HOW DO WE FIX OUR AILING FOOD SAFETY SYSTEM?

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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SUBMITTED MATERIAL

HOW DO WE FIX OUR AILING FOOD SAFETY SYSTEM?

WEDNESDAY, MARCH 11, 2009

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

The subcommittee met, pursuant to call, at 10:10 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone Jr. (chairman) presiding.

Members present: Representatives Pallone, Dingell, Eshoo, Engel, Green, DeGette, Schakowsky, Gonzalez, Barrow, Christensen, Castor, Sarbanes, Space, Sutton, Waxman (ex officio), Stupak, Deal, Shimkus, Buyer, Pitts, Murphy, Blackburn, Gingrey, and Barton (ex officio).

Staff present: Phil Barnett, Staff Director; Karen Nelson, Deputy Staff Director for Health; Karen Lightfoot, Communications Director; Rachel Sher, Counsel; Steve Cha, Professional Staff Member; Virgil Miller, Legislative Assistant; Jennifer Berenholz, Deputy Clerk; Lindsay Vidal, Press Assistant; Alli Corr, Special Assistant; Alvin Banks, Special Assistant; Caitlin Sanders, Staff Assistant; Clay Alspach, Counsel; Ryan Long, Counsel; and Chad Grant, Legislative Analyst.

OPENING STATEMENT OF HON. FRANK PALLONE, JR.

Mr. PALLONE. The subcommittee is called to order. Today the subcommittee is meeting to discuss the topic of food safety. Unfortunately, news of unsafe food products has continued to make front-page headlines. The outbreak of E. coli in spinach a few years ago, the outbreak of salmonella in peppers this past summer, and the most recent outbreak of salmonella in peanut butter all emphasize that now is the time for us to act. Nine people have died as a result of this most recent peanut butter outbreak, and hundreds more have gotten sick. And millions of dollars have been lost in sales due to products being recalled.

Food safety, or perhaps more accurately the lack thereof, continues to be one of my top priorities. In every Congress for the last 12 years, I have introduced food safety legislation that aims to bolster the FDA's enforcement and regulatory authority over the food industry.

This year, I have collaborated with my colleagues Mr. Dingell and Mr. Stupak to introduce a comprehensive FDA reform bill. Many of the food provisions within the FDA Globalization Act built upon concepts and provisions I have put forth in my previous bills,

and they emphasize prevention and shifting the responsibility of safe food from the FDA to the manufacturers.

What it all comes down to is that it is not the government's duty to make food safe. The companies, in my opinion, should be responsible for the products they make and must be held accountable for that responsibility. It is their job to make their food safe and to implement a plan that will ensure that they achieve that goal.

It is the government's job, on the other hand, to set standards for food safety and hold the food industry accountable for meeting those standards through regulatory and enforcement authorities. We must empower the FDA with those authorities so that the agency can effectively prevent problems from ever occurring rather than simply reacting when something bad has happened. And we must also require manufacturers to put in place the food safety plans to ensure that their products and production lines are safe.

But there are other mechanisms aside from food safety plans that companies can implement to ensure the safety of their products. And we will hear testimony this morning from industry experts on the various safety mechanisms companies can implement in order to product their product lines and keep our Nation's food supply safe.

We will also hear about some of the regulatory authorities that the FDA needs in order to ensure that companies are actually implementing and following these preventative mechanisms.

And finally we will hear from witnesses about the enforcement tools the FDA needs to fulfill its mission of protecting the public health and protecting Americans from harmful products both in the United States and abroad.

I am looking forward to the discussion today and the information we will glean. We do want to pass food safety legislation rather quickly this year if we can, and so obviously today's hearing will be very helpful in that regard.

And I do want to mention—I don't see him—but Congressman Stupak has done an excellent job in the O&I Subcommittee in bringing attention to this issue over the last, actually over the last 3 years. He and I and Congressman Dingell have this legislation, but he has repeatedly had hearings addressing some of the concerns that have led to the legislation.

[The prepared statement of Mr. Pallone follows:]

CHAIRMAN FRANK PALLONE, JR.

HEALTH SUBCOMMITTEE HEARING

"HOW DO WE FIX OUR AILING FOOD SAFETY SYSTEM"

OPENING STATEMENT

March 11, 2009

Good morning. Today the Subcommittee is meeting to discuss the topic of food safety. Unfortunately, news of unsafe food products has continued to make front page headlines. The outbreak of e-coli in spinach a few years ago; the outbreak of salmonella in peppers this past summer; and the most recent outbreak of salmonella in peanut butter all emphasize that now is the time for us to act. Nine people have died as a result of this most recent peanut butter outbreak; hundreds more have gotten sick; and millions of dollars have been lost in sales due to products being recalled.

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What it all comes down to is that it is not the government's duty to make food safe. The companies should be responsible for the products they make and must be held accountable for that responsibility. It is their job to make their food safe and to implement a plan that will ensure they achieve that goal. It is the government's job, on the other hand, to set standards for food safety and hold the food industry accountable for meeting those

standards through regulatory and enforcement authorities. We must empower the FDA with those authorities, so that the agency can effectively prevent problems from ever occurring, rather than simply reacting once something bad has happened. And we must require manufacturers to put in place the food safety plans to ensure that their products and production lines are safe.

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the FDA needs to fulfill its mission of protecting the public health and protecting Americans from harmful products, both in the US and abroad.

I look forward to our discussion today and the information we will glean from this hearing. This information will be vital as we move towards passing food safety legislation this year.

I would like to thank the witnesses for appearing before us today to share their expertise and I now recognize my colleague from Georgia, Mr. Deal, for three minutes for his opening statement.

Mr. PALLONE. And I now recognize my colleague, Mr. Deal.

OPENING STATEMENT OF HON. NATHAN DEAL

Mr. DEAL. I want to thank the Chairman Pallone for holding this hearing as we evaluate concepts that we as policymakers should consider in approaching reform of the Nation's food supply as a food safety issue at the Food and Drug Administration. I appreciate the timeliness of this hearing, particularly since my home state of Georgia has itself been under a lot of attention as a consequence of a rogue peanut processing operation in the state, as you indicated, contributed to nine deaths and several hundred Americans being sickened all across our country.

But let me be clear. I support giving FDA the resources it needs to ensure our Nation's food supply remains safe and reliable for American dinner tables across the country. I believe a modernized approach to risk identification and prevention, particularly through hazard analysis and critical control point plans and similar prevention-minded procedures is a realistic and evidence-based solution to mitigating the hazards in the Nation's food supply chain.

We must focus on pursuing reforms with public safety protection as a top priority. However, we must do so diligently and methodically to ensure our actions do not cripple small businesses in the food industry across the country.

Our Nation's food supply needs a great deal of improvement in terms of the safeguards and fallback measures expected of a 21st century food supply chain in the United States. Recognizing the need for a risk-based approach to food safety reform, I have joined Representatives Jim Costa and Adam Putnam in cosponsoring H.R. 1332, The Safe Food Enforcement Assessment Standards and Targeting Act of 2009, Safe FEAST Act as it is referred to. This act takes an aggressive yet realistic effort to improve food safety by granting FDA enhanced statutory authority to do its job as well as require implementation of safety measures to prevent food-borne problems before they even manifest themselves.

It is my hope that any legislation that we pass out of this committee is similar to the provisions contained in H.R. 1332. I look forward to continuing to work with my colleagues on both sides of the aisle as we look at concepts that are aimed to improve the safety of America's food supply. Thank you for holding this hearing today. I look forward to the testimony of our witnesses, and I welcome them to this hearing today. Thank you. I yield back my time.

Mr. PALLONE. Thank you, Mr. Deal. Next is Chairman Waxman. I forgot to mention the work that you did on your previous committee on government oversight on the food safety issues as well. Thank you.

OPENING STATEMENT OF HON. HENRY A. WAXMAN

Mr. WAXMAN. Thank you very much, Mr. Chairman. America does not need another deadly outbreak to understand that our food safety system is in desperate straits. We have ample proof of that. This is a bad situation not just for the American public but for the food industry itself. We must act now to address the problem, and this hearing today is the first step on that legislative path.

Today we will hear about some of the major concepts that our witnesses believe must be included in a model food safety bill. The FDA Globalization Act of 2009 provides an ideal starting point, and I commend Chairman Emeritus Dingell, Chairman Pallone, Chairman Stupak for their work on this bill. Using this bill as a foundation, this committee will work with the President's FDA to implement some commonsense food safety measures that are long overdue.

As we move forward, we will also draw upon the work of Chairman Stupak and Ranking Member Walden who lead our subcommittee on Oversight and Investigations. It is clear we need to give FDA some basic authorities that will enable it to do its job.

As the Oversight and Investigation hearing illustrated, FDA does not have the authority to routinely access records documenting the steps that manufacturers take to assure safety. FDA also lacks modern and flexible enforcement tools like administrative civil monetary penalties. It is our job to get FDA the resources and authorities it needs to get the job done and to do it well.

But with over 300,000 registered food facilities throughout the U.S. and abroad, it is clear we can't rely on FDA alone to prevent food-borne illness outbreaks. Manufacturers must implement preventive systems to stop outbreaks before they occur, and we need to hold them accountable when they fail.

Dr. Stephen Sundlof, FDA's director of food safety and applied nutrition, agreed at our hearing last month that each company in the chain of manufacturing has an obligation to ensure that the ingredients they are using as well as their final products are safe for Americans to consume.

Related to this, I would like to announce now that next Thursday, on March 19, we will hold another investigative hearing that focuses on the companies that purchased these tainted peanuts and why their food safety systems failed to prevent these deaths and illnesses.

We have a challenging job ahead of us, but we also have many reasons to be optimistic. In his budget, President Obama called for over $1 billion for FDA's efforts to increase and improve inspections, domestic surveillance, laboratory capacity, and domestic response to prevent and control food-borne illnesses.

I also know that President Obama is committed to naming an FDA commissioner soon, and I look forward to his announcement. The food safety crisis calls for strong leadership at that agency, and we need it now.

Let me say a few words about the notion of a so-called single food agency. A lot of good points have been made about the need to improve our fragmented system and ensure that food safety is given appropriate attention by our regulatory agencies, but reorganizing large federal bureaucracies takes a great deal of time. And this is time we do not have when it comes to food safety. We have to act now. We have to concentrate the additional resources we can get at this point on the job at hand.

Our first goal should be to address the problems that plague this program where it currently sits. After we finish that job, we can consider whether a reorganization is necessary, and if so, how to go about it.

I look forward to hearing from our witnesses about what steps we can take to begin this process. Thank you, Mr. Chairman. Yield back my time.

[The prepared statement of Mr. Waxman follows:]

Statement of Chairman Henry A. Waxman
Subcommittee on Health Hearing on
"How Do We Fix Our Ailing Food Safety System?"
March 11, 2009

Americans do not need another deadly outbreak to understand that our food safety system is in desperate straits. We have ample proof of that. This is a bad situation not just for the American public, but also for the food industry itself.

We must act now to address this problem. Over the next few months, the Energy and Commerce Committee will move a strong food safety bill. This hearing is the first step on that legislative path. Today, we will hear about some of the major concepts that our witnesses believe must be included in a model food safety bill.

The FDA Globalization Act of 2009 provides an ideal starting point, and I commend Chairman Emeritus Dingell, Chairman Pallone, and Chairman Stupak for their work on this bill. Using this bill as a foundation, this Committee will work with President Obama's FDA to implement some common-sense food safety measures that are long overdue.

As we move forward, we will also draw upon the work of Chairman Stupak and Ranking Member Walden, who lead our Subcommittee on Oversight and Investigations. The Subcommittee's hearing examining the recent salmonella outbreak caused by the Peanut Corporation of America provided a powerful glimpse into just how extensive the problems plaguing our food safety system truly are.

It is clear that we need to give FDA some basic authorities that will enable it to do its job. As the O&I hearing illustrated, FDA does not have the authority to routinely access records documenting the steps that manufacturers take to assure safety. FDA also lacks modern and flexible enforcement tools, like administrative civil monetary penalties. It is our job to get FDA the resources and authorities it needs to do its job — and to do it well.

But with over 300,000 registered food facilities throughout the U.S. and abroad, it is clear that we cannot rely on FDA alone to prevent food borne illness outbreaks. Manufacturers must implement preventive systems to stop outbreaks before they occur, and we need to hold them accountable when they fail.

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But reorganizing large federal bureaucracies takes a great deal of time — and this is time we do not have when it comes to food safety. We must act now. We have to concentrate the additional resources we can get at this point on the job at hand. Our first goal should be to address the problems that plague this program where it currently sits. After we finish that job, we can consider whether a reorganization is necessary, and, if so, how to go about it.

I look forward to hearing from our witnesses about what steps we can take to begin this process.

Mr. PALLONE. Thank you, Chairman Waxman. Our ranking member of the full committee, Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON

Mr. BARTON. Thank you, Chairman Pallone and Chairman Waxman. As we all know, there are differences between the political parties in Congress, but there are also many similarities. On food safety, there is no daylight between Henry Waxman and Joe Barton, between the Republican minority and the Democratic majority. We both agree it is important. We both agree we need to take a look at the problem in a serious fashion, and we both agree that if necessary we need to work together to move legislation to fix that problem.

This committee in the last Congress through the Oversight and Investigation Subcommittee held nine hearings on food safety, and just this past month, as has already been mentioned, we held another hearing on the most recent food safety outbreak, the peanut butter salmonella outbreak.

This committee and the various subcommittees have been active on food safety and we are going to continue to be active. The food safety debate in the past few years has centered on funding additional money for the Food and Drug Administration. Unfortunately, in my opinion, instead of asking the appropriators to give the FDA additional funding, some have wanted to raise the additional money through a pay-to-play fee on food companies.

Last Congress, Nathan Deal of Georgia, ranking member on this subcommittee, and myself wrote the appropriators and asked them to give the FDA additional funds through the appropriation process. The appropriators responded positively, increased the appropriation for the FDA by $150 million in last year's supplemental appropriation bill.

We are the authorizing committee, and it is our job to give the FDA the authority to have the tools that it needs to make sure that our food is safe to eat. We must then get industry, consumers, the Food and Drug Administration, and the Congress together to strengthen the food safety system.

Last week, I cosponsored the bipartisan Safe Food Enforcement Assessment Standards and Targeting Act. That takes up a page just the name of the thing. Which was introduced by Congressman Costa, Congressman Putnam, Congressman Deal, among others, because I think that it is the right approach to food safety. It takes a risk-based, prevention-based approach to fixing the problem.

We need to focus on preventing food problems before they occur. One way the legislation I just enunciated does that is by requiring that companies create and properly execute food safety plans. Experts say that if the peanut corporation of America had had one, the salmonella outbreak never would have happened in the first place. The Costa Putnam bill also take a risk-based approach to food safety. It requires the FDA to focus the resources on high-risk facilities first where we get the most bang for our regulatory buck.

Mr. Chairman, this is an issue that unites consumers and producers. Consumers want to be confident the food they eat is safe. Producers rely on that confidence because without it, their brand means nothing. In fact, it is a negative. There seems to also be a

bipartisan and a bicameral support for moving food safety legislation.

Again I say that on the Republican side, we stand united with our friends on the Democrat majority side. We want to outline the problems in hearings like the one we are having today. And if we need a legislative solution, we are prepared to cooperate in preparing that solution. Thank you, Chairman Pallone, again for holding this hearing.

Mr. PALLONE. Thank you. Next is the gentleman from Texas, Mr. Gonzalez. Thank you. The gentlewoman from the Virgin Islands, Ms. Christensen.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN

Ms. CHRISTENSEN. Thank you, Mr. Chairman. Mr. Chairman, when the Subcommittee on Oversight met last month to take testimony on the salmonella outbreak, Chairman Pallone, you promised that you would hold this hearing. So I want to thank you and Ranking Member Deal for following up so quickly.

In listening to the tragic stories of the families who were here that day and hearing the callousness of the peanut corporation executives from the emails that the subcommittee had uncovered, it was clear that there were gaping holes in the food safety system, which needed to be closed.

In reviewing the testimony, several themes emerge with which I agree. One, the health and well being of the American public could not wait any longer for solutions to address our broken food safety system. Two, that the system must be completely overhauled in a manner that prioritizes coordination, resources, prevention, surveillance, accountability, transparence, and response and that empowers the FDA. And third, that we paid the price for our Nation's broken food system, and we paid in human lives and health, direct and indirect economic costs in the way that citizens both here and abroad view products coming from the U.S.

So I look forward to the testimony of our outstanding panel and to working to make bills like H.R. 759 law. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY

Mr. GINGREY. Thank you, Mr. Chairman. Mr. Chairman, public health officials estimate that each year 76 million people become sick, 325,000 are hospitalized, and 5,000 die from food-borne illnesses caused by contamination. And of course, the most recent of these incidents in my home state of Georgia sickened more than 677 people in 45 states and caused at least nine deaths due, in part, to a breakdown at FDA Oversight.

We therefore have an important oversight and legislative role in ensuring confidence in the safety of our food supply. And I do commend the chairman for holding these hearings. While I am pleased to see this committee engaged on such a critical issue as food safety, we must avoid sending mixed signals.

If we are trying to build a consensus that the FDA is overworked and lax on food safety oversight, adding things like tobacco to FDA's responsibilities, I hope, will not take away from the very

thing we are advocating here today. People understand the dangers of tobacco. There is no safe cigarette, but what they don't understand and they don't expect is a spinach salad or a scoop of peanut butter to kill them or their loved ones.

So, Mr. Chairman, I hope that these hearings will help us reach a greater understanding of the breakdowns in the current system as well as the appropriate solutions to safeguard the health and the welfare of all Americans. And I do look forward to working with you in a bipartisan way. And I thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you. The gentleman from Maryland, Mr. Sarbanes.

OPENING STATEMENT OF HON. JOHN P. SARBANES

Mr. SARBANES. Thank you, Mr. Chairman, for holding the hearing and for the work you have been doing on food safety and also want to salute Chairman Stupak, Chairman Waxman for their work as well as so many others who have been part of this effort.

There are so many obvious negative consequences to not having good oversight of our food supply. Among them, of course, are when there is a severe contamination, which can lead to harm and to death, and we have seen that recently once again.

A little less obvious is the low level contamination that can be broadly distributed across the food supply, but it is also certainly the province of those who are supposed to guard our food safety.

The third that I am particularly intrigued with, and I have read some of the testimony and look forward to the witnesses today, is the effect that occurs when there is an outbreak and a crisis and alarm in the public that then causes people to turn away from healthy food, which, of course, undermines our overall objective of getting people to eat right in this country. So we have got to make sure we protect the food supply so that we can advance our overall goal.

I look forward to the hearing today. Thank you. I yield back.

Mr. PALLONE. Thank you. Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS

Mr. PITTS. Thank you, Mr. Chairman. Like to thank you for convening this hearing on a topic that we read about in the newspapers every day, food safety. The ongoing salmonella outbreak linked to the consumption of products containing peanut ingredients from a single firm, Peanut Corporation of America, is only the latest in a string of high profile food safety related incidents.

The U.S. food supply is widely regarded as among the safest in the world. Nonetheless, as we have just heard, public health officials estimate that each year 76 million people become sick, 325,000 are hospitalized, and 5,000 people die from food-borne illnesses caused by contamination from any one of a number of microbial pathogens.

Recent scares about spinach and peppers and peanut butter and other products, both imported and domestic, have lead to public confusion about which products are safe and whether the food items they have in their refrigerators and pantries could be contaminated.

These instances have also lead to a lack of confidence among many Americans in the government's ability to keep them and their families safe from food-borne illnesses. Our constituents must have confidence that when they go to their local grocery store or convenience store, the food they buy is safe and it has met the highest standards and safeguards of our food safety system.

The U.S. food safety system, which includes as many as 15 different federal agencies collectively administering at least 30 different laws related to food safety must be modernized to meet the conditions of the 21st century.

I look forward to hearing from our witnesses today, specifically on the role FDA plays in food safety on what must be done to prevent or mitigate future food-borne illnesses and outbreaks, what changes must be made to FDA's current practices, and whether FDA's current resources are adequate to accomplish these goals.

And I would like to thank all of our witnesses for testifying today. I look forward to your statements. I yield back my time.

Mr. PALLONE. Thank you, Chairman Dingell, and thank you for introducing this bill and all your efforts on this issue.

OPENING STATEMENT OF HON. JOHN D. DINGELL

Mr. DINGELL. Thank you, Mr. Chairman, and thank you for holding today's hearing on the adequacy of our food safety system.

I want to say that this is a most timely and necessary hearing because we have before us one of the finest messes in history. Everybody is busily blaming Food and Drug for the inadequacy of the protection of American consumers. The blame for that lies right here in the Congress and downtown in the executive branch because of the failure of the agencies in the federal government and this Congress to see to it that FDA has, first of all, a good and adequate basic fundamental statute on which they may work, and our failure to see to it that they have an adequate and reliable revenue stream to enable them to do what has to be done.

Food safety is long a concern of mine, and today's hearing is very timely and necessary. You have mentioned, and it has been mentioned already, that we have a fine piece of legislation before this committee, which I will mention later. We do, and its enactment could do much to resolve the problems at Food and Drug.

There are not only problems with regard to food, but there are problems with regard to pharmaceuticals and devices. And there are severe problems in an uncooperative food processing industry that has done everything it can to obfuscate the matters and to see to it that we don't get legislation.

As you know, Mr. Stupak and his sister subcommittee has had some fine hearings, and he has brought folks in here to explain what is going on out there and to have Food and Drug tell us whether we have the resources. And we have had hell's own time prying the truth out of them.

We have a major problem on our hands relating to the safety of the food supply. It is killing Americans. The government accountability offices recognize this when they designated federal oversight of food safety as a high risk area for the first time in 2007. The Congress has done nothing about this except to talk and to come

forward with a lot of wondrous plans like setting up a single agency to administer the business.

Now, we have given them some more money, and that has been useful, but we have a lot more that has to be done. FDA is responsible for 80 percent of the food supply in the United States, but it is receiving only 24 percent of the expenditures. And I repeat, as a result of this, people are getting sick and dying.

Every year, 76 million people contract a food-borne illness in the United States. About 325,000 of these require hospitalization, and about 5,000 die according to the Center for Disease Control. So we have that on our backs and upon our hands.

More specifically, in the last two years, we can cite just a few events which have occurred. Melamine in infant formula and in milk products coming in from China. Nothing done to stop it. Tainted peppers from Mexico, harmful seafood and harmful fish from China, E. coli in spinach. That is just a little, and every year we get new information about the Food and Drug's inability to protect the American people.

Unfortunately the theme of a failed food supply system has not receded. We currently find ourselves in the middle of what is possibly the largest food recall in history, and it is costing billions of dollars to consumers and to innocent food processors because Food and Drug could not and did not do its job. And we have had hearings, by the way, on that which read like a joke book.

We currently find ourselves with FDA wrestling with a food-borne illness outbreak associated with salmonella which has been found in peanut products produced by the Peanut Corporation of America, PCA. And because of the outright negligence of this company, more than 2,100 products from ice cream to dog food have been recalled. And by the Department of Agriculture can investigate and can inspect dog food manufacturers every year. Food and Drug can't do the same thing for food processors for human beings.

Because of the outright negligence of this company then, more than 680 people in 46 states have been sickened, and so far, we know of nine who have died from these events. And I think we can assume, given the way things have been going, that this is not yet over.

What we have found in this instance and in many others is that FDA funding is woefully inadequate and their authorities are outdated. They have proven to be incapable of protecting our food supply. I commend the President for recognizing the inadequacy of FDA's resources and for proposing increased funding for food safety activities in his budget package.

However, my experience in the Congress has shown me that the only way to adequately address the problem of resources is by ensuring a steady predictable revenue stream for FDA. I propose to do this by establish a registration fee for manufacturers so that we can look and see what is coming into this company.

And I would note to you because of Food and Drug's inability to address this problem that we are finding controlled substances are coming into this country right alongside of other commodities uninspected by Food and Drug or anybody else.

This is the only way we can make sure that Food and Drug is able to carry out its responsibilities. In addition to the shortage of resources, we must address the issue of authorities. It is shameful that FDA does not have authority to mandate recalls, to require manufacturers to identify and develop plans to mitigate hazards before they occur rather than after people are sick and die. And to identify safety questions by having full access to safety records without delay and to appropriately trace the ability and not only their own ability, but the origin of tainted products.

Mr. Chairman, you and I, along with Chairman Stupak, have an appropriate safety solution to our food problems, H.R. 759, and I urge and invite our colleagues to join us in this particular undertaking. As a result of the failure to have Food and Drug given the authority it needs and the resources, people, I repeat, are dying.

The Congress is working to address a mess left behind by another industry that has been left to self-regulate. I refer to the banks and the securities industry. And there, they are destituting people all across the United States in all kinds of ways from their 401(k)s to their retirements to their saving account and to their hopes of the future and their homes and their mortgages.

I look forward to our witnesses' testimony today. I apologize for taking so much time, but I hope that this process will shake some folks up so that we will get some progress that we need in making the American people safe. I thank you, and I commend you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman, and I will be brief. I want to thank the Chairman Emeritus. He is passionate about this. I see my friend Bart Stupak here, and I got to serve on ONI, had numerous of these hearings. We know the need, and we know we need to move rapidly.

I have always been supportive of a risk-based approach in making sure that the money that is needed goes to where it is needed. And I think we need to focus on that. There are a lot of preventive aspects that we can do like irradiation in a lot of those areas that doesn't affect food quality. I think we identified that, and we ought to help and incentivize movement in that direction. And funding is always going to be an issue. Make sure we fund appropriately so the money is going to where it is needed.

That is why I am excited about being back on this committee. Mr. Chairman, I think serving with Bart has helped me get up to speed on this issue, and I look forward to being helpful. I yield back.

Mr. PALLONE. Thank you. The gentleman from Georgia, Mr. Barrow.

OPENING STATEMENT OF HON. JOHN BARROW

Mr. BARROW. Thank you, Mr. Chairman, and thank you for keeping your promise to stay on this issue until we get something done about it. I can add nothing to the comprehensive statement of the Chairman Emeritus. But as befits my diminutive stature in the picture, I will focus on something smaller.

I know that colleagues of mine are working on more comprehensive legislation from subjects like increasing the resources and increasing the amount of FDA inspections to creating a system of traceability to creating mandatory recall authority. There are a whole bunch of major elements that need to be put in place.

I want to focus on something that I think ought to be a part of any comprehensive bill or can stand alone as a genuine contribution to this. And that is a measure to increase the effectiveness of both the sampling and the testing that is done of food. What we need in this country is a system that doesn't give manufacturers the option of knowing what they need to know and when they need to know it, but requires them to know what they need to know when they need to know it, and that provides real-time information, reporting that information at the very same time to an effective regulator of the public interest so that the public knows what we need to know when we need to know it.

I think that would go a long way toward cleaning up what is broken in this system, but we cannot continue to rely on a system that is essentially the honor system that allows folks to use the American people as a population of lab rats to test the food on them first to find out what is wrong with it. That won't work. We have to be proactive about it, and that is what I hope the witnesses will be able to share with us about today. Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you. The gentlewoman from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN

Mrs. BLACKBURN. Thank you, Mr. Chairman, and welcome to our witnesses. We are ready to hear from you today, and I have just a couple of thoughts to add to the comments that have been made. The hearings on food safety are not new. I will also say that as we have worked through this process over the last several years, one of the things that we have repeatedly asked you all for is clarification on your internal communications. How you communicate with one agency, one division knowing what work is being done in another one. It seems as if you continually have stumbles that do harm to the work that you are trying to do.

Also, best practices. You seem reticent to talk about best practices and how you address some of the problems that face you all with food safety and with other parts. We know that you have to change the way you deal with quality control, that that is something for the suppliers as well as for you all internally. And we know that you need a reformed review system, that you also need some organizational changes to take place.

Now, with the Chairman Emeritus in his remarks, which we all agree with much of that. I will differ on one point. I think before you start spending more money, what you need to do is show how you are going to reorganize and how you are going to address the problems that are before us.

And thank you, and I yield back.

Mr. PALLONE. Thank you. The gentlewoman from Colorado, Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE

Ms. DEGETTE. Thank you very much, Mr. Chairman, and I want to thank my compadre, Bart Stupak, for all the work we have been doing in ONI over the last 10 years on these food safety issues. I think that the bill that the chairman and the Chairman Emeritus and Mr. Stupak introduced is excellent, especially since it includes several issues I have been working on for many years, which is mandatory recall authority for the FDA and also traceability because we had the ability to do mandatory recall right now.

Most people think we have it, and if we had had it, perhaps some of those people in this latest peanut butter outbreak would not have died because the FDA would have been able to recall that peanut butter sooner.

Two things I will say. The first thing is I think we need to improve the traceability provisions in the bill, and I look forward to working with the chairman on that. The technology exists, and there is no reason we shouldn't be doing it.

The second thing is, as well as more resources, we need to give the FDA more authority to obtain the information that they need through subpoena authority and other kinds of authority.

And finally, I agree completely with Chairman Waxman when he says that we need to do all of this now, and then after we do it, we need to look at structural changes in the way we oversee our food safety in this country. Congresswoman DeLauro and I have worked for many years on a unity food safety agency, but that will take time. And time is certainly something we don't have right now, given what is happening with all these outbreaks. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentlewoman from Florida, Ms. Castor.

OPENING STATEMENT OF HON. KATHY CASTOR

Ms. CASTOR. Thank you, Mr. Chairman, and I want to thank my colleague, Mr. Stupak, as well. Food safety is vital to the health of all Americans. And many of you know, the Government Accountability Office keeps a very short list of major government problems that require significant reform. It is called the high risk series, and it includes notorious governmental failures such as the Financial Regulatory System, maintenance of our roads and bridges. Food safety also is on this high-risk list, and reform is vital.

Let me give you one example. Tomatoes from my home state of Florida last year were blamed for a nationwide salmonella outbreak that was eventually traced to jalapeno and Serrano peppers from Mexico. In the meantime, the FDA's warning not to consume tomatoes from Florida cost tomato producers at least $100 million. All of the time and effort spent warning consumers about Florida tomatoes only served to delay the solution to the real problem and allow more Americans to get sick.

We have to address a lack of resources, the labyrinth regulatory regime, the lack of federal authority. The problems facing the food safety and oversight are legion, and they are difficult, but they are not insurmountable. So I look forward to the witnesses' thoughtful recommendations today. Thank you.

Mr. PALLONE. Thank you. The gentleman from Ohio, Mr. Space.

Mr. SPACE. Thank you, Mr. Chairman. In yielding back, I would just like to thank you and Chairman Stupak and Chairman Dingell for your good work in this area. I look forward to the testimony.

Mr. PALLONE. Thank you. The gentlewoman from Ohio, Ms. Sutton.

OPENING STATEMENT OF HON. BETTY SUTTON

Ms. SUTTON. Thank you, Mr. Chairman, for having this hearing and, you know, it was only a month ago today that under the tremendous leadership of Chairman Stupak that we had a hearing in the Oversight Subcommittee on the recent salmonella outbreak associated with peanut products. And at that hearing, I told the tragic story of an elderly woman from my district who died of salmonella poisoning.

Sadly, Mr. Chairman, since then, another elderly woman from northeast Ohio by the name of Nellie Napier has died from salmonella. In fact, her death was announced that day. There have been over 99 cases of salmonella reported in Ohio and 680 nationwide.

Now, I know, Mr. Chairman, that you and others have long been working to fix our broken food safety system, and I thank you. I thank Chairman Waxman and Chairman Emeritus Dingell and Ms. DeGette and others.

The bottom line, Mr. Chairman, is that Congress needs to act quickly and comprehensively to address the food safety in our country. It is clear that the FDA does not have the current authority or capacity to properly oversee the safety of our food supply. That is why I reintroduced the Protect Consumers Act, to give FDA mandatory recall authority. It is a very simple measure. Certainly should be part of a comprehensive overhaul, but frankly I would love to see it moved quickly in its own right if we cannot move the comprehensive bill as quickly as we would like.

We cannot sit back and let any more people become ill from food they eat. I look forward to hearing from our panelists today and working with my colleagues to fix our broken food system, and I yield back.

Mr. PALLONE. Thank you. The gentleman from New York, Mr. Engel.

Mr. ENGEL. Mr. Chairman, I would like unanimous consent to have Mr. Green's remarks entered into the record.

Mr. PALLONE. Without objection, so ordered.

[The prepared statement of Mr. Green follows:]

Statement of Congressman Gene Green
Committee on Energy and Commerce
Subcommittee on Health
How do we Fix Our Ailing Food Safety System?
March 11, 2009

Mr. Chairman, I want to thank you for having this hearing today on our food safety system. Having participated in the peanut butter hearing last month, and learning about the deplorable condition of our food supply though that hearing and other hearings we had over the last Congress, I hope this year will be the year we overhaul the FDA.

Over the past year or so there have been several high profile food contamination incidents in the US involving: spinach, cantaloupes, peanut butter, and tomatoes. This Committee has diligently investigated all of these incidents.

These hearings on the FDA have clearly shown us that the FDA simply does not have the resources, funding, manpower, or technology it needs to protect the American food supply and fulfill its mission.

These outbreaks also led the GAO to call our food safety program "high risk" and the FDA's own Science Board to say that the FDA does not have the capacity to ensure the safety of food for the nation.

The findings of this committee, the GAO, and the Science Board are alarming to say the least and most certainly indicate the FDA needs more resources to protect our food supply.

I have the great honor of representing Houston. The Port of Houston is the largest port in the US in terms of foreign tonnage. A large portion of that is related to our energy industry, but the port imported 606 thousand tons of imported food products in 2007.

The Port of Houston does not have an FDA lab and in fact there is no FDA lab in the entire state even though we share the longest border with Mexico.

I have yet to understand why Texas, with its level of trade and southern border with Mexico, does not have an FDA lab. In fact, there are over 300 ports of entry in the US and only 13 ports actually have FDA labs. If we can't ensure the safety of the food in our own country, how can we ensure the food entering our country is safe if we don't have enough inspection labs?

It is also alarming the FDA does not have the ability to require a mandatory recall. We should not to rely on the voluntary efforts of food manufacturers to ensure the safety of their product. There is no greater example of how this voluntary system fails us time and time again than the Peanut Corporation of America.

The Peanut Corporation of America was operating and unlicensed and uninspected plant in Plainview, Texas. This plant was never inspected until the FDA began investigating the salmonella outbreak. Unfortunately, Texas

is among states where the FDA relies on state inspectors to oversee food safety.

Department of State Health Services finally shutdown the Plainview plant after it tested positive for possible salmonella. It is unbelievable that a food processing plant can deliver possibly tainted products into our food supply without a license and without *ever* being inspected.

One thing is clear; no plant should ever be able to operate in the manner in which the Peanut Corporation of America had operated.

We have said for years the FDA is underfunded and that is still true, but I am happy the President has allocated $1 billion for FDA food safety oversight in his budget. However, simply giving money to the FDA will not solve this problem. We need to overhaul the way the FDA reviews and inspects our food processing plants and food supply.

Mr. Chairman, I look forward to working with you on food safety this year and I hope we will finally be able to pass comprehensive legislation

STATEMENT OF
CONGRESSMAN MICHAEL C. BURGESS, M.D.

BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE

March 11, 2009 HEARING
"How Do We Fix Our Ailing Food Safety System"

The size of the food industry and the diversity of its products and processes have grown tremendously – both in the amount of domestic food manufactured and the number and kinds of foods imported. At the same time, the FDA as well as state and local agencies has had the same limited level of resources to ensure food safety.

This has caused, in this past year alone, two outbreaks of salmonella – once in jalapenos and once in peanut butter – and various other food safety concerns, making us seriously doubt the efficacy of our food safety system as well as the capacity of the Food and Drug Administration to supervise this ever burgeoning industry.

As we look today towards legislative fixes to our food safety system, it is obvious the pathway forward is more modernization, specifically a greater reliance on a risk-based approach. The FDA should be given the authority to mandate the use of the Hazard Analysis and Critical Control Point (HACCP) in domestic and imported products. This would allow the FDA to access necessary records to quickly identify the source of any food borne pathogens.

The mandate for HACCP is already in place. In 1995 the FDA mandated the use of HACCP in seafood – and then in 2001 for juices – and the USDA mandated the use of HACCP for meat and

poultry processing plants. Thus it would hardly be too much to demand the other domestic and imported product groups to use this system.

Finally, we must give the FDA the resources they need to do the job they have been given to do. We should fully fund the FDA and THEN demand full accountability of their actions and expenditures.

Thank you.

OPENING STATEMENT OF HON. ELIOT L. ENGEL

Mr. ENGEL. Thank you, Mr. Chairman. Thank you for holding this important hearing today. If there is any good that may come of the Peanut Corporation of America salmonella crisis, it is now more clearly than ever that our food safety system is broken and in need of critical reforms.

An AP poll last year found that 46 percent of people were scared that they would get sick from tainted food, and there is a reason for this fear: U.S. food-borne illnesses result in 76 million illnesses, hundreds of thousands of hospitalizations, and up to 5,000 deaths each year.

As one of our witnesses astutely pointed out in his testimony, our Nation is sustaining deaths equivalent to those that perished in the World Trade Center attack in New York every six months. When you think about it in those terms, it just takes your breath away. And yet, we have set up the FDA to fail here. We expect the FDA to ensure the safety of our Nation's food supply, but we haven't given it the resources or authority to get the job done.

Sure there are many food companies and facilities that are employing best practices to preserve their own food products, but unfortunately it is those that don't that cause crippling problems for our public health and economy. This is why it is so important to grant FDA the ability to mandate clear preventative controls, strong traceability, and mandatory recalls within their food safety authority.

Mr. Chairman, the costs are clear. I look forward to working with you on a comprehensive food safety reform bill this year. I yield back.

Mr. PALLONE. Thank you. Gentlewoman from California, Ms. Eshoo.

OPENING STATEMENT OF HON. ANNA G. ESHOO

Ms. ESHOO. Thank you, Mr. Chairman, for holding this very important hearing on the issue of food safety, which is so needed. The American people should be able to trust their government to protect them from food-borne illnesses, and right now, to put it mildly, we are not even doing an adequate job.

When people are dying or becoming seriously ill as a result of what they ingest in the United States of America that has always had the highest standards, we are really in trouble. And it is an area that most frankly the Congress has neglected for a long time.

So I think that now is the time to address it because the FDA really should be the world's premier food inspection authority. It is an issue that affects everyone. Doesn't matter whether you are rich or poor, where you live in the country, whether you are a youngster or an oldster, God help you if you have ingested something that has not been reviewed.

And we live in a global economy, and we have things pouring into our country, and unless it is inspected, then our citizens are placed at risk. I have cosponsored legislation that Congresswoman DeLauro has offered. I think it is a very good bill. I think that there are good ideas, both in this committee and from outside the committee. I think that the system has to obviously be modernized, and I really think that we should separate our food from the FDA.

I think we should have a food safety administration. I, for one, am a little tired of running the FDA on user fees. I think we are doing it on the cheap, and as long as we do that, we are going to be plagued with the problems that we are here to discuss today.

So I look forward to working with all of my colleagues on this issue. I don't think anyone has a corner on the market of wisdom on it, but I do think that the committee should take into consideration all of the bills that are being introduced on this because there are very good ideas that are contained in each one.

So thanks again, Mr. Chairman, and to the witnesses that are going to testify today, thank you. We know that you will be instructive. We will learn from you, and hopefully we will pay close attention to you. Thank you.

Mr. PALLONE. Thank you. I think that concludes opening statements by the members. So we will now turn to our panel. I want to welcome you, and I ask you to come forward. We only have one panel today, but they are distinguished. And they are actually quite—let them sit down first.

I will start on my left with Ms. Caroline Smith DeWaal, who is the food safety director for the Center for Science in the Public Interest, and she has been dealing and calling attention and been a watchdog on this issue for a number of years. Many of your ideas have been incorporated in my bill and then into the larger bill sponsored by Mr. Dingell and Mr. Stupak and myself.

Mr. William Hubbard, who is former associate commissioner for policy and planning at the Food and Drug Administration and an advisor for the Alliance for a Stronger FDA. Good to see you again.

Dr. Martin Cole, who is research professor of biology and director of the National Center for Food Safety and Technology at the Illinois Institute of Technology.

Mr. Thomas Stenzel who is president and CEO of United Fresh Produce Association.

And finally Jim Lugg who is former executive vice-president, Food Safety and Quality, Fresh Express, and consultant for Chiquita Brands. Thank you all for being here, and we have 5-minute opening statements, and we will start with Ms. DeWaal.

STATEMENTS OF CAROLINE SMITH DEWAAL, FOOD SAFETY DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST; WILLIAM HUBBARD, ADVISOR, ALLIANCE FOR A STRONGER FDA, FORMER ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION; MARTIN COLE, PH.D., RESEARCH PROFESSOR OF BIOLOGY AND DIRECTOR, NATIONAL CENTER FOR FOOD SAFETY AND TECHNOLOGY, ILLINOIS INSTITUTE OF TECHNOLOGY; THOMAS E. STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION; AND JIM LUGG, CONSULTANT, CHIQUITA BRANDS, FORMER EXECUTIVE VICE PRESIDENT, FOOD SAFETY AND QUALITY, FRESH EXPRESS

STATEMENT OF CAROLINE SMITH DEWAAL

Ms. DEWAAL. Thank you very much, Chairman Pallone and also Chairman Deal for having this hearing. I do want to recognize just the tremendous food safety leadership that is in this room from

you, Chairman Pallone, to former Chairman Dingell, Mr. Stupak, and Representatives DeGette and Eshoo. You have all been tremendous leaders, and we are thankful to be hopefully at this point of having legislation poised to really address these problems.

I am the director of food safety for the Center for Science in the Public Interest. And we represent over 900,000 consumers both in the U.S. and Canada. We are focused on food safety, nutrition and even alcohol issues. Pretty much anything you put in your mouth we worry about.

The impact of the Peanut Corporation of America outbreak and recall are still reverberating through the food supply. It has caused nearly 700 confirmed illnesses and nine deaths and the recall of over 3,200 separate products. Despite its size and scope, this event is neither rare nor unexpected. Congress has held nearly 20 hearings in the last two years focused on similar failures of FDA's food program linked to everything from spinach tainted with E. coli, pet food containing an intentionally added melamine, which sickened and killed many, many animals, and even a previous peanut butter salmonella outbreak, which was thoroughly investigated in this committee.

These events are causing steep declines in consumer confidence, both in the overall safety of the food supply and in FDA's ability to protect the public. Nearly half of those questioned by Consumers Union in November said their confidence in food safety had declined.

Also last fall, a poll conducted by Ipsos-McClatchy reported that 28 percent of those polled believe food safety had gotten worse, and 46 gave food safety controls a failing grade. In July 2008, in the midst of the salmonella outbreak linked first to tomatoes and then to peppers, an Associated Press-Ipsos poll found that 46 percent of people were worried that they might get sick from eating tainted products. Clearly it is time for Congress to take action to fundamentally reform and fully fund our food safety system.

I will now outline a couple of the essential elements that CSPI thinks need to be in any legislation moving forward to begin the process of reforming FDA's food safety program.

The heart of any effective reform effort lies in prevention, not response. Legislation should include at least the following three components for preventing food safety problems at food processors. First, Congress should require every food plant 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 requirements are already in place for all meat and poultry processors today but not in plants regulated by FDA.

Legislation should set risk-based inspection frequencies for food plants and establish clear auditing parameters when states are conducting inspections on behalf of the federal government.

And finally specific authority should allow the agency to set testing frequencies and require food processors to report adverse reports to government inspectors. Without these checks on the plants, companies can follow the practices of PCA, which instead of fixing its salmonella problems, it fixed the tests.

Consumer concerns extend up and down the food chain from the farm to the table. So legislation also needs to provide on-farm food safety plans that will give farmers tools to manage risks like raw manure, unsafe water, and worker hygiene.

Imported foods also pose special challenges as they enter the U.S. from all over the world including many countries where they are essentially unregulated. CSPI supports the use of certification systems operated by foreign governments and some third parties if they are subject to appropriate oversight by FDA. Certifiers of imported product can give FDA boots on the ground and greatly increase the agency's capacity to enforce our food safety requirements among the foreign facilities from 175 different countries that export to the U.S.

President Barack Obama has promised a government that works. These new authorities, together with increased funding will certainly help FDA improve. But to deal with the root of the problem, Congress and the Obama administration will need to go beyond making a few improvements. Structural reforms are also essential.

FDA is responsible for 80 percent of the food supply, and yet the commissioner's attention is frequently on drugs, medical devices, and cosmetics, animal feed, many other issues that FDA regulates. Food issues frequently unfortunately fall to the bottom of the pile. Today there is no single expert in charge of the policies budget and enforcement staff and no credible voice communicating to the public and the industry what needs to be done to prevent outbreaks.

It is time to elevate food monitoring functions within the Department of Health and Human Services. With both the public and the regulated industries clamoring for change, we are very happy to be here today and to have the tremendous leadership on this committee. Thank you.

[The prepared statement of Ms. DeWaal follows:]

Testimony of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
before the
Subcommittee on Health of the
House Committee on Energy and Commerce

Washington, DC
March 11, 2009

Good morning Mr. Chairman, Ranking Member Deal and Members of the Committee. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a 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.

Thank you for this opportunity to speak about the lessons learned from the most recent outbreak linked to peanut products and how Congress can address these problems. This massive outbreak caused confirmed illnesses of nearly 700 people and the likely deaths of nine from tainted peanut products. Clearly, we don't need further evidence that the food safety system is broken. Much of my presentation today will focus on the recommendations I have made in prior testimony and the proposals in "Building a Modern Food Safety System for FDA Regulated Foods," which CSPI released in 2007.

The Food and Drug Administration (FDA) is operating under an antiquated legal structure. The Federal Food, Drug and Cosmetic Act of 1938 gives FDA responsibility for regulating the safety of 80 percent of the food supply. But this statute is marred by its reactive posture, giving the agency authority to act principally when food is found to be adulterated or misbranded. Even its enforcement provisions, which are more focused on economic adulteration, will likely prove inadequate to address the facts in this case – with evidence that the management intentionally released products believed to have killed nine people.

It is time for Congress to address long-standing deficiencies that are causing a crisis in consumer confidence. In the wake of the Peanut Corporation of America (PCA) outbreak, the University of Minnesota's Food Industry Center reported that only 22.5 percent of consumers were confident the food supply is safer today than a year ago.[1] In another poll released last month, 48 percent of those questioned by Consumers Union in November said their confidence

[1] *Consumer Confidence in Food Safety Plunges in Wake of Peanut Butter Contamination, University of Minnesota Study Finds*, UMNews, Feb. 23, 2009.

had declined.[2] In July 2008, in the midst of a *Salmonella* outbreak attributed to tomatoes/peppers, an Associated Press-Ipsos poll found that 46 percent of people were worried that they might get sick from eating tainted products.[3] Last fall, a poll conducted by Ipsos-McClatchy reported that 28 percent of those polled believed food safety had gotten worse and 46 percent gave food safety controls a failing grade.[4]

Most specific foods have a high "elasticity of demand," meaning that shoppers simply switch from one food to another when they lose confidence due to an outbreak or recall. This can have adverse health effects if repeated outbreaks in the fresh vegetable sector, for example, cause consumers to repeatedly switch away from these healthy food choices. And it is felt by the industries that experience losses in the market of hundreds of millions of dollars.[5] Even companies that are not named in a recall experience reduced demand and increased costs, especially if they increase advertising to differentiate their products in the face of a massive product recall, as we observed in the PCA recall.

Since 2007, Congress has conducted 19 oversight and legislative hearings on food safety. These hearings, many within this committee, followed outbreaks caused by spinach tainted with *E. coli* O157:H7, chili sauce canned with deadly botulism spores, and pet food ingredients intentionally adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers' processes and in FDA's oversight.

With evidence of both unintentional and intentional contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has placed food safety in its high risk category three years in a row.[6] The need for action is clear and Congress has developed an excellent record of the gaps and deficiencies that should be addressed.

The first lesson of the 21st century is that deregulation doesn't work. FDA's approach of relying on what amounts to a food safety honor system is clearly not effective to protect consumers from food-borne illness. It is essential that Congress give FDA strong authority to oversee the safety of the food supply.

Peanut Corporation of America:
Case Study of a Broken Food Safety System

The *Salmonella* Typhimurium outbreak caused by PCA is only the latest – and certainly not the last – incident pointing to failures in FDA's authority. The outbreak is a case study in what is wrong with our food safety system.

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[2] Food-Labeling Poll 2008, Consumer Reports National Research Center, NRC #2008.18, Nov. 11, 2008.
[3] *Tomato growers: Salmonella scare damages industry,* USA Today, July 19, 2008.
[4] Jane Byrne, *US Consumers Concerned About Safety of Food Imports: Poll,* FoodUSA.navigator.com, Oct. 22, 2008, at http://www.foodnavigator-usa.com/layout/set/print/layout/set/print/content/view/print/224119.
[5] *See,* Craig Schneider, *Peanut Creditors Expect Losses; Producer Bankrupt by Salmonella Owes Ga. Businesses,* Atlanta Journal-Constitution, March 7, 2009; Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA Today, Sept. 20, 2007.
[6] Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety,* Rep. No. GAO-09-271, Jan. 2009.

1. PCA Could Engage in Improper Acts Without Fear of Being Caught

Because FDA doesn't require companies to have a plan to prevent hazards commonly linked to similar products, the company could engage in what is likely criminal behavior without fear of discovery. Although state agencies visited the plant several times a year, its inspections were only a spot check. Without a written plan and the records to back up the plan, the agency's inspectors lacked information needed to fully assess conditions in the plant.

2. PCA Could Hide Its Positive Test Results from Inspectors

PCA's management intentionally shipped contaminated product on 12 separate occasions because there was no reason to fear regulatory consequences. Georgia inspectors could not determine that *Salmonella* had been detected in the plant because they lacked the ability to require companies to share their production records. Meanwhile, PCA routinely ignored positive *Salmonella* tests and retested samples to get a negative result in the interest of invoicing product.[7] Under the Bioterrorism Act , FDA may only request records when there is a food emergency and it has clear evidence food is adulterated and presents a threat of serious adverse health consequences or death.[8] In most cases, this compels records production only after an outbreak has occurred. It is not sufficient to prevent outbreaks in advance of product release.

3. The Absence of Federal Inspections and Inadequate State Inspections Let Problems at PCA Fester

FDA's last inspection of the PCA plant was in 2001. In 2006, it contracted with the Georgia Department of Agriculture (GDA) to conduct inspections for the federal agency. The GDA cited the plant for unsanitary conditions many times between 2006 and 2008. However the state inspections proved inadequate, failing to find the numerous problems a more thorough FDA inspection turned up in January.

Following the outbreak, FDA conducted an inspection and found numerous deficiencies, such as roaches, mold, dirty utensils and equipment, and open gaps in the roof and doors that allowed rain and rodents access in to the building.[9] The plant was operating in such poor conditions that workers at the plant had to step over puddles of water inside the building after a heavy rain, an environment allowing *Salmonella* to thrive.[10]

Elements of a Modern Food Safety System:
Moving Forward to Protect Consumers

The PCA outbreak – like countless episodes in the previous decade – illustrates numerous failures and areas where improvements are needed. The company seemed to have had no food

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[7] *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 email from Stewart Parnell to Sammy Lightsey).

[8] *Regulatory Failure: Must America Live with Unsafe Food?*: Hearing before the House Subcommittee on Oversight and Investigations, 110th Cong. (2008) (Statement of Dr. Stephen F. Sundlof, Dir., Center for Food Safety and Applied Nutrition); 21 U.S.C. 350c(a).

[9] FDA, *Peanut Corporation of America Inspection Report,* Feb 4, 2009.

[10] Michael Moss, *Peanut Case Shows Holes in Safety Net*, N.Y. Times, Feb. 8, 2009.

safety operating plan. It did not respond appropriately to repeated positive *Salmonella* findings. The state of Georgia failed to provide effective inspection, in part because its inspectors lacked full access to the plant's food safety records, and in part because FDA failed to provide oversight for the state inspection program. Finally, the penalties available to FDA to prosecute the company are not adequate to deter future violations of the Act.

1. Preventive Controls Are the Heart of a Modern Food Safety System

The heart of any effective reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have food safety plans detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. This Hazard Analysis and Critical Control Points (HACCP) style planning is already a requirement for all meat and poultry plants, and it should be a prerequisite for all food processors that want to sell food in the U.S. This establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for government audit inspections. However, the history of these programs in the seafood area demonstrates that Congress must also give FDA the authority and funding to enforce compliance through regular inspections with evaluation of the plan's implementation and access to company processing and testing records.

2. Enforceable Performance Standards Are Essential to Effective Preventive Controls

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 sanitary manner that limits the likelihood of contamination by pathogens, chemicals, or physical hazards, like glass or metal. In the case of PCA, performance standards would have provided inspectors with a benchmark for regular sampling of products.

Combining HACCP planning with performance standards would focus food safety activities on prevention and permit more efficient and effective government oversight through analysis of records as well as visual and laboratory inspection.

3. Regular and Frequent Inspections Will Assure Compliance

The failures to detect and correct the unsafe practices at PCA highlight how FDA's infrequent inspections (averaging one visit in 10 years)[11] and the agency's deficient oversight of state-contracted inspections contribute to illness outbreaks. Even when FDA received a clear signal of problems in the plant from its own import alert system, the agency failed to send its inspectors to conduct a review of the plant and instead relied on state inspectors.

To address these problems, legislation should set specific inspection frequencies for all food plants. Higher-risk foods should be inspected at a greater frequency, preferably no less than annually, with lower risk food facilities being inspected at least once in any two year period. Those rates would still be well below the rate established for restaurant inspections of once every

[11] House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, Oct. 30, 2006.

six months.[12] The rate is also far less than the monthly inspection rate many consumers, when polled on the question, believe is appropriate.[13]

Setting frequencies will require a commitment to fund the agency or find new resources, and some legislative proposals have established a modest registration fee to offset the costs associated with increased inspection oversight. Current FDA funding shortfalls have reached a critical level, leaving the agency with fewer inspectors, even as the workload continues to increase. Since 1972, domestic inspections conducted by FDA declined 81 percent.[14] Just since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, there was a 47 percent drop in federal inspections. [15] Just those declines in inspectors and inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars.[16]

Improving inspections will also require a different approach. FDA should rely on written records maintained by the plants, including a written food safety plan and the processing records that support that plan. While these records may differ by the type of plant, FDA inspectors need to be able to see sampling results and corrective actions taken in response to production problems.

PCA clearly showed the risk posed to the public in not giving FDA and state inspectors access to records, but the same evidence was presented to this Committee in 2007 after another outbreak linked to peanut butter products.[17] Relying on the Bioterrorism Act to provide records access for food inspectors is too little, too late. Congressional action is warranted and urgent to prevent future problems.

With regard to the shortcomings in state inspection, we must avoid drawing the wrong conclusions. Instead of illustrating that Federal/State cooperation is unreliable, the PCA example argues for improving federal oversight of and assistance to state inspectors who are used to leverage resources for inspections.

In addition to leveraging inspection resources, state health departments are the front line for detecting outbreaks. The Minnesota Department of Health with its innovative approach to epidemiology determined that peanut products were the source of the outbreak.[18] Yet, many states do not have the resources to establish programs modeled on Minnesota's. Congress needs to strengthen the state inspection and surveillance system by providing assistance through

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[12] Center for Science in the Public Interest, *Dirty Dining: Have Reservations? You Will Now.*, 2008, at http://cspinet.org/new/pdf/ddreport.pdf.
[13] Food-Labeling Poll 2008, *supra* note 2.
[14] Fact Sheet, *supra*, note 11.
[15] Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Lanquish*, Associated Press, Feb. 29, 2007.
[16] FDA Science Board Subcomm. on Tech., *FDA's Mission at Risk: Estimated Resources Required for Implementation*. Feb. 25, 2008.
[17] *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?*: Hearing before the House Subcomm. on Oversight and Investigations 110th Cong. (2007).
[18] Julie Schmit & Elizabeth Weise, When Food Illnesses Spread, Minnesota Team Gets the Call, USA Today, at http://www.usatoday.com/money/industries/food/2009-03-04-food-illness-detection_N.htm (accessed March 10, 2009).

training and grants.

4. Import Requirements

Americans eat about 260 pounds of imported foods – approximately 13 percent of their total diet – each year. While imported meat and poultry products must be certified by USDA as meeting safety standards equivalent to those applied to domestic meat and poultry, no such system exists for FDA regulated foods. Imported fruits and vegetables, for example, have caused numerous large and sometimes deadly outbreaks. Imported berries, melons and green onions, coming from areas with substandard hygiene practices, have alone sickened thousands of Americans in the last 10 years. Last year, peppers and possibly tomatoes from Mexico were implicated in an outbreak that caused more than 1,400 illnesses and contributed to two deaths.[19]

FDA must have the authority to establish a system under which imported food is certified as meeting the same food safety standards for production, inspection, labeling, and consumer protection that domestic products must meet. This authority should:

- Require FDA to review and audit foreign national food safety programs regularly;
- Impose strict conflict-of-interest requirements on private third party auditors, where used;
- Allow FDA to withdraw certification from a national or third-party auditor if a food product is linked to an outbreak of human illness or if the foreign importer no longer meets equivalency standards; and
- Give FDA authority to enter and inspect foreign plants and the ability to refuse imports from countries or facilities that obstruct FDA inspections and investigations.

5. Research and Education

Today, FDA conducts limited research related to pathogenic microorganisms and other contaminants that threaten the safety of food. More FDA-directed research is needed, however, to support both FDA regulatory programs, state food-safety agencies and the food industry. The program of research should include a public health assessment with improvements to our surveillance system, such as stronger coordination and assistance to state programs. Research into effective control and prevention strategies and tools is vital to improving techniques for monitoring and inspecting food. This must include research into more efficient, sensitive and faster methods for detecting contaminants and reducing harmful pathogens. Education efforts should encompass instructions for food preparers in the safe handling of food, and for health professionals to improve diagnosis and treatment of food-related illness and to advise individuals at special risk.

6. On Farm

Since 1998, fresh fruits and vegetables have been linked to an increasing number of outbreaks. Given the importance of produce consumption and its central role in a healthy diet, it

[19] Centers for Disease Control, *Investigation of Outbreak of Infections Caused by Salmonella Saintpaul*, Aug. 22, 2008, at http://www.cdc.gov/salmonella/saintpaul/archive/082208.html

is imperative that FDA have authority to set specific, mandatory standards that apply to farmers who grow food for human consumption.

7. Mandatory Recall

CSPI believes that giving FDA authority to order a recall if necessary is a critical tool for responding to future outbreaks. Today, when you see the notices of the recall, they often mention that it is voluntary. Unfortunately, while true, this may not compel consumers to act with urgency, because they might reason "If it were serious, FDA would issue a mandatory recall."

8. Traceback

A traceability system is a recordkeeping system for tracking the flow of product through the production process or supply chain.[20] It should be mandatory across all points and have (1) the *breadth* to catalog each processing step that implicates safety, (2) the *depth* to identify all handlers as well as the ultimate source of the product and its ingredients, and (3) the *precision* to pinpoint the movements of a particular item of food.[21] The current system established under the Bioterrorism Act was inadequate for tracing fresh produce during the *Salmonella* Saintpaul outbreak from April-July 2008, further documenting the need for new traceability requirements.

9. Detention

If an FDA inspector has reason to believe that a domestic or imported food is unsafe, adulterated or misbranded, the agency must have the authority to temporarily detain the food for a reasonable time. The current detention standard of credible evidence has proven too high and unworkable. Detention is an important precautionary authority that allows inspectors to serve like cops on the beat by acting based on their knowledge and experience to prevent unsafe food from entering commerce.

10. Penalties

FDA needs a greater range of penalties to punish violators. The punishment for committing a prohibited act under the Food, Drug and Cosmetic Act is one year in jail and/or fine, a Class A misdemeanor.[22] This punishment, which may have been substantial in 1938, has not kept pace with the modern commercial world. Compared to PCA's annual revenues of $17.5 million[23] it is hard to see how the threat of a misdemeanor fine serves as an incentive for companies to improve their food safety practices. With over 600 people reported sick, more than 100 hospitalized and nine dead as a result of PCA putting contaminated product on the market, a misdemeanor charge seems trivial and unfair to the victims. The Committee should consider updating the criminal penalties to make it a felony punishable by up to five years in prison if people are injured by the violation, and 10 years in prison if people die.

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[20] USDA, *Traceability in the U.S. Food Supply: Economic Theory and Industry Studies*, Econ. Research Serv., March 2004.

[21] Breadth, depth, and precision are the key characteristics of good traceability systems. Id. at 3.

[22] 21 U.S.C. § 333(a)(1).

[23] Peanut Corporation of America Company Profile, Bizjournals.com, (accessed Feb. 3, 2009), *at* http://www.bizjournals.com/gen/company.html?gcode=904819E282CB4C8B9DAE476F9A3F632D.

Criminal liability should not be the only option. It is a burden on the agency inspectors, as they must conduct a criminal investigation, coordinate prosecution with the Justice Department, and then go through a criminal trial.[24] For lesser offenses, Congress should provide FDA with authority to impose substantial civil penalties that can get the attention of managers and stockholders, and that can be sustained if violations are continuous. Civil liability provides a flexible response to corporate misconduct that can be tailored to the violation. These remedies are available for addressing violations on the drug and device side of FDA, but not the food side except for illegal pesticide residue.[25] It is time to bring FDA's penalties for food violations in line with what is used for drugs and medical devices.

11. Whistleblower

When an employee or inspector sees problems they should report them. But when reporting may mean loss of a job, a person can be faced with a difficult dilemma – especially in these hard economic times. Interviews with PCA employees revealed they witnessed dangerous practices at the plant but did not come forward because in a small town with few employers they could not risk being fired.[26] Perhaps if whistleblower protections had been in place, and PCA workers could have informed officials of conditions in the plant without fear of retribution, it might have triggered a clean up of the plant, prevented the outbreak from occurring, and ultimately saved both the company and their own jobs. Employees must be protected from the threat of being fired, demoted, suspended or harassed as result of providing information or assisting in the investigation of a violation of a food safety law.

Conclusion

President Barack Obama has promised a "government that works," and recently promised a complete review of FDA's food safety program. Luckily for the President and the public, Congress has been investigating problems at FDA for several years, and many elements of a reform plan are "shovel ready" – they could be accomplished quickly and deliver real benefits to consumers.

But to deal with the root of the problem, Congress and the Obama Administration will need to go beyond giving FDA more authority and funding. Structural reforms are also essential. Although FDA is responsible for the safety of 80 percent of the food supply, the FDA's commissioner must divide his or her attention among drugs, medical devices, foods and cosmetics – and food issues frequently fall to the bottom of the pile. Food responsibilities are divided among at least three centers within FDA, and there is no single food safety expert in charge of the policies, budget and enforcement staff. This means there is no credible voice communicating to the public and the industry what can be done to prevent outbreaks.

It is time to elevate the food monitoring function within the Department of Health and Human Services (HHS), which oversees FDA. The agency needs to be divided in two, with a

[24] For a description of FDA's procedures for prosecuting a case see section 6-5 of the FDA Regulatory Procedures Manual.
[25] Civil penalties for pesticide residue are found at 21 U.S.C. § 333(f)(2).
[26] Dahleen Glanton, *Inside 'Nasty' Nut Processor: Ex-employees Say Rodents, Roaches and Mold Commonplace*, Chicagotribute.com, Feb. 3, 2009.

new Commissioner of Food and Nutrition Policy who reports directly to the HHS Secretary. Food safety functions under the Department of Agriculture have this sort of direct reporting, leading to greater involvement by the Secretary of Agriculture when problems arise in the meat area.

Now is the time for Congress to fundamentally reform and fully fund our food safety system. 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 and fund it adequately to fulfill its mission in the Food and Drug Administration Amendments Act of 2007.[27] Last month, members of this committee made commitments to the victims of the current outbreak that change is coming to FDA. It is time to move forward with strong legislation that will prevent outbreaks by requiring safety to be built into the processing of food. With both the public and the regulated industries clamoring for change there is no reason to delay. Preventing future illnesses and deaths is within our grasp.

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

Mr. PALLONE. Thank you. Mr. Hubbard.

STATEMENT OF WILLIAM HUBBARD

Mr. HUBBARD. Thank you, Mr. Chairman. I have a written statement for the record. I will just make a few brief remarks if I may.

As you know, the public is confused and even frightened by what is going on. Imagine a fully loaded 737 crashing every other week. That is the type of toll we are talking about here, but yet we continue to tolerate the intolerable. And the public health costs have been mentioned by many of the members today, and they are very real.

Suffering out there is very real, and also I don't think we should disregard economy costs that companies and the health care system are being burdened by food-borne disease outbreaks that are largely preventable. So we are allowing things to happen that we can stop, and I would like to make two main points about the problem.

First is the issue of FDA resources. I believe I have a slide if we could put it up, and I think really in a way it captures the problem that FDA has gone through. Do we have that slide? When I came to the FDA in the 1970s, there were 70,000 food processors in the United States. FDA had the resources to inspect 35,000 times a year, which meant everybody could get a visit every other year. There were very few imports at the time.

[Slide.]

As you can see from this slide, we are now doing about 6,000 or 7,000 a year, but if you plotted the increase in the industry, that has gone from the 70,000 domestic firms at that period to 150,000 today and another 216,000 farm firms. So we have gone from inspecting about 50 percent of the food supply at any time to five percent of the domestic processors and about two percent of all processors. And that has largely been a function of resources. FDA's budget has been cut and cut and cut for 30 years, and we simply need to find a way to reverse that.

And you can also plot, as those numbers go the direction they go, recalls have gone up. FDA's adverse findings when they do do inspections have gone up, and you have a general lack of overall quality in many of these firms.

I will say, however, as I say in my testimony, I think the food supply is generally safe. We have gaps though that are willing to cause the problem. Unless everybody does it right, no one can get it right.

And then the other main point I wanted to make is authorities. FDA has authorities dated to 1906. It is essentially a relic of the 19th century. It doesn't work. It requires an inspector to perhaps catch a problem the day he happens to get there if he gets there at all. FDA needs the kind of preventive controls many of you have mentioned and Ms. DeWaal mentioned, in which they can require a firm to examine how they make their food and control hazards so the food never gets contaminated to begin with.

And those are practices that the leading food firms use now, so we are not talking about imposing on the food industry some strange new regulatory regime. We are talking about adopting in-

dustry-developed preventive control technology that has been proven to work.

And then lastly there are some other provisions that I think are very important. Trace back has been mentioned. We saw with the tomatoes last year and the spinach earlier how these outbreaks drag on for weeks or even months because FDA doesn't have adequate trace back authority.

They need access to the records of these firms so they know where the food has come from and where it is going. They need mandatory recall authority. Clearly some firms simply stall for a few days, and during those few days while FDA is begging them to do a recall, the food is moving and being consumed.

And we also need to accredit these labs that are doing a lot of the work because you need to know you have a high level of quality in the laboratories.

There are some other things in my testimony; however, in the interest of time, I will stop there. But I certainly do urge you to act this year on food safety legislation.

[The prepared statement of Mr. Hubbard follows:]

Statement By

William K. Hubbard

Before the

Committee on Energy and Commerce

United States House of Representatives

Washington, DC

March 11, 2009

INTRODUCTION

Mr. Chairman and members of the Committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Today, I serve as an advisor to The Alliance for a Stronger FDA, a consortium of patient, public interest, and industry organizations whose mission is to urge that FDA's appropriations be increased. The Alliance and its constituent members are greatly concerned that FDA's resource limitations have hampered the agency's ability to ensure the safety of our food and drug supply. Today's hearing is focused on the need to strengthen our nation's food safety system that has been under constant strain in recent years and is widely viewed as being in dire need of improvement. I commend the Committee for your effort to shine light on this problem and possible solutions.

BACKGROUND

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices—filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As the 20th Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to

claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. Throughout the last century, there was steady progress in the food safety system – in learning how to protect food from contamination and in implementing procedures to translate that knowledge into safer food production. But, unfortunately, that record of progress appears to have largely ground to a halt, at least when it comes to the ability of FDA to effectively oversee improvements in food safety, and the limitations under which FDA attempts to do its job have been dismayingly exposed. I will attempt to describe those limitations in this testimony, but first, let me give you my view of the risks imposed on our society by foodborne disease.

HOW RISKY IS OUR FOOD SUPPLY?

The food safety threat in the United States presents a contradiction in many ways. On the one hand, we do basically have a safe food supply. Most growers, food processors, transporters, grocers and restaurants care about the health of their customers and do a good job of practicing safe production, storage, and handling techniques. Americans can generally go about their daily lives without fear that opening a can of soup or preparing a sandwich will subject them to illness or death.

But, as recent foodborne disease outbreaks have well demonstrated, our system is only as strong as its weakest points – and there are simply too many of those. We saw this recently with the peanut butter contamination, in which a small Georgia firm's product

was sold to dozens of larger firms and ended up contaminating hundreds of different products and potentially endangering millions of our citizens. Last year's pepper contamination with Salmonella saintpaul – initially focused on tomatoes – apparently resulted from one small distributor on the U.S.- Mexico border, yet caused a nationwide panic over the safety of tomatoes and related products. In the 2006 E Coli in spinach outbreak, the entire nation's spinach crop was blamed until the source of the contamination was isolated to three farms in California.

Those peanut butter, pepper and spinach examples are just a few of the breakdowns that have caused our citizens to question their leaders' ability to carry out this most quintessential governmental function – the safety of commodities that are so necessary for a healthy society. Indeed, some argue that our food supply is becoming less safe despite the progress that has been made in science and medicine in recent decades. It is certainly clear that there are trends that cry out for intervention by the Congress, namely:

- New pathogens have emerged in foodstuffs, some unknown to science in years past, that are especially lethal when they contaminate our food. They have exotic names, such as *Enterobacter sakazakii, E Coli 0157:H7, Listeria monocytogenes, Vibrio cholerae 0139, and Salmonella Typhimurium DT104,* but they all pose a significant threat of severe illness and death when our citizens contract them. And there is an expectation among scientists that yet more of these threats will be discovered in the future.

- There are very substantial public health and economic costs imposed on our society from the steady – and perhaps increasing – numbers of foodborne disease outbreaks in the United States. The Center for Science in the Public Interest has tracked foodborne disease outbreaks for many years and their data shows outbreaks increasing from an average of 100 per year a decade and a half ago to almost 350 annually in recent years. Even if those increases are the result of better reporting of outbreaks, I know of no one who believes outbreaks are declining for foods regulated by the FDA;
- There has been a steady growth in the number of domestic food producers and, even more alarmingly, a tremendous increase in imported food from other countries -- particularly developing countries in Latin America and Asia, where food safety standards are often lax or unenforced; and
- Our system of food production and distribution in increasingly complex, often necessitating the movement of food across long distances and through many hands and into many finished products.

TOLL OF FOODBORNE ILLNESS

Even if one accepts the premise that our food supply is mostly a safe one, the impact of the food contaminations that do occur is remarkable. As you know, the Centers for Disease Control estimated in 1999 that 76 million Americans contract a foodborne illness each year. Of those, 350,000 are hospitalized, and 5,000 die. And, if we update those statistics to our current population level, as recently calculated by the Associated Press, it's likely that the current estimate would be over 87 million cases and almost 6,000

deaths. That means that we are sustaining food-related deaths of an equivalent number of our citizens to those killed in the World Trade Center attack every 6 months; yet many, if not most, of those deaths are preventable. And beyond the obvious human suffering, and the associated economic costs to sickened consumers, there are tremendous economic costs to food producers. The 2006 spinach outbreak, for example, resulted in the destruction of much of that year's spinach crop and cost producers an estimated $100 million; and last year's tomato/pepper outbreak resulted in producer losses in the hundreds of million of dollars. In fact, it is estimated that the overall negative economic impact of foodborne illness in the United States may be has high as $83 billion per year. Worse yet, these repeated outbreaks and their attendant publicity paint a picture, erroneously I believe, of a food industry that cannot assure safe products. Indeed, after the spinach outbreak, the government of Mexico – a nation derided in the past as the home of Montezuma's Revenge – announced it would evaluate whether American produce was safe to import into Mexico. And this is happening at a time in which one of America's few remaining sources of a positive trade balance is our food exports.

FDA'S FOOD SAFETY SYSTEM – BROKEN BEYOND REPAIR?

"FDA does not have the capacity to ensure the safety of food for the nation." Those are not my words, but rather the summation last year of FDA's Science Board, an advisory committee of experts from many fields of study. And that conclusion has been echoed by a cascade of expert reports in recent years, by the Institute of Medicine, the Government Accountability Office, the HHS Inspector General, the National Academies of Science, and several Congressional committees. All of those studies have concluded that the FDA

regulatory system, as currently constructed, simply cannot adequately oversee a large and diverse food production system within its current structure and resources.

Let me give you just a flavor of the metrics by which FDA's inability can be counted. When I arrived at FDA in the 1970s, the Official Establishment Inventory of food facilities subject to regulation was about 70,000, and FDA was able to conduct 35,000 inspections each year, meaning that, on average, each facility could be inspected every other year. Today, the domestic OEI is 150,000, and FDA conducts about 7,000 inspections per year. This means that FDA can realistically inspect only the 6,000 or so facilities that are designated as "high risk," which, of course, means that most food facilities never see an FDA inspector. Attached is a chart illustrating the dramatic decline in food inspections since the 1970s.

The more recent history of FDA capacity is even more disheartening. In 2003, FDA had just over 4000 field investigators and compliance officers to inspect our food facilities and carry out outbreak investigations (as well as inspect drug and medical device facilities). Entering 2008, that force had been reduced to 3354, a loss of almost 700 inspectors. The cadre of food scientists in FDA headquarters underwent a 20% reduction during that time (from 950 to 782). And this occurred as the number of foodborne disease outbreaks appear to have more than doubled. These recent trends are part of a larger scenario over many years, in which we have declined to provide the FDA with robust capacity to oversee the safety of our food. And, of course, none of this counts the

216,000 foreign facilities making food for our market, of which FDA inspects only about 100 per year.

AN INEFFECTIVE PARADIGM

I will not dwell on FDA's resource woes; they have been well documented and are indisputable. The more important point is that the resource shortfalls are but one of the two principal causes of FDA's inability to protect our food supply. The other is that FDA's food safety system is a relic of the 19th century, one that should have been discarded years ago.

Let's look back to FDA's origins, in the dawn of the 20th century. Americans grew much of their food, and food that was purchased tended to come from a nearby source, such as a farm near the consumer's home. Processed foods were relatively few in number, and tended to be staple goods, such as molasses, flour, and sugar. The "state of the art" method of ensuring food safety was the visual inspection by a government official of food processing facilities and the products emanating from them. Imports were few, and were also mostly staple goods. An inspector could easily open a barrel of flour and examine it for insect or rodent infestation, mold and mildew, and other signs of contamination. So Congress embodied that concept into the original Pure Food and Drug Act of 1906. Itinerant Federal inspectors could visit facilities and examine their overall sanitation as an indicator of safe food production. With new provisions added in 1938,

those inspectors were give enforcement tools believed to be adequate for the day – prosecution of the business's chief executive, an injunction against the business to stop it from selling contaminated food, and authority to seize food found to be contaminated.

Meat, on the other hand, was considered a far riskier food in those pre-refrigeration days. That concern, combined with the need to assure export markets that U.S. beef was free of brucellosis and hoof and mouth disease, prompted Congress to require a continuous inspection model for slaughter facilities, in which Federal inspectors examine and provide a Federal stamp to every meat product as it is processed. Meat regulators were also given a range of strong enforcement tools to ensure that processors adhere to Federal standards. That system, administered by the Department of Agriculture, remains largely unchanged today.

While the meat inspection program also has its critics, the FDA food safety system has been determined to have severe flaws in its conception and implementation, in the context of the modern world, viz.,

- It is a system with random success. That is, it relies on the infrequent inspection by FDA (or perhaps a state inspector) to identify and correct deficiencies in a processing facility;
- Each FDA inspection is only a "snapshot" of the condition of the food processor the day of the visit, thus it cannot assure that the facility is operating safely at all times;

- There are few true standards by which most food processors can be judged. FDA has general "sanitation" regulations, but has not been empowered to set food-specific requirements to which producers should adhere;
- It does not take advantage of state-of-the-art food protection mechanisms, such as HACCP, that industry leaders have developed and implemented in recent years;
- Food safety inspections and oversight by state and local authorities are inadequately coordinated with the FDA; nor are training of state and local inspectors done jointly with FDA inspectors, resulting in differing inspection procedures and varying thoroughness;
- FDA lacks enforcement tools common to modern regulatory agencies, such as authority to recall contaminated food, to require periodic registration of food facilities, to fine firms failing to comply with requirements, and to require detailed records of a food's movement through commerce (so that contaminated food can be found and recalled promptly); and
- FDA lacks a modern and robust laboratory system that can effectively and rapidly test food samples for the hundreds of possible contaminants that can attack our food.

WHAT IS NEEDED – A MODERN, RISK-BASED FOOD SAFETY SYSTEM

Despite the considerable gloom we have been seeing in recent years related to the failures of our food safety system, there is great reason to be optimistic that we can successfully fix its many flaws. The key will be to move from the current reactive, fragmented system to one that is focused on prevention. FDA and the industry have already demonstrated

the possibilities, through development of procedures for preventive controls for low-acid canned foods, seafood, and juice. Under a system of preventive controls, producers undertake steps to assure the safety of their food, and whose complexity is based on the risks posed to the food:

1) Analyze hazards, that is, understand what hazards their food might be subjected to so that they can eliminate them,

2) Develop an adequate food safety plan, under which they will take the necessary steps to adequately control and monitor the identified hazards,

3) Document the steps the facility takes to implement the plan, thereby creating a record of how they successfully control the hazards, and can thus assure both regulators and their customers that they are always vigilant about food safety, and

4) Meet standards for minimizing risk in their food, such as by periodic testing for hazards to assure that the finished product is indeed uncontaminated.

Under such a new paradigm, FDA's role would shift from its current "gotcha" mode via random inspections to one in which they set the requirements for preventive controls and any necessary quantitative tolerances for contaminants; train and educate processors in the use of such controls; assess the adequacy of firms' food safety plans and their implementation of these plans; and oversee an inspection regime under which FDA, state, local, and other third-party inspectors can confirm the proper implementation of food safety plans.

WHAT IS NEEDED FROM CONGRESS

FDA cannot move to the type of modern food safety system that is needed without statutory change. Specifically, I believe the Congress should enact legislation with the following elements:

First, empower FDA to mandate preventive controls for all food. Many, if not most, large processors have already adopted some form of preventive controls, but such a system will only be as strong as its weakest link, and FDA must be specifically charged with requiring food producers to have an adequate food safety plan that assesses and controls for any risks intentionally or unintentionally present in their food or its production processes, as well as the ability to require specific preventive controls for specific foods, if appropriate. As part of that regime, FDA will need access to the firm's records documenting its adherence to its food safety plan.

Second, give FDA the resources to be successful in a new food safety system. In the 1970s, when FDA's food program was at its zenith, its budget was one-half of the agency's budget, and that could be a short term goal for restoring the program to health. Additional funding of about $500 million, or about 2 cents a week for each American, would allow FDA to begin ramping up its food safety capabilities, although additional increases will be needed over the next few years. Without the resources to strengthen the FDA, no authorities can or will bring the change that is needed, but I believe the vast majority of Americans would gladly pay a penny every few days for a safer food supply. Indeed, the cost to the taxpayer would likely be recouped by savings to consumers through the elimination of just one major outbreak a year.

Third, FDA's scientists believe they need modern enforcement authorities of the type that many other regulatory agencies possess:

a) Annual registration of food facilities – Currently, food facilities need register only once, meaning that FDA cannot keep an accurate and up to date record of who is manufacturing food. A necessary companion provision would be authority to suspend a registration if FDA determines that the facility cannot safely produce food.

b) Mandatory recall authority – Currently, FDA must cajole a firm found to have sold contaminated food to the public; while FDA can usually prevail, days can go by in which contaminated food continues to be sold and consumed. However, recall authority should be limited to instances in which the food is believed to pose a threat to human health, not for minor infractions such as harmless labeling errors.

c) Laboratory accreditation – In the recent peanut butter incident, the processor had received test results from private laboratories that found salmonella contamination; but neither the firm nor the laboratory was required to notify FDA. Agency scientists would like to have the authority to require laboratories to be accredited and access their test results.

d) Traceback – When a foodborne disease outbreak occurs, FDA must determine where the contamination originated, and where the contaminated food was sent (so as to warn consumers and have contaminated food recalled). The agency does not have sufficient authority to require food processors to keep adequate, interoperable records that quickly and accurately show the movement of food. This has been most problematic in the produce area, and the produce industry has called for enhanced product tracing.

e) Importer Requirements – Currently, authority over food imports is focused on FDA's ability to inspect an imported food as it enters the country, but the agency has resources to inspect only 6/10 of 1% of food imports. The agency needs authority to require importers to implement appropriate preventive measures so that the food they import is more likely to be safe before it ever begins on its way to the U.S.

f) Administrative Detention - Currently, FDA can detain a food in commerce only if the agency has compelling evidence that it presents a threat of serious harm. That standard is so high that they agency has never used it; a less burdensome standard like "reason to believe" that a food may be contaminated is needed.

h) Civil Money Penalties – Most regulatory agencies can fine violators, but FDA cannot fine a firm that produces or sells contaminated food. A strong CMP authority would give FDA a tool that is intermediate between prosecuting the firm and merely admonishing them, and can serve as an effective deterrent for future misconduct.

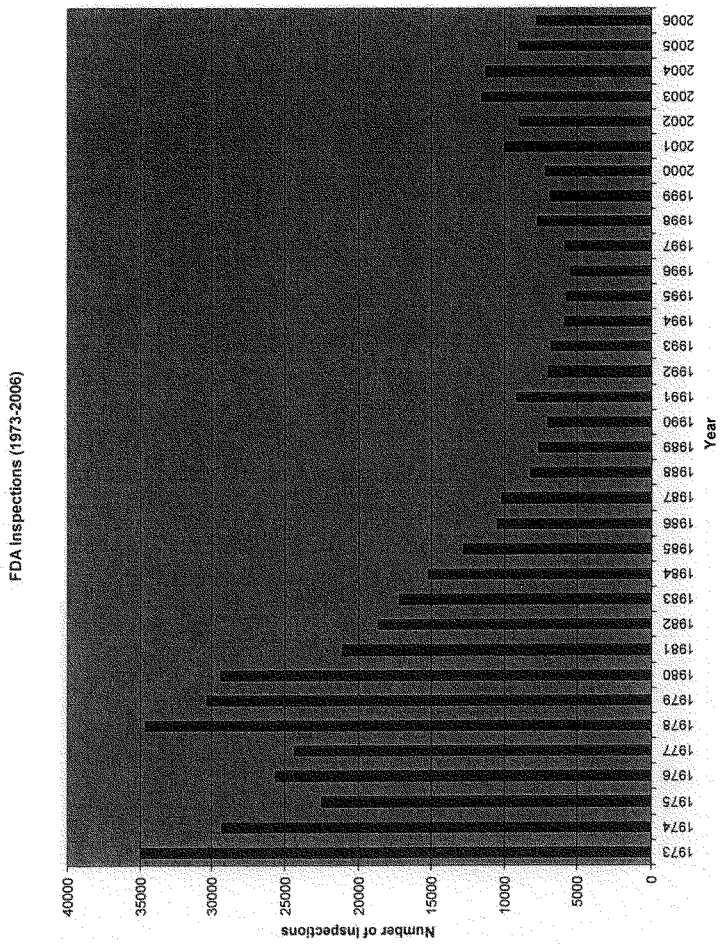
Finally, the recent peanut butter case illustrates the inconsistencies among state and Federal inspection regimes. Our food safety system needs a national food safety training Academy, analogous to Law Enforcement Training Academy in Glynco, Georgia, that will provide uniform, science-based training for all food inspectors, at all levels of government, and that can be accessed as well by private, third-party inspectors.

A NEED TO MOVE FROM TALK TO ACTION

In conclusion, Mr. Chairman, today's hearing is another in a series that Congress has held to highlight instances where FDA needs to improve, and I agree with your concerns that FDA is not as effective as it can and should be. In the case of food, we have a real dichotomy between our rhetoric and our action. We say we want a strong FDA and a strong food safety system, but our actions belie that stated objective. We have not given FDA the authority and resources it needs to be the agency we want it to be, and then we are critical of it when it fails to meet expectations. Meanwhile, as report after report recommends dramatic change in our food safety oversight, foodborne disease outbreaks continue unabated and public confidence in our government's ability to protect us declines steadily. That is a record for which we should be truly embarrassed, and I sincerely hope that you and your colleagues will agree with my conclusions and resolve to act upon them.

Thank you for giving me the opportunity to provide my views on this subject.

Food Inspections 1973-2006



Mr. PALLONE. Thank you. Dr. Cole.

STATEMENT OF MARTIN COLE

Mr. COLE. Chairman Pallone, Ranking Member Deal, good morning. I guess what I would like to try and do, I have written testimony. I would like to make a few remarks to try and help this committee wrestle with the complexities of the food safety systems and what approaches they should take.

I really do applaud the important work and the urgency and the opening remarks that have been made this morning. Certainly we have seen, I think we are all acknowledging, the complexity of the supply chain. The food business is global now. Go to the supermarket, the products can be from anywhere in the world. Global sourcing of ingredients.

Look at consumer trends now. You know we want people to eat healthy food. There is a trend toward more natural, fresher products, less preserved, more convenient products, longer shelf life. All of those, as a food microbiologist, they go against traditionally what you would like to see in the marketplace. So we want food to be healthy, but we want it to be safe.

And we certainly need to, I think as the opening remarks have mentioned, we have new issues, and we need a new approach, OK. We need to have a modern food safety system here in the U.S. I think really in simple terms, I look at that in terms of four main components to a modern food safety system.

First of all, risk-based preventative measures. You need programs to monitor progress. That can be trend analysis. That can be testing, inspection, even Epidemiology, but you need programs to be able to monitor progress.

You need appropriate government oversight. Without government oversight, you get the issues that we have in peanut butter and salmonella.

And then lastly you need a strong research program because things are changing so fast. If you don't have a world class research program, you can't deal with issues proactively and deal with them swiftly.

Dealing with microorganisms—and I am a microbiologist by trade—dealing with microorganisms is even more complicated because they are alive, OK. So bacteria have the ability to grow and survive and adapt throughout the food chain. So when we are designing food safety systems, we need to be cognizant of the ability of bacteria to change and to grow and adapt. So that adds another complexity with what we are dealing with.

Now, in response to these issues, I mean this is not just a U.S. issue. Internationally, the food safety community has responded by developing new tools, risk-based tools, to try and ensure the safety of the food supply. And it now possible through modeling and risk assessment to be able to link the level of hazard or the prevalence of a hazard in the food supply to the likely illness that it is likely to cause. And that has allowed us to develop new risk management frameworks that will provide for scientific underpinning to the develop or risk-management options, the science behind the frequency of inspections, et cetera. So these new developments we need to be using.

It is ironic that, you know, in the U.S. much of these developments have been led by U.S. scientists, and yet we need to start walking the talk here. So we have done a good job, I think, in tracking sporadic cases of food-borne illness through new tools, food safety net, Wholesfield, del electrophoresis fingerprinting if you like, of organisms. But we are really falling behind in the prevention side, and that is really where we need to up our game.

A quick word about oversight testing and inspection. I think the short answer is you can't test and inspect safety into food. OK you need that oversight because without that, you get the PCA issue. But testing alone, think of the issue with salmonella where a very low infective dose can give you an illness. It is like looking for a needle in a haystack. The statistics of sampling are such that you can't test safety into food.

Think also of the volume of foods that are coming into the U.S. now. What is it? Over 60 percent of fresh produce, fruit and vegetables, coming to the U.S. from overseas, over 80 percent of seafood coming from overseas. You know we need to be practical about the percentage of foods we can realistically inspect. We need the inspection there as a deterrent, but we need to be smart about where we use those resources. And we need to use them where the highest risks are.

Now, in industry, there are two main tools for really applying and implementing risk-based measures, and as was mentioned before, these are standards tools that have been adopted through Codex. The two main tools are good manufacturing practice, or GMP, and hazard analysis critical control point, or HACCP. And you can think of GMP as like the building blocks, the standard operating procedures for sanitary design, equipment, people, labeling, recall procedures, et cetera.

Many of the recall issues that we see from FDA actually, if you look at whether GMP would deal with them or whether HACCP would, many of them actually would deal with GMP, and it is an oversight issue that we have. So we need to think about where we should be using GMP and also where we should be using HACCP.

HACCP is a more systematic approach identifying, evaluating the food safety hazards. It is usually more quantitative in nature, usually defining a critical control point in the food chain that you must control to reduce, eliminate, and prevent hazards. Typically in a value chain, you would be looking at a performance standard for HACCP as well.

Now, I also have one slide to share with the committee this morning. I could take that. I think it is a good lead in to some other testimony relating to fresh produce. You can go to slide three please. That is great. So really I think it kind of illustrates a good lead in to the next witness. If you look at the complexity of the supply chain for fresh produce, you can't pasteurize lettuce, OK. You would have lettuce soup if you were to do that.

OK, so there isn't one kill step in the chain. So you have to take a through chain approach. You have to take good agricultural practice. You have to look at what you are doing in terms of washing of the produce, and you have to look at what you are doing in terms of the distribution.

So I just wanted to share with you this is a complex business. There is research going on at the moment between industry and government to really try and come up with the risk management options that would build some robustness into the value chain for fresh produce. This is a category of food we want people to eat more of, OK. Hugely impactful in terms of nutrition, and yet we need to build more robustness in terms of safety.

My final comment, Mr. Chairman, is around research. You know the U.S., I think, should be really at the forefront of research in terms of the safety and health of food. It is such an important driver of public health, but also very important in terms of trade for the U.S. With that, thank you very much.

[The prepared statement of Mr. Cole follows:]

Written Testimony of Prof. Martin Cole

Illinois Institute of Technology

Director, National Center for Food Safety and Technology

Before

Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

"Food and Drug Administration Globalization Act of 2009"

March 11, 2009

Good morning. I am Prof Martin Cole, Director of the National Center for Food Safety and Technology.

Diseases caused by foodborne pathogens constitute a worldwide public health problem and preventing them is a major goal of national governments. Microbiological foodborne diseases are typically caused by bacteria or their metabolites, parasites, viruses or toxins. Here in the US, foodborne illness outbreaks continue to make headlines and worry consumers. The Centers for Disease Control and Prevention (CDC) estimates that foodborne diseases result in 76 million illnesses, with 325,000 hospitalizations, and 5000 deaths, each year. In addition, the complexity of issues relating to food safety has also increased considerably in recent years. The rapid globalization of the food processing and retailing industries, consumer demand for more natural and more convenient products, and an overall increase in the population's susceptibility to foodborne illness are believed to be the most important factors that have led to changes in the very nature of foodborne

disease itself. In order to successfully respond to these challenges and to restore consumer confidence, the US needs to increase its emphasis on the development of a modern system for the management of microbial food safety. The elements of a modern system—risk-based preventative controls, programs to monitor their effectiveness, appropriate government oversight, and a strong program of research—will help us keep pace with emerging food safety issues, assuring safe and wholesome foods for consumers.

Managing the microbial safety of food is a complex business because microorganisms can grow and adapt to different conditions within the food supply chain. At the production and processing level, the ability to assess and manage the risk of microbial contamination is key to effective food safety control. When designing and controlling food operations this means analyzing the microbial hazards likely to be present, their ability to grow and survive in the production environment, and the best means of eliminating them. Consideration must be given to the subsequent conditions to which the food is likely to be exposed, including further processing and potential abuse during storage, distribution and preparation for use.

Regulatory efforts here in the US and internationally therefore have been focused on the use of risk assessment tools to drive food policy and standards away from prescriptive measures to outcome-based control measures. The safety of foods in international trade is governed by the World Trade Organization (WTO)/Sanitary and Phytosanitary (SPS) Agreement, which recognizes that governments have the right to reject imported foods when the health of the population is endangered. The criteria used to determine whether

a food should be considered safe should be clearly conveyed to the exporting country and should be scientifically justifiable. In order to achieve this, the term 'appropriate level of protection' has been used, which is defined as "the level of protection deemed appropriate by the Member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". Traditionally, this has been defined in terms of having a chemical or microbial risk "as low as reasonable". This definition has caused great difficulties for a number of reasons. Although trade is becoming increasingly global, the technological capabilities of different countries, and even different companies within the same country, remain very different. Also, the idea of what is considered "reasonable" differs from country to country; acceptable risk is culturally defined.

Developments in the areas of predictive modeling and risk assessment now offer the potential to link exposure to a microbial hazard to the likely number of cases of illness in the population and are driving new risk management approaches. The approach enables the food industry to meet specific food safety objectives by the application of the principles of Good Manufacturing Practice (GMP), Hazard Analysis and Critical Control Points (HACCP) systems, performance criteria, process/product criteria and/or acceptance criteria. It provides a scientific basis that allows industry to select and implement control measures for each specific food or food operation. This approach should enable regulators to better develop and implement inspection procedures to assess the adequacy of the control measures implemented by industry and to quantify the equivalence of inspection procedures in different countries. Thus, the practical value of

using a risk based approach is that it offers flexibility of operation; it does not prescribe how an operation achieves compliance - it defines the goal.

Government oversight is an important aspect to ensuring a safe food supply, especially for unbranded goods where market disincentives for failure are less pronounced. Regulations also allow a level playing field, ensuring that companies that do not pay for food safety controls cannot gain a cost advantage in the marketplace over companies that do make that investment. However, government oversight through regulations and inspection alone is a relatively poor means of ensuring the safety of food. The statistics of sampling means that an extremely high number of product samples are needed to detect the low level of pathogens that can cause illness. For example, if one lot of food is contaminated with Salmonella at a level of 1% and five samples are taken, there is still a 90% chance that results will be negative for Salmonella and that the lot of food will accepted even though the lot is contaminated. This means that for pathogens with a low infective dose, where relatively low numbers can cause illness especially in children or the elderly, testing is not a good means to ensure safety. Similarly, given the volume of food traded both nationally and internationally, the amount of food that can be inspected practically is relatively low and is also therefore a poor means to ensure safety. In other words, it is not possible to test or inspect safety into foods—effective management requires risk-based preventative controls as well as government oversight.

Preventative control measures may be applied at different steps along the food chain to eliminate, prevent, or reduce a hazard to an acceptable level. Each participant along the food chain has a responsibility to apply those control measures that contribute to

providing safe foods. These control measures fall into one of two programs applied by food manufacturers: Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) systems.

The first program, GMP, can be viewed ás the basic sanitary conditions and practices that must be maintained to produce safe foods. It also includes certain support activities, such as raw material selection, product labeling, and coding or recall procedures. Effective application of GMP provides the foundation upon which the second program, HACCP, is developed and implemented. The development of an effective HACCP system involves a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation.

The major components of GMP include:

- Design and facilities
- Control of operation
- Maintenance and cleaning
- Personal hygiene
- Transportation
- Product information and consumer awareness
- Training

The Hazard Analysis and Critical Control Points (HACCP) system involves the following seven principles:

1. Conduct a hazard analysis
2. Determine the critical control points
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish record keeping and documentation procedures

HACCP is not implemented in lieu of GMP, and failure to maintain and implement GMP can invalidate a HACCP system and result in production of unsafe food. Effective control of a hazard in a food necessitates consideration of the components of GMP likely to have significant impact in controlling the hazard. It is necessary to consider the hazards that are most likely to occur in each particular food operation and to pay particular attention to those elements of GMP and HACCP that will contribute most to controlling those hazards. For example, in the contamination of peanut butter with Salmonella, this is usually an issue of recontamination after the roasting process, most effectively dealt with through the application of GMP measures including sanitation and separation of finished product from raw materials.

The development of an effective HACCP system involves a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation. HACCP plans specify the actions to be taken in a food operation to control food safety hazards.

HACCP plans also specify records to be generated during the operation for use in verification that critical limits have been met at critical control points in production. In the event that a deviation occurs at a critical control point, the deviation should be detected in time to ensure that corrective actions will prevent unsafe food from reaching consumers. For example, the development of the Juice HACCP regulations introduced the requirement for pasteurization as a critical control measure in assuring the safety of the product.

Control measures, GMP and HACCP, must be appropriate for the hazard and are used to prevent, eliminate or reduce hazards to acceptable levels. Producing safe food requires food operators selectively to apply GMP and the principles of HACCP to develop and implement a food safety plan that will control the significant hazards in the food that is being produced. The development of regulations or guidelines relating to the use of preventative controls within a food safety plan or performance standards should be considered based on risk to public health, as well as a consideration of what is feasible and practical. For example, some microbial concerns will be better dealt with through the use of GMPs and the use of HACCP-like principles, whereas for foods where there is epidemiology linking consumption to foodborne illness it might require the articulation of specific performance standards, which might require research, especially for newly emerging issues such as fresh produce.

Recent attribution data suggests that fresh produce has emerged as the leading cause of foodborne illness in terms of number of cases in the US, with salads accounting for about

a quarter of this burden. From a global perspective, leafy green vegetables also currently represent the greatest concern in terms of microbiological hazards. Leafy greens are grown and exported in large volume, have been associated with multiple outbreaks with high numbers of illnesses in at least three regions of the world, and are grown and processed in diverse and complex ways, ranging from in-field packing and bagged product. There is currently no validated kill step in the production of leafy greens and hence food safety often relies on prevention of contamination, which is usually the weakest form of hazard control especially in a raw agricultural setting. Research is required to help validate new preventative controls measures and to determine the most effective point in the production chain for them to be applied. The example of fresh produce also illustrates the need to improve the technologies for traceability systems that are used by the industry. Traceability is essential for the effective and timely linking of foodborne illness to the source of contamination.

Given the continued globalization of the food supply and consumer trends that will continue to drive the emergence of new issues, especially in microbial food safety, it is important to establish a strong research program in order to be able to develop risk-based control measures in a proactive manner. I therefore urge this Committee and Congress to provide the means for the U.S. Food and Drug Administration (FDA) to continue the development of a modern, risk-based food safety system that requires risk-based preventative controls, programs to monitor their effectiveness, government oversight, and a strong program of research to assure the highest level of confidence for the US consumer.

Figure 1

Hierarchy of Preventative Approaches to Managing Food Safety

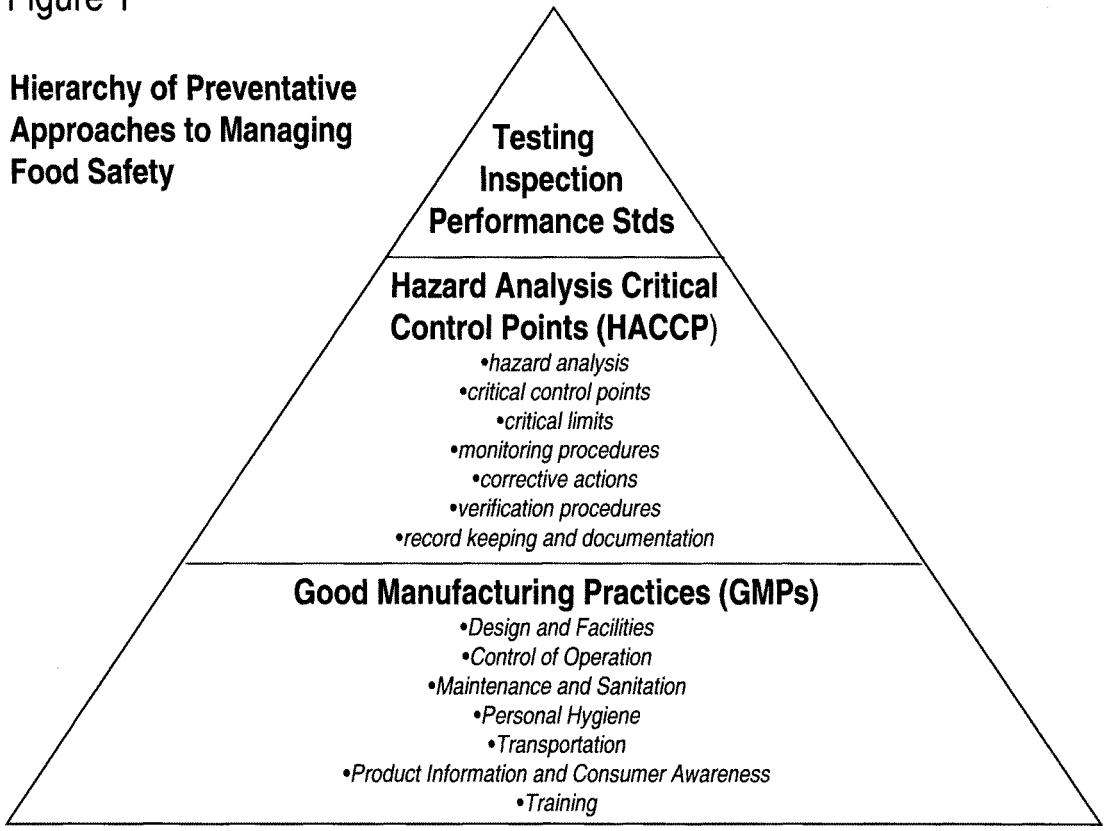
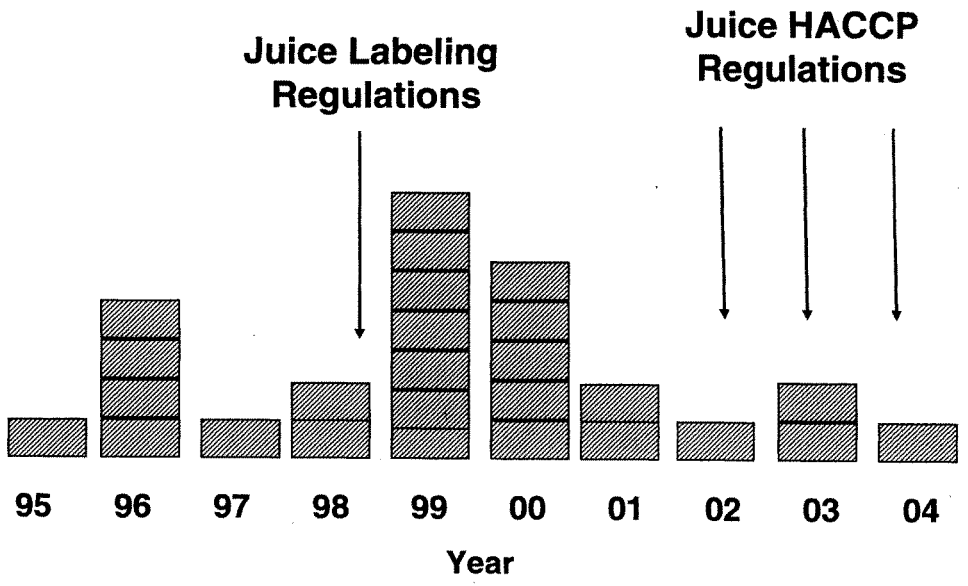


Figure 2

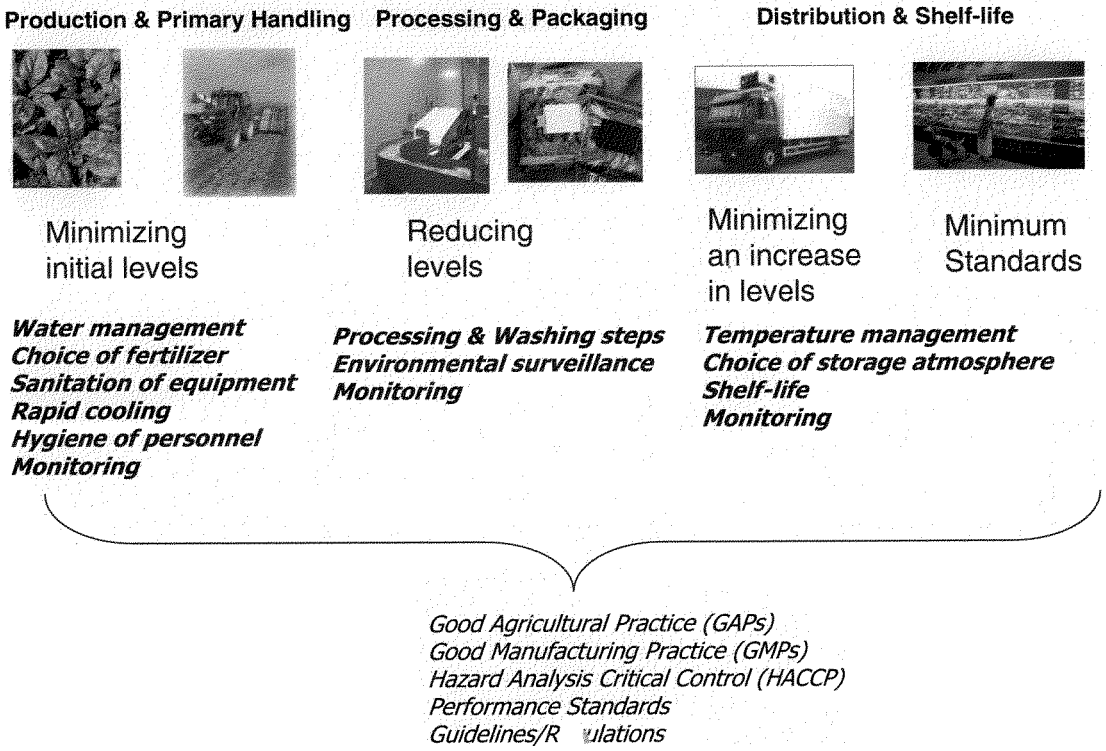
Reported Juice-Associated Outbreaks United States, 1995 - 2004



(CDC)

Figure 3

Risk-based use of preventative controls in the production chain of fresh produce



Mr. PALLONE. Thank you, Dr. Cole. Mr. Stenzel.

STATEMENT OF THOMAS STENZEL

Mr. STENZEL. Thank you very much, Mr. Chairman. I don't have a slide, but I will thank Dr. Cole for sharing on behalf of the fresh produce industry. And I will affiliate myself with his remarks.

In my written testimony, I have provided a number of specific policy provisions that I will call to the committee's attention, but I would like to spend just a few minutes this morning talking a bit more personally about some of these issues.

First, I would encourage all of you to eat more fresh fruits and vegetables. At a time when Congress is debating health care reform, all public health authorities agree that one of the most important things we can do to improve health is to eat more fruits and vegetables. But achieving that goal is dependent upon the main issue that we are talking about today, and that is the critical challenge to modernize and reform food safety law.

Now, I personally am confident in my produce choices today. We consume over a billion servings of fresh produce every day in the United States, over five million bags of salad every day. And out of the hundreds of different produce items in the supermarket, a very small number, only five, have been related to any type of foodborne disease in recent years in quantity.

But we also know that we have issues. Consumers know it, and consumers are fearful of fresh produce at the moment. And that is something we have to address. Now, our industry has been working in this area for many, many years, but the spinach crisis almost three years ago now was a watershed moment for us.

Remember the unprecedented national response. We pulled spinach off of the shelves of every grocery store in America for weeks. In fact, we now know the only contaminated product came from one farm through one processing plant on one day's production, even one afternoon shift. It wasn't even the whole day. There has been no contamination from that processing plant or from spinach in the last two and a half years. And yet today, spinach consumption is still down in the United States, one of the healthiest vegetables that we should all be consuming.

Following that outbreak, we undertook a mission. First, to look at a comprehensive reevaluation of all our leafy greens production. Mr. Lugg will talk about that, and his leadership in that area of our industry has been tremendous. We looked at every possible step and have adopted the most rigorous good agricultural practices with strong compliance measures and audits, some conducted by the California Department of Food and Agriculture, but also other states and private sector auditors.

But our industry also had to address the broader question of federal regulation. In January of 2007, our board of directors adopted a series of policy principles for mandatory federal oversight of our business. Let me explain the three principles briefly.

First, 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 little industries, one size clearly does not fit all. For example, food safety requirements applicable to products grown

close to the ground would be very different from food safety practices for fruit grown on trees.

Secondly, we believe produce safety standards must be consistent for any individual commodity wherever it was grown or processed anywhere in the United States or imported into the country. Consumers must have confidence that the same safety standards were applied no matter whether the produce is grown in California, New Jersey, or Mexico.

Finally we believe achieving consistent produce safety standards across the industry does require strong federal government oversight and responsibility. That is going to take credibility for consumers, and it is also going to create equity for producers across all of our industry. The FDA must determine the most appropriate nationwide safety standards in an open and transparent process with full input from the states, industry, academia, consumer groups, and all stakeholders.

Most of my testimony this morning has been about prevention. Preventive controls are where it is at. That is what we have to do. As Dr. Cole said, we are not going to test food safety into our products. But I do have to take just one moment to talk about outbreak investigations as well.

When I testified before the ONI subcommittee last summer in the midst of the jalapeno outbreak, I raised several issues that were critical, and I think the peanut paste fiasco of the last several months continues to reinforce those. It is clear that no one is in charge of these outbreak investigations. There is no chain of command. There is no command and control procedure, and American consumers and industry alike are left to be whipsawed back and forth from momentary change to change.

Crisis planning is not done in advance. It seems to be learned on the job. The government's failure to use industry expertise, at least in our case, to help reduce and end the outbreak last summer was a tragedy.

Now, let me say that this needs to be transparent. It has to be supported by consumer groups, and it has to be a squeaky clean system. But there is expertise in industry that can help reduce, moderate, and end outbreaks even in the tragic situations when they occur. And we have to find a way for CDC and FDA to take advantage of that expertise.

Finally risk communication is critical. The principle of timely and rapid communication with the press and public cannot be underestimated. But it is also critical that any risk communication expert would advise precision and care in communicating exactly what needs to be said and not speculating. One single office at FDA needs to have the authority and accountability for public communications with one single officer designated as the media spokesperson.

Let me conclude. There is a public health imperative that we consume more fresh produce. We as an industry are doing everything we possibly can to make sure that we are delivering safe and healthy products. But because science tells us there is no such thing as zero risk, government must also be able to assure the public that our food safety systems are based on the best available

science and are enforced by strong and appropriate oversight. Thank you.

[The prepared statement of Mr. Stenzel follows:]

United Fresh
PRODUCE ASSOCIATION

Prepared Statement

Thomas E. Stenzel
President and CEO
United Fresh Produce Association
Washington, DC

Before the
U.S. House of Representatives
Committee on Energy and Commerce

Subcommittee on Health

March 11, 2009

Introduction

Good morning Chairman Pallone, Ranking Member Deal, 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 toward perfection, 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. But as

long as there is the potential of even one individual getting sick, we will do all we can to prevent that from happening.

Now, I personally am confident in my produce choices today. I know many of the people who are growing and processing fresh produce, and I trust them to be doing their very best to market safe products. 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 new concerns, new 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.

How We Got Here

Let me first state that our industry has worked to address food safety for many, many years. In fact, 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 U.S. Food and Drug Administration to publish federal guidelines soon thereafter. Food safety has been at the forefront of our mission to serve the American public for many years.

When the spinach outbreak occurred in 2006, our entire industry immediately pulled all spinach from shelves nationwide, and cooperated fully with FDA in tracking this problem back to its source. That total industrywide shutdown was an unprecedented response, but FDA felt it necessary until they were certain any contaminated product was removed from the market.

In fact, we now know that the only contaminated product came from one 50-acre farm, packaged in one processing plant, and only on one production shift. That's out of more than 300,000 acres of lettuce, spinach and leafy greens being grown, with salads being prepared in dozens of processing plants around the country. Yet today, two and half-years later with no further outbreaks, spinach consumption is still down with many consumers shying away from one of the healthiest vegetables they could be eating.

Our mission following this outbreak was twofold –

1) First, 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 the 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 the California Department of Food and Agriculture.

2) Second, our broad industry had to address the role of federal government oversight of food safety. In January of 2007, six months after the spinach outbreak, our Board of Directors adopted a series of policy principles calling for mandatory, science-based regulation by the federal government.

> *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.*

Put simply, we concluded that we had to work to rebuild public confidence in our system of food safety government oversight, such that when another outbreak occurs, the public can have confidence that it is the result of an isolated breakdown in one situation, not an endemic problem causing them to question the safety of all the produce they eat. With an analogy of the airline industry, we must have rigorous government oversight and strong industry compliance with the clear, scientifically vetted safety practices. But, when an isolated tragedy occurs, we must get back on the an airplane knowing that next flight is inordinately safe – just as spinach from thousands of farms was safe on the day of the tragedy in our industry, and the next day, and the next day.

Let me explain 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. And, the large majority of produce commodities have never been linked to a foodborne disease. In fact, a recent FDA federal register notice in 2007 confirmed that five produce commodities have been associated with 80% 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 rule-making procedure that establish 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.

Together, these three policy principles provide a direction for 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.

With this hearing and others conducted over the last several years, it is clear that Congress and the Administration will be looking closely to overhaul of our food safety laws. We support that effort and want to work closely with this committee and others in the design of strong and credible laws that would help rebuild public confidence in food safety.

In this context, our Board of Directors has expanded on the policy principles above to adopt a *Food Safety Policy White Paper* to provide specific policy recommendations for food safety legislation. I have attached this policy paper to my written statement (see Appendix 1) as it reinforces my comments here.

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 Oversight and Investigation subcommittee (July 31, 2008) on the *Salmonella* Saintpaul outbreak associated with jalapeño peppers, I called on Congress to develop policy that will address the then current failures and lack of leadership in managing outbreak investigations. Since then, the peanut paste fiasco has only provided more fuel to my comments, unfortunately this time affecting thousands more consumers and tearing down another whole industry.

In that testimony, I highlight five fundamental flaws that I believe must also be addressed in reform of food safety laws.

1. There's No One in Charge

The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. It was clear in last summer's *Salmonella* outbreaks that no one was 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 coordinated investigation moving forward in a logical and expeditious direction.

Recommendation: We suggest Congress consider how to put in place a command-and-control structure with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must ask. We suggest looking at other agencies for insights, such as National Transportation and Safety Board investigations. From afar, such a system seems designed for a 24-7 immediate response, with clear authority and command leadership, supported by a team of well-prepared experts.

2. We Need Better Crisis Preparedness and Transparency

Crisis planning should be done in advance of a crisis, not learned on the job.

Recommendation: Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future.

3. The Current System Doesn't Use the Expertise Available

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 transparent, supported by consumer groups, and squeaky clean. 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

Recommendation: Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak 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.

4. Government Is Ill-Prepared To Make Complex Risk-Benefit Decisions

Every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing."

Recommendation: Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. The broad brush approach taken with tomatoes, then jalapeños, is not an appropriate risk management strategy to best protect public health, either in the short- or long-term.

5. Today's Risk Communication Is Unacceptable

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, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. Consider again the example of a National Transportation and Safety Board press conference investigating an airline accident. There's no speculation about whether a crash might have been caused by pilot error, or bad hydraulics, or a flaw in wing design. Those are precisely the things under investigation and are NOT discussed until there's a conclusion by the experts.

Recommendation: Risk communication must be a central part of any crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation.

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. And 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.

United Fresh
PRODUCE ASSOCIATION

Appendix 1

United Fresh Produce Association
Food Safety Policy White Paper

Approved by the Board of Directors
January 25, 2009

Introduction

Food safety is the produce industry's top priority. The men and women who grow, pack, and market fresh produce are committed to providing consumers with safe and wholesome foods. We are constantly working to enhance and improve our performance in growing crops in the field, carefully harvesting and handling them for distribution, packaging and processing commodities into convenient, ready-to-eat products, and maintaining the safest possible delivery chain all the way to the consumer's table.

In addition to our own efforts, the produce industry also supports a strong role by the federal government in ensuring that produce sold in the United States is grown, packed and distributed in accordance with appropriate science-based safety standards. It is critical that American consumers have confidence that the federal government is exercising diligent and appropriate oversight of food safety standards and compliance for all foods, including fresh produce. For fresh fruits and vegetables, any breakdown in consumer trust of either government or industry in our mutual food safety responsibilities will lead to a loss of confidence in the very foods that we should all be eating more of to improve public health.

KEY FOOD SAFETY POLICY ISSUES

PRODUCE SPECIFIC PROVISIONS

OVERVIEW

First and foremost, the fresh produce industry has been at the forefront of developing comprehensive food safety programs for many years. In fact the first *Food Safety Guidelines for the Fresh-Cut Produce Industry* were published 16 years ago in 1992, and was just updated by FDA in February 2008. The industry also developed Good Agricultural Practices (GAPs) in the mid-1990s to minimize on-farm microbiological food safety risks for fruit and vegetables, and worked closely with FDA as the agency published its overarching GAPs document in 1998. More recently, we have worked with scientists from government, academia and industry to develop extensive commodity-specific food safety guidelines for tomatoes, melons, sprouts, and leafy greens, and have implemented strong compliance systems based on state inspections and audits by government personnel. Put simply, food safety has been at the forefront of our industry's commitment to serve the American public for many years.

In addition, it is clear under current law and regulation, that FDA is responsible for ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the United States. We believe that responsibility is at the very core of the discussion today with Congress. FDA has the legal responsibility to assure American consumers that their produce meets all acceptable safety requirements. Our industry must and will do all

we can to grow, pack and process the safest possible products. But no matter what steps we take as an industry, the law requires, and the public demands, that FDA as an independent, public health agency be the final arbiter of what is safe enough. In that vein, we believe FDA already has strong regulatory authority by statute to achieve these goals. In particular, FDA has the authority to promulgate rules and regulations, issue guidance that compels industry action, enter into agreements with states to allow for field investigations, and generally set standards to protect the public health.

Lastly, we believe one of the most important issues for produce is whether FDA is adequately funded, has sufficient staff with scientific training and experience in our sector of the food industry, has research dollars available to address key questions, has strong working agreements with the states to provide support as needed, and has the commitment of the President and full support of Congress.

POLICY STATEMENT

Any new food safety legislation affecting the fresh produce industry should be based on the best available science, be risk based, and consider that fresh produce is a raw agricultural commodity. In that regard, any new legislation should aim at reducing the incidence of foodborne illness by minimizing the risk of adulteration. It is imperative that it is understood that most fresh produce is not sold as ready-to-eat commodities and should not be held to RTE standards. Any food safety effort should, however, encompass the entire supply chain regardless of size, location or operation type.

SPECIFIC POLICY RECOMMENDATIONS

- 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. And, the large majority of produce commodities have never been linked to a foodborne disease. In fact, a recent FDA federal register notice in 2007 confirmed that five produce commodities have been associated with 80% 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 rule-making procedure that establish 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.

  We also believe FDA must have relationships with other governments, USDA, and state agriculture and regulatory officials to ensure that compliance is taking place. Cooperative agreements between FDA and the states have been extremely effective in providing oversight of food safety standards. In particular, USDA has been a strong ally and has offered a number of means to assist the produce industry in safely growing, handling and processing fresh produce. For example USDA through AMS offers several auditing programs that assist the industry in measuring good agricultural practices, good handling practices, and HACCP programs in processing plants. These are good education and training programs, as well as a means to measure individual operators' understanding and implementation of food safety practices.

  However, HACCP is not the equivalent of a food safety program, as HACCP is merely a component of an overall food safety program and cannot be established without prerequisite programs such as GAPs, cGMPs, and sanitation standard operating procedures (SSOPs) being in place. Conversely, it is unclear if HACCP can or should be used as a component of a food safety program for production agriculture as these types of programs are well defined and may function well within the control environment of a food processing plant. This does not mean that process hazards should be ignored but simply that the risks and hazards associated with a process need to be dealt with via an alternative mechanism. For production agriculture, in particular produce, risk reduction and mitigations programs such as GAPs, are considered an essential element in controlling and minimizing food safety risk.

THIRD-PARTY CERTIFICATION

OVERVIEW

Currently, most third-party certification programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of audit standards. The basic reason that current programs do not ensure compliance with FDA requirements is that FDA has not clearly established the standards that it believes must be audited against. This leaves open to interpretation to a wide range of competing interests – market players, auditing companies, etc. – to develop their own standards. Also, many produce audits currently overemphasize documentation and testing, which seems designed more to satisfy private commercial liability concerns than compliance with FDA food safety standards.

Finally, most other third-party certification programs measure a wider range of practices that might be of interest to the person requiring the audit. For example, many audits measure procedures and practices outside of FDA food safety requirements, thereby diluting the assessment of a facility's compliance with those requirements.

POLICY STATEMENT

We believe there may be potential benefits to FDA, the industry and consumers by use of certain 3rd party certifiers under specific conditions. However the process must overcome many obstacles we see in implementation of such programs today, as well ensure a consistent, science-based, and credible certification system in the future that garners the widespread confidence of consumers, industry and government. Because of these concerns, we propose three specific policy recommendations for third-party certification programs currently being considered by Congress.

SPECIFIC POLICY RECOMMENDATIONS

- FDA must retain a definitive role in setting fair and appropriate audit fees initiated by third-party certification programs to demonstrate compliance with FDA standards. Currently, produce industry food safety certification programs range in cost (auditor/certification fees alone) from a few hundred dollars per audit (generally by the not-for-profit organizations) to tens of thousands of dollars (generally by the more complex certification bodies like SQF or ISO). Yet, we do not have evidence that the increased costs of some audits result in better evidence of compliance with standards or better evidence of safer food. The tremendous range in audit fees can have a significant impact on the ability of particularly small businesses to participate. If exorbitant audit fees were required, we fear that many producers would be financially challenged to comply with these requirements.

- A third-party certification program should be based on a harmonized set of FDA endorsed standards, and have industry-wide public recognition to preempt additional redundant audits. Today, the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. Most buyers will only accept the results and certification of certain certification bodies, thus leading to proliferation of different audits for different buyers. In some cases, the same auditor will visit a facility multiple times to perform different audits to verify compliance with different and potentially conflicting standards. In addition, inconsistencies in audit standards among the different certification bodies have created frustration and confusion, have unnecessarily increased operational costs, and may create an obstacle to training in food safety practices. To date, every effort to create a harmonized set of produce food safety audit standards has only added another set of standards to the list. If third-party certification programs are to be successful, there must be a system in place that requires buying companies to recognize and approve the results of these audits without requiring their own duplicative audits to recognize the same results.

- USDA/state department of agriculture GAP audits should be designed to certify against FDA standards. Most current audit programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of standards. If given authority, training and adequate oversight, we believe that USDA/state department of agriculture GAP audits could be designed to certify against FDA standards, although most would be considered more educational and benchmarking tools for individual growers at present. Perhaps the one audit program that most closely ensures compliance with FDA standards today is the California Leafy Greens Marketing Agreement (LGMA).

TRACEABILITY AND OUTBREAK INVESTIGATIONS

OVERVIEW

The produce industry is committed to the capability of effectively and quickly tracking the source of our products from retail stores and restaurants back to their original farm source.

The Bioterrorism Act of 2002 requires mandatory record-keeping 'one-step-up' and 'one-step back' of all foods, with the ability to provide such records within 24 hours. The industry is committed to full compliance with these requirements, and urges FDA to rigorously enforce the requirements of this law. We know of no instances where FDA has taken any regulatory action to cite a produce company or its customer for failure to provide adequate records as required by the Act. Rather, we hear generalized concerns about adequacy of records, without specific examples with specific companies where compliance is inadequate. The produce industry stands ready to work with the Agency to ensure full and total compliance with these requirements.

In addition, outbreak investigations are multi-disciplinary processes, with tracking of product records only one element of successful investigations. FDA, CDC and the states must enhance their epidemiological work to identify which foods are associated with illness; must enhance their understanding of and/or access to expertise on produce industry distribution patterns; and must enhance the expertise of individual investigators. The produce industry has publicly committed to work cooperatively with FDA to help the agency better understand existing industry traceability and recordkeeping practices, and to better understand any areas where the agency believes we could improve those practices.

Concurrently, a number of produce companies throughout the entire distribution chain have begun to adopt a standardized system of case coding for all produce sold in the United States, including bar codes that contain source information and lot numbers, which will then be scanned and stored by subsequent buyers through the distribution chain. This Produce Traceability Initiative is a multi-year effort to standardize the broad adoption of state-of-the-art processes across the industry. As more in the industry adopt this initiative, it will maximize the effectiveness of industry's current traceability procedures, improve our internal efficiencies, and assist the Agency greatly in its work.

POLICY STATEMENT

Strong FDA enforcement of existing record-keeping laws, together with work by industry to ensure full compliance today while continuing to enhance the efficiency of tracking systems, provides the public with assurance that produce items can be effectively tracked in an outbreak investigation. Therefore until the current federal law is proven to be deficient, we oppose any additional mandatory legislative or regulatory requirements for traceability as premature and unwarranted.

SPECIFIC POLICY RECOMMENDATIONS

- Congress should consider how to put in place a command-and-control structure for outbreak identification and management, with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must review. The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. Local and state governments are usually first to discover illnesses, and are free to draw their own conclusions and issue press

releases at any time. The diffuse responsibility continues at the federal level, even within the Department of Health and Human Services. CDC has the "official" responsibility to determine what food vehicle is the cause of an illness. FDA must wait on the scientists at CDC to make that call, only after which FDA staff are responsible for the traceback investigation. Lack of a true chain of command brings lack of accountability, and a rush to protect one's own turf or reputation. Even in the investigation itself, field investigators are all over the map. Some are FDA field staff employees, some CDC, some state, some local. Suffice it to say, outbreak investigations today do not resemble a well-prepared, well-organized, or well-drilled team operating as a cohesive unit.

- A stronger crisis preparedness and transparency needs to be developed by FDA and CDC. One of the most important parts of an investigation is the original work by states and CDC with food recall surveys among ill people. However, as we saw in the *Salmonella* Saintpaul outbreak this summer, CDC's first case control study showed an association with tomatoes, but its second more detailed case control study showed a greater association with jalapeños. Today, these facts are all open to second-guessing, not only because we now know tomatoes were not the continuing cause of illness (or much more likely never the cause at all), but because no one outside of CDC knows how these studies were conducted with the state of New Mexico who did the initial work. Could there not be consistent food survey protocols set in advance, peer-reviewed by expert epidemiologists outside government, and kept at the ready for a case like this?

  Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future. Many in the private sector hold workshops on crisis management and many in the produce industry do recall and traceback drills all the time. The industry stands ready to cooperate with government in planning and testing overall traceback investigations.

- Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak investigations. The government's failure to use industry's expertise in outbreak investigations is one of our most important lessons today. First and foremost this needs to be transparent, supported by consumer groups, and completely open to all interested parties. There is an abundance of knowledge in the produce industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves

  We recommend a broad group of stakeholders be convened to look at all potential options and provide recommendations to Congress and the agencies. We also 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.

- Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. Every health or safety regulatory decision requires an

assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing." We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot. FDA must find appropriate ways to advise consumers that the legal responsibility for food safety assurance lies with individual companies who offer food for sale, not the federal government. How can a grower of summer tomatoes in Michigan maintain his livelihood selling to local retailers? How can a fast food chain that knows every detail of where and how its tomatoes are grown maintain the option to keep sliced tomatoes on its burgers? How can a produce company that invests hundreds of millions of dollars in food safety stay afloat when its business is shut down the same as others who never made those investments? The unintended message to industry is don't bother investing in food safety, if you're going to be tarred with the same brush and face the same costly consequences in every single outbreak.

- Risk communication must be a central part of an overall crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation. The principle of timely and candid communication with the press and public cannot be compromised. Yet, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. This also comes back to our recommendation about a clear chain-of-command – someone has to be in charge of talking with the media. Good risk communication is not just an art; it is a science, and a science that needs to be studied in advance and rigorously followed in outbreak investigations.

IMPORT REQUIREMENTS

OVERVIEW

Food imports in general and fresh produce imports in particular have increased in recent years where there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/ territories. In the last decade, the number of food imported items has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories, a much higher percentage is imported with imports of fresh produce varying seasonally.

FDA primarily relies on an electronic screening process to review imported produce -- typically only inspecting foreign produce firms for cause, such as a potential link to an outbreak of foodborne illness. The basic import process consists of two stages--prior notice and food safety evaluation. In the first stage, FDA must receive prior notice before a food shipment arrives in the United States. Prior notice information is screened electronically by FDA's import database, the Operational and Administrative System for Import Support (OASIS), for potential risks associated with intentional contamination. Once the prior notice review has been completed, the food safety evaluation is conducted. For this evaluation, OASIS screens each entry line--or portion--of the shipment for risk factors associated with unintentional contamination to determine whether the shipment may proceed automatically or whether it requires further review.

According to FDA officials, import alerts are the agency's primary mechanism for keeping products with a history of violations out of the country, and they use them regularly. Through the use of import alerts, the agency may detain potentially adulterated products at the border without a physical exam. Additionally, import alerts place the burden on the importing firm to demonstrate that the product is safe.

POLICY STATEMENT

We believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. In particular, imports must be treated equitably in all areas of food safety regulation, including similar and equal assessment of imports and domestic production in all areas such as Good Agriculture Practices and Good Manufacturing Practices. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed.

SPECIFIC POLICY RECOMMENDATIONS

- Food importers should be required to ensure their foreign suppliers meet all U.S. food safety requirements. In particular, Congress should require that all food importers, subject to FDA guidance, document the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier food safety plan available to FDA. Food importers who demonstrate their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports.

- Build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards. In addition, FDA should provide for the possibility that official controls and certification are used instead of, or in combination with, third party systems. It would be more efficient for FDA to enforce an appropriate level of protection through administrative collaboration with governments rather than third parties in some cases. Finally, FDA should consider accredited third party certification programs for imports when foreign government food safety oversight capacity is limited. Under these types of programs, third party certification should be able to verify compliance with federal safety standards, foreign supplier safety plans, and identify those imports eligible for expedited entry.

MANDATORY RECALL AUTHORITY

OVERVIEW

Many in industry have long held that regulatory agencies do not need recall authority, since companies almost never refuse to conduct a recall when asked. Moreover, the regulatory agencies have the "power of the press" to issue a public warning indicating the product is adulterated or otherwise harmful AND the company is not cooperating with the agency in getting the product off the market (which can be much more harmful to a business than a recall). The agencies can go to court to seize adulterated product, which takes time, but under the Bioterrorism Act, FDA can also "detain" product to allow time to process a seizure action, or can ask states to "embargo" the product. Moreover, because companies generally do not refuse to conduct a recall, mandatory recall authority is more of a perceived gap in the food safety system than a real one.

One of the biggest food industry concerns has been the criteria to be used by FDA to determine the need for a recall. The key issue is where to draw the line between protecting public health and preventing the unintended consequences of unjustified recalls (should FDA elect to take precautionary action "in the interest of public health"). Congress recently passed new legislation amending the Food Drug and Cosmetic Act, establishing a reportable food registry, which requires reporting of foods for which there is a reasonable probability that consumption will cause "serious adverse health consequences or death" (the same standard incorporated into the Bioterrorism Act and the basis for a class I recall) within 24 hours of determining that a food meets the criterion.

Policy Statement

Although food companies routinely recall contaminated products, we believe Congress should give the FDA the power to order a recall, subject to due process protections, when a product poses the risk of severe health consequences or death and the company has refused to conduct a recall. In addition, Congress should consider a mechanism to ensure that if FDA issues unsubstantiated recall notice, that impacted companies or producers have an appropriate mechanism for redress.

FUNDING

OVERVIEW

One of the key components to modernizing our food safety laws is the ability to fund these new requirements. The produce industry strongly opposes any food tax related to growers, food facilities or food importers. All Americans are the beneficiaries of enhanced food safety oversight. Food safety is a public health issue affecting our entire society and, accordingly, the cost of federal regulatory oversight should be borne by U.S. general revenues for both equity and overall trust and credibility.

Moreover, a governmental policy of recouping inspection costs based on some type of user fee system would tend to shift fruit and vegetable production in favor of larger, more complex farming operations and away from many smaller, traditional, and local family truck-farms, groves, and orchards. This shift could work against product diversity and support for local agriculture, and act as a barrier to entry for smaller operations that today already contribute substantially to the safe and wholesome supply of fruits and vegetables. Additionally, fees specifically targeting imported produce or facilities handling imported produce will likely be viewed as duties, import taxes or trade barriers and invite retaliatory measures by foreign governments and harm exports of fresh produce to these countries.

POLICY STATEMENT

We believe the costs of FDA inspections and research should be financed from general tax revenue, not from taxes imposed on food importers or facilities. While we support increased resources for FDA, we strongly oppose food taxes and fees that are not tailored to provide a government service to our industry and that will likely compound food costs at a time of record food inflation. As a matter of public policy, it is much preferred to have direct governmental oversight of such critical matters as the safety of the nation's food supply paid by the general treasury—as opposed to the private commercial companies subject to inspection.

FOOD FACILITY REQUIREMENTS

OVERVIEW

FDA oversees the vast food industry that includes about 46,000 U.S. food processors and warehouses, and comprises a significant segment of the nation's economy. FDA regulated products account for about two-thirds of consumer spending on food, with an annual retail value of $430 billion. Every year, U.S. food processors spend $1.4 billion on research and development and introduce 15,000 new products.

Food facilities impose a variety of food safety measures and controls such as Good Manufacturing Practices to ensure the safety and quality of products they process. These regulations cover the basics of producing food under clean and sanitary conditions. The following is just a partial list of matters of concern to the public that are addressed by FDA's food facility regulations:

- Pathogens (bacteria, viruses, parasites)
- Chemical contaminants (pesticides, natural toxins, heavy metals, animal drug and antibiotic residues)
- Loss of wholesomeness (molds, decomposition)
- Mislabeling (false nutrition information or other misleading statements)
- Economic deception (violation of standards, counterfeit foods)
- Safety of food and color additives

POLICY STATEMENT

While we support the requirement that all food companies have a food safety plan, we believe food facilities should be given the discretion to identify appropriate safety controls and measures beyond those controls and measures already required by regulation. Prescriptive, across the-board new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.

MISCELLANEOUS PROVISIONS

Export Certification Programs – Several bills introduced in the 110th Congress provided FDA with the authority to issue export certificates as the Secretary determined appropriate, and on a fee-basis. This new authority, if adopted by the new Congress, could help some raw agricultural commodities (and processed food) exporters access markets that are currently closed due to sanitary-related concerns by the importing country, e.g., dairy imports to India. FDA certification should be safeguarded, however, so that it does not become a customary requirement by our trading partners, and instead is granted only under special circumstances supported by technical justification. This will help to control costs for our exporters and help ensure that certification does not become a convenient trade barrier.

Food Safety Research – In recent years, federal funding for food safety research has been woefully inadequate, with little to no research focused directly on mitigating risk factors associated with potential field contamination of fresh produce, or to developing effective microbial reduction and elimination techniques after harvest and in processing. While there's no obvious silver bullet around the corner, developing a "kill step" akin to pasteurization while still protecting the natural texture and flavor of our product would be a critical advancement in preventing even rare future illness outbreaks. As a nation, we need Congress to fund scientific research to help prevent future outbreaks. Specific produce safety research at FDA that is field oriented and implemented to find practical solutions is critically important, and we urge Congress to include a robust research agenda when considering reforming our nation's food safety laws. We believe that boosting produce safety research is a vital part of reducing risk in the future.

Mr. PALLONE. Thank you, Mr. Stenzel. Mr. Lugg.

STATEMENT OF JIM LUGG

Mr. LUGG. Thank you, Mr. Chairman and members of the subcommittee. My name is Jim Lugg. I am former executive vice-president of food safety and quality at Fresh Express and today a consultant to Chiquita Brands International.

The strategy or food safety plan is a requirement for any company that is in the food business. And it must be a solid one, and it must be adhered to. Regular reviews of that food safety plan are required so that we are constantly updating it for new risks that we have become aware of.

In our business in Fresh Express, we have to look at really three areas. One is the production area. Second is harvesting, and third is processing. Each of those areas are unique unto themselves and require specialized plans. But these reviews that we do of these three areas are what help us identify risks and prevent contamination from occurring.

More importantly, I think the overall lesson we have learned from these plans are that we have to do a very good job at focusing on preventive efforts. That means that in our case we have really four things that we look at: where are we planting the crop, what is the environment surrounding the crop along with its creatures, third, what kind of water will we use to irrigate with and then process it with, and finally, all along that supply chain we have the worker issue, worker hygiene.

But again I stress the fact that even though we have a robust plan and we have been doing fresh cut lettuce since 1978, we constantly must update that plan so as we can identify new risks that we didn't realize because of new science or whatever the case may be.

But I can point out a simple case that you can all identify with, I think. If we have a lot of lettuce that we are ready to harvest and one of our people can identify what seems to be an animal incursion into that field of product, we have two choices. If we can clearly identify where the incursion occurred, we can avoid harvesting that product. If we can't clearly identify that risk, we abandon the field completely.

But I emphasize that this issue of risk evaluation is a never ending process in the food industry. And that is true whether it is fresh, whether it is frozen, or whether it is canned. Almost without fail, these risk evaluation lead to more effective preventive steps, and that is the bottom line.

And I also would emphasize that these food safety plans, at least at our company where we handle a number of different vegetables, are not transferable. Lettuce is different from tomato, so they must be commodity specific.

And then I want to go on and just mention that in our company when we do identify a risk, we focus intently on how to manage that risk and how to evaluate whether our management practices are safe. This requires a lot of record keeping, what has been measured, when it was measured, and all those sorts of details. But the important point I want to make is that once the risks are identi-

fied, the preventive process controls must be put in place and then measured for their effectiveness.

I also want to conclude actually by saying that we have a lot of tools that we can use to measure our effectiveness such as third party audits, testing, inspections, and so forth. And these tools are very effective in helping us evaluate how well we are doing.

But the one thing I just want to give you a simple example of in closing is an acre of spinach has more or less three million plants in it. The typical practice for sampling a spinach field to measure, see if a pathogen is present, is to collect something less than 100 plants from that acre of three million plants. You can calculate for yourself how challenging the odds are of finding a pathogen in that sort of a regime.

Finally and just to summarize, I believe the FDA should insist on every food company having a very current food safety plan. Secondly, the FDA should satisfy itself that regular risk evaluations are being done. Third, FDA should have access to preventive action steps that have been taken to manage the risk. And finally, my message is it is all about prevention. Thank you.

[The prepared statement of Mr. Lugg follows:]

Written Testimony of Jim Lugg
Former Executive Vice President, Food Safety and Quality,
Fresh Express and
Consultant, Chiquita Brands

before
House Energy and Commerce Subcommittee on Health
March 11, 2009

Thank you Mr. Chairman and Members.

My name is Jim Lugg and I am former Executive Vice President of Food Safety and Quality for Fresh Express and Consultant for Chiquita Brands.

All food manufacturers are committed to having a food safety strategy in place. A solid food safety strategy minimizes food contamination and resulting public health issues.

Even though a solid food safety strategy is in place, experience has taught us that regular reviews and a thorough analysis of each and every step of the production, harvesting, and processing is necessary to understand where contamination could come from and address methods to eliminate the source.

At Fresh Express we have focused intensely on choosing production locations that allow us to easily see where contamination could have occurred. Rules are in place to

abandon a lot, or at least abandon the portion of the field suspected of having been compromised.

We produce nearly one hundred percent of our crops out of doors and we know there are serious risks from creatures in the environment, workers, and certainly irrigation water. Each of those risks must be identified, quantified, and a strategy must be in place to manage the risk. We also package produce in a facility subject to FDA's Good Manufacturing Practice regulations, which we stringently enforce in our operations.

I am convinced that any responsible food manufacturer is constantly conducting risk evaluations, addressing any possible source of contamination. This relentless process of risk evaluation leads to developing process adjustments or new preventive controls to manage the risks.

There are certain fundamental processes that all food manufacturers follow, but fresh produce is different from frozen or canned products. This means that each type of product has unique sorts of risks and this is why it is so vital that producers and processors carefully analyze their own unique risks and develop plans to address them.

At Fresh Express we rely on regular and frequent measurement of all the risks we have identified in our business. For example, before a field of lettuce is harvested someone has to walk the perimeter to look for animal incursion, sanitizer chemicals in plant wash water must be constantly measured, and harvesting equipment must be

inspected before use. All of these steps require that a written record must be kept telling us who did the inspection and at what time of day and on which day. Records are invaluable, but someone in our food safety group must review them before product gets into commerce and look for risks that we might not have previously identified.

I have just made a point of how critical monitoring, inspections, and testing are; however, I assure you they are steps that only tell us how effective our preventive process controls are. They do not tell us if we have contaminated product.

We urge Congress to require all food manufacturers to conduct a thorough risk evaluation that documents each and every risk. A part of that analysis must be a description of the preventive controls that are in place and regularly monitored to document and verify that the controls are effective. At Fresh Express we have company documents for Good Agricultural, Harvesting, and Processing practices. The documents are regularly reviewed and updated based on the latest information available to us.

At Fresh Express we believe FDA's role should be to review these plans and, where appropriate, to work with food manufacturers to improve those plans. We do not believe FDA approving those plans would gain anything. During the spinach crisis in 2006 we voluntarily provided FDA with the food safety documents developed by our company, even though we were not implicated in the outbreak.

A critical part of any risk evaluation is frequent review and that should be an absolute requirement along with review findings. Corrective actions taken following the reviews are every bit as important as the reviews themselves and must be documented. This should be a standard requirement for all food manufacturers because it would continuously increase the level of food safety.

FDA inspections could then be conducted frequently enough to verify that companies are evaluating foodborne hazards and implementing preventive controls according to their plan. Equally important would be to inspect the records documenting the changes made following the evaluation.

This approach is vital to a successful food safety result because it is a process that goes on daily. Another approach that some have suggested is more testing. The challenge with testing is where to take the sample. An acre of spinach has 3,000,000 plants. Even if we take sixty plants selected randomly, the odds of finding a human pathogen are not good. This is but one illustration of why we believe so strongly in developing processes through the supply chain that alert us to problems before product gets into commerce.

In summary, a vital role for FDA is to insist on complete and thorough food safety plans from all manufacturers that ensure regular risk evaluation is done. Just as important as the risk evaluation are the corrective action plans. Both the risk evaluation and the corrective action plan must be documented and confirmed by an audit of the

process. Such audits may be done by company auditors or by competent third parties, but they should not be mandated. Rather, audits should be used as a self-improvement tool for preventive control programs and their implementation. We must all work together to maximize the safety of food in the United States. However, ultimately safe food is industry's responsibility. Congress should explicitly recognize this by requiring that companies assess hazards and implement appropriate controls that are then verified by regulatory agencies.

Mr. PALLONE. Thank you, Mr. Lugg, and thanks to all the panel. We will have 5 minutes questions from each member who desires, and I will start with myself.

I wanted to ask Dr. Cole. You explained the difference between the hazard analysis and critical control points or HACCP and good manufacturing processes. But I am not sure I understand how that relates to many of the bills that are now—you know, they are calling them preventive safety plans which you flashed up in your chart or preventive controls.

Just describe to me a little better maybe the differences between the HACCP and many of the bills, the language in the bills preventive safety plans or preventive controls if you could a little better. I know you flashed one of those up, but I don't necessarily understand the difference.

I understand that the GMPs are like the basic fundamentals but——

Mr. COLE. Yes, I think the best way to think about it is the term preventative food safety plan is a broad term which could include a whole range of different preventative measures. The way that those preventative measures could be implemented within industry and then inspected are things like GMP which is the, as you said, are the basic kind of building blocks. You can't do HACCP unless you have the building blocks in place, unless you have the basic sanitary conditions in place.

Mr. PALLONE. But then these preventative control systems can vary widely. So if that is the case, is it sufficient to just require that all manufacturers or producers simply have a food safety plan in place, or do we have to—if it has to be a need for FDA to have ability to be more specific than that?

Mr. COLE. I think the trick there is, because even with the additional resources, there is always going to be finite kind of resources we can bring to bear on a public health burden. So we have to be smart about the way that we apply these tools. And so we have to use either GMP or HACCP or both appropriately to the hazard that we are trying to control and the risk that we are trying to manage.

So, you know, let us take a fresh produce example. I think the comments from one of the testimonies here relating the products—is it product specific. If we were to look at the safety of potatoes, OK. Potatoes usually end up being cooked and prepared, and we are not really that concerned about the safety of potatoes.

Mr. PALLONE. So it is going to vary from product to product?

Mr. COLE. It is going to vary depending on the level of risk that we are trying to control, yes.

Mr. PALLONE. Now, let me go to Ms. DeWaal then. I mean you can comment on this as well, but if there was a system of mandatory preventive controls in place prior to the PCA outbreak, would that have helped to prevent it from ever occurring in the first place? And if you want to comment on what Dr. Cole mentioned.

Ms. DEWAAL. Well, thank you, and I do agree with Dr. Cole that the preventive control plan covers your underlying GMPs, sanitation plans, as well as your HACCP plan if you have one, and your testing.

The key element for the PCA recall and outbreak is that the company, because of the absence of a plan and the records to sup-

port that plan, they were not compelled during the inspections to actually show what they knew to the inspectors, which meant that when the State of Georgia went in and did inspections, they were just doing a spot check. Conditions on that day were what they could inspect. If a bill passes that contains this kind of requirement, when an inspector arrives, they will not only to get to inspect the plants and the products that are there, they will be able to go back and look through the records. And hopefully in that case, they would have found and acted on the causative salmonella test result findings that PCA had.

Mr. PALLONE. Because they basically have a plan in place about what they have to check for is what you are saying?

Ms. DEWAAL. That is right. It gives the inspectors the access to the information on food safety that the plant itself maintains, which today FDA doesn't have it and the states don't have it.

Mr. PALLONE. Well, just give me a little more. Maybe, Mr. Stenzel, you know, talk about how a plan might be different, you know, like tomatoes versus spinach. And are there certain things that you would require, you know, for both versus things that would be different?

Mr. STENZEL. There are. You are seeing the full chain here in this panel discussion. We actually start at the farm level with good agricultural practices, which are kind of the GMPs of the farm level I might say. That is the basics that all farms should be following. There are also then commodity specific standards and practices that we believe are appropriate, we have called for FDA to implement. Particularly for those products that have been associated with a pathogen in the past, even rarely. So for tomatoes, there would be different sets of standards and practices, commodity-specific guidelines.

Today that exists. The industry has worked hard in different sectors, tomato industry, the leafy greens. In fact, we have done a pretty good job, but we need FDA to be the holder of that standard so that it is applied across the industry and is not left just to individuals to follow it on our own.

Mr. PALLONE. OK, thank you. Mr. Deal.

Mr. DEAL. I think there seems to be general agreement that a food safety plan needs to be in place, and they will vary depending on what level of production you are in. Mr. Lugg, though, if we do make these plans mandatory and FDA comes in to inspect, in your opinion, what records should be disclosed to the FDA inspector in terms of those safety plans?

Mr. LUGG. We would really like to have happen is when the plans are being developed, we would like to have FDA input along with our own so that the plan has all of the steps that the FDA would like to see included in it so that when the inspector arrives, he has been a part of that architecture, and he can easily see what he wants to see.

Mr. DEAL. So he would, by having access to the plan, know what they have done from a preventive standpoint?

Mr. LUGG. Exactly. I think the owner of the food needs to own the food safety plan, but certainly there are very good advisors within CFSAN, for example, that can assist in making that plan even better.

Mr. DEAL. Let us go to the next step on this in a logical sequence, and any of you that would like to respond, please do so. The next logical step is what do you do with regard to laboratory testing? Now, I would imagine that many firms have internal labs that do internal testing, and they would, of course, I presume, maintain records of their own internal testing. Others would rely on external labs to provide testing and test results back for them. The one big question that I still have is to what extent do we require those lab tests to be disclosed to FDA?

And the reason I have some concern about it is that you may have tests being done for a variety of different reasons. One might be someone who is going to process a product, but they want to find out what the status of the raw product is. Let us say peanuts for example. In its raw stage, they may get a result that may have some salmonella contamination.

But if they are intending to follow through with the kill cycle, then obviously that should eliminate that particular problem. My concern is that I don't think we ought to necessarily overburden FDA with every lab report given under every circumstance and for every purpose.

So how do we differentiate what lab report should be disclosed? And do you have any thoughts on that?

Mr. HUBBARD. I will take a shot at that if I may. The FDA's concern is that if you require these lab tests to be routinely submitted, people may just stop doing them.

Mr. DEAL. That is right.

Mr. HUBBARD. Firms often do them as part of their quality control process at the end to make sure that their systems are working. I think the state of Georgia was considering legislation that would require notification. But the theory is if you require it and the firm just stops doing the lab testing, you have not improved things.

Mr. DEAL. Right.

Mr. HUBBARD. But it would be important if FDA finds a connected problem, say, in a PCA example, is in their inspection and says to them do you have any laboratory findings that would help us understand if you are the source of the problem. And if they say yes, then, of course, FDA should be able to access those records.

Mr. DEAL. So you are saying then that should be a part of the maintain records subject to inspection when the FDA inspector comes in, not that the lab, upon receiving a negative or positive, as the case may be, report that the lab has to directly report at that point to FDA.

Mr. HUBBARD. I understand that that is the FDA position, yes.

Mr. DEAL. OK. All right, anybody else want to comment on that? Ms. DeWaal.

Ms. DEWAAL. Thank you. I just want to note that today most of the bills that you are looking at do have some lab reporting, but the different bills are different in their strengths. And we really want to get, first of all, this access that Mr. Hubbard is talking about. Any time an inspection is done, the inspectors should be able to see the full range of what the plant is looking at.

But there are times, for example, where, if testing is compulsory for an industry or where there is some kind of public health alert,

that you might want to compel some kind of reporting to the agency. So I think you need to leave the door open in some of those circumstances for testing direct reporting. But the reporting really should go from the plant to the agency, not necessarily from the lab.

Mr. DEAL. Dr. Cole.

Mr. COLE. Yes, I think that is a pretty good answer. Again it comes back to based on risk. So if we are looking at the testing results as part of an ongoing food safety plan, I think the agency should have access to those records as part of that. They should have access as to what follow-up actions were taken as a result of those results. And then for certain products, you might want to make it compulsory that a positive salmonella, for example, is a notified situation. If I am making infant formula, for example, and I get a positive salmonella, that should be a notifiable instance, and that should go directly to the agency.

So again unfortunately the devil is in the detail with the risk, managing the risk versus the resources.

Mr. DEAL. Well, just a quick comment. That is where we need your help, in fleshing out the devil because we can get the broad principles. I think it is the fleshing out of that I would appreciate hearing from you if you have any further thoughts about how we do that. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Deal. Mr. Gonzalez is next.

Mr. GONZALEZ. Thank you very much, Mr. Chairman. First question, and I need to get the pronunciation. Is it Ms. DeWaal? Is that correct?

Ms. DEWAAL. DeWaal, that is correct.

Mr. GONZALEZ. DeWaal. Thank you. We have DeWaals in San Antonio that came from Minnesota, but they spell their name a little different, but it is DeWaal.

Page three of your written testimony, "the absence of federal inspection, inadequate state inspection have let problems at PCA fester." No matter how much we, I guess, empower the FDA, it is just going to be overwhelming. We are never going to have all of the assets and resources truly because of just the expanse of the issues. And we are going to have to form partnerships obviously with state authorities and, of course, private enterprise.

With the Peanut Corporation of America, my understanding is that they had an operation in Texas. You are probably very familiar. It may have been Georgia-based, but we had peanut butter, a lot of it obviously out of the state of Texas.

Mr. DEAL. Virginia-based.

Mr. GONZALEZ. It is Virginia-based? Well, then we are a subsidiary and happy to have been a subsidiary. But the question comes down to is that they did have private testing. And I am just wondering. I don't know what we have out there now as far as certification of the labs that are actually hired. The question always is that the closeness of the relationship generally will lead to whatever conclusion the person that is requesting the testing.

Do you have concerns about that particular aspect going forward?

Ms. DEWAAL. Yes, I think it is critically important that the legislation should contain a lab accreditation provision. Now, that won't

apply to every in-house lab that a company may have. But lab accreditation will raise the confidence that both inspectors at the state level, federal level, can have in the results of those tests.

But getting to your question on the complexity and how will FDA actually manage its job, I mean they have a huge job of regulating both the domestic industry and the imports. And the reality is the agency has been starved for resources. There are certainly management structures that could work that would allow for FDA to have very consistent programs working with the states to do inspection, but I don't believe those programs have been designed at the agency.

And unfortunately the public is really losing confidence in the ability of this agency to do those tasks. So it is important to get the funding in place, to get the new legislation and these new authorities in place where there is common agreement on so much of this.

But I am not sure that even with those elements we are going to be able to restore consumer confidence in the functioning of this agency. So I was very glad today to hear Chairman Waxman say that the question of structure, which was also raised by Representative Eshoo, would be one that they would leave open for further consideration because it is very important that consumers trust the agency to manage this huge responsibility.

Mr. GONZALEZ. And I think the authors of the bills recognize that, and we are going to be moving forward, and hopefully we will do as complete a job as possible under the circumstances and the competing bills.

This is going to be to Mr. Stenzel and Mr. Lugg. And that is what really establishes accountability? In my view, it is liability. Not that this may have an application, one concern I have is that the FDA is, in essence, not just the floor of the standard of care but represents the standard, which we all agree today is totally inadequate in form and in practice.

And yet many people will look to that as what would govern the behavior of individuals out there in this particular chain as we say from the farm to the retailer. Do you all have any views on the liability of individuals out there and how important that aspect in this whole, what I say, the accountability established by liability?

Mr. STENZEL. Mr. Gonzalez, you raise an important point. I think the chairman mentioned it in the beginning. It is the responsibility of food companies and food purveyors to ensure that we have safe foods. It is government's responsibility, we believe, to make sure that there is a system of oversight and integrity and set the standards that we have to comply with. But ultimately that liability on the individual food company is a pretty darn important motivator. Look at PCA, you know, for the example of when you do something wrong, I think they were called a rogue operator, Mr. Deal, look at what that penalty is going to be.

I would also like to comment on your earlier question if I may about partnerships particularly on farm. This is very important. We don't anticipate a reality of FDA hiring 3,000 inspectors to go across farms in the United States or abroad. The partnership there we would recommend is with USDA who knows agriculture in the

United States, knows it abroad as well, in partnership with state departments of agriculture.

FDA needs to set the public health standard. That is for the integrity and confidence. But then in terms of actual outreach education auditing on farm, a strong partnership with Agriculture would make sense.

Mr. GONZALEZ. And Mr. Lugg, I apologize but my time is up. And I yield back to the chairman.

Mr. PALLONE. Thank you. The gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I want to start with Mr. Lugg, and like the comments that were just addressed by my colleague from Texas, I understand that the heavy hand of a liability process will also punish the bad actors, and it is in the best interest of everyone to have a safe and efficient operation.

Mr. Lugg, is it safe to say that sometimes the inspections conducted by you all are maybe more specific than you might get from an FDA inspection?

Mr. LUGG. Yes, our inspections particularly with respect to good agricultural practices in the field are very detailed.

Mr. SHIMKUS. Can you give us an example——

Mr. LUGG. Sure.

Mr. SHIMKUS [continuing]. Of something that you may have spotted that FDA may not have?

Mr. LUGG. Yes, in the agricultural production sector, which the FDA really doesn't spend a lot of time with, we have our own staff that will go and select a piece of ground that we are going to plant on, and that piece of ground is chosen based on the environment that surrounds it, and the quality of the water that we could use to irrigate with. That is something that the FDA wouldn't normally be concerned with.

Now, we have a new group in California called the leafy greens marketing agreement, and they do get concerned with the good agricultural practices. But the FDA folks generally come into our manufacturing facilities.

Mr. SHIMKUS. And I think, Mr. Stenzel, I think that is kind of your point you were making as far as having USDA deal kind of with the agricultural end of this process. I think a lot of us, depending upon the, you know, what your life experiences are. I used to be in the active military, and we feared the inspector general coming down. And the inspector general would have—we knew the list, right. We knew the standards, and by golly, by knowing they were coming down, it made us clean up. Really we want to be careful. I mean we really want to go after the bad actors.

I mean we want to go after the people who would take a report, falsify the records, inspect them, and nail them versus those who have a proven track record of having—or, I think you testified once before or when we were doing the Oversight Investigation, if you talk about leafy greens. And if the processing facility has irradiation and salmonella is—you may want to inspect to make sure that the irradiation machine is working. But if that is killing salmonella, then you have addressed that need versus maybe the multitude of other things that you might have to do.

Ms. DeWaal, I have talked about this because I really want to focus, and I have talked about the risk-based approach. And that talked about the food safety plan, but then identifying for particular crops. I mean you can have a generic system, but you do have to identify for the specific crop. But what about the debate of the inspection regime? If you have a successful manufacturing facility, has good manufacturing process, has a food safety plan, has historically been graded at 100 percent, A plus, super duper, five star quality. Do you think it is a good use of our resources to be in there twice a year versus—my issue is if they are a good actor, we ought to incentivize them. And we ought to take the time for the second investigation and go after the bad actors. Could you comment on that?

Ms. DEWAAL. Certainly. The question of trying to create a risk-based inspection system but one that also gives the agency the flexibility to identify the best performers and spend less time and less resource there is one that we have really spent a lot of time looking at. I wish we were dealing with legislation that required six-month inspections. Most of the bills actually are looking at, you know, maybe one year, maybe two years, maybe four years, depending on the type of facility. So there is a broad range of inspection.

But there is one bill that actually provides strict inspection, a risk-based inspection system, but then gives a lot of flexibility to FDA to set alternative inspection frequencies when plants show that they deserve it. And that type of language is contained in Representative DeLauro's bill, the Food Safety Modernization Act.

So the bills range from very general language also to very specific language. Her bill has more frequent inspection frequencies, and maybe, I don't know how the committee would feel about the affordability of some of the inspection frequencies in the bill. But it is a very good model to look at it because it really defines what is risk-based inspection for the agency and then sets these alternative inspection frequencies based on criteria.

Mr. PALLONE. Thank you. Ms. Christensen.

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and I want to thank the panelists for their testimonies and particular for their recommendations.

Some of you have recommended a separate agency, and I will ask. Anyone can answer or all can answer. For those who think we should have a separate agency or for those who don't, do you think it would be just as effective to have just a specific office under FDA with a single head? Would that equate well enough for you?

Ms. DEWAAL. I think I will start this answer. You all are welcome to join in. We have looked at the question of a single agency ranging from a unified agency with all of meat and poultry inspection combined with all of FDA inspection to one that is more narrow.

The approach that we are looking at right now is one which just separates out the food functions at FDA under a separate food standards administration, similar to what they have done in many European countries and in other developed countries around the world.

The food standards agency would be headed by a food safety expert, and we don't have that in place today at FDA. There is no line authority for food safety. The policy issues are handled at CFSAN, the Center for Food Safety and Applied Nutrition. The inspection force is managed by the Office of Regulatory Affairs. The budget comes out of the commissioner's office.

There is really no line authority here, and really there is no risk communicator. When something bad happens, I mean who is going to be on the call? Right now, we hear from CFSAN. We hear from ORA and CDC. So I think there is a structural problem that needs to be addressed at FDA. It is possible that you could have a deputy commissioner for food issues, for example, that might play that role, but it is very important to us that you have someone with direct line authority to the secretary of agriculture.

Just looking at the sister food safety agency for a moment, at the U.S. Department of Agriculture, they did about 10 years ago pass a law that required food safety to be headed by an undersecretary of food safety, and that person does have direct line authority to the secretary of agriculture.

So our concern about some kind of deputy commissioner model is that you would still have everything going through the commissioner who has just an incredibly large job for consumer protection today.

Mr. HUBBARD. I will give it a shot too. I have spent some time over the years thinking about that. It may be necessary to do that at some point, but if we could wave a magic wand right now and create a single food agency, tomorrow nothing would be any different because you would still have an under-resourced, under-authorized agency that couldn't solve these problems. So I think you are doing the right way which is fix the underlying problem. Then go back and see if the structure can work with that and be effective. And if it is not, then I think the next step would be to look at a single agency.

Mr. STENZEL. If I may, I think I am going to agree with Caroline on this, that I do think that there is a fundamental problem in the lack of direct food authority within the agency at this point. So I would urge you to think about at least that narrow issue in the current food safety legislation.

Whether is the equivalent of undersecretary of FSIS at USDA I think is a good one. We have to untangle food authority from everything else within FDA.

Ms. CHRISTENSEN. Thank you. I came from the Committee on Homeland Security, and, of course, there as well, food security is also a major concern. And the way the system is today, I don't have any degree of comfort that if the terrorists wanted to do something to our food system that they would have any problem. I was noting that then Secretary Tommy Thompson had raised that concern, and he remarked that he couldn't understand why terrorists had not attacked our food supply because it was so easy to do.

But your recommendations talks about preventing contamination at the production, at the storage and transportation lines. Do you feel that the recommendations that you are giving us around the food safety system now are adequate also for protecting from an attack either from a homegrown or outside terrorist?

Mr. HUBBARD. Well, the principles are the same because you would analyze the risk and how easy it would be, say, to introduce a microbial agent into food and then have it, you know, be shipped around to a lot of different places and injure a lot of different people. So you still would be looking at well, how accessible is my facility? Might be as simple as making sure there is a security guard every night and the doors are locked. And of course, in other areas, it might need to be more sophisticated than that.

Mr. PALLONE. Mr. Gingrey.

Mr. GINGREY. Thank you, Mr. Chairman. A couple of weeks ago when we were having a hearing about the salmonella outbreak, unfortunately from the processing plant in my home state of Georgia down in southwest Georgia. The testimony told us that the labs, these private labs that the processing plant contracted with to check for salmonella, apparently there were several positive results, and then finally one negative. And you know the rest of that story.

But the question I want to ask of the entire panel is what came up during that hearing. The fact that the labs were not required, maybe even prohibited, as I understood it, from sending that positive information to anybody else except from whence it came, from who they were contracted with to do the laboratory testing, and it just seemed to me that it would be fairly easy to get that information to the FDA. Computers allow us to do that.

I would like to ask the entire panel in fact what your thoughts are in regard to these positive results from the private labs actually being required to submit those to the FDA. And we will start from my left, your right.

Ms. DEWAAL. Thank you. The facts situation that was outlined in that committee hearing was just tragic, and I think the committee did a tremendous service to get those facts out. The mandatory requirement for labs to report would—it looks like an appealing solution because they are the ones doing the test. But we have real concerns that if you don't couple any mandatory testing reporting with a requirement to test, then the result will be, as Mr. Hubbard said, that companies just won't test.

So you need to have in the legislation the ability for FDA to say for peanut processors, you might have to test for this pathogen or that indicator organism, and then determine when those test results would be appropriate. I do think that there are some pathogens—botulism is an example—where mandatory reporting by a lab might be appropriate.

But I think the legislation should be clear that FDA has the authority to require companies to test. They should be able to test their test records when they inspect the plants, and that means anybody, the Agricultural Department of Georgia or the FDA. And then on certain pathogen combinations that, in fact, it would be open to mandatory testing either by the plant or by the lab.

Mr. HUBBARD. Mr. Deal touched upon that earlier. Certainly it would be important if FDA went to a facility like PCA and was doing an inspection and identified PCA as a source of a problem, that they should be able to say as part of their inspection process have you done any lab testing? And if the answer is yes, could we see that so we could see what you knew and when you knew it?

But to require all labs to automatically send information to the FDA could actually cause people to stop doing the testing, which would not be an outcome that I think most people would want. I think Ms. DeWaal sort of——

Mr. GINGREY. But as Ms. DeWaal said, FDA certainly could require in certain commodities at——

Mr. HUBBARD. In certain commodities.

Mr. GINGREY [continuing]. Certain steps in the process——

Mr. HUBBARD. Yes.

Mr. GINGREY [continuing]. That the testing be done for particular pathogens, and that could be a requirement.

Mr. HUBBARD. And that might be necessary in some cases. That is right.

Mr. COLE. I would agree with those comments. I think this is a situation where given, you know, this is not the first outbreak we have had with peanut butter. We had one two years ago. There have been outbreaks overseas. I think we should be viewing this product as a high-risk product. We should have a requirement to test and a requirement to report those tests. I think also we need to have preventative controls in place to prevent contamination. Once salmonella is in that product, it is very resistant, oK, to heat processing et cetera. So we need suppliers or companies buying that product too should have, you know, really done a better job in supplier assurance of that product rather than just looking at test results as well.

Mr. STENZEL. I think we share a pretty common view on the panel, particularly the access to those test records is the most critical aspect. I share the same concern in terms of required every single test to be automatically forwarded to FDA. I am not sure that that is the most effective answer for a company that deliberately retested and retested until they found something they wanted.

That is criminal behavior, and no matter what standard we would put in place, I am not sure we are going to prevent someone who does that. They would not send the results——

Mr. GINGREY. Yes, agreed. In that situation, it wouldn't have made a difference.

Mr. STENZEL. But the access to the records I think is absolutely critical.

Mr. GINGREY. Thank you, Mr. Stenzel. Mr. Lugg? Your microphone is not on.

Mr. LUGG. I am sorry. Because we are in the fresh business, and the difficulty we have in collecting a representative sample, we rely so heavily on prevention that we just have a lot of lab results from our agricultural fields. We do have a program of what we call intelligent testing, and we do share those results routinely with researchers and our California Department of Public Health.

As far as a requirement to furnish test results, I think that might discourage people from actually getting tests done and might in the end result in not the result that you would like.

Mr. PALLONE. We have to move on. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. I want to elaborate on some of the points Mr. Gonzalez raised. We have learned at numerous hearings the foods program at FDA has been starved for re-

sources over the years and, Mr. Hubbard, in your testimony, you state there are currently 150,000 registered facilities in the U.S. And the charts you provided us today on the plummeting numbers of inspections in the U.S. paint a stark picture of the effects of this loss of resources, and that has a real impact on food safety.

But the problem doesn't stop there. We are all acutely aware of the fact that we now have an increasingly globalized food market. We import foods from all over the world, apparently more than 200,000 registered foreign food facilities. How much does each inspection cost? Do you have any kind of estimate you can give?

Mr. HUBBARD. Domestic inspection or HACCP inspection can be around $3,000 and regular sanitation GMP inspection can be around $2,000. So they are not cheap.

Mr. WAXMAN. Well, if we are talking about having FDA inspect over 360,000 facilities with some regularity, that is an overwhelming task in terms of the workload, and it will obviously cost a great deal.

I have heard many suggest that the answers to extend FDA's workforce by supplementing it with private inspectors working on behalf of FDA, but I want to raise some concerns about that. There was a recent article in "The New York Times" that raised problems with these private inspectors. They say that food company being inspected often hires and pays for its own private inspector creating a conflict of interest, how those private inspectors frequently did not catch the problems at plants, whose products later sickened consumers.

And some of those companies who later were found to have contaminated products were even given excellent or superior or ratings. That was the case with both PCA peanut outbreak and with the children's snack Veggie Booty in 2007.

So in some ways, I am even more concerned about the notion of relying on private inspectors in foreign countries. Obviously the primary reason domestic companies want to import from other countries is that these products are less expensive. And the reason they are less expensive is usually that they are not produced under strong food safety protection. So relying on third parties in those countries raises some serious questions.

My fundamental concern with a third-party system for imported foods governed by FDA is that it still puts a huge burden and responsibility on FDA. I think that a company benefiting from the importation of cheaper products and ingredients should have a duty to check up on these foreign companies and be held accountable when there are failures.

Indeed, some companies are already doing very thorough inspections of their foreign suppliers on their own. Do you agree that a company should have a responsibility to check on its own suppliers? And if we are forced to rely on third-party private inspectors, what sort of protections do you think can be put into place to address some of these concerns?

Mr. HUBBARD. Yes, Mr. Chairman. You have touched upon a very important issue, and it may be your single hardest policy choice in this debate because you are absolutely right. The third-party system has not proven itself to be working properly now. It clearly is

not working. FDA does believe that there are ways of beefing up that system——

Mr. WAXMAN. Don't pay attention to that.

Mr. HUBBARD [continuing]. With prohibitions against conflict of interest, with better training, with FDA audits behind them. The fundamental dilemma is you can never have enough inspectors to go to 316,000 facilities of FDA inspectors. But on the other hand, these third-party folks need to be under a very serious regimen of oversight, and I do think that your question about having the importers, the U.S. importer bear more responsibility for the quality of the product they are buying from, say, China is an important piece of it.

And, in fact, the major food companies are beginning to acknowledge that they need to do that, that they need to know who they are buying from and what their quality is. And if they don't know that, they should not be buying from that foreign firm.

Ms. DEWAAL. Thank you.

Mr. WAXMAN. Do you want to add anything to that?

Ms. DEWAAL. I do. The concept you have laid out in terms of having the company take more responsibility works well when you are dealing with ingredients. But, sir, it doesn't work so well when you are dealing with whole foods. There are a lot of foods that come in a port of entry and go directly into retail. And who is going to be that importer of record becomes a real issue because it is defined today in regulations. But it could give rise to some fly-by-night situations.

Mr. WAXMAN. Well, we have to look at these concepts carefully because we can't afford all the inspectors that we think we are going to need, and I don't know that we can rely on all those third-party inspectors either to feel that we are being protected.

I see my time has expired, and other members are waiting for their turn. So I will yield back the time I have overdone.

Mr. PALLONE. Thank you, Chairman Waxman. I am going to ask Mr. Sarbanes to ask questions, and then that will be it before the votes. We have three votes, a 15, a 5, and a 5. So we will ask you to stay so we can continue with questions. So we will do Mr. Sarbanes, and then we will come back for the rest of the members.

Mr. SARBANES. Thank you very much, Mr. Chairman. Thank you all for your testimony. I was particularly interested in the discussion about consumer confidence and how difficult it is going to be to restore consumer confidence. And I take it that, if I am hearing the discussion properly, even with the best food safety regime in place, there is still going to be outbreaks, right? So if you link your bid to boost consumer confidence to the notion that you would prevent outbreaks, that is sort of a dead-end aspiration.

So it really comes then, I would imagine, the thing that is going to bolster consumer confidence the most effectively is a rapid response when there is—because that is the high profile incidences, right, that occur? Otherwise it is like oxygen. You are not going to notice it, right, if things are working well. So it is when there is an outbreak that you have a rapid response, that you have the traceability opportunities and so forth. And you show the public that you can quickly isolate it, you know, within hours, within days, whatever is feasible to do with a good safety regime. And

then they come away from the experience saying, you know, the cop is on the beat. This is being handled, and, you know, we are protected.

And I would just like to get your reaction to that. And maybe there is other leverage points to help with this consumer confidence question, but it seems to me that is probably one of the most obvious. Yes, Ms. DeWaal.

Ms. DEWAAL. Thank you. You are right that we are always going to have outbreaks. The issue is how many and how big are they. The bills that you are considering address both ends. If we can prevent the problems from occurring, then the number of outbreaks will be reduced. If we can increase the traceability, the ability to find the contaminated product, then we are going to reduce the size of those outbreaks.

So I think there are components that address both of those issues, but I think they are both essential.

Mr. SARBANES. Any other comments? Yes?

Mr. HUBBARD. I would like to make the point, Mr. Sarbanes, most of my career at the FDA, Roper and Washington Post and Harris polls showed FDA with the second highest consumer confidence in the entire—among all civilian agencies, next to the National Park Service. But since, 2000, that has reversed.

Mr. SARBANES. Um-hum.

Mr. HUBBARD. It used to be around 70 percent confidence level. Now it is around 30 percent. That is a tremendous reversal that I think reflects the kind of concern you are talking about because when FDA can't find the source of these things quickly and then stamp them out, get the food out of the commerce, then I think the public just feels their government is not serving them well.

So the speed at which outbreaks can be responded to and stopped is absolutely important. But that will require more than FDA.

Mr. SARBANES. Right.

Mr. HUBBARD. You have the CDC component, and then the state health departments are a big piece of that.

Mr. SARBANES. Let me ask a question about the deterrent effect because you all have alluded to this. And I am just curious now where the number of inspections relative to the number of facilities and so forth is so low. I mean is there an operative deterrent effect at the current time, or not really?

Mr. HUBBARD. I actually tracked that a few years back. As the inspections went down, the recalls went up. And the adverse findings from the FDA inspections that did get done went up. So in other words, as inspectors disappeared, the vigilance in the firms disappeared with them.

Mr. SARBANES. Right.

Mr. HUBBARD. So I think the fact that they think FDA might come helps, and the fact that, you know, FDA won't come now is clearly not helpful.

Mr. SARBANES. Well, and I imagine there is a sort of tipping point that you have to get past to create an effective deterrent in this process. I have no further questions. Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you. So we are going to break. We have three votes. Should be back in about half an hour, but we will come

right back and finish with the rest of the members. Committee stands in recess.

[Recess.]

Mr. PALLONE. If I could ask the panel to take their seats again, and thank you. And our next member for questions is the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman. To the panel, just as folks all across the country would be surprised that FDA does not have mandatory recall authority, I think they would also be quite surprised that the FDA does not have the authority to fine bad actors.

Has this always been the case? Compare that to other agencies that have that authority to institute civil monetary penalties and then if you would provide a recommendation on what you think an FDA reform food safety bill should contain.

Mr. HUBBARD. I will give that a shot if I may. If you line up the various authorities of agencies all across government, the newer agencies tend to have a much broader range of authorities, such as civil money penalty and subpoena authority.

FDA is one of the oldest agencies, and it was created in 1906. And at the time, it was believed that the way to enforce the law is to put the owner in jail if he sold a bad food. But, you know, you are not going to put the Kraft CEO in jail because one of his firms made a little mistake. And to enjoin the company that is making the food, which is a good thing, and seize the food if it was considered adulterated.

But it did not give FDA these more modern tools that provide them more leverage. So, for instance, civil money penalties, the industry won't like, but it is a nice intermediate tool to say OK, tomorrow it is going to cost you $1,000. And if you don't fix it, it might cost you $2,000. And finally they will fix it.

And those kind of flexible tools have been shown to be very helpful for FDA in other contexts such as medical devices where it does have that authority.

So I absolutely encourage you to look at the modern toolbox that regulatory agencies have and consider giving FDA those tools as well.

Ms. DEWAAL. We strongly agree. There are a whole set of tools, including things like even citizen sue provisions which are used in statutes that have been developed in the last 20 or 30 years. FDA doesn't have any of this capacity. So I think the bill should include updating both the criminal penalty section but also giving this new authority for civil monetary penalties, traceability, and mandatory recall. Thank you.

Mr. STENZEL. Honestly, Ms. Castor, I really don't have the experience to answer the question historically or related to other agencies. I do think some of the civil penalty areas can make sense in this area as well.

Ms. CASTOR. Anyone else? Are any states that you know of, have they adopted their own civil penalties under their state inspection regulatory authority? Do you know? OK, thank you very much, and I will yield back.

Mr. PALLONE. Thank you. The gentlewoman from Ohio, Ms. Sutton.

Ms. SUTTON. Thank you, Mr. Chairman, and thank you for the witnesses for waiting for us. A couple of things very quickly. Mr. Lugg, you made an observation that has been made here in the past in our oversight hearing in which when discussing the concept of required reporting of test results to the FDA, you indicated that that may result in the failure to test and have an opposite effect.

But I have to tell you that after we heard that sort of proffered at the last hearing, I received a lot of feedback, and it was certainly running through my mind, from my constituents who all well, we will fix that. We will just make them test. And so I mean I just have to tell you that in the realm of America, people are like that seems ridiculous to this congresswoman and to the people at least who I heard back from.

So I think we can correct that problem if we need to by mandating the test. And I just appreciate having the opportunity though to address that. The other questions that I have, a lot of you have talked about imports and the complex sort of questions that it creates in ensuring the safety of the process and the food that results on our dinner tables.

Ms. DeWaal and I think, Dr. Cole, you also addressed this issue. And, Dr. Cole, I think, if I am not mistaken—let us see if I can find it—you explained the way that this works under the WTO. And I think that that is really, really helpful because I am not sure that people out and about really understand our limitations on ensuring the safety of imports into this country. That in many ways—and perhaps this is a simplification, and I certainly ask you to explain in more detail—but in summary, when I read your statement about this, in essence we rely on the standards of other countries. Is that sort of an accurate assessment, or would you like to expand on that?

Mr. COLE. I think through WTO, appropriate level of protection is defined by the member, in this case a country, and the regulations are set up to provide a shield, not a sword. So if a country can decide that it is going to have a more stringent standard than the default CODEX standard, it needs to have evidence that its own safety system can meet that standard as well. That is kind of how it works in a nutshell.

So there are frameworks there from CODEX that we can borrow from. There are default criteria that we can use. It doesn't stop us setting our own standard, but we need to be able to show actually that we are meeting that standard for our own public health benefit, if you know what I mean.

Ms. SUTTON. But with respect to the WTO and as things currently exist, you mentioned that the idea of what is considered "reasonable" differs from country to country, and acceptable risk is culturally defined.

And I think that those are important things for the American people to understand when we talk about certainly another subject that is related to this, and that is the way our trade system is working and what kind of exposures we have as a result of some of the policies that we follow. So I appreciate that assessment.

Now, there are so many things that I would to explore more. But, Ms. DeWaal, as you noted in your testimony and we have heard some conversation here today about, the ability to access records

from food manufacturers is now currently found in the Bioterrorism Act of 2002. And, of course, the FDA cannot demand access to food company's records unless they believe that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

And if you could just take this moment to explain how the limitations of working under that framework have resulted in adverse results.

Ms. DEWAAL. Thank you for the question. Probably one of the best examples of the failing of records access when it was needed by FDA was in an inspection of another peanut butter processor. That company, and it was disclosed actually in this committee's investigations, that company found that they had an inspection going on, and the inspector wanted to see the salmonella testing records. But the company itself said well, you have to submit the request in writing. FDA never circled back with that written request, and the company never disclosed those records. Another major multistate recall resulted from peanut butter linked to that company.

It is clear that FDA does not have the record access that it needs under the Bioterrorism Act. So I think it is essential that in any legislation that should emerge from this process that that be fixed. And records access should be tied into this food safety plant. It should be broad. It should go to testing. It should go to processing records and corrective actions. Thank you.

Mr. PALLONE. Thank you. Ms. Eshoo.

Ms. ESHOO. Thanks again, Mr. Chairman, and thank you to the witnesses for your patience and waiting and for the testimony that you have given.

I wanted to highlight something that appeared in the "New York Times" last week, and Chairman Waxman made reference to it. But I want to read this, and with your permission, Mr. Chairman, I would like to place the full article in the record of the hearing.

Mr. PALLONE. Without objection, so ordered.

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

Ms. ESHOO. Thank you. The story starts out "when food industry giants like Kellogg want to ensure that American consumers are being protected from contaminated products, they rely on private inspectors like Eugene A. Hatfield. So last spring, Mr. Hatfield headed to the Peanut Corporation of America plant in southwest Georgia to make sure its chopped nuts, paste, and peanut butter were safe to use in things as diverse as granola bars and ice cream. The peanut company though knew in advance that Mr. Hatfield was coming.

He had less than a day to check the entire plant, which processed several million pounds of peanuts a month. Mr. Hatfield, 66, an expert in fresh produce, was not aware that peanuts were readily susceptible to salmonella, which he was not required to test for anyway. And while he was inspecting the plant to reassure Kellogg and other food companies of its suitability as a supplier, the Peanut Corporation was paying for his efforts."

You can tell where I am going with this. Now, here is a quote. "The overall food safety level of this facility was considered to be SUPERIOR"—that is in capital letters—"he concluded in his March

27, 2008 report for his employer, the American Institute of Baking, which performs audits for major food companies. A copy of the audit was obtained by the "New York Times."

Now, it seems to me we have a big problem here. We know, according to your testimony, what it costs to do inspections. It is not cheap, but it seems to me that outside of national security, there are two major functions the government has—and I have always kept this with me, from local government to the Congress—public health and public safety.

And this issue bears both responsibilities. We are now not only talking about preventing. We are talking about life and death in our system, the American system, that should be the gold standard of the world. So for the record, what I would like to know is do you think that this third-party, these private inspectors are really the best way to go? I mean it said in this article that the contributions of third-party audits to food safety are the same as the contribution of mail order diploma mills to education.

Why don't we start over here? I heard your comments earlier. Why don't we start over here with Mr. Lugg?

Mr. LUGG. Thank you for the question. That is a very good subject that you raise, and that is——

Ms. ESHOO. I know it is, but I want to know what you think of these private inspectors. Do you think they should be retained? Do you think they have a place in the system? Do you think that we can reform it so that private inspectors have to exercise more responsibility? Tell me what you think representing you—who are you representing?

Mr. LUGG. Chiquita Brands——

Ms. ESHOO. Chiquita.

Mr. LUGG [continuing]. International.

Ms. ESHOO. Right.

Mr. LUGG. Our philosophy has been from day one we cannot rely on third-party inspectors.

Ms. ESHOO. Um-hum.

Mr. LUGG. We do believe that there should be in place a system for licensing third-party inspectors, and they should be regularly brought in to keep their licenses in force. And——

Ms. ESHOO. So they are not paid by the very people that they are inspecting? Is that what you are saying?

Mr. LUGG. Whoever pays, I didn't address the payment issue.

Ms. ESHOO. I see.

Mr. LUGG. But I just am——

Ms. ESHOO. Well, how is what you just said, how does it differ from what we have today?

Mr. LUGG. Well, we are very concerned that standards are different depending on the audit firms that do the audit.

Ms. ESHOO. I see.

Mr. LUGG. And if we always go back to the CODEX Almuntarius, which is a fundamental document and auditors are licensed based on their knowledge and so forth of how to conduct inspections, there should be an improvement in the third-party audit, regardless of who pays for it.

Ms. ESHOO. Good. Mr. Stenzel.

Mr. STENZEL. Congresswoman, I would say that private inspectors are an essential and important part of our food safety system today.

Ms. ESHOO. But what I just read——

Mr. STENZEL. Because we have one example where it didn't work——

Ms. ESHOO. But this is—so you think it is the only one?

Mr. STENZEL. I didn't say it is the only one, nor that it is the end of the solution. But private inspection is one way that private sector companies do audit each other, and that is an important part. No one is more concerned than Kellogg in that story that the people they hired to do inspections didn't do an adequate job.

Ms. ESHOO. But where is the safety valve in this, in what you are saying?

Mr. STENZEL. But here is where I think is important when we get to this legislation. Should FDA incorporate third-party private inspectors? And if that becomes the case, then there has to be much more rigorous certification of inspectors.

Ms. ESHOO. So you are acknowledging that there are holes in what the system does now?

Mr. STENZEL. Absolutely.

Ms. ESHOO. Good. All right. Well, at least you are doing that. I am glad. And, Mr. Chairman, I think that when we do a bill, we have to pay a lot of attention to this area. And I think that it is important to have a stand-alone NHHS.

I worry a great deal that what Congress is going to fall back on is what we have done with so many other areas of FDA and fund it through some kind of user fee. And I don't think that is the way to approach this. I think we are skating on very, very thin ice.

I also think that Congress should be taking a look at an overlapping term for the FDA commissioner so that it is never politicized. I think it should be a six-year term and not be subject to the whims of politics that we have seen. That hasn't come up today, but I think there is a lot of work to be done relative to the FDA.

And if we come up with all kinds of reforms but we don't fund what needs to be funded, we are going to be right back here with these good people hearing testimony all over again. So thank you. I was glad to return from the floor. I did want to ask the questions, and I thank the witnesses and the chairman. This is a big issue for us in the country.

Mr. PALLONE. Thank you. Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Mr. Stenzel, I wanted to ask you. With produce in particular, the industry now has the ability to trace produce not just from the field but from the exact part of the field it was planted all the way to the end wherever it is, the grocery store or the restaurant. Correct?

Mr. STENZEL. That possibility exists. It is certainly not in place across the whole industry.

Ms. DEGETTE. But it is done in parts of the industry?

Mr. STENZEL. In some cases, yes.

Ms. DEGETTE. Some companies have instituted voluntary traceability within their companies, correct?

Mr. STENZEL. Absolutely. Many companies are doing that.

Ms. DEGETTE. And, in fact, California has enacted standards that involve traceability, correct?

Mr. STENZEL. Yes, ma'am.

Ms. DEGETTE. And so I guess I am wondering what your industry's view would be if we enacted traceability laws as part of comprehensive food safety legislation?

Mr. STENZEL. I would comment on the whole area. Traceability is an essential part of food safety. I think it is something that we have to look at. I would first ask in the Bioterrorism Act in the one up, one down, I am not aware of any case where FDA has ever cited a company for failure to produce records in an adequate time. So a lot of what we talk about in produce traceability, even last summer's episode was chasing the wrong commodity.

Ms. DEGETTE. Right.

Mr. STENZEL. Not the fact they couldn't trace the tomatoes.

Ms. DEGETTE. Right. Well, we need to fix the one up one down too.

Mr. STENZEL. Right.

Ms. DEGETTE. I think everybody agrees with that. But if we did fix that, we could do traceability.

Mr. STENZEL. On traceability for produce, about 18 months ago, our industry launched an industry-wide initiative to handle bulk produce. If it is in a bag or if it is in a package, you have a UPC code, and it is much more easily tracked. But for bulk produce in cartons——

Ms. DEGETTE. I hope you don't mind if I interrupt you.

Mr. STENZEL. Please.

Ms. DEGETTE. I only have 5 minutes, and the question I asked you was does your industry support traceability?

Mr. STENZEL. We are doing everything we can to implement traceability across the——

Ms. DEGETTE. And would you support it as part of a comprehensive——

Mr. STENZEL. Certainly as part of comprehensive food safety.

Ms. DEGETTE [continuing]. Legislation. Thank you very much. And, Mr. Lugg, what is your view on traceability? Would you be supportive as well?

Mr. LUGG. We certainly are 100 percent supportive, and if you look at any of our packaged salads, you can trace them immediately.

Ms. DEGETTE. Now, Mr. Hubbard, I want to ask you a question about traceability because, as you know, we have discussed this in my legislation. And I have also talked about it with Ms. DeWaal. So you might actually have some input too.

What my traceability legislation says is that the FDA shall develop guidelines for each different industry. Do we have the technology to do that in the different parts of the food industry?

Mr. HUBBARD. I think we do, and in fact, I think the tomato folks showed some of that technology to you last summer. And clearly there is bar code and radio frequency identification technology and others that allow you to track a product all the way back to its origin. And the Defense Department is using it for everything from tanks to nuts and bolts. And so it is becoming widely used anyway.

And I would hope that that might be one avenue for a solution here.

Ms. DEGETTE. This is an issue we started talking about some years ago. And people in the industry didn't think that they could do it. And so they opposed it, but now I call it the salsa fiasco of last year where first we thought it was tomatoes, then jalapenos. And it took months and months. It not only hurt the consumers, it devastated the tomato industry. I think people are now realizing not just the health benefits but the commercial benefits.

Ms. DeWaal, I wanted to ask you a question. I think you talked about this before, and I just wanted to put a little fine point on it. With the peanut problems we have had this year, it seems to me that the types of records production, you would both need to have mandatory inspections of some kind in every industry. And you would also have to have mandatory production of those documents because if you just had mandatory production of the documents without the mandatory inspections, then people might not do the inspections. Is that what you were saying?

Ms. DEWAAL. That is correct. The inspections are an essential part of the enforcement program. This is to prevent outbreaks from occurring. The records production should be part of that, and also mandatory testing for certain pathogens that might be linked to those products. So all of this goes into a preventive approach.

Ms. DEGETTE. Right, because you don't want people to get sick in the first place if possible. I just have one last question for all the witnesses if you can just answer yes or no. Would you support mandatory recall authority for the FDA as part of comprehensive food safety legislation?

Ms. DEWAAL. Yes.

Mr. HUBBARD. Yes.

Mr. COLE. Yes.

Mr. STENZEL. Yes.

Mr. LUGG. And yes.

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

Mr. PALLONE. Thank you. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman, and thanks for allowing me to sit in even though I am not part of the subcommittee. You know my interest in this and in our legislation. The hearing focused today a lot on inspection fees, certifications, even brought up the 6-year term for the FDA commissioner. But no matter what we do in this field, whether it is inspection fees or whatever we are doing, we still have to change the culture of the FDA.

You can have all the laws and all the money in the world, but if we don't have a culture at the FDA that is willing to be aggressive in this area, we are still going to have food-borne illnesses. For instance, we talked a lot about the tomato industry. The tomato industry and members of our Committee on Oversight Investigations repeatedly told the FDA because of the time of the outbreak, the only place that tomatoes could have possibly affected it were from south Florida. South Florida has a very good trace back and certification of their product. So it couldn't have come from the United States.

But what did the FDA do? They still—and if you go to their Web site today—still insist it is tomatoes. They have killed the tomato

industry. Last year, $125 million they lost because the FDA wouldn't listen to anybody. And we find out it is jalapenos out of Mexico. But go to Web site, the tomato industry is still being associated with this outbreak. So I think we need leadership at the FDA, and we haven't had that.

Mr. Hubbard, you said that we can never make food 100 percent safe, and I guess I would tend to agree with you somewhat. And then you said that there are gaps in our food safety system. What are those gaps?

Mr. HUBBARD. Well, principally, it is that the system relies upon this infrequent inspection process and forces FDA to pay got-you or state inspectors, instead of putting the burden on the producer to demonstrate at all times that they are producing a safe food. That is the paradigm shift that needs to occur.

Mr. STUPAK. OK, let me ask you this. Our committee's research has found that more than 10 years ago, recommendations to develop a national food protection training center have been repeated made, yet no action has been taken to date.

More than 8 years ago, the Department of Health and Human Services office of inspector general concluded that an effective food safety system depends on the collective effort and coordination among federal, state, and local levels on government. Yet that same report noted the FDA provides limited training for state food protection professionals, and that states themselves cannot afford the cost of such training.

Nearly 2 years ago, the FDA issued program standards, which requires states to have training plans that ensure all inspectors receive training required to adequately perform their work assignments. Still only a few states have done it. So let me ask do we need a national food protection training center to train state and local inspectors to federal standards, and maybe even these private inspectors we have heard so much about today?

Mr. HUBBARD. I think we do, and in fact, I would urge you to consider in your legislation authorizing or mandating that FDA creates such a thing. I think the Georgia example showed that states were not perhaps up to snuff, and these third-party inspectors, as several members have raised, clearly are not up to snuff either. So that sort of a training academy would, in my view, raise standards for everyone.

Mr. STUPAK. OK, there is some limited training, I know, through University of Maryland, but it is very limited. You don't have to go through it, so we are almost looking like a college curriculum. That is being developed through some legislation. That is why I wanted to ask you that question.

But let me ask you this, and if you know this. What is the current practice? Like take the PCA, Peanut Corporation of America. Georgia and Texas state inspectors inspected it. What happened to those reports? Do they go to the FDA and sit on a shelf or in someone's computer program? Is there an internal audit about what is being done in these inspections?

We heard about Mr. Hatfield from Ms. Eshoo about never inspecting or gave a superior rating. The one in Texas received a very good rating. Is there an internal audit conducted by the FDA

then of these reports that come in? Or do they just sit until something happens? Do you know?

Mr. HUBBARD. Well, there is the paper process that says how it should work, and there is a way it apparently really works. What should have happened in that case is that state inspector should have been trained to an FDA standard, which I gathered didn't happen.

Mr. STUPAK. Right.

Mr. HUBBARD. Then they should have presented the FDA with the findings, but, of course as you know, the state inspector didn't find any problems. So, you know, I suppose you could argue there was nothing for FDA to follow up on.

Mr. STUPAK. But wouldn't the FDA at least have some standards like especially since you had the 97 ConAgra peanut butter outbreak? Wouldn't they at least inspect for salmonella?

Mr. HUBBARD. They did do guidance after that ConAgra example, and the way it works is the FDA actually commissions state officials. So when they go in, they carry two badges, the Georgia badge and the FDA badge. And they are supposed to do the equivalent of an FDA inspection, but that apparently did not happen in this case.

Mr. STUPAK. Correct, because a true FDA inspection takes a little bit of time. I think you indicated $2,000 up to $5,000 for an inspection and more than 8 hours.

Mr. HUBBARD. Yes, on average, an FDA inspection of that nature would take a day to a day and a half, whereas state inspections are often done in a couple of hours.

Mr. STUPAK. So even if these inspectors are trained, certified, everything, you still need an internal audit of what they are doing, or someone at the FDA looking at this to make sure it is being done properly, do we not?

Mr. HUBBARD. I think you are right.

Mr. STUPAK. OK, was there ever internal audits like that of state inspectors on foods? Do you know in your time there?

Mr. HUBBARD. You know, I am sorry. I don't know, but I would hope so.

Mr. STUPAK. Well, I think that is one of the questions in our follow up period that we are having next week is, you know, were there internal audits and what was going on with these things? One more if I may, Mr. Chairman.

Mr. Lugg, you indicated that I think your first priority, you said, when you come to work on food is you select the land and then you watch the water and that. Is that in this country or other countries too? Chiquita bananas come from all over, right? Costa Rica, everywhere?

Mr. LUGG. Yes, our company operates in approximately 70 countries around the world, but particularly in the Fresh Express packaged salads, whether the product is coming from Guatemala, which we have to get our snow peas from in winter months, or down in Chile where get in the winter months. We send our own inspecting staff down to locate the land, and then we use special, global, geospacial technology to make sure that those lots are actually being harvested when they say they were.

Mr. STUPAK. OK, what about the chemicals that they use during the process? Is that all approved by your company?

Mr. LUGG. Those are chemicals that we approve, and then there are samples taken to make sure that they are within the residue limits.

Mr. STUPAK. Thank you, Mr. Chairman.

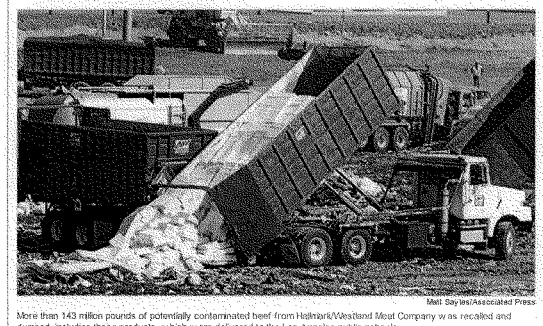
Mr. PALLONE. Thank you, Mr. Stupak. Let me thank the whole panel. I mean we are done with our questions, but, you know, we really do appreciate your input not only today but throughout the process. Mr. Stupak has had hearings and hearings in the full Government Reform Committee with Mr. Waxman. We do intend to move a bill. You know, I this subcommittee, probably our next hearing will be a legislative hearing on legislation that we would move. We are still waiting for the new FDA. I mean there isn't a commissioner. So we would still like to get that input. But, you know, it is our intention to move fairly quickly.

So thank you very much. We appreciate all your input. Without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 1:25 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Food Problems Elude Private Inspectors



Matt Sayles/Associated Press

More than 143 million pounds of potentially contaminated beef from Hallmark/Westland Meat Company was recalled and dumped, including these products, which were delivered to the Los Angeles public schools.

By MICHAEL MOSS and ANDREW MARTIN
Published: March 5, 2009

When food industry giants like Kellogg want to ensure that American consumers are being protected from contaminated products, they rely on private inspectors like Eugene A. Hatfield. So last spring Mr. Hatfield headed to the Peanut Corporation of America plant in southwest Georgia to make sure its chopped nuts, paste and peanut butter were safe to use in things as diverse as granola bars and ice cream.

The peanut company, though, knew in advance that Mr. Hatfield was coming. He had less than a day to check the entire plant, which processed several million pounds of peanuts a month.

Mr. Hatfield, 66, an expert in fresh produce, was not aware that peanuts were readily susceptible to salmonella — which he was not required to test for anyway. And while Mr. Hatfield was inspecting the plant to reassure Kellogg and other food companies of its suitability as a supplier, the Peanut Corporation was paying for his efforts.

"The overall food safety level of this facility was considered to be: SUPERIOR," he concluded in his March 27, 2008, report for his employer, the American Institute of Baking,

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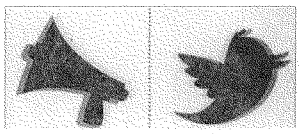

Nicole Bengiveno/The New York Times

A private inspector was given less than a day to inspect the Peanut Corporation of America's plant in Blakely, Ga., which was closed after it was linked to nationwide outbreak of salmonella.

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which performs audits for major food companies. A copy of the audit was obtained by The New York Times.

Federal investigators later discovered that the dilapidated plant was ravaged by salmonella and had been shipping tainted peanuts and paste for at least nine months. But they were too late to prevent what has become one of the nation's worst known outbreaks of food-borne disease in recent years, in which nine are believed to have died and an estimated 22,500 were sickened.

With government inspectors overwhelmed by the task of guarding the nation's food supply, the job of monitoring food plants has in large part fallen to an army of private auditors like Mr. Hatfield. And the problems go well beyond peanuts.

An examination of the largest food poisoning outbreaks in recent years — in products as varied as spinach, pet food, and a children's snack, Veggie Booty — show that auditors failed to detect problems at plants whose contaminated products later sickened consumers.

In one case involving hamburgers fed to schoolchildren, the Westland/Hallmark Meat Company in California passed 17 separate audits in 2007, records show. Then an undercover video made that year showed the plant's workers using forklifts to force sickly cows into the slaughterhouse, which prompted a recall of 143 million pounds of beef in February 2008.

"The contributions of third-party audits to food safety is the same as the contribution of mail-order diploma mills to education," said Mansour Samadpour, a Seattle consultant who has worked with companies nationwide to improve food safety.

Audits are not required by the government, but food companies are increasingly requiring suppliers to undergo them as a way to ensure safety and minimize liability. The rigor of audits varies widely and many companies choose the cheapest ones, which cost as little as $1,000, in contrast to the $8,000 the Food and Drug Administration spends to inspect a plant.

Typically, the private auditors inspect only manufacturing plants, not the suppliers that feed ingredients to those facilities. Nor do they commonly test the actual food products for pathogens, even though gleaming production lines can turn out poisoned fare.

As in the Georgia peanut case, auditors are also usually paid by the food plants they inspect, which some experts said could deter them from cracking down. Yet food companies often point to an auditor's certificate as a seal of approval.

The baking institute, which is based in Manhattan, Kan., and is also known as AIB International, says it inspected more than 10,000 food production sites in 80 countries last year. James R. Munyon, its president and chief executive, said his group's inspections were reliable and tough, no matter who pays for them, but he declined to elaborate on specific audits.

Kellogg officials declined to be interviewed for this article. The company has said it is reviewing its use of private audits, including those by the American Institute of Baking. Kellogg said it required the Peanut Corporation to provide it with annual audits of the Georgia facility. Kellogg has recalled more than a dozen products, including Keebler crackers and Famous Amos cookies.

The retail giant Costco, which had already limited the institute's audits to bakery vendors, has now told suppliers to stop using the group altogether.

Both the food industry and federal officials say they are aware of the problems with third-

party audits. Nonetheless, the F.D.A. has proposed expanding the role of private auditors to inspect the more than 200,000 foreign facilities that ship food to the United States. The agency has proposed a voluntary certification program that would toughen audit standards and alert federal authorities of problems -- an idea that has met stiff resistance from the food industry.

Food safety advocates say that audits can play a useful role in improving sanitation and catching problems. But in case after case, the audits have failed to prevent major outbreaks.

In 2007, Keystone Food Products, the Easton, Pa., plant that makes Veggie Booty, received an "excellent" rating from the American Institute of Baking. But the audit did not extend to ingredient suppliers, including a New Jersey company whose imported spices from China were tainted with salmonella.

As many as 2,000 people in 19 states were sickened, according to federal estimates. The incident prompted the New York company that sells the snack, Robert's American Gourmet, to add its own inspections and regularly test ingredients for contamination.

Even when audits do turn up problems, it is up to the discretion of food companies to fix them.

After Nebraska Beef was linked to an E. coli outbreak in 2006, officials from the United States Department of Agriculture found that the company had not carried out the recommendations of auditors who had identified numerous problems at the plant in the preceding months.

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This article has been revised to reflect the following correction:

Correction: March 7, 2009

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A version of this article appeared in print on March 6, 2009, on page A1 of the New York edition.

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Food Problems Elude Private Inspectors

Published: March 5, 2009

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Nebraska Beef has disputed its culpability in the outbreak, which sickened at least 17 people. A company spokesman said Thursday that the problems identified in the audit had been corrected but could not provide documents to verify that claim.

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Rob Bennett for The New York Times

World Spice in Roselle, N.J., owned by Bela Lowy, supplied a spice powder, imported from China, for Veggie Booty snack chips. The powder turned out to be tainted with salmonella.

Robert A. LaBudde, a food safety expert who has consulted with food companies for 30 years, said, "The only thing that matters is productivity." He added that "you only get in trouble if someone in the media traces it back to you, and that's rare, like a meteor strike."

Dr. LaBudde said a sausage plant hired him five years ago to determine the species of bacillus plaguing its meat. But the owner then refused to complete the testing. "I called them 'anthrax sausages,' and said they could be killing older people in the state, and still they wouldn't do it," he said, declining to name the company.

There are more than 200 companies and numerous independent operators in private food inspection. Few have grown faster than the American Institute of Baking. In addition to the peanut factories, the organization's 120 auditors handle clients who process meat, seafood, vegetables, spices, oils and dairy products.

The baking institute also sells educational services to food industry personnel; the Peanut Corporation of America said some of its employees attended the organization's food safety training classes. Audits provide nearly half the income for the organization, according to tax filings and the organization's Web site.

Mr. Munyon, the organization's president, said its auditors were drawn from industry experts with vast experience in food safety. "AIB emphasizes the educational value of its inspection procedure to the management and employees of the facilities it provides services to," he said.

Mr. Munyon acknowledged that auditors were allowed to solicit contracts from plants that

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they then audited, but said this posed no ethical issues because the auditors were on salary, not paid by commission. Mr. Hatfield first audited the Peanut Corporation plant in Georgia in 2007 after contacting the plant's managers to solicit their business.

The American Institute of Baking's dual role as an educator and inspector troubles some in the food industry, as does its expansion beyond baking audits. Before the salmonella outbreak, Costco had rebuffed repeated proposals by the organization to inspect all its food suppliers.

"The American Institute of Baking is bakery experts," said R. Craig Wilson, the top food safety official at Costco. "But you stick them in a peanut butter plant or in a beef plant, they are stuffed."

Costco, Kraft Foods and Darden Restaurants are among a group of food manufacturers and other companies that use detailed plans to prevent food safety hazards. They also supplement third-party audits with their own inspections and testing of ingredients and plant surfaces for microbes.

The American Institute of Baking was not alone in missing the trouble at the Peanut Corporation plant in Blakely, Ga. State inspectors also found only minor problems, while a federal team last month uncovered a number of alarming signs, as well as testing records from the company itself that showed salmonella in its products as far back as June 2007. Federal health officials say there are now 677 officially reported cases of salmonella poisoning in the outbreak, which reflects only about 3 percent of the total number of people sickened.

But the baking institute's private audit of the peanut plant had particular heft in assuring food makers that the processed peanuts were safe. Plant workers, in interviews with The Times, also cited the audits' findings when asked why they did not pursue their own concerns about the plant.

Another audit of the peanut plant, by the Michigan-based NSF Cook & Thurber, raises further questions about the usefulness of private audits. That audit found nearly two dozen problems that it characterized as "minor," but it nonetheless gave the peanut plant an overall score of 91 out of 100.

NSF officials said that for their audits, this was a low score. But the company that paid for the audit, the insurance giant American International Group, then sold the peanut company insurance to cover the costs of recalling products, according to lawyers for the Peanut Corporation.

Mr. Hatfield, who audited the peanut plant for the American Institute of Baking, referred questions to the organization, which said he "is degreed in biology" and "trained to do the job." In auditing the Blakely plant last March, Mr. Hatfield became concerned about his ability to check the plant thoroughly and asked for more than the one day allotted, according to people familiar with the audit. The Peanut Corporation agreed to pay for the additional time, but only in future audits, according to those people.

Mr. Hatfield checked to see that the plant had a system in place to test its products for contamination, but the audit indicated that he did not ask to see any test results for salmonella and therefore did not know that the plant had found the bacteria.

"I never thought that this bacteria would survive in the peanut butter type environment," Mr. Hatfield wrote to a food safety expert on Jan. 20, after the deadly salmonella outbreak was made public, according to a copy of his e-mail message. "What the heck is going on??"

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