENZI. If you can get me some more information on that, I'd appreciate it.

Mr. Ragan, I was particularly interested in the FDA's relationship with the State and the local regulatory authorities. And you mentioned the partnerships and training arrangements. I've heard a bit from my State that there's some problems with that training. In your opinion, do these activities need updating?

Mr. RAGAN. The training itself?

Senator ENZI. Yes.

Mr. RAGAN. Yes, sir. Our primary goal in working with FDA, I guess, has been through a consulting program. We consult with them on the issues that we find. We consult with them on their scientific issue. But, we certainly can use more training from them, on a formal basis. Presently, our inspectors are—before they're released to the field—undergoing approximately 62 courses online. I believe most of those online courses are provided by FDA. But, training in-house is always better than something online.

Senator ENZI. OK. Thank you.

You mentioned that you had 31 inspectors and they did 5,000 inspections. On average, how frequently does your department inspect a North Carolina food facility?

Mr. RAGAN. Our goal is to do them annually. Again, we're trying to do it based on a risk basis. I can't say that we're meeting that goal at this point in time, but we're trying to do it on an annual basis. Our program is annually.

Senator ENZI. How many establishments are there in North Carolina?

Mr. RAGAN. Fifteen hundred manufacturers and 6,000 retailers.

Senator ENZI. OK. Thank you.

I see that my time is expired. I'll submit a bunch of questions to Mr. Stenzel.

Thank you.

The CHAIRMAN. Thank you very much, Senator Enzi.

Senator Hagan.

Senator HAGAN. This is a question to Mr. Ragan. One of the things that I'm really concerned about, in particular, is the farmers in North Carolina. I know, during the tomato recall, that so many of them had to throw their tomatoes out. They lost that whole season, and obviously they are very concerned about anything that would impact their livelihood. So, I mean, obviously we want food safety, but I think we have got to be very secure in what it is that we're putting out, as far as the recall. Any comments?

Mr. RAGAN. I think you're correct. The tomato industry in North Carolina was damaged with the incorrect information, last year.

We had a listening session with FDA with some of our smaller and medium-sized farmers, and they all came across with two issues. One is that they would like to see this be a scalability issue, based on the size of the farm. They'd also like to see that there will be some sort of restoration—financial restoration to them, when they are damaged from these type of issues.

Senator HAGAN. What do you mean by "scalability"?

Mr. RAGAN. We're talking about smaller farms not meeting quite the same strict requirements as the huge, large farmers.

Senator HAGAN. OK. Alright.

Also, this question has three parts, having to do with North Carolina—how often does North Carolina have to initiate a recall? How does the voluntary recall actually work? And then, the last part, What additional authority does the State need to better facilitate recalls?

Mr. RAGAN. Actually, our recalls are not part of our law. All of our recalls are voluntary. We can't go in there and demand that someone recall something. We had an issue recently where a firm was very slow in recalling their product, and we had to—that's when we used the reverse 911.

Other things that we could do is increase our laws to require that they do do their recalls, requiring that they have an obligation to the public, as the manufacturer or as the distributor, to pull a product back in.

Senator HAGAN. One final question.

Can you discuss the ways in which the Federal, State, and local entities actually collaborate when a recall takes place?

Mr. RAGAN. Certainly.

Typically, our recalls are generated from information from our department, from our laboratory. We contact FDA. We contact them for their scientific basis, also for their regulatory basis. If it's a widespread issue, we contact DINR. We've gotten help from DINR, we've gotten help from Public Health. We've released press releases. They've released press releases. Anything to get information to the public so that a product that is out there that is potentially contaminated is not being consumed.

Senator HAGAN. Thank you. Thank you very much.

I really do appreciate all of you coming and testifying, today.

Mr. RAGAN. Thank you.

The CHAIRMAN. Thank you, Senator Hagan.

Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chair.

Earlier this year, a father and son came to my office—Jake Hurley the son, and Peter Hurley, his father—and their story, I think, raises a couple of concerns about our food safety. Jake loved peanut butter and crackers, in the little packages that came out. When he became sick earlier this year, they knew about the King Nut peanut butter issue, but they were assured that the brand that they were eating was fine. And so, they continued—even while he was sick, he continued to eat his favorite food, peanut butter. And it turned out it was, in the end, a brand also coming from the same source.

Another piece of this was—and I think Ms. DeWaal made reference to this—there is a third-party inspector who had found a series of positive tests at this particular site, but, those tests had not been passed on to the FDA. So, a couple of questions:

The first is—several of you talked about traceability. What can we do to greatly improve the traceability so that, when there are several brands coming out of a factory, the public finds out about that quickly? Do we need to go further than the bill currently goes? Do you have any specific recommendations?

And second, in regard to third-party inspections, the bills do call for using third-party inspectors, both the bill on the House side and the bill on the Senate side; but, when you have a situation where an inspector hasn't reported the results, what kind of penalties—I'd like to know what happened in this case and certainly what should happen in future cases.

Ms. DeWaal, do you want to start off?

Ms. DEWAAL. Thank you very much, Senator Merkley.

First of all, on the issue of traceability, it's critical, and traceability needs to be on food products from the consumer all the way back through the production cycle.

Now, the bill that's in front of you has a pilot study for traceability, and the House legislation has a slightly stronger provision. It's really a mandate they move to traceability, but also it gives the FDA the opportunity to spend some time exploring what is the right approach.

With respect to the second question you asked, the issue of third-party certifiers, I want to be very clear that that only applies to imports. That's true for both the Senate bill and the House bill. This is not a system that should replace inspection by FDA of our domestic plants.

And the last issue you raised is, What are the penalties? FDA is operating with very inadequate penalties. I mean, their penalties were designed around the turn of the last century. They need civil penalties. They need the ability to give meaningful penalties to people who violate the law. Right now, they can—they have criminal penalties, but they need the ability to move forward with civil monetary penalties. That is missing from this legislation, except for in the recall area. So, I would hope you would look at that issue.

Senator MERKLEY. Well, help me understand this. Am I correctly informed about it being third-party inspectors, or was it in-house inspectors, who failed to pass on the information to the FDA?

Ms. DEWAAL. My understanding is that the owner of the plant had the information. I'm not sure whether he passed it on to the third-party auditor. But, it is clear that the third-party auditor involved didn't do a very good job. And because the system of third-party auditing—both in the international area and domestically—has come out from the industry itself, there is different levels of quality. I mean, certainly American consumers shouldn't be relying on subpar or poor quality third-party certifiers. That's why it's important that FDA be the agency charged with domestic inspections, in all cases.

Senator MERKLEY. So, let me push this a little further. Is there an inherent conflict of interest? If I'm a third-party inspector and I'm tough, and I pass on positive results to the FDA, am I going to get hired again anywhere? I mean, is that an inherent challenge we have right now in the system?

Ms. DEWAAL. Well, one of the ways that the legislation actually addresses this is, it does put that responsibility on the labs, as well. So, the laboratories involved will be certified, hopefully, under the legislation, and they will also have some obligations to pass on results. So, the third-party certifier is a private contractual relationship for domestic products. They may pass on the results or may not. But, you're right, they probably won't get hired if they do. But, it's critically important that the company themselves have the responsibility to share that information with FDA, and also, the requirement to actually conduct the tests. One of the things that's critical in this bill is that we not just pass the requirement to report tests, but not a requirement to actually do the verification testing. We need both.

Senator MERKLEY. I'm over time, but after my colleague asks questions, if we have a chance to come back to this traceability issue, I'd appreciate it.

The CHAIRMAN. Senator Merkley, the vote has been called.

Senator Franken.

Senator FRANKEN. I'll try to keep it short. The other Senators' questions have been so good.

But, Ms. DeWaal, I just want you to explain in more detail the improvements that you think should be made in the bill.

Ms. DEWAAL. Thank you very much, Senator Franken.

There are probably three areas that—where we're most concerned. One is the area of the frequency of inspection. The bill requires high-risk plants to be inspected once a year. In the House bill, there's a range provided, but there could be some greater specificity as to what exactly are high-risk facilities. So, we're asking for at least three categories of risk built into the bill, with appropriate inspection facilities.

The second is in the area of testing. As I mentioned earlier, we want a mandatory verification testing built into the bill, together with this issue of reporting positive tests results.

The final area is the area of imports. We've got this accreditation body in the bill that's playing a role that we think is—it's a role that could be played on—if FDA chose to do it, but it certainly

shouldn't be a requirement that an accredited body approve a foreign government. Yet, that appears to be what's in the bill today. So, we would like the committee to look very closely at the language around the accreditation body. And we can certainly provide the committee with specific recommendations on that.

Senator FRANKEN. Thank you.

Just briefly, Mr. Roberson, you mentioned the Food Safety Rapid Response Act, in your testimony, which is an effort to model regional centers of excellence after the system at the University of Minnesota. Others have mentioned the need to improve the workforce for outbreak investigations. Are you familiar with Senator Klobuchar's bill, S. 1269, at all?

Mr. ROBERSON. I am not very familiar with it, Senator Franken.

Senator FRANKEN. OK. Anybody else on the panel?

[Laughter.]

All right. Well, I think it would be a good start in improving our Nation's capacity to conduct outbreak investigations, so I'm just shilling, here, for my senior Senator, I guess.

[Laughter.]

But, thank you.

And thank you, Mr. Chairman.

We should vote, huh? I guess?

Thank you all. Really. Great.

The CHAIRMAN. We've gone into the second half.

Senator Merkley, did you just have a quick followup on that before we leave here?

Senator MERKLEY. If anyone would like to comment on the traceability and ways that we really need to push to make it work. It's been mentioned that we have a pilot project in the bill. Is that enough? Is there a promising technology we need to pursue? Just any comments on this traceability.

I just want to note that it's so important, for example, not just to find the problem to alert consumers, but also to protect every other agricultural segment that may be—there may be suspicion, but tracing down the fact that they're not involved, that the tomato growers were not involved, is very important, as well.

Mr. STENZEL. That's exactly right, Senator Merkley. The produce industry is totally committed to a total supply-chain traceability of our products. Following the hearing, I'd like to submit some background on that, for you, so you can see we do have the technology today to supply a total traceability system.

Senator MERKLEY. Please.

That's it.

The CHAIRMAN. Very good.

Senator MERKLEY. Thank you.

The CHAIRMAN. Well, thank you.

Any other last things for the record?

[No response.]

The record will remain open for 10 days, to allow submission of statements and questions for the record from other Senators.

I thank you all for being here. And again, not only that, thank you for your total involvement in this effort to get a good food safety bill through.

As I said at the opening, we have one that has broad support, which we always like. Hopefully we can go to a markup, here, pretty soon in this committee. I'll be talking with Senator Enzi about that, and others on the committee, to see if we can get a markup scheduled pretty soon, and hopefully we can get this bill passed and on down to the White House before year's end.

Thank you all very much.

The committee will stand adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR BURR

Good morning. I would like to thank Chairman Harkin for holding today's hearing on the important subject of how we can better ensure the safety of our Nation's food. I would also like to thank all of our witnesses for traveling to be with us today, and I would like to extend a particularly warm welcome to Dan Ragan, the Director of the North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division. I am pleased Dan will be able to share the experiences and perspectives of North Carolina as we consider legislation to better protect our Nation's food supply.

We are all too familiar with the high-profile nationwide outbreaks and recalls in recent years in which pathogens in peanut butter, pistachios, peppers, and spinach resulted in illnesses in people across our country. In addition to the health concerns, many of these incidents also had a significant economic impact on American growers and producers across our Nation. These outbreaks have led me to believe that the Federal Food and Drug Administration needs improved regulatory tools to protect our Nation's food supply. The Centers for Disease Control and Prevention estimate that 76 million food-related illnesses occur annually in the United States, with 325,000 people hospitalized and 5,000 dying as a result. Our committee has held several hearings on the topic of food safety over the years, and I have enjoyed working on bipartisan food safety legislation with my colleagues on both sides of the aisle. While the devil is always in the details when it comes to the legislative process, I sincerely hope we can advance bipartisan food safety legislation this Congress. It is time for Congress to take action to modernize and strengthen our Nation's food safety system.

I am proud to be a cosponsor of The FDA Food Safety Modernization Act of 2009. This bill improves FDA capacity to prevent food safety problems by requiring additional hazard analysis and preventive controls and increased scrutiny of imported foods. In addition, our bill also improves our capacity to detect and respond to food-borne illness outbreaks by increasing FDA resources to conduct more periodic inspection of facilities. This legislation would also improve planning for intentional human contamination or adulteration of food, providing food manufacturers with the tools to defend against intentional contamination.

Within the last 2 weeks, the North Carolina Department of Agriculture and Consumer Services initiated a recall of sandwiches due to the potential for the contamination of *Listeria monocytonegenes*, a bacterial infection that can result in still births or miscarriages in pregnant women or cause very serious illness in elderly or immunocompromised individuals. This recent episode illustrates that an effective response to any food incident requires the appropriate collaboration between Federal, State, and local agencies.

I'd also like to point out that increased regulation and testing alone will not fix our food safety system. We need to pay special attention to training the next generation of food safety inspectors and using our Nation's land grant universities to educate food suppliers and processors. Having qualified, competent individuals

working with our food suppliers will ensure the proper relationship between industry and government. Utilizing the existing infrastructure our land grant college and universities have to educate suppliers and processors on good manufacturing practices will foster a proactive response rather than a reactive response. Only when we have a collaborative process among all involved will we be able to fully implement a comprehensive food safety system.

I hope this morning's hearing will provide a frank discussion of what is working well and what is not working well to protect our Nation's food supply and keep our constituents safe and healthy as we continue to work on bipartisan food safety legislation. I thank the Chair.

PREPARED STATEMENT OF BOB BAUER, PRESIDENT, THE ASSOCIATION OF FOOD INDUSTRIES

The Association of Food Industries (AFI) appreciates the opportunity to present testimony regarding legislation intended to improve the safety of America's food supply.

AFI is a trade association serving the food import trade. AFI is committed to developing programs that facilitate the businesses of its member companies, encourage free and fair trade, and foster compliance with U.S. laws and regulations for the food industry. AFI members are responsible for importation into the United States of a significant percentage of products such as olives, olive oil, pasta, nuts, dried fruit, canned seafood, canned vegetables, canned fruit and many other processed food products from around the globe.

AFI is pleased to support enactment of S. 510, "FDA Food Safety Modernization Act," though we feel modest changes would strengthen the legislation. Specifically, we endorse recommendations that would assure the integrity of sampling and analysis of imported products subject to Import Alert. Further, we note that implementation of sound legislation may give rise to trade violations. In the current climate of significant tensions in trade relations, we recommend addition to the bill of a provision specifying that no provision of S. 510 may be construed to authorize a violation of international trade obligations of the United States.

We believe that the provisions of S. 510 could be implemented in a manner that avoids violation of international trade agreements. Express direction for implementation to avoid such violations would assure due consideration to international obligations during the rulemaking process. Provisions of the legislation that could give rise to trade issues include, for example, the provisions requiring all registered food facilities to implement preventive controls plans and authorizing performance standards to minimize food hazards, if these provisions were implemented in ways that go beyond what is necessary to protect human health. Other provisions in S. 510 could be implemented in a manner that discriminates against imported products. These include, for example, provisions requiring third-party certification for designated imported foods and provisions imposing supply chain verification requirements on importers, but not on domestic producers.

To address these concerns, AFI recommends that S. 510 be amended to provide that no provision of S. 510 may be construed to authorize a violation of international trade obligations of the United States.

AFI has grave concerns about the "Food Safety Enhancement Act of 2009" (H.R. 2749), passed by the House on July 30, 2009. The House legislation includes provisions that appear to be in clear conflict with U.S. obligations under international trade agreements.

COUNTRY OF ORIGIN LABELING—SECTION 202

Section 202 provides that a processed food is misbranded unless its labeling identifies the country in which final processing of the food occurred. It provides that a non-processed food is misbranded unless its labeling identifies the country of origin of the food. A food would not be deemed to be misbranded if: (a) in the case of a processed food, the label informs the consumer where final processing occurred in accordance with existing Customs and Border Protection requirements; and (b) in the case of a non-processed food, the label informs the consumer of the country of origin in accordance with existing U.S. Department of Agriculture requirements.

Although country of origin labeling is not normally considered to be a food safety measure, its presence in a bill exclusively devoted to food safety (and called the

"Food Safety Enhancement Act") suggests that it is intended as a sanitary or phytosanitary measure in this case. It therefore would likely be analyzed under the Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement").

According to Article 2.2 of the SPS Agreement, "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence. . . . " Section 202 of H.R. 2749 does not appear to be based on any scientific or public health justification. In fact, since the vast majority of imported foods are already required to have country of origin labeling, the principal effect of section 202, although probably not intended by its authors, would be to require country of origin labeling for all domestically produced U.S. foods. It is not clear how this change would protect human health.

Section 202 also appears to violate Article 5.1 of the SPS Agreement. Article 5.1 states that:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

Section 202 of H.R. 2749 does not appear to be based on any assessment of risk.

RECORDKEEPING AND TRACEABILITY—SECTION 107

Section 107 would require FDA to issue regulations creating "a tracing system for food that is located in the United States or is for import into the United States." This tracing system would require food companies to maintain records sufficient to enable FDA "to identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food in as short a timeframe as practicable but no longer than 2 business days." Section 107 also would generally remove the current exemption for farms, thereby requiring them to maintain traceability records. Violations of the traceability requirements would be a prohibited act subject to criminal prosecution.

When read in conjunction with section 213 of the bill, which gives FDA extraterritorial jurisdiction over violations that relate to food intended for import into the United States, it appears that section 107 would create detailed recordkeeping requirements for foreign food companies at every stage of production and distribution all the way back to the farm. In addition, H.R. 2749 would apparently authorize civil and criminal penalties against foreign companies that fail to comply with traceability recordkeeping requirements.

Section 107 may violate several provisions of the SPS Agreement, including the following:

- It may violate Article 2.2, because it imposes traceability requirements beyond what is necessary to protect human health.
- It may violate Article 5.1, because it is not supported by an assessment of risk. We are not aware of any attempt by FDA to show that this traceability requirement would reduce the risk of foodborne illness as compared to existing recordkeeping requirements.
- It may violate Article 5.6, which requires that sanitary and phytosanitary measures may not be more trade-restrictive than necessary to achieve the appropriate level of protection, "taking into account technical and economic feasibility." In many foreign countries, producing records capable of tracing food back to the farm within 2 business days is not currently technically or economically feasible.
- It may violate Article 10.1, which requires members to "take account of the special needs of developing country Members, and in particular of the least-developed country Members." Section 107 would disproportionately impact countries that export raw agricultural commodities, which tend to be less developed countries.

IMPORTER DOCUMENTATION REQUIREMENTS—SECTION 136

Section 136 provides that the Secretary of Health and Human Services (Secretary) may, by regulation or guidance, require the submission of unspecified "documentation or other information for articles of food that are imported or offered for import into the United States" and may specify the format in which such documentation or other information must be submitted. Section 136 further provides that failure to submit such unspecified documentation or information, or submission of inaccurate or incomplete documentation or information, is a prohibited act that would subject the party in violation to criminal prosecution or civil penalties of up to $7.5 million.

Section 136 appears to violate Article 2.3 of the SPS Agreement, because it discriminates against imported foods by authorizing open-ended documentation requirements applicable only to imports. Article 2.3 states that:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

Section 136 could be implemented in a way that would impose arbitrary and unjustifiable documentation requirements on imports.

Section 136 also may violate Article 8 and Annex C, Sections 1(c) and (e) of the SPS Agreement, which requires that import control requirements must be limited to "what is reasonable and necessary." Specifically, members are required to "ensure, with respect to any procedure to check and ensure the fulfillment of sanitary or phytosanitary measures, that: . . . (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures . . . ; (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary . . . "

Section 136 also appears to violate Article VIII of the General Agreement on Tariffs and Trade of 1947 (GATT 1947), because it has the potential to impose excessive documentation requirements on food imports and because it would impose substantial penalties for minor breaches of such documentation requirements. According to Article VIII of GATT 1947,

> "Contracting parties also recognize the need for minimizing the incidence and complexity of import and export formalities and for decreasing and simplifying import and export documentation requirements. . . . No contracting party shall impose substantial penalties for minor breaches of customs regulations or procedural requirements. In particular, no penalty in respect of any omission or mistake in customs documentation which is easily rectifiable and obviously made without fraudulent intent or gross negligence shall be greater than necessary to serve merely as a warning."

IMPORTER FEES—SECTION 204

Section 204 would require food importers to register with FDA and pay an annual registration fee of $500.

Section 204 may violate Article VIII of GATT 1947. Article VIII provides that:

> "[a]ll fees and charges of whatever character (other than import and export duties and other than taxes within the purview of Article III) imposed by contracting parties on or in connection with importation or exportation shall be limited in amount to the approximate cost of services rendered and shall not represent an indirect protection to domestic products or a taxation of imports or exports for fiscal purposes."

The registration fee that H.R. 2749 would impose on food importers is not related in amount to any services rendered to importers. The fee amount appears to be arbitrarily set to equal the registration fee that H.R. 2749 would assess on registered food facilities.

Therefore, AFI respectfully opposes enactment of legislation that includes these problematic provisions of H.R. 2749 because they would apparently violate international trade obligations without meaningful benefit to the safety of the U.S. food supply.

Once again, we want to thank the committee for this opportunity to submit our views. We are grateful to the Chairman and Ranking Member for seeking public input, and to Senator Durbin for his bipartisan leadership on this issue. AFI and its members are ready to work with the committee and the Senate in developing legislation that advances the safety of the U.S. food supply, which need not raise concerns about compliance with international trade obligations.

PREPARED STATEMENT OF KRAIG R. NAASZ, PRESIDENT & CEO, AMERICAN FROZEN FOOD INSTITUTE

Chairman Harkin, Ranking Member Enzi and members of the committee, I am pleased to submit this statement on behalf of the American Frozen Food Institute (AFFI). We appreciate your commitment to food safety and commend the committee for holding this important hearing.

The American Frozen Food Institute (AFFI) serves the frozen food industry by advocating its interests in Washington, DC, and communicating the value of frozen food products to the public. The Institute is comprised of 500 members including

manufacturers, growers, shippers and warehouses, and represents every segment of the $70 billion frozen food industry. As a member-driven association, AFFI exists to advance the frozen food industry's agenda in the 21st century.

AFFI's members are committed to food safety, which is their highest priority. Consumers have a reasonable expectation that the food products they buy are safe. While much is being done to ensure the safety of food, safeguards must be continually updated. To that end, since 2004, AFFI has led a coalition of trade associations and food companies advocating for modernization of the Current Good Manufacturing Practices (CGMPs) administered by the Food and Drug Administration. These regulations, which form the foundation of food safety assurance programs in manufacturing facilities, were last updated in 1986. AFFI continues to encourage FDA to review and modernize the CGMPs.

Consistent with modernization of FDA's regulations, AFFI also supports efforts to modernize our Nation's food safety laws. In particular, AFFI believes that S. 510, the "FDA Food Safety Modernization Act of 2009," is a reasonable, common sense approach to enhancing food safety and consumer confidence in our food supply. Importantly, the food industry accepts primary responsibility for ensuring the safety and quality of the food supply. As such, AFFI agrees with the bill's cornerstone provision that food companies must identify hazards that may occur in the production of their products and implement the most effective controls for mitigating those hazards. These measures must be documented in a written plan and should be available for FDA review during inspections.

AFFI concurs with the bill's adoption of a risk-based inspection regime. And we concur with the increased focus on raw agricultural commodities. AFFI also believes that FDA should have the authority to order a mandatory recall of products presenting serious adverse health consequences when a company has refused to conduct a voluntary recall. Moreover, AFFI supports stronger enforcement authorities for FDA, provided such authorities are not overly broad and incorporate basic elements of due process.

AFFI supports increased appropriated funding for FDA as outlined in S. 510 to enable FDA to do the job that Congress prescribes and consumers and the food industry expect. Food safety can best be enhanced when both government and industry apply proven, science-based approaches and work cooperatively with one another.

Although AFFI is in conceptual agreement with the direction and content of S. 510, we look forward to working with the committee to refine the bill and to address certain specific concerns. For example, in our view, requirements for implementation of safeguards related to food security and defense should not be treated the same as preventive controls for food safety. Guarding against deliberate contamination, which presents risks that cannot readily be anticipated, requires a different approach than controls implemented to prevent unintentional food safety hazards that may be deemed reasonably likely to occur. Food defense requires a different analytical framework and process control terminology. Food defense vulnerability assessments should not be confused with food safety preventive controls. S. 510 should be revised to reflect these differences and the requirement to implement a food defense plan should be separate from that for food safety plans.

AFFI believes the scope of the administrative detention provision in the bill is overly broad and subjective. In particular, the bill would allow FDA to prevent the distribution of food because the agency has "reason to believe" that a food is "adulterated or misbranded." Instead, FDA's ability to detain food should be limited to situations where there is "credible evidence" that the food presents a serious threat of adverse health consequences. This is the standard that was adopted when the Bioterrorism Act was passed after the events of 2001.

S. 510 would subject a company to criminal penalties for the failure to comply with a mandatory recall order. Current law already provides for criminal penalties for distribution of adulterated or misbranded food. Moreover, the potential damage to a food company's reputation and the potential for civil liability from the distribution of food believed to be unsafe is by far the most significant incentive to remove a violative product from the marketplace. For these reasons, AFFI questions the need to authorize regulators to impose additional civil money penalties.

Additionally, AFFI understands the rationale that has been offered in support of imposing re-inspection and recall fees. However, we believe that these are government functions; fully funding FDA through the appropriations process is the preferable approach and the appropriate pathway for assuring FDA has adequate resources to do its job.

Finally, AFFI wishes to comment on a few provisions that are not part of S. 510, but are found in the bill passed by the House of Representatives, H.R. 2749. First, AFFI favors improvements in traceability, but it is critical that any new legal requirements be commensurate with existing technology and the capabilities of all

food companies, especially small businesses. Therefore, food safety legislation should make information gathering and analysis the centerpiece of any traceability provision and a clear prerequisite to government rulemaking. Such analysis is essential to determining what traceability actions are feasible, practicable, cost-effective and useful. In addition, we believe FDA should have the flexibility to establish traceability performance goals based on the information gathering process. In effect, dictating specific traceability requirements in advance of adequate study prejudges this process.

Second, although AFFI supports making finished product testing results available to FDA during inspections, we do not support sending those test results directly to FDA. Nor would we support relying on selected test results for regulatory action. Finished product testing is just one tool used to ensure the effectiveness of a food safety system, essentially a snapshot; mandated testing and reporting regimes perpetuate the mistaken belief that finished product testing is a substitute for proper manufacturing and process controls. A robust food safety system, including environmental sampling and zone control which uncovers and controls potential sources of contamination, is the key to pathogen eradication.

As a final point, AFFI is supportive of providing FDA expanded access to food safety records during routine inspections and during investigation of the actual distribution of an adulterated product. We oppose, however, the records access proposal in H.R. 2749 granting FDA routine and remote access to food safety plans. In our experience, records reviewed remotely and out of the context of an on-site inspection are of little benefit and can be misleading.

In summary, AFFI and its members are strongly committed to ensuring that consumers receive safe and wholesome foods. Accordingly, AFFI supports modernization of the Nation's food safety laws and regulations. Thank you for this opportunity to testify. AFFI looks forward to working with the committee to shape the future of food safety and to ensure the well-being of American consumers.

PREPARED STATEMENT OF THE CHEESE IMPORTERS ASSOCIATION OF AMERICA

The Cheese Importers Association of America (CIAA) appreciates the opportunity to submit testimony for the record of this important hearing regarding a topic of the highest priority for our members. The CIAA is an association consisting of cheese importers who support efforts to enhance America's food safety regulatory systems. We are concerned that public confidence in food safety has eroded, and we support legislative actions to provide meaningful improvements to better assure food safety. While the FDA Food Safety Modernization Act of 2009, as introduced by Senator Durbin takes great strides to remedy the issues plaguing our food supply, we have significant concerns about some provisions.

The CIAA represents the vast majority of firms engaged in the business of importing, selling, promoting, and distributing cheese and cheese products in the United States. Its members are long-tenured food importers, many of whom operate a business that has been in their family for many years. They have a track record of success and compliance with requirements relating to food safety, product security, and trade facilitation.

The CIAA has a long record of mutual cooperation with the FDA. Due to the proximity of the East Coast ports in New York and New Jersey, through which many of our members' products enter the country, we have developed good rapport with the FDA New York District Office. We continually work with the District management to ensure efficient importation and clearance of goods. In the past, we have held seminars for both New York and Buffalo FDA personnel to educate them on our industry and products. These seminars help FDA better understand the specific nature of our imported products, while continuing to foster a good working relationship between cheese importers and the FDA. Additionally, we recognize the importance of a safe food supply, which is why we have worked in conjunction with FDA to stop importation of products that do not conform to FDA standards, specifically raw milk cheeses that are less than 60 days old.

We appreciate the bipartisan approach the Senate has taken to this issue. It is often difficult to achieve consensus on food safety, and we view this bill as a tremendous opportunity for the Senate to provide meaningful improvement in food safety on a bipartisan basis. As the American consumer has developed a palate for imported and specialty cheeses, our members continually strive to supply a safe supply of imported cheeses. Importers support supply chain improvements, and other such advances designed to ensure a safe food supply.

We have serious reservations regarding the Food Safety Enhancement Act as passed by the House of Representatives. As the committee considers the FDA Food Safety Modernization Act, we respectfully ask that you take into consideration our

concerns regarding specific provisions in the House bill. We appreciate your consideration of our comments.

TRADE CONCERNS

While we appreciate that the provisions of the Food Safety Enhancement Act are not intended to breach U.S. duties under international trade agreements, we are concerned that implementation of its provisions could cause that result. We respectfully request addition of a provision to any final legislation specifying that no provision of the bill shall be construed to authorize a violation of international trade obligations. Such a provision would ensure that FDA consults with the U.S. Trade Representative in development of implementing regulations. Thereby, trade violations that Congress did not intend may be avoided.

CIVIL MONEY PENALTIES

We respectfully oppose the excessive civil money penalty authority provided in the House bill. Traditionally, civil money penalties have been justified as a means of imposing a penalty for relatively minor regulatory violations that do not justify prosecution. If an agency determines that a civil money penalty should be imposed, agency personnel serve as both prosecutor and judge. Judicial review is not on a *de novo* basis, meaning that a reviewing court must sustain the penalty if the agency acted within its authority and there was evidence to support its finding. Under this standard, the reviewing court is charged to accept every factual assertion of the agency and no factual assertions of the appellant.

While this procedure is highly efficient for a regulatory agency, it also grants the agency vast power to impose fines without meaningful accountability. When an agency has authority to impose civil money penalties that can threaten the viability of a business, it is imprudent to contest the civil money penalties even if the accused is innocent. Instead, the accused company "settles" with the agency by paying a relatively modest fine and signing a "consent agreement" in which the company is required to perform various acts, including actions the agency has no authority to require.

The House bill authorizes extreme civil money penalty authority, especially for unintentional violations. With respect to unintentional violations, the bill provides for civil money penalties of up to $20,000 for individuals and up to $250,000 for other persons for each day a violation occurs, with a cap of $1 million in any single proceeding. The bill authorizes such fines for almost any error in the intensively regulated arena of food production and marketing, including minor errors in record keeping or food labeling. In food law, it is common for a single mistake to result in scores of violations. Further, it is common for a minor error to remain undiscovered for weeks or longer. So, if a minor labeling error caused violations on 30 lots that were shipped on a single day and the error went undiscovered for one month, the House bill would authorize civil money penalties of $225,000,000.

In reviewing these facts, we mean to imply no disrespect for the officials of the Food and Drug Administration. However, we have grave concerns regarding the effect of such sweeping authority without meaningful accountability.

The current Senate bill amends the Food, Drug, & Cosmetic Act by providing that any person who does not comply with a recall order will be assessed the civil penalties spelled out in the current law. We understand the necessity for such a provision for noncompliance when there is a serious public health threat which demands a recall. We encourage the Senate not to add extraneous penalties which may have the effect of harming small businesses that mistakenly and unintentionally commit a violation.

INFORMATION TECHNOLOGY (IT)

The single step that could most dramatically improve FDA's effectiveness in scrutinizing the safety of food imports would be to provide the agency modern information technology capabilities. While inter-operability with the IT systems of other Federal agencies would be desirable, we suspect that delays to achieve inter-operability mandates are likely to cause delay and expense that far exceed the potential benefit of comprehensive inter-operability. We respectfully recommend that the bill include a requirement that the committee be provided an annual GAO report regarding FDA's IT capabilities regarding imports.

COUNTRY OF ORIGIN LABELING

We respectfully oppose the House bill's Country of Origin Labeling (COOL) provision. This provision mandates that all processed food labels list the country in which

final processing occurred. Without this information, products would be "misbranded."

Imported processed foods already are required to declare their country of origin on the label under the Tariff Act of 1930 and U.S. Customs regulations. There is absolutely no need to create a redundant set of FDA regulations on country of origin labeling.

TRACEABILITY

Cheese importers proudly comply with the "one-up, one-back" recordkeeping requirements of the Bioterrorism Act. Under the current regime, companies must maintain records of where their raw materials come from, both suppliers and transporters, and where their finished products go, both customers and transporters. However, we are gravely concerned that sweeping traceability system recordkeeping requirements for all foods and food ingredients in the House passed legislation would impose exorbitant costs without meaningful food safety benefit.

The Food Safety Enhancement Act would mandate a tracing system under which industry would be required to identify each person who grows, produces, manufactures, processes, packs, transports, holds or sells food . . . within 2 business days. This farm to retail tracing system would require companies to maintain "pedigrees" for each food and food ingredient at an expense beyond estimation. It would also require records capable of tracing foods back to coffee bean growers in the Andes, cocoa bean growers in West Africa, harvesters of wild Brazil nuts in South America, wheat farmers in Kansas or dairy farmers in Switzerland. No need has been demonstrated for this sweeping requirement.

It is inappropriate to require such a system in the absence of a determination by FDA that the system is necessary to protect public health and an estimate of the cost of compliance. Processed foods, such as cheese imports, which are already heavily monitored under current law, do not require such a "farm to fork" traceability system.

FEES

Both the House-passed and Senate bills include new fees that would affect cheese importers. Under the FDA Food Safety Modernization Act, importers will be charged an annual fee to participate in the Voluntary Qualified Importer Program, as well as fees charged if FDA needs to re-inspect the importer's facility.

Understanding that food safety legislation is likely to include some form of revenue generation, food importers request that the language be written in such a manner that importers are not charged several times for the same fee. While importers are not required to participate in the Voluntary Qualified Importer Program, it behooves them to do so, as the program allows for expedited processing of their imports. Yet, because many importers are small businesses, we would ask that fees for both the Voluntary Qualified Importer Program and the reinspection costs be set in a manner that accounts for the size of the business (or the frequency of imports) so that the assessment is proportionate to the size of the firm.

INSPECTIONS AND INSPECTION FREQUENCY

The new risk-based inspection schedule set forth in the Food Safety Enhancement Act is inappropriately prescriptive. The legislation before the committee today does not set forth such a detailed risk schedule for foods; rather, it directs the FDA to allocate resources for inspection of registered facilities according to their risk profile based on numerous factors set forth in the legislation. While these are reasonable factors upon which to create a risk profile, we respectfully submit that food science, rather than legislated directives should determine level of risk. A true science-based approach to categorizing risk would lead to the most appropriate and effective allocation of FDA resources.

Cheese importers appreciate that, under the FDA Food Safety Modernization Act, the FDA may enter into agreements with foreign governments to facilitate inspection of foreign facilities registered with FDA. Source inspections provide the surest proof that products imported for sale in the United States are safe.

THIRD-PARTY INSPECTIONS

Cheese importers support regulatory oversight of third-party inspections. Given the long-standing resource concerns at FDA, certified third-party inspectors could play a critical role in closing some of the gaps in our food safety system, especially with respect to overseas facilities. Commissioner Hamburg requested authority to examine the use of third-party inspectors as a way to expand the capacity of the

FDA. The FDA Food Safety Modernization Act requires that the FDA implement a system to recognize accreditation bodies no later than 2 years after enactment, and cheese importers support the implementation of such a system for accrediting third-party auditors to certify "eligible entities". We believe these accreditation bodies and "third-party auditors" can be an important asset, but how the FDA would certify these entities, what their role would be, how their work integrates with the agency, and other important questions remain to be answered.

Cheese importers urge that Congress give FDA flexibility in its implementation of such a system to assure maximal use of FDA resources.

Once again, we want to reiterate our appreciation of the opportunity to submit these comments. We are grateful to the Chairman and Ranking Member for seeking public input, to Senator Durbin for his bipartisan leadership on the issue, and the committee for their work.

The CIAA, and its members, stand ready to work with the committee and the Senate to craft legislation that addresses the challenges facing our system in the most responsible manner.

PREPARED STATEMENT OF THE FRESH PRODUCE ASSOCIATION OF THE AMERICAS

The Fresh Produce Association of the Americas (FPAA) would like to thank the HELP Committee for holding a hearing on food safety, and we would like to take this opportunity to present information for the record concerning food safety and imported produce. The FPAA is a trade association headquartered in Nogales, AZ, the largest port of entry for fresh fruits and vegetables imported into the United States from Mexico. Last year alone companies in Nogales imported over 4 billion pounds of fresh produce for distribution across North America.

IMPORTED PRODUCE

As an association of U.S. importers, the members of the FPAA experience first-hand the scrutiny that each shipment of fresh produce is subject to before entering the United States. One hundred percent of all shipments of fresh produce must submit detailed information to the U.S. Food and Drug Administration and Customs and Border Protection. Our Federal agencies use this information to target inspections on any and all trucks that they would like to receive further examination and any product that they would like to sample, inspect or test. Again, this applies to every single truck, every single day, 365 days a year.

While every box is not individually inspected by the FDA or the USDA, information on every shipment is reviewed and a statistically valid sample is inspected to insure the quality and safety of imported fresh produce. Actually, imported produce is inspected nine times more often than domestically grown produce which is grossly out of proportion to risks from imported fruits and vegetables versus domestic fruit and vegetables. Our Federal agencies, including FDA, CBP, USDA, the U.S. Department of Transportation, as well as other Federal, State, and local agencies have the ability to deny entry to any shipment arriving at our ports of entry and exercise that authority when necessary.

Fresh produce from Mexico has been imported for over a century. From the very beginning, growers have continuously looked for better ways of growing and harvesting fresh produce. By constantly looking for ways to improve the quality and safety of fresh fruit and vegetables, they are able to continue to sustain their businesses and to provide jobs to the hundreds of thousands of employees that rely on them for work. Food safety is good for business, and they know it.

As the development of food safety legislation moves forward, the FPAA would be very open to testifying before the HELP Committee if there are future hearings. Legislation that has passed the House of Representatives and current bills in the U.S. Senate have importer-specific sections. It is in the interest of the industry and the U.S. Congress to make these regulations as effective as possible in increasing the safety of our food supply. For that reason, the FPAA would like be considered for any future hearings.

EQUAL LEVEL OF STANDARDS USING RISK-BASED ANALYSIS

The FPAA supports the efforts of Congress to pass legislation that would work to maximize the efforts of the FDA and the food industry and to create a system where domestic and imported produce must be held to the same level of standard. The FPAA strongly believes that FDA should be regulating domestic produce with the same level of vigor as that of imported produce. In addition, FDA needs the flexibility, through rulemaking and changes to operational procedures, to best imple-

ment systems for a domestic and an import supply chain and to develop risk-based systems that provide the maximum benefit.

Microorganisms are present in all countries. No geographic location, be it domestic or foreign, makes a commodity more or less susceptible to contamination. Preventative controls, proper monitoring, and research are the keys to decreasing the chance of unintentional contamination. By working together to ensure that food safety and security procedures cover all facets of the produce industry, imported and domestic, we are better able to bring consumers a greater variety of fresh, wholesome, and safe fruits and vegetables that contribute to a healthy diet. Again, the FDA and the industry must be given the flexibility to focus the maximum amount of resources on the processes, items, and areas representing greatest risk.

As with all facets of life, nobody has all the answers to make the world 100 percent safe but we continue to implement the best science-based food safety programs available and undergo stringent third party food safety audits by American auditing bodies to showcase these efforts.

ONGOING FOOD SAFETY EFFORTS

FPAA members work closely with FDA, CBP, and other agencies to continue to improve processes and procedures that will strengthen oversight of imported food while expediting trade with our trading partners. We feel this is important in dealing with broader, long-term issues, and also on streamlining and strengthening the day-to-day technical issues. As an industry, we are committed to continuing that dialogue, no matter the outcome of legislation moving through Congress.

In fact, the FPAA and its members pushed for years to bring the FDA's mobile laboratory to Nogales, AZ, the Nation's largest port of entry for fresh produce from Mexico.

After years of working with the FDA, the mobile lab was stationed in Nogales, AZ in April 2009. Of the hundreds of samples and thousands of tests taken, I am proud to report that not one shipment tested positive for microbial contamination. We continue to work with FDA to bring the mobile lab back to Nogales for future season. The mobile lab allows the FDA to gather information on a broader number of shipments and commodities, gives faster test results, and helps the industry and FDA add another layer to the monitoring of food safety processes.

ADEQUATE FUNDING FOR FDA

Food safety legislation is just one facet of successfully implementing procedures to increase the safety of the food supply. The FPAA also strongly supports proper funding for FDA to allow the agency to hire the necessary number of personnel and to develop the necessary infrastructure, including regional labs and mobile labs. Congress must continue to increase FDA funding to levels that allow the FDA to perform the mission outlined by Congress. This is especially critical given that new food safety legislation will increase the amount of resources that FDA will need to complete its mission.

The current bill being discussed in the U.S. Senate, S. 510, "The FDA Food Safety Modernization Act," gives the FDA authority to create a fee structure for certain activities that would be paid by the industry. The FPAA believes that legislation should clearly state that fees for importers and for domestic growers should be equal. If fees are higher for imports, it is likely that legislation would violate WTO and other trade agreement obligations.

FOREIGN GOVERNMENT AND THIRD-PARTY CERTIFICATION RECOGNITION

The FPAA strongly supports collaboration with foreign governments in reviewing and recognizing the food safety systems of foreign governments. This is especially important concerning the oversight of what will become required food safety plans. The FPAA believes it is important for FDA to engage with foreign government to understand current food safety systems in place with U.S. trading partners, and to acknowledge those systems that equally contribute to the overall requirements of the FDA.

The FPAA also supports a careful consideration of third-party certification in the context of S. 510, "The FDA Food Safety Modernization Act," given that limited FDA resources could hamper the FDA's capacity to inspect and verify all domestic and foreign entities for what will become required food safety plans.

CONCLUSION

Again, the FPAA would like to thank the HELP Committee for their dedication in discussing food safety and in trying to develop common-sense, effective legislation

that will develop equal oversight of imported and domestic produce and will work to strengthen the safety of the U.S. food supply. We hope we can be of assistance as this process moves forward. The combined efforts of the FDA, Congress, and the industry are integral to our future success.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES,
RALEIGH, NORTH CAROLINA 27699–1070,
November 6, 2009.

SENATOR ENZI, I would be honored to respond to your questions regarding my testimony provided at the Senate HELP Committee Hearing, "Keeping America's Families Safe: Reforming the Food Safety System" on October 22, 2009.

As you recognize, the relationships between FDA and State regulatory programs are critical for ensuring the safety of the food supply. In North Carolina, we have formed the NC Fresh Produce Task Force, which consists of Cooperative Extension, Farm Bureau, NCDA&CS, and industry. The Fresh Produce Task Force has been a leader in developing a training curriculum for Good Agricultural Practices (GAPs), conducting research, and other initiatives to ensure the safety and economic viability of fresh produce in North Carolina. In September 2009, the Fresh Produce Task Force hosted FDA and USDA for a listening session with small and medium-size farmers in North Carolina. Both agencies quickly realized the strong interagency and public-private partnerships that exist in North Carolina. The trust between the regulatory community and industry allowed the farmers to openly express their concerns regarding new food legislation, especially in the areas of indemnification, traceability, and scalability of regulations. I firmly believe FDA does recognize the importance and value the relationships State officials have with industry along the entire farm-to-fork continuum of food production.

Multiple challenges face a State regulatory agency when a food product is recalled. Ingredient-driven recall, such as the peanut butter recalls earlier this year, can be extremely difficult to contain since the list of recalled product changes by the minute as thousands of products are affected. Also, the distribution of the recalled products is often unknown. Today, retailers receive foods from multiple nontraditional sources, such as the Internet. Small, independent grocery stores and convenience stores often do not receive the recall notices and fail to properly respond to the recall. When a distribution list is available, it is often in a paper-based format and it is time-consuming to extract the data to conduct recall effectiveness checks. The act of conducting a recall effectiveness check costs us approximately $65 per inspection and resources are diverted from conducting inspections, responding to consumer complaints, and other preventative measures.

The recent recall of contaminated sandwiches distributed across several Southeastern States marked the first time the Food and Drug Protection Division utilized the Reverse 911 capabilities of our Department. The State of North Carolina, through the leadership of Commissioner Troxler and the Emergency Programs Division, has invested in a number of technologies to facilitate emergency communications and public notification. Operating from a list of firms which received recalled product and past customers which may still have product, we contacted 1,473 firms who received a notification of the potential hazard posed by these products. The Division received dozens of follow-up calls from retailers across the State and in subsequent recall effectiveness site visits, found that many firms removed the tainted product from shelves as a result of our Reverse 911 campaign, as well as our traditional media outreach. The Emergency Programs Division also has capacity for blast fax and e-mail release, and we are currently developing emergency contact databases for rapid notification of regulated firms. We have developed several web-based software platforms which allow for real-time personnel management, resource expenditure tracking, and food emergency data collection. Each of these systems has been used in actual food emergencies and has been presented to and shared with other State and Federal agencies. In addition, our division is equipped with modern radio communications equipment, allowing for communication during large scale disasters and facilitating instant communication with emergency response personnel across the State.

North Carolina is in a very unique position in regards to audits of our FDA contract inspection program. With the guidance and assistance of FDA, we are able to conduct our own audits of our inspectors conducting FDA contract inspections. Instead of the FDA conducting audits of our inspections, the FDA is auditing our auditors to ensure equivalency in our auditing programs is achieved. Seven percent of inspections performed under contract with FDA are audited. Last year, NCDA&CS conducted 17 contract inspection audits and FDA completed 1. The audit ensures the physical inspection of the firm is being conducted in a manner equivalent to the

FDA. In addition, as part of the Manufactured Foods Regulatory Program Standards (MFRPS), NCDA&CS conducts audits of the physical inspection, inspection report, and sample transcript. The MFRPS has been one of FDA's greatest achievements in promoting equivalency and continuous improvement in State regulatory programs.

Please let know if I can provide any additional information.

Sincerely,

DANIEL RAGAN.

FOOD AND DRUG ADMINISTRATION,
ROCKVILLE, MD 20857,
November 9, 2009.

Hon. TOM HARKIN, *Chairman,*
Committee on Health, Education, Labor, and Pensions,
U.S. Senate,
Washington, DC 20510.

DEAR MR. CHAIRMAN: Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the October 22, 2009, hearing entitled "Keeping America's Families Safe: Reforming the Food Safety System." This letter provides responses to questions for the record, which we received on November 2, 2009.

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

Thank you again for your continued leadership on food safety. We look forward to continuing to work with you on this important legislation. Please let us know if you have further questions or concerns.

Sincerely,

JEANNE IRELAND,
Assistant Commissioner for Legislation.

RESPONSE TO QUESTIONS OF SENATORS ENZI, BROWN, REED, AND BINGAMAN BY THE FOOD AND DRUG ADMINISTRATION

QUESTIONS OF SENATOR ENZI

Question 1. FDA has indicated it will spend $2.5 billion on information technology contracts at FDA in the coming years to help improve food safety. In June of this year, the Government Accountability Office (GAO) released a report highlighting deficiencies with FDA's plans for modernizing its information technology systems. What has FDA done to address the weaknesses highlighted by GAO, and what still needs to be done?

Answer 1. FDA's success in protecting the public health depends on its effective use of information technology. Accordingly, we are committed to continuing improvements in the strategic management of our information technology resources. GAO's main finding was that FDA lacks a strategic plan for IT. FDA is now in the process of putting together such a plan, with the assistance of the MITRE Corporation, which is a federally funded research and development center with extensive experience supporting complex information technology (IT) planning for Federal agencies. It is anticipated that this plan will be adopted in the spring of 2010.

GAO recommended further progress in enterprise architecture (EA). The chart below lists FDA's current EA initiatives and the progress regarding each initiative:

EA Initiative	Value Added	Status
IT Information Management	Ensures project requests are justified and support FDA business and IT objectives. Ensures software and hardware requests are justified and comply with FDA standards.	Operational.
IT Applications Assessment	Provides information to be used in determining applications that can be retired, reused or combined in order to improve business support and reduce application development and maintenance costs.	Operational.

EA Initiative	Value Added	Status
Enterprise Performance Lifecycle (EPLC).	Promotes project management best practices through proactive integration with IT investment owners/project management teams by providing advice, counsel, guidance and recommendations on the approach to conduct regular review cycles of planning, requirements, design, development, testing, implementation, and maintenance of IT investments.	Under development.
EA Repository Enhancement	Provides high level summary reports based on stakeholder inquiries providing immediate value to assist in proactive planning to support business and IT decisionmaking.	Under development.
Enterprise Information Management (EIM).	Provides key data to business and investment decisionmakers regarding the status and maturity of agency IT investments.	Under development.

GAO also recommended several changes to strategically manage IT human capital including the development of a skills inventory, needs assessment, and gap analysis, and develop initiatives to address skills gaps as part of the strategic approach. As part of our response to these recommendations, senior management in each division within OIM have assessed strategic workforce needs for their respective divisions to analyze and identify gaps. The Chief Information Officer is developing a release management plan incorporating the EPLC and capacity planning to ensure high quality and on time delivery of IT requests. In addition, the Chief Information Officer is continuing to look at these assessments and is developing hiring plans and priorities. The resultant information is being used to recruit skilled personnel to FDA. A survey was developed by a communications team made up of members from each division within OIM and facilitated by an external consultant to determine baseline areas where the organizational working "climate" could be improved. The survey results are being used to generate constructive dialogue with staff during meetings and to further identify pertinent organizational challenges and opportunities that OIM staff feels should be top priorities.

Question 2. What progress is FDA making to achieve its goal to improve its use of information technology?

Answer 2. FDA is making progress in a variety of fronts. In September 2008, FDA announced the selection of 10 contractors to receive a total of up to $2.5 billion for IT and data center management services during the next 10 years. The contract is the cornerstone of FDA's Information Technology for the 21st Century (ICT21) bioinformatics initiative, an extensive IT modernization program encompassing data management, data warehousing, IT infrastructure, and IT security. The 10 contractors will compete for data information technology task orders through this contract. To date, FDA has competitively awarded seven task orders through the ICT21 contract vehicle: three in fiscal year 2008 and four in fiscal year 2009.

FDA has made excellent progress on the data center modernization activities under the ICT21 investment. The three task orders awarded on September 29, 2008, are for the transition of all FDA software applications and hosting operations to FDA's new data centers over a 2-year period. These task orders are currently on schedule. The architectural design of the two new data centers has been completed and will greatly improve the security and reliability of FDA's IT platform that serves the regulatory programs. The data center on the White Oak campus supports the test and development environment and the contractor-hosted data center in Ashburn, VA supports all production IT systems.

As noted, FDA issued four task orders in fiscal year 2009. The Agency issued a task order for the Parklawn IT lab on March 13, 2009, and it is on schedule to achieve all of its milestones. FDA issued the remaining three task orders for the White Oak Data Center IT Lab, White Oak Data Center equipment, and the FDA mail on September 10, 2009, September 23, 2009, and September 30, 2009, respectively. We are also on track with these three remaining task orders.

Question 3. Do you think FDA takes the necessary steps to assure these IT contracts are being awarded to qualified entities with a history of good business practices?

Answer 3. Yes, FDA is awarding its IT contracts to qualified entities with a history of good business practices. Since the passage of the Federal Acquisition Streamlining Act of 1994, FDA has implemented procedures to document contractor past performance on in-process/current contracts and use past performance information in the source selection process. The collection and use of past performance information motivates contractors to improve their performance because of the potential use of that information in future source selection decisions. As a result of the increased attention on past performance, FDA is achieving better performance on its in-process/current contracts because of the active communication and feedback between the contractor and the Government, and FDA is better able to select highly qualified contractors for new contracts as confidence in a prospective contractor's ability to perform satisfactorily is an important factor in making a best-value source selection decision.

Question 4. How do you envision the requirement for food safety plans be enforced for foreign facilities? Do you foresee a different approach to securing the foreign supply chain based on whether the product is sourced from developed or developing countries?

Answer 4. S. 510 requires foreign facilities that export foods to the United States to have food safety plans in place, a requirement which also applies to domestic facilities. This requirement is important, because foodborne illness outbreaks occur with both domestically and foreign-sourced food. Prevention of problems in the first place is critical for all foods and is a much more effective approach for imports than relying primarily on detection of unsafe food at the border. Enforcement of this requirement for food safety plans will depend partially upon inspections. To accommodate the need for increased foreign inspections, FDA has established a cadre of experienced investigators who will exclusively conduct foreign food inspections.

Given the volume of foreign facilities, however, FDA inspections alone will not provide adequate coverage of the firms exporting products into the U.S. market. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting a strong accredited third-party inspection program, and increasing targeted, risk-based foreign inspections.

FDA would not base its approach to foreign supply chain safety on whether the food came from a developed or developing country. There are clearly a number of countries that have safety systems that ensure a level of safety comparable to that of the United States, and we would be more apt to utilize those regulators to perform audits and potentially certify food as meeting FDA safety criteria. On the other hand, in countries where the food safety systems are not as robust, FDA would more heavily utilize the other mechanisms noted above, such as increased import oversight, third-party audits, and inspections by FDA personnel.

Question 5. A GAO report issued just last week places great emphasis on the fact that the computer systems at FDA and Customs and Border Protection cannot communicate. GAO indicated staff from both agencies were developing and using workarounds, but this doesn't strike me as being the best solution. Could you comment on the potential gaps in enforcement caused by this lack of interoperability, and what is FDA doing to improve the systems?

Answer 5. To clarify, FDA collects and maintains import data in a system known as the Operational and Administrative System for Import Support (OASIS). This system has been in operation since 1998 and was built as a tool to manage workflow for entry reviewers and compliance officers. The data in OASIS is received via the automated interface between CBP's Automated Commercial System (ACS) database and OASIS. OASIS is the only system in the Federal Government that exchanges import admissibility data with the CBP's ACS in real time. Accordingly, OASIS and ACS do communicate with each other.

Although FDA and CBP benefit from the data flow between these two systems, improvements can be made. FDA strongly supports and works closely with CBP in its efforts to complete the Cargo Control portion of their Automated Commercial Environment (ACE) system. This new system will provide additional data elements to FDA and enhanced capability in the exchange of data between the two agencies.

Regarding GAO's finding about insufficient information-sharing between FDA's and CBP's computer systems, FDA and CBP developed an interagency agreement that calls for CBP to modify its existing software to provide FDA with time-of-arrival information for land and air shipments. FDA and CBP are working to test the system.

Regarding GAO's recommendation that FDA streamline its refusal process with CBP's redelivery process to address the lack of communication, FDA believes that

continuing to engage with CBP to develop a joint refusal/redelivery process is important. CBP and FDA have begun discussions of the joint form as a prerequisite to considering this joint notice as a national procedure. Additional discussions are needed to complete this evaluation, after which we hope that national procedures can be drafted, cleared, and implemented. If approved, this joint notice should:

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

Question 6. I think that a lot of the things we need to do depend ultimately on FDA having good information about who is producing and processing what food products. There seems to be general agreement that the current database of food facilities is not up to the task. One proposal that makes a lot of sense to me is making sure each facility has a unique numerical identifier. Do you agree? If so, please update me on the progress FDA has made toward implementing this identifier.

Answer 6. Yes, the Administration believes that a requirement for unique facility identifiers (UFI) would be very useful. FDA needs a provision that will distinguish between numbers that FDA currently assigns to registered food facilities and a true UFI, such as a Dunn & Bradstreet Data Universal Numbering System (DUNS) number, particularly one for which the accuracy of the supporting information is independently verified.

Specifically, such a provision would require each person in the distribution chain who manufactures, processes, packs, transports, or holds food to use a unique identifier for each facility owned by such person, as established or designated by FDA. The UFI would be interoperable with other parties in the distribution chain that manufacture, process, pack, transport, or hold food. UFIs would help FDA correct and eliminate inaccuracies in its inventory of registered food facilities, and assist in establishing enforcement priorities, targeting risky imported products, and tracing products linked to specific establishments in the event of a safety issue. The current lack of a UFI complicates proper identification and targeting, which can lead to cases of mistaken identity, and prevents automated interagency data exchanges and queries on foreign firms of interest, both for purposes of security and for admissibility.

Mandating use of a UFI from a single system would permit FDA to link to information systems in other agencies, allowing FDA to share information with other agencies based on the common identifier. This would permit, for example, FDA and USDA to instantly deteimine whether they are dealing with the same firm.

In order to provide express authority for a UFI requirement, we would recommend that the Senate bill, like H.R. 2749, include provisions to require that registrations for food facilities, importers, and brokers include the submission of appropriate UFIs; that traceback systems include the ability to reference to UFIs; and that appropriate UFIs are required when food products are offered for import.

Question 7. FDA conducts "filer evaluations" to assess the accuracy of information provided by importers and customs brokers. Approximately what percentage of registered importers and brokers are evaluated in this way?

Answer 7. In fiscal year 2009, the Agency evaluated 32 percent of FDA filers. FDA selects filers for evaluation based on the volume of import entries the filer submits, the date the filer was previously evaluated, and the results of that evaluation, and other criteria. An FDA filer may be an importer or a broker. There is no general requirement for importers or brokers to register with FDA. An importer or broker would only be required to register if they also are an owner, operator, or agent in charge of a facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act. Note that sections 136 and 204 of H.R. 2749 include a requirement for importers to register and provisions to help ensure they provide complete and accurate information regarding imported food.

Question 8. Could you tell me more about FDA's audits of State inspectors who perform inspections under contract? For example, how often are they audited? What does that entail?

Answer 8. The table below provides the total number of audits performed for the years 2000 through 2008.

FDA Food Contract Inspection Audit Summary for 2000–2008

CY 07–08	358

FDA Food Contract Inspection Audit Summary for 2000–2008—Continued

CY 06–07	442
FY 05	355
FY 04	386
FY 03	421
FY 02	326
FY 01	47
FY 00	52
Total	2,387

FY = Fiscal Year, CY = Contract Year.

FDA's Manufactured Food Regulatory Program Standards (MFRPS) are being used to improve FDA's oversight of the food contract inspection program with State agencies. The standards are based on performance (i.e., how inspections are conducted) rather than inspection outcomes. Consequently, the standards provide a comprehensive examination of a State's inspection program as well as a program for continuous improvement.

MFRPS Standard No. 4, Inspection Audit Program (the Audit Program) is a standardized quality assurance program available to FDA and States for evaluating the food contract inspections. The Audit Program was developed jointly by FDA and the States to audit the food contract inspections and it has been in use since fiscal year 2008. The audit program established (1) procedures for conducting audits of contract inspections, (2) a percent-based performance standard, (3) a required frequency of audits, (4) auditor training requirements, and (5) standardized records (an audit form, and quarterly and annual summary report forms of audit findings) to document the audits.

State inspectors must be audited every 3 years; however, most State inspectors are audited each year. The audit is used to evaluate State inspectors' knowledge, skills, and ability to conduct a food inspection. Performance criteria are grouped into three components of the inspection process: (1) preinspection assessment, (2) inspection observations and performance, and (3) oral and written communication. The preinspection assessment evaluates State inspectors' review of any previous inspections. State inspectors' ability to recognize violative conditions or practices, distinguish between significant and insignificant observations, and recognize isolated incidents versus trends is included in the auditor's evaluation of State inspectors' inspection observations and performance. State inspectors are also evaluated on their ability to explain findings clearly and adequately.

Although FDA audits the State inspection programs with which we contract, we recognize that there are limitations in our current approach, and the Agency is engaging in internal discussions on potential enhancements to the audit program.

QUESTIONS OF SENATOR BROWN

Question 1. Last month, the Government Accountability Office (GAO) released a report which found that the agencies responsible for ensuring the safety of our Nation's imported food are hampered in their efforts by gaps in enforcement and collaboration. For example, the Customs and Border Protection's (CBP) computer system does not currently notify FDA or the Food Safety and Inspection Service (FSIS) when imported food shipments arrive at U.S. ports. FDA points out that this lack of communication may potentially increase the risk that unsafe food could enter U.S. commerce without FDA review. Second, the GAO report notes that FDA has limited authority to ensure importers' compliance with its regulations. And third, the report says that CBP and FDA do not identify importers with a unique number, resulting in FDA not being able to target food shipments originating from high risk importers. Do you believe that current legislative proposals before the Congress (H.R. 2749 and S. 510) go far enough in addressing the problems identified in the GAO report? Is FDA supportive of GAO's recommendations which include civil penalties on firms and persons who violate FDA laws and identifying foreign firms with a unique identifier?

Answer 1. Both H.R. 2749 and S. 510 contain important provisions, which will enhance FDA's ability to address the safety of imported food. However, it is the House bill, H.R. 2749, which contains the authorities recommended by GAO relating to civil penalties and unique identifiers.

With regard to civil penalties, FDA is supportive of the GAO recommendation that FDA seek authority from Congress to assess civil penalties on firms and persons

who violate FDA's food safety laws. The Administration supports section 135 of H.R. 2749, which would establish such civil monetary penalties for violations relating to food.

With regard to unique identifiers, FDA agrees with the GAO recommendation that FDA explore ways to improve the Agency's ability to identify foreign firms with a unique identifier. The use of a unique identifier would improve the Agency's ability to accurately identify foreign, as well as domestic, firms. This ability would be especially helpful in enabling FDA to target high risk shipments. Requiring a unique facility identifier as part of registration for both domestic and foreign facilities also will be helpful in traceback activities during a foodborne illness outbreak or other emergency.

The Administration supports the provisions relating to unique identifiers in H.R. 2749, which appear throughout the bill. For example, facility registration must include a unique facility identifier (see sections 101 and 206). Importer and broker registration must include appropriate unique facility identifiers (see sections 204, 205, and 206). FDA must identify technologies for a traceback system to use unique facility identifiers (see section 107). Appropriate unique facility identifiers are required when food is offered for import (see section 206).

Question 2. H.R. 2749 requires country of original labeling requirements for both processed and non-processed foods. In the case of processed foods, the labeling must identify the country in which the final processing of the food occurs. In the case of non-processed foods, the labeling of the food must identify the country of origin of the food. S. 510 does not specifically provide for country of origin labeling. What is the FDA's position on country of origin labeling with respect to processed and non-processed foods? Does the FDA believe that food safety legislation should include a requirement that imported foods have country of origin labels?

Answer 2. FDA does not consider country-of-origin labeling to be a food safety measure because it does not provide any information regarding the safety of the food.

Congress has already assigned responsibility for enforcing mandatory country-of-origin labeling to two other agencies: Customs and Border Protection (CBP) and USDA's Agricultural Marketing Service (AMS). The Tariff Act, enforced by CBP, generally requires imported articles to be marked to indicate country of origin to the ultimate purchaser. Foods in their natural state, such as fresh produce, are not required to be marked individually at the point of importation. However, at the point of retail, produce must be marked to indicate country of origin in accordance with AMS requirements. The AMS requirements apply to seafood, produce, peanuts, macadamia nuts, pecans, ginseng, and certain meats.

Question 3. H.R. 2749 contains new user fees (an annual $500 registration fee for each facility; fees to cover either the government cost of reinspection due to a violation or the cost of a food recall; fees to cover the cost of issuing exportation certifications for foods when needed to meet foreign specifications; and an annual $500 fee for the registration of food importers). S. 510 only includes fees to cover the government cost of a reinspection or recall action and fees paid by some importers to cover certain administrative costs. Instead of registration fees, the Senate bill pays for food safety through increasing authorization levels for FDA. Dr. Hamburg, in your testimony you advocate for the inclusion of registration fees, in part, to fund the inspection mandates. Can you explain why the FDA would prefer user fees versus simply increasing authorization levels?

Answer 3. The President's fiscal year 2010 budget called for a registration fee to help FDA increase its inspection coverage and to enhance its other food safety activities. A registration fee will help provide a guaranteed and consistent funding source to help FDA fulfill its responsibilities. Registration fees should not supplant appropriated funds. An effective food safety system provides benefits to consumers and industry by protecting the public health and protecting the economic health of industry. Therefore, it is appropriate that the cost of implementing and maintaining this system be shared by taxpayers through appropriations and industry through user fees.

Question 4. H.R. 2749 requires domestic and foreign food facilities to register every year. The Senate bill requires domestic and foreign food facilities to register every 2 years. There is a strong argument to be made that facilities should have to register annually so that the FDA can have the most current information about foreign importer facilities. Does the FDA have a position on whether domestic and foreign food facilities should register every year (as the House bill requires) or every 2 years (as the Senate bill currently requires)?

Answer 4. The requirement in the Senate bill, S. 510, for facilities to register every 2 years represents a significant improvement over the existing statutory provision, which only requires registrants to notify the Secretary in a timely manner of changes to their registration information. However, the Federal Food, Drug, and Cosmetic Act requires FDA to maintain an up-to-date list of registered facilities. Requiring updated information on an annual basis would significantly increase the likelihood that registration information is current. Having accurate, current information is obviously of great importance during an emergency.

QUESTIONS OF SENATOR REED

Question 1. Dr. Hamburg, as you know, the shellfish industry has a long history of collaborating closely with the FDA and State regulators to reduce food-borne illness associated with shellfish. Their efforts in this area, which have led to a significant level of investment by industry members, include the implementation of quicker and more effective refrigeration practices and the dissemination of educational messages to encourage those at increased risk of illness to refrain from eating uncooked shellfish.

It is my understanding that at a recent meeting of the Interstate Shellfish Sanitation Conference (ISSC), the FDA announced its intention to mandate additional postharvest processing measures such as individual quick freezing, high hydrostatic pressure, mild heat, and low-dose gamma irradiation for oysters harvested in the Gulf of Mexico during certain parts of the year. These new requirements will be implemented beginning in 2011 with the aim of reducing the risk of infection from the bacteria *Vibrio vulnificus*.

Industry members along the East Coast have expressed concern that these Gulf of Mexico mandated post-harvest processing rules could be extended to other regions without a full assessment of the risks and benefits, the cost of compliance, or the impacts on sales. Would you clarify the FDA's plans for implementing its new requirements for post-harvest processing, including the potential economic impacts on the industry as well as any plans to cover additional regions or strains of bacteria?

Answer 1. FDA's announcement planning to propose new requirements relates only to processing of oysters harvested during warm months in the Gulf of Mexico and that are intended to be eaten raw, with the goal of reducing the risk of infection from *Vibrio vulnificus*. *Vibrio vulnificus* is not found outside warm coastal waters. FDA believes that *Vibrio vulnificus* raises unique issues for public health and that further discussion with industry and review are necessary before any additional action, with respect to other pathogens.

QUESTIONS OF SENATOR BINGAMAN

RISK-BASED SCREENING OF IMPORTS

Question 1. The September 2009 GAO report on food safety has a good discussion of the importance of the PREDICT screening system to quantify the risk of imported food shipments. I am pleased that FDA continues to value the participation of New Mexico State University in the continued development and deployment of PREDICT.

What is the current status of PREDICT and what are FDA's plans in terms of schedule and budget to continue the development and deployment of PREDICT for all FDA-regulated products?

The GAO report discusses the need to identify foreign manufacturers with a unique identifier, and I understand FDA supports new statutory authority to require the use of a unique identifier by food facilities, such as sec. 206 of H.R. 2749. Does FDA need additional statutory authority to implement and to take full advantage of the capabilities that PREDICT provides for all FDA-regulated products? If not, can you please provide a list of any additional statutory authority that FDA believes is needed.

Answer 1. During the summer of 2007, FDA conducted a pilot test of a limited version of the PREDICT prototype, using seafood entries in Los Angeles. Beginning in January 2008, FDA further developed and enhanced the PREDICT prototype. Beta testing of the full production version began in late September 2009 in Los Angeles, using a limited set of targeting criteria, covering all products subject to FDA jurisdiction. National deployment is expected to begin during December 2009 and will require several months to complete.

FDA does not need additional statutory authority to implement the PREDICT system per se; however, we do believe that enactment of new authority for a unique facility identifier, as is contained in H.R. 2749, would provide an important component of a more robust and better targeted import-review program. The additional

information about food facilities provided under the changes to the facility registration requirement (section 101 of H.R. 2749) also would be helpful in this regard.

SMALL PRODUCERS AND SCALE OF ENTERPRISE

Question 2. In implementing the recommendations of the President's Food Safety Working Group for fresh produce, what specific accommodations, if any, does FDA believe are appropriate for small producers, including organic farmers and local direct-to-consumer operations?

Answer 2. FDA has begun work on a regulation to establish enforceable standards for produce safety under our current authorities. The regulation will be based on the prevention-oriented public health principles embraced by the Working Group.

FDA recognizes that the produce sector consists not only of large national and international operators but also many small producers, including many who market directly to consumers through roadside stands, farmers markets, and other arrangements. FDA will carefully consider the public health and economic impacts of applying the requirements of the new rules to small producers and will consider appropriate adjustments in the regulation.

FDA will work with the industry to facilitate compliance with the new regulation through the following ways:

- issuance of a science-based "hazards guide" to assist producers and processors in designing their preventive controls;
- provision of other technical assistance and guidance on how to comply with the new rules;
- establishment of reasonable time periods for implementation of the rules, taking into account firm size; and
- cooperation with USDA extension programs and industry-sponsored education efforts to foster understanding and implementation of the requirements.

To learn more about the concerns of small growers/processors, FDA has held three listening sessions—a small one in Delaware; one in North Carolina, which included approximately 60 growers; and one in Florida, with approximately 60 growers. In these three States, FDA also toured a total of eight farms of varying size, commodity types, and farming methods. We are planning a session in December for the States of Washington and Oregon.

In developing these regulations, FDA also is working closely with USDA to tap into USDA's expertise with the different scales and approaches to agriculture. For example, USDA has detailed a fresh produce expert to FDA to help integrate these perspectives on scalability and production methods into our produce safety standards. In addition, FDA has recently hired noted experts on food safety and agriculture from the States of California and North Carolina to work on food issues. This team is focused on developing produce safety standards that accommodate the needs of the varying scales and approaches to agriculture and adhere to the prevention-based public health principles endorsed by the President's Food Safety Working Group.

RESPONSE TO QUESTIONS OF SENATOR ENZI BY CAROLINE SMITH DEWAAL

Question 1. You suggest that developing regulations food-by-food is inefficient. I see your point, but I also give weight to Mr. Stenzel's arguments that a commodity-specific approach is the right way to proceed. Could you address the disparity?

Answer 1. First and foremost, let me thank you for the opportunity to testify before the Senate HELP Committee on reform of our Nation's food safety system. This was a very important hearing and a milestone in the effort to get a modern food safety system in place for FDA regulated foods.

While they may sound inconsistent, the statements made by Mr. Stenzel and I are not, so I welcome the opportunity to clarify this point. The consistency lies in the fact that my specific statement related to the food processing area, whereas his comments were in the area of on-farm food production and standard setting.

A preventive approach in the food processing area requires the use of process control systems, like HACCP, throughout the food chain. For the last 15 years, FDA has been implementing process control systems in a few sectors, like the seafood and juice industries. But the agency stopped and the absence of these programs has resulted in significant problems over the last 10 years.

S. 510 will put every food processor under the requirement to conduct a hazard analysis that identifies the hazards most commonly linked to the type of foods being produced and to develop a plan to prevent those hazards from arising in the food facility. These specifics of the plans are developed by the food facility itself but they will be a requirement across the board for all facilities, just as they are today re-

quired for all meat and poultry plants regulated by the U.S. Department of Agriculture.

Thus the same systematic review and plan is required for all food facilities, but the approach may vary by facility. Thus the plan would look very different for a peanut processor and for a company producing canned vegetables. The food control plans would be reviewed by FDA inspectors during their visits who would determine the overall effectiveness and make suggestions for improving the plans.

Mr. Stenzel's statements addressed the on-farm aspects of fruit and vegetable production. Under S. 510, FDA is largely involved with setting standards for this sector. While there may be a number of commonalities in the standards for different commodities, there are also important differences. So I agree with Mr. Stenzel that FDA's written standards for on-farm production should provide for necessary commodity-specific differences. This is comparable to previous example highlighting the difference between process control plans for a peanut processer and a canning facility.

Question 2. FDA has estimated a cost of $16,700 per inspection for foreign food facilities. You have recommended an inspection frequency of 6–12 months. Resources for the agency, both in dollars and personnel, are increasing, but are not infinite and are certainly not enough to achieve your recommended inspection frequency. Given these pressures, what do you think is a more realistic goal for inspection frequency?

Answer 2. Inspection is a cornerstone of credible food safety legislation. Frequent inspections are essential to ensuring business compliance and justifying public trust. As the spate of recent foodborne-illness outbreaks and contamination incidents prove, our current food safety system does not ensure compliance with safety standards. Without a mandate to perform inspections, FDA has not devoted sufficient resources to this task, resulting in an average inspection frequency of approximately once every 5 to 10 years. It is essential that the Senate food safety bill include a mandate for a rigorous risk-based inspection schedule.

- Under S. 510, inspections are conducted to review food safety plans and ensure an adequate hazard analysis.
- Inspections also assure compliance with performance standards, and sanitation and microbial testing requirements.

With respect to imports, the legislation adopts a "lifecycle approach," giving FDA the authority to examine practices before the food reaches the U.S. ports of entry, in an effort to ensure that imports meet the same high standards applied to our domestic food industry.

The schedule we are proposing would require FDA to inspect high-risk facilities at least once every 6 to 12 months, low-risk facilities at least once every 18 months to 3 years, and warehouses at least once every 5 years. While the public, when polled by Consumers Union in 2008, expressed a preference for monthly inspections, we recognize the constraints placed on agency funding. The schedule we propose takes a responsible position between the need for an effective, mandated rate of inspection and responsible budgetary restraint. We believe it is manageable within the proposed structure of S. 510 due to the following factors.

We are not proposing that foreign food facilities be inspected by FDA on the same schedule as domestic facilities. Provisions within S. 510 allow for less frequent direct inspection by FDA of foreign facilities without sacrificing safety. Let me outline those provisions.

First, the bill requires every importer to have a Foreign Supplier Verification Program (Sec. 301). This program mandates importers to have in place a program that assures food products are produced in compliance with U.S. law and are not adulterated or misbranded. Additionally, importers can take advantage of the Voluntary Qualified Importer Program for many products, and that program could further increase FDA's level of confidence that a product is produced in compliance with our laws and to our standards.

Second, the bill gives FDA the option to review a foreign country's food safety system to determine whether it is capable of providing assurances that the food produced in that country is subject to statutes, regulations, standards, and controls that are sufficient to ensure exports meet our standards for safety (Sec. 305). These are nation-to-nation agreements that indicate that though the practices may vary slightly, the government asserts equivalent controls and achieves the same level of consumer protection as is required in the United States. This review includes an audit of how the country inspects its own food supply that can establish whether FDA can rely on the foreign country inspections. This provision will permit FDA to focus its resources on those countries where the government cannot assure a proper level of safety for its exports.

In these circumstances, the legislation provides an additional tool for FDA: Certification of imported foods by national governments or approved third-party agents. When it comes to national governments, the use of "export certification" is well understood. It is also used by the Department of Agriculture when it comes to meat and poultry products and that the Department relies on the foreign governments to provide the inspections required under the law. USDA's job is to audit the foreign national program, including plants that that government has approved to ship products to the United States, on a regular basis to ensure that the program continues to meet our national requirements. FDA should follow the same approach.

Third-party certification agents are a more innovative approach, one adopted from the private sector, and can be used for countries or industry segments where the national government is not capable of providing an export certification role. Clearly the preference of consumer organizations would be to have a national government playing this role, but we agree third-party certification agents—with appropriate oversight and restrictions on conflict of interest—are an improvement over FDA's current approach. Again, the third-party agent would be regularly audited by the FDA to assure that it is conducting appropriate oversight, including inspections, to assure that food products meet the U.S. requirements.

The bill permits FDA to require that certain high-risk foods be imported only once they are certified as being produced in compliance with U.S. law (Sec. 303). Certification audits, while not a substitute for inspections, if properly structured and administered provide a heightened degree of assurance that an item offered for import is safe. (As I testified at the hearing, there is one aspect of how the certification program is structured in S. 510 that should be revised. The bill should be amended to avoid placing private accrediting bodies in the position of accrediting foreign governments, and to improve the accountability of private accrediting and certifying entities. Consumer groups have forwarded to the committee a description of our concerns and proposed changes to the import certification provisions within the bill.)

FDA may still want to rely on some direct inspections for some foreign food products and the bill provides for this by permitting FDA to enter into agreements with foreign governments for the direct inspection of high-risk facilities and mandates the agency to direct resources toward inspection of those facilities, but permits FDA to determine the appropriate schedule (Sec. 307).

These tools are all useful, because as you rightly point out, it is not feasible for the agency to conduct inspections in every plant that ships foods to the United States. A robust inspection framework is essential to restore consumer confidence in FDA-regulated foods and the cost of a vigorous inspection schedule becomes manageable once the inspection schedule for domestic facilities is delinked from the one for foreign.

[Whereupon, at 12:03 p.m., the hearing was adjourned.]