HEARING TO REVIEW FOOD SAFETY STANDARDS FOR HORTICULTURE AND ORGANIC AGRICULTURE

HEARING

BEFORE THE

SUBCOMMITTEE ON HORTICULTURE AND ORGANIC AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES

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SUBMITTED MATERIAL

HEARING TO REVIEW FOOD SAFETY STANDARDS FOR HORTICULTURE AND ORGANIC AGRICULTURE

THURSDAY, MAY 14, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HORTICULTURE AND ORGANIC AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10:05 a.m., in Room 1300 of the Longworth House Office Building, Hon. Dennis A. Cardoza [Chairman of the Subcommittee] presiding.

Members present: Representatives Cardoza, Massa, Costa, Schrader, Murphy, Peterson (*ex officio*), Schmidt, and Lummis.

Staff present: Alejandra Gonzalez-Arias, Keith Jones, John Konya, Scott Kuschmider, John Riley, April Slayton, Rebekah Solem, Patricia Barr, John Goldberg, Pam Miller, Pete Thomson, and Jamie Mitchell.

OPENING STATEMENT OF HON. DENNIS A. CARDOZA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

The CHAIRMAN. Good morning. I would like to call this hearing of the Subcommittee on Horticulture and Organic Agriculture to review food safety standards for those two areas, and this hearing will now come to order.

I would like to thank you all for taking time from your busy schedules to attend today's hearing of the Subcommittee. Today we will review the current strategies and standards used by the horticulture and organic sectors to prevent, monitor and control potential food safety hazards.

This is the third hearing the Committee on Agriculture has held to help our Members gain better understanding of how to move forward on improving and modernizing the current food safety system. Maintaining the integrity of our nation's food supply is a paramount concern of mine, not only as the Chairman of this Subcommittee, but as a consumer and as a father.

In America, we spend over $1 trillion every year on food both at home and in restaurants and we place our faith in food processors, producers, retailers and the Federal and state regulators to ensure those products are safe to consume. While consumers must play an active role in food safety efforts to handle products properly and to prevent cross-contamination, without strong controls throughout the system, consumers can fall victim to foodborne illnesses from

unexpected sources; as we have seen with the recent disease outbreaks caused by peanut products and there was the tomato and then there was—well, it wasn't tomatoes, it was peppers instead.

I believe that it is safe to say that, in general, we have the safest, highest quality food supply in the world. However, there are times when the system fails. Part of the problem may be that there are currently 15 different agencies tasked with monitoring the safety and security of our food supply. From the Food and Drug Administration to the Department of Agriculture and to the National Oceanographic and Atmospheric Administration, there are multiple agencies with various requirements for different food products that all share in the responsibility for food safety. Each year, thousands of Federal employees, most of them at USDA, inspect, verify and approve products at multiple points in the food distribution chain. However, when the system fails, consumers' confidence in the food supply suffers. Furthermore, the impact on farmers and processors, who often have nothing to do with the problem, are often unable to recover from the financial strains of severe market disruptions caused by these outbreaks.

In 1998, the Food and Drug Administration issued fresh produce safety guidance. However, this guidance does not have the force of law, FDA has failed to meet its goals it set for itself for food safety inspections, and has not adequately supervised the states that do most of the inspection on behalf of FDA. Over the past 11 years, faced with weak guidance and safety standards, private stakeholders have stepped in using their own resources to fill this void. Following a number of financially devastating disease outbreaks, many in the fresh fruit and produce industry have created their own food safety standards and enforcement mechanisms. Their actions should serve as a model to other food industries that have not engaged proactively in food safety efforts.

Shortly after the spinach crisis, the affected industries in California organized the California Spinach and Leafy Green Marketing Agreement which licenses first handlers to certify compliance with best management practices for fresh produce. Last year in Florida, the state implemented guidelines for fresh tomato supply chain and tomato best practices. These efforts are a solid first step towards commodity-specific risk and science-based standards to assure consumers of the safety of domestic produce.

But food safety standards for fresh produce should not be limited to just leafy greens and tomatoes. Instead, these concepts, if proven to be effective, should serve as a nationwide model for improving food safety. I am pleased to have Joe Pezzini, Vice President of Ocean Mist Farms and Chairman of the Leafy Green Marketing Agreement, and Ron Ratto here to discuss food safety standards and protocols included within the California agreement.

While examining the food safety needs of horticulture or the specialty crop sector, Congress must recognize that one standard does not fit all. The unique risk profiles of tree fruits and other producers must be recognized. Indeed, the old saying that you can't compare apples to oranges is most appropriate when discussing food safety. The unique nature of the organic sector with its existing Federal Government-sanctioned third-party certification also has its own story to tell. Today we will also have the opportunity

to examine the role of third-party audits and how those audits play into assuring compliance with food safety standards, such as Good Agricultural Practices and Good Manufacturing Practices, in a wide range of products under varying conditions.

Overall, I believe consumer confidence in fresh produce is growing and is stronger than ever. Americans recognize and appreciate the benefits of fresh fruit and vegetables in their diets, and have recognized the efforts of the regulators and industry to correct the flaws in the food safety surveillance system. But unfortunately, it will only take one incident to break down this progress and move us back to square one and revive unproven fears that our food supply is susceptible to dangerous pathogens. As the Administration and Congress begin to identify administrative, regulatory and legislative changes to strengthen the nation's food supply, I remain extremely concerned that our food safety oversight must firmly reside in an agency that understands agriculture and the supply chain. That it leads to a better understanding, generally, with regard to food safety. A patchwork arrangement of multiple agencies leading to a systemic lack of responsibility over the safety of food supply is intolerable. However, tasking the wrong agency with food safety oversight responsibilities is just as bad. I am anxious to hear from our Federal witnesses about the capacities, capabilities and cultures of their respective agencies in understanding and working with the nation's food producers.

In closing, every individual within the food supply chain from farm to fork has the responsibility to do their part to ensure that food served on America's dining tables is safe, wholesome and the best that it can be for the American people. We in Congress are committed to doing our part to oversee and direct the Federal efforts to improve food safety. I thank all of our witnesses for taking the time to appear before this panel today and for their efforts.

[The prepared statement of Mr. Cardoza follows:]

PREPARED STATEMENT OF HON. DENNIS A. CARDOZA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Thank you all for taking time from your very busy schedules to attend today's hearing of the Subcommittee on Horticulture and Organic Agriculture. Today the Subcommittee will review the current strategies and standards used by the horticulture and organic sectors to prevent, monitor and control potential food safety hazards. This is the third hearing the Committee on Agriculture has held to help our Members gain a better understanding of how to move forward on improving and modernizing the current food safety system.

Maintaining the integrity of our nation's food supply is a paramount concern of mine, not only as the Chairman of this Subcommittee, but as a consumer and as a parent. In America, we spend over $1 trillion every year on food—both at home and in restaurants—and we place our faith in food producers, processors, retailers, and Federal and state regulators to ensure those products are safe to consume. While consumers must play an active role in food safety efforts to handle products properly and prevent cross-contamination, without strong controls throughout the system, consumers can fall victim to foodborne illness from unexpected sources, as we've seen with recent disease outbreaks caused by peanut products and pistachios.

I believe that it is safe to say that in general, we have the safest, highest quality food supply in the world. However, there are times when the system fails. Part of the problem may be that there are currently 15 different Federal agencies tasked with monitoring the safety and security of our food supply. From the Food and Drug Administration to the Department of Agriculture to the National Oceanic and Atmospheric Administration—there are multiple agencies with various requirements for different food products that all share in the responsibility for food safety. Each

year, thousands of Federal employees—most of them at USDA—inspect, verify and approve products at multiple points in the food distribution chain.

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In 1998, the Food and Drug Administration issued fresh-produce safety guidance. However, this guidance does not have the force of law, and FDA has failed to meet the goals it set for itself for food safety inspections and has not adequately supervised the states that do most inspections on behalf of FDA.

Over the past 11 years, faced with weak guidance and safety standards, private stakeholders have stepped in, using their own resources to fill this void. Following a number of financially devastating disease outbreaks, many in the fresh produce industry have created their own food safety standards and enforcement mechanisms. Their actions should serve as a model to other food industries that have not engaged proactively in food safety efforts. Shortly after the spinach crisis, the affected industries in California organized the California Spinach and Leafy Green Marketing Agreement, which licenses first handlers to certify compliance with Best Management Practices for fresh produce. Last year in Florida, the state implemented guidelines for the fresh tomato supply chain and tomato best practices. These efforts are a solid first step toward commodity specific, risk and science based standards to assure consumers of the safety of domestic fresh produce. But food safety standards for fresh produce should not be limited to just leafy greens and tomatoes.

Instead, these concepts, if proven to be effective, should serve as a nationwide model for improving food safety. I am pleased to have Joe Pezzini, Vice President of Ocean Mist Farms and Chairman of the Leafy Green Marketing Agreement, and Ron Ratto here to discuss the food safety standards and protocols included within the California Agreement.

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Overall, I believe consumer confidence in fresh produce is growing and stronger than ever. Americans recognize and appreciate the benefits of fresh fruits and vegetables in their diets and have recognized the efforts of the regulators and industry to correct flaws in their food safety surveillance. But unfortunately, it will only take one "incident" to break down this progress, move us back to square one, and revive unproven fears that our food supply is susceptible to dangerous pathogens.

As the Administration and Congress begins to identify administrative, regulatory and legislative changes to strengthen the nation's food supply, I remain extremely concerned that our food safety oversight must firmly reside in an agency that understands agriculture and the supply chain that leads to the dinner table. A patchwork arrangement of multiple agencies leads to a systemic lack of responsibility over the safety of the food supply. However, tasking the wrong agency with food safety oversight responsibilities is just as bad. I am anxious to hear from our Federal witnesses about the capacities, capabilities and cultures of their respective agencies in understanding and working with the nation's food producers.

In closing, every individual within the food supply chain, from farm to fork, has a responsibility to do their part to ensure that food served on American's dining tables is safe and wholesome. We in Congress are committed to doing our part to oversee and direct Federal efforts to improve food safety, and I thank all of our witnesses for taking the time to appear before this panel today to help us in that effort.

The CHAIRMAN. I would like to now introduce my Ranking Member of the Committee, Mrs. Jean Schmidt, and Jean, would you please proceed to make your opening statement?

OPENING STATEMENT OF HON. JEAN SCHMIDT, A REPRESENTATIVE IN CONGRESS FROM OHIO

Mrs. SCHMIDT. Thank you, Mr. Chairman, and thank you for holding this hearing as part of the Committee's series on food safety hearings. In my role as Ranking Member of the Horticulture and Organic Agriculture Subcommittee, I look forward to working with you and other Members as we examine this issue and any other issues that need our attention.

This morning the Subcommittee will consider issues associated with the safety of fresh fruits and vegetables. I want to personally thank all of our witnesses for being here today to give us your insight. I am sure that every Member and witness will agree the United States enjoys the safest, highest quality, most abundant, affordable and diverse food supply in the world. However, the recent foodborne illness outbreaks involving *Salmonella* in serrano peppers last year, the peanuts processed by the Peanut Corporation of America, and most recently pistachios and raw alfalfa sprouts have caused concern among constituents about our food safety regulatory system.

I think it is useful for us to review the current system to better understand what changes may improve food safety and restore consumer confidence *versus* those changes which are unnecessary and unscientific and impose regulatory costs and burdens. As Members of the Agriculture Committee, we must ensure that any proposed legislation does not hinder the ability of our producers to continue to provide our consumers with a safe and plentiful food supply. I know many producers in my state have concerns about the FDA regulating on-farm activities. I share these concerns based on the recognition that while the FDA has vast expertise regulating food processing, the agency has limited expertise or infrastructure to fairly and effectively regulate farm production practices. While one agricultural sector or region of the country may believe the FDA regulation is the right approach for their business, another sector or region may have a completely different view. A one-size-fits-all regulatory approach may work for processing, but given the diversity in crops, geography, climate and many other differences, it is simply wrong to believe that this approach would work in regulating on-farm production practices.

I am very pleased that Steven Hirsch from Chillicothe, Ohio, will be ale to testify this morning. Mr. Hirsch grows a variety of fruits and vegetables in Ohio, and I know he will be a great voice for Ohio's produce industry.

Mr. Chairman, while I know your home state is the largest producer of specialty crops, I am sure you are aware that we also grow specialty crops in Ohio. I want to thank you for allowing us to hear from other regions of the country to ensure a balanced approach to what the needs are of all the growers across the country large and small; from those selling in major retail outlets to those selling on local farm markets. I know this is a busy time of year for our producers in Ohio. Thankfully it is raining today. And I greatly appreciate Mr. Hirsch in taking the extra time to join us today.

I look forward to today's discussion. I am going to be brief so that we can get started. I hope this hearing will give us a better understanding of what, if any, changes may be needed to keep our food

safe. Thank you, again to all the witnesses that are here for joining us, and thank you, Mr. Chairman, for holding this timely hearing.

The CHAIRMAN. Thank you, Mrs. Schmidt. I am very pleased that you can be with us today and welcome to the ranking membership on our Committee.

I would like to now recognize the other Members of the Committee who would like to make brief opening statements. I would also like to mention though that I have been told that votes are imminent at any minute, and we are going to have to suspend the hearing during the votes. So, anyone who would make their statements brief, we would like to get into the testimony if possible before we break for votes. Any Member who would like to be recognized this time is welcome. Mr. Costa.

OPENING STATEMENT OF HON. JIM COSTA, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Mr. COSTA. Thank you very much, Mr. Chairman. I too want to commend you for holding this hearing. It is a part of the critical debate, I believe, this year as we look at how we improve food safety in America as the Energy and Commerce Committee is contemplating several pieces of legislation by the Chairman, by former Chairman Dingell, Congresswoman DeLauro and Senator Durbin on the Senate side. You and I have introduced legislation, H.R. 1332, that also attempts to, we think, bring an important perspective in terms of how we approach food safety in our country.

Certainly, horticulture and specialty crops have unique challenges as we deal with the question of food safety. I think, as you have indicated and the Ranking Member, we believe that food produced and processed and consumed in America is among the safest of food products anywhere in the world, but that doesn't mean that we can't improve. That doesn't mean that in the past that we have not had contamination issues that we have had to deal with, whether they be *E. coli* or *Salmonella* or other factors.

I just want to make a couple of quick points as we discuss and listen to the witnesses both on the first panel and the second panel. You and I have witnesses on the second panel that are particularly involved and experienced with the California experience. Along with Florida, and a number of other states, they have among the highest standards anywhere in the country, and therefore anywhere in the world. But I think as we discuss this very, very important issue of food safety, we need to remind ourselves of several factors.

First of all, American farmers and producers of food are consumers. They consume the food products that they grow, so they have a direct focus to make sure that they eat the very best food that they produce as do their families, their friends, their neighbors, and their employees. So it is illogical to think that people that produce this food would somehow be careless about that safety factor. In addition to that, guess what happens if in fact you have a contamination problem, as took place last year as you noted with the issue of what was first thought to be contaminated tomatoes, which later turned out to be jalapeño peppers imported from Mexico. It dropped the bottom out of the tomato market. Anyone who produces food knows that any time you have a potential contamina-

tion, it will dramatically impact their market. Therefore, they have not only their personal interest to make sure that they produce the very safest food possible, but they also have an economic interest to make sure in fact that that takes place.

So as we discuss this issue, I am going to be looking forward to the panel testimony, both in the first and the second panel, of looking at risk assessment *versus* risk management, how do we do that best to improve our safety standards, to have the best gold standard in the country that is uniform, and not only is uniform but by the same token requires that any food that is imported to America meet the same standards that we do, as we intend to raise the bar.

In addition, I think that it is important that we understand that there are differences. There are differences between how you apply best management practices on the farm whether it is products that are grown above the ground, *i.e.,* permanent crops, citrus products, pistachios, walnuts, almonds, *versus* products that are grown in the ground, leafy greens, carrots, potatoes, those things. In addition, there are also distinctions between how that product is grown and harvested and then processed. It is much more controllable to deal with safety standards as food is being processed than when food is being harvested. So one size doesn't fit all as we try to increase and improve the safety standards.

Let me close by making two other points that I think are critical in this discussion and in this debate: traceback, otherwise known as the ability to track potential products that are contaminated. American agriculture has made amazing strides in this effort. We can, whether it is tomatoes or oranges, within hours—if there is a potential concern or a contamination—traceback from the product that is in the grocery store to where it was processed, at what plant, in what orchard it grew in. I mean, we will be able at some point in time to be able to determine which tree that orange came from. So the ability to use best science and best traceback abilities has made phenomenal progress on a whole host of American products, fruits and vegetables that we grow.

Now, one of the key issues as we improve food safety standards, and the Chairman mentioned this, the 13 agencies that are overlapping, that are cumbersome, that make it difficult to really do the better job that we need to do, is who is going to pay for this. We certainly need to improve the ability to monitor and to ensure consumer protection. However, the new Administration has provided additional funding to the Food and Drug Administration. That is good. We also need to figure out where the hand-in-glove operation is between the United States Department of Agriculture together with the Food and Drug Administration. That relationship, in the past, oftentimes has been lacking. We heard yesterday from the White House summit that they want to do a better job of coordinating their efforts between Secretary Vilsack and Secretary Sebelius. That is a good thing, but we need to ensure that when they do this that they understand that farmers are price takers and not price makers.

Therefore, as we try to develop an improved and more robust food monitoring effort to protect consumers in America and when we export our products, that the ability to ensure that farmers have the ability to deal with those costs if they are increased can

be done in such a way that they don't have to take the brunt of those additional costs.

Those are the key areas I think we have to deal with, Mr. Chairman. I look forward to your active involvement. I know you are passionate about this subject matter as am I, and obviously we have some work to do as this larger debate continues. Thank you.

The CHAIRMAN. Thank you, Mr. Costa. I appreciate your comments.

I would like to welcome one of our newest Members to the Committee, Mr. Schrader. You can't say that you are the newest Member anymore because there are several others that just joined us today, but as they come in I will introduce them. Thank you for being here with us. I understand you are giving up your right to make an opening statement and we will let you ask many questions as the hearing goes forward. The Chairman requests that other Members submit their opening statements for the record.

[The prepared statements of Mr. Peterson and Mrs. Lummis follow:]

PREPARED STATEMENT OF HON. COLLIN C. PETERSON, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Thank you, Chairman Cardoza, for holding this hearing today to focus on food safety efforts in the horticulture and organic agriculture industries.

Last month, the Committee held a Full Committee hearing and a Livestock, Dairy and Poultry Subcommittee hearing on food safety issues, so we are committed to looking at this issue from all angles before we decide how best for the Committee to move forward. Food safety is an important issue on the minds of many in Congress as well as in the Obama Administration. We've all witnessed the impact of recent foodborne disease outbreaks, both on the public and the growers involved.

These incidents have highlighted the gaps in our current food safety system and the important role of government, industry and consumers to prevent foodborne illness.

Time and again, we've seen evidence that the Food and Drug Administration does not have the capacity to take the preventive measures needed to adequately protect the food supply. In many cases, states and industry groups have stepped in to fill the void.

The need to improve and modernize food safety at the Federal level is clear, and the Agriculture Committee is one of the Committees responsible for developing a roadmap to accomplish this. We will be open and transparent in our approach, working with everyone who is interested in this important issue.

I look forward to hearing from our witnesses today and to working together as Congress considers action on this important issue.

PREPARED STATEMENT OF HON. CYNTHIA M. LUMMIS, A REPRESENTATIVE IN CONGRESS FROM WYOMING

Thank you Mr. Chairman,

It is an honor to serve on this Subcommittee with you and Ranking Member Schmidt. I am pleased that this first hearing delves into the important task of ensuring our nation's produce continues to be safe for consumers. I look forward to hearing from today's industry witnesses about how their own efforts to bolster food safety have been successful.

I am particularly interested to hear the opinions of today's panels about the costs to producers and consumers associated with food safety efforts. American farmers already produce the safest food supply in the world. Many producers exercise stringent, voluntary food safety procedures because they understand that the quality of their product is the primary determinant to the success of their business.

I certainly agree that in light of recent outbreaks of foodborne illnesses that these issues require careful attention by consumers, industry, and the government. I am concerned that overreach on the part of the Federal Government with regard to on-farm practices would raise the cost of doing business to unsustainable levels. As we

all know, the costs of producing are simply passed on to consumers in the form of higher food prices. I think we all understand the need to pay for the continued safety of our food, but I'm not certain a one-size-fits all approach, foisted on producers by the Federal Government will be the most cost-effective solution.

This is especially true in light of current efforts to impose a national energy tax on all Americans through a cap and trade system. Energy related inputs are the single largest operating costs most producers incur. A government imposed energy tax would, by any estimation, increase the cost of energy to plant, grow, harvest and deliver food. Under the burdensome weight of a national energy tax, I am concerned that producers seeking any means to recover capital will have less incentive to voluntarily invest in food safety precautions. Worse, a national energy tax combined with a one-size-fits-all food safety mandate would clearly be a double edged sword, slicing producer's profitability at every turn and raising food prices at the grocery store at precisely the wrong time for our economy.

I look forward to hearing the thoughts of the panelists about these important issues facing the agriculture industry. I yield back.

I now would like to introduce our witnesses today and welcome them to the Committee. The first witness that we would like to welcome is David Acheson, who is Associate Commissioner for Foods at U.S. Food and Drug Administration, Rockville, Maryland. Thank you, Dr. Acheson, for being here with us today. Mr. David Shipman, acting Administrator of the Agriculture Marketing Service at the U.S. Department of Agriculture here in Washington. Accompanying Dr. Acheson is Dr. Steven Solomon, D.V.M., Assistant Commissioner for Compliance and Policy, Office of Regulatory Affairs, U.S. Food and Drug Administration, also in Rockville. Welcome all three gentlemen for being here. Dr. Acheson, please begin when you are ready.

STATEMENT OF DAVID W.K. ACHESON, M.D., F.R.C.P., ASSOCIATE COMMISSIONER FOR FOODS, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD; ACCOMPANIED BY STEVEN M. SOLOMON, D.V.M., M.P.H., ASSISTANT COMMISSIONER FOR COMPLIANCE POLICY, OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION

Dr. ACHESON. Thank you, and good morning, Chairman Cardoza and Members of the Subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at FDA. It is part of Health and Human Services. With me today is Dr. Steven Solomon, Assistant Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs, which oversees the agency's field staff.

We are very pleased to be with you to discuss the issues relating to the safety of fresh produce. My testimony will briefly describe some of the challenges that we face in preventing fresh produce from becoming contaminated, as well as some of the specific measures the agency is taking to prevent future outbreaks.

Improving our food safety system is a high priority for the Administration. The President has established a working group on food safety and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, strengthening surveillance and enhancing enforcement. FDA is playing an integral part in that working group's efforts.

The President's Fiscal Year 2010 budget includes an increase of approximately $260 million for food safety efforts at FDA. This funding will enable the agency to increase the number and scope of food inspections, improve domestic food surveillance, lab capacity

and domestic response capabilities to prevent and control foodborne illness. The budget will allow FDA to increase the number of field staff working in the foods program by 400 full-time equivalents.

Supply chain safety and security rely on the principle of risk-based prevention with verification. The budget will strengthen food safety by improving the science upon which regulatory decisions and enforcement rely. FDA will conduct additional risk analyses and modeling and evaluation to improve decision making and better target our resources.

Food can become contaminated at many different steps, on the farm, in processing, distribution facilities, during transit, at retail or in the home. Changes in consumer preferences and industry practices, and the rising volume of imports, pose challenges that require us to adapt our current food protection strategies.

Fresh produce presents specific safety challenges and the number of illnesses associated with fresh produce is a continuing concern for FDA. The fact that produce is often consumed raw or with minimal processing contributes to its potential as a source of foodborne illness. Because most production is grown in an outdoor environment, it is susceptible to contamination from pathogens that may be present in soil, water, animals, in or near fields or packing areas. Produce is vulnerable to contamination from environmental conditions, inadequate production safeguards or inadequate sanitation of equipment and facilities. Traceback investigations are more difficult when they involve fresh produce because the food is perishable, its labeling is minimal or no longer available for review.

I want to emphasize the critical role of food producers and processes in ensuring the safety of foods they introduce into commerce. Strong food safety programs begin with the promotion of strong food safety throughout each farm, processor or distributor in the supply chain. Establishing such a culture requires a strong sense of corporate responsibility and continuous oversight.

In recent years, FDA has initiated numerous activities to address the safety concerns associated with production of fresh produce. I would like to describe some of these efforts to strengthen the research that supports the food safety programs. Many of these efforts are conducted in collaboration with industry and our state and Federal regulatory partners. FDA's current research agenda is focused on improving the identification and detection of disease-causing bacteria and contaminants in a variety of foods. We are undertaking extensive research on the detection, characterization and behavior of foodborne pathogens, microbial genetics and molecular biology.

For instance, FDA has developed rapid methods for serotyping *Salmonella* in produce such as cantaloupes, tomatoes and peppers. These rapid methods will aid in the analysis of domestic and imported produce samples, and are vital in our attempt to develop risk assessment models for pathogens and intervention strategies that protect public health.

Collaborative research efforts further strengthen the science base for our food safety programs. FDA works closely with several USDA agencies including analysis of water samples from California's Salinas watershed for *E. coli O157:H7* and to relate the location of bacteria to geographical, seasonal and rainfall variations.

In September 2008, FDA established the Western Center for Food Safety at the University of California, Davis to conduct research, education outreach addressing issues that interface production agriculture and food safety. In its first year the Center will conduct produce safety research addressing the science behind Good Agricultural Practices and develop outcome metrics, and an updated literature review related to perchlorate and its impact on food safety. The Center quickly responded to our need for help on the validation of processes to destroy *Salmonella* in pistachios and is working with both the pistachio and almond industries to control *Salmonella* on those tree nuts.

FDA is currently working on updating our *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* based again on the input of industry, states and other stakeholders. FDA has assisted industry in developing commodity-specific food safety guidelines for commodities such as lettuce, melons and tomatoes and we are working on similar guidance for herbs and green onions.

Building food safety partnerships with our Federal, state and local colleagues is key to having a comprehensive food safety system. FDA looks forward to strengthening these partnerships by building up each other's skills to further improve the safety of the U.S. food supply.

Thank you for the opportunity to discuss these important issues and I would be happy to answer any questions that you may have.

[The prepared statement of Dr. Acheson follows:]

PREPARED STATEMENT OF DAVID W.K. ACHESON, M.D., F.R.C.P., ASSOCIATE COMMISSIONER FOR FOODS, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD

Introduction

Good morning, Chairman Cardoza and Members of the Subcommittee. I am Dr. David Acheson, Associate Commissioner for Foods at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). With me today is Dr. Steven Solomon, Assistant Commissioner for Compliance Policy in FDA's Office of Regulatory Affairs, which oversees the Agency's field staff. We are pleased to be with you today to discuss issues related to the safety of fresh produce.

FDA is the Federal agency that has statutory responsibility for the safety of almost everything we eat, except for meat, poultry, and processed egg products, which are regulated by our partners at the U.S. Department of Agriculture (USDA). FDA is committed to ensuring that the U.S. food supply continues to be among the safest in the world.

My testimony will describe some of the challenges we face both in preventing fresh produce from becoming contaminated in the first place and in investigating outbreaks associated with fresh produce. I will also discuss some of the specific measures FDA is taking to enhance the safety of fresh produce and other foods to prevent future outbreaks and to improve product tracing when an outbreak occurs or there is a product recall.

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

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising vol-

ume of imports pose challenges that are requiring us to adapt our current food protection strategies.

Improving our food safety system is a high priority for the new Administration. The President has established a Food Safety Working Group and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, strengthening surveillance and enhancing enforcement. FDA is playing an integral part in the working group's efforts.

The President's Fiscal Year (FY) 2010 budget includes an increase of $259 million for food safety efforts under the "Protecting America's Food Supply" initiative. The level of new funding will increase the number and scope of food inspections, and improve domestic food surveillance, laboratory capacity, and domestic response capabilities to prevent and control foodborne illness. The budget will allow FDA to increase the number of field staff working in the Foods Program by 404 full-time equivalents (FTEs), an approximate 20 percent increase compared to FY 2009 appropriations.

The overall goal of the Protecting America's Food Supply initiative is to better protect American consumers by preventing intentional and unintentional contamination. This effort invests in priorities that strengthen the safety and security of the supply chain for foods. Supply chain safety and security relies on the principle of risk-based prevention with verification. Under this principle, FDA will hold all segments of industry accountable for ensuring that their products meet U.S. safety standards.

The initiative focuses on foreign and domestic sources of food ingredients, components, and finished products at all points in the supply chain, including their eventual use by the American public. Within this initiative, the budget provides for $94 million in new user fees to register food facilities and increase food inspections, issue food and feed export certifications, and reinspect food facilities that fail to meet FDA's safety standards.

The budget also will allow FDA to strengthen the safety and security of the supply chain by working with domestic and foreign industry to develop new control measures for all levels of food production and processing, and verify that these control measures are effective when implemented.

The Agency will strengthen food safety by improving the science upon which regulatory decisions and enforcement rely. FDA will conduct risk analysis, modeling and evaluation to improve risk-based decision-making and better target our resources. This work will also include improving FDA's ability to attribute contamination to specific foods and thereby promote faster response and better resource targeting.

Finally, the budget provides resources for FDA to work with state and other Federal agencies to collect baseline data to measure the impact of our food safety efforts and measure the reduction of foodborne illnesses in the United States. This will allow the Agency to adjust food safety priorities and ensure that food programs achieve the best results for public health.

Challenges of Fresh Produce

Fresh produce presents special safety challenges, and the number of illnesses associated with fresh produce is a continuing concern for FDA. For example, consumption of produce in its fresh (or raw) form, particularly "ready-to-eat" products, has increased substantially during the past decade. The fact that produce is often consumed raw or with only minimal processing, without intervention that would eliminate pathogens (if they are present) prior to consumption, contributes to its potential as a source of foodborne illness. New products and new consumption patterns challenge our food safety efforts.

Because most produce is grown in an outdoor environment, it is susceptible to contamination from pathogens that may be present in the soil, in agricultural water or water used for post-harvest practices (e.g., washing or cooling), in manure used as fertilizer, or due to the presence of animals in or near fields or packing areas. Produce also may be vulnerable to contamination due to inadequate worker health and hygiene protections, environmental conditions, inadequate production safeguards, or inadequate sanitation of equipment and facilities. Fresh produce is produced on tens of thousands of farms, and contamination at any one step in the growing, packing, and processing chain can be amplified throughout the subsequent steps.

We also note that traceback investigations for contaminated food, which we discussed with this Subcommittee last year, are more difficult when they involve fresh produce because the food is perishable and the produce item (along with any packaging or labels) is usually no longer available for testing by the time illnesses are reported. In addition, fresh fruits and vegetables are often sold loose without any packaging that could provide information about its source. Further, practices such

as packing or repacking produce from multiple sources add complexity to traceback investigations.

Consequently, addressing the way fresh produce is grown, harvested, and moved from field to fork is crucial to minimizing the risk of microbial contamination. In recent years, FDA has initiated several activities to address safety concerns associated with the production of fresh produce. Some of these activities include: working with industry and others to develop commodity specific guidance on ways to prevent or minimize potential contamination; conducting educational outreach to consumers on safe food handling practices; intensively investigating farms and packing sheds implicated in outbreaks to learn how the produce may have been contaminated; sampling and analyzing both domestic and imported produce for pathogens; and working with industry and foreign countries to promote the use of good growing, harvesting, packing, transporting, and processing practices.

It also is important to emphasize the critical role of food producers and processors in ensuring the safety of the foods they introduce into commerce. Strong food safety programs in food production facilities begin with the promotion of a strong culture of food safety throughout each farm or firm in the supply chain, including the need for preventive measures and ways to detect and correct problems before they cause harm. Establishing this culture requires a strong sense of corporate responsibility and continuous management oversight.

One of the key messages that FDA has been emphasizing over the last few years is that all food companies, both large and small, must know their suppliers. In today's complex, global market, this may require close interaction with entities throughout the food supply chain, including growers, manufacturers, distributors, retailers, food service providers, and importers.

From the perspective of both public health and the food industry, preventing foodborne illness from occurring is much more desirable than having to minimize the damage caused by such outbreaks by undertaking food recalls, which can often bring production to a halt, disrupt markets, affect consumer confidence, and cause financial loss. It is critical that all segments of the food production industry, from farm to retailer, take measures to ensure the safety of their ingredients and their finished products.

Initiatives To Enhance Produce Safety

To reduce the risk of foodborne illness at all points in the food chain, FDA utilizes a "farm-to-fork" approach to food safety. This approach systematically applies risk management principles at each step as food moves from growers and producers to consumers. While FDA has been working to enhance produce safety for a number of years, the Agency has sharpened its focus in response to recent produce-related outbreaks.

I will elaborate on the following key areas where FDA has focused its food safety efforts:

- strengthening the research programs that support FDA's food safety program with an emphasis on prevention; and
- enhancing effective partnerships.

Strengthening the Scientific Basis for FDA's Program to Improve Food Safety

Strengthening the research programs that support FDA's program to improve food safety is essential to improving the Agency's effectiveness at protecting public health. Our current research agenda is focused on improving the identification and detection of disease-causing bacteria and contaminants in a variety of foods. Current research topics include questions related to how and where in the food chain microbiological and chemical contamination of foods takes place, biotechnology and allergenicity issues, seafood safety, dietary supplement safety, color additive safety, and consumer studies. The determination of microbiological and chemical risks and their mitigation drives our research program.

FDA and our regulatory partners are doing extensive research on the detection, characterization, and behavior of foodborne pathogens, microbial genetics, and molecular virology. For instance, the Centers for Disease Control and Prevention (CDC) and FDA have developed rapid methods for serotyping *Salmonella* in produce (such as cantaloupes, tomatoes, and peppers). These rapid methods will aid FDA as we perform analysis of both domestic and imported produce samples. These efforts also are vital in our attempt to develop risk assessment models for pathogens and intervention strategies to reduce the public health risk that these pathogens present. FDA's research in the area of chemical contaminants focuses on the development of detection methods and toxicology studies. More rapid and precise testing methods to identify contaminants are important for minimizing the spread of foodborne disease once it occurs.

Collaborative research efforts further strengthen the scientific basis for our food safety programs. For example, for the past decade, FDA has worked closely with USDA's Agricultural Research Service (ARS) and Cooperative State Research, Education, and Extension Service (CSREES) to coordinate and mutually support our respective research efforts related to produce safety. In this spirit, we collaborated with ARS and CSREES to analyze water samples from California's Salinas watershed for *E. coli O157:H7*, and to relate the location of bacteria to geographical, seasonal, or rainfall variation. An extension of this research will look for sources of *E. coli O157:H7* in the Salinas Valley. Information obtained from this study will be used to inform produce growers about strategies to prevent pre-harvest microbial contamination.

In addition, we are working with academia, industry, other Federal agencies, and state governments to develop both risk-based microbiological research programs and technology transfer programs to ensure that the latest food technology reaches the appropriate end-users along the supply chain. We strengthen the scientific basis for our program by collaborating and learning with others, such as participating in many scientific and technical meetings on food safety.

In 2006, FDA began working with officials in California and with industry to assess the prevalence of factors in and near the field environment, which may contribute to potential contamination of leafy greens with *E. coli O157:H7* and the extent to which Good Agricultural Practices and other preventive controls were being implemented as part of a multi-year Leafy Greens Safety Initiative. In 2007, FDA began a similar initiative, in collaboration with state health and agriculture officials from Florida and Virginia, CDC, and several universities, to prevent foodborne illness associated with tomatoes from those states. A significant component of these ongoing initiatives is assessing factors (including irrigation water, drought and flooding events, the proximity of animals to growing fields, and post-harvest water use) that are most likely to have been associated with previous contamination of tomatoes and leafy greens. We have made significant progress in our understanding of how *Salmonella* contaminates tomatoes on the farm. We also have improved testing methods to recover *Salmonella* from fresh tomatoes. These findings have already been factored into our regulatory surveillance testing and farm inspections and underscore the importance of our Good Agricultural Practices guidance.

Through the safety initiative, FDA has learned that farms and processing firms are committing resources to implement current Good Manufacturing Practices (cGMPs) and Good Agricultural Practices (GAPs). The initiative also revealed that the extent to which growers implemented GAPs was variable and that improvement could be made. FDA currently is evaluating information that was gathered through the initiative and plans to utilize this information to develop produce safety-related policy and outreach. By identifying practices and conditions that can lead to product contamination, FDA and our safety partners hope to further improve guidance and policies intended to minimize chances of future disease outbreaks, as well as ascertain future produce-safety research, education and outreach needs.

In 2007, the FDA-affiliated Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the University of Florida sponsored a workshop to improve understanding of how tomatoes become contaminated with *Salmonella* and other pathogens. Also that year, FDA, the National Center for Food Safety and Technology (NCFST), and the University of Georgia's Center for Food Safety cosponsored a workshop on microbial testing to reach a consensus on the role of microbial testing in ensuring the safety of produce.

Last year, FDA convened an Interagency Risk Assessment Consortium (lRAC) and, working with JIFSAN, held a workshop to identify and prioritize research needs for conducting a quantitative risk assessment of foodborne illness caused by *E. coli O157:H7* from the consumption of leafy green vegetables. In September 2008, FDA established the Western Center for Food Safety at University of California in Davis to conduct research, education and outreach that addresses issues that interface production agriculture and food safety. In its first year, the Center will focus on conducting produce safety research addressing the science behind Good Agricultural Practices and develop outcome metrics and an updated literature review related to perchlorate and its impact on food safety. The Center quickly responded to our need for work on the validation of processes to destroy *Salmonella* on pistachios and is working with both the pistachio and almond industries to control *Salmonella* on those tree nuts.

In June 2009, FDA and NCFST will participate in a Food Safety and Technology Day in conjunction with the annual meeting of the International Sprout Growers Association in Chicago.

FDA also has conducted a number of activities to share information with, and solicit information from, our stakeholders. In 2007, FDA held two public hearings con-

cerning the safety of fresh produce to share information about recent outbreaks of foodborne illness related to fresh produce and to solicit comments, data, and additional scientific information on this issue. In late 2008 and early 2009, FDA held two public hearings requesting data and other information on industry practices and available technologies relevant to improving our ability to more quickly and accurately track fresh produce through the supply chain, especially during a produce-associated foodborne illness outbreak. Through these and other meetings, we are soliciting input from, and actively engaging, all our stakeholders on ways to improve the safety of fresh produce.

Enhancing Effective Partnerships

To succeed in our science-based efforts to promote food safety, we need to enhance our collaborations with stakeholders interested in food safety, particularly with respect to fresh produce. FDA has worked with the public and private sector to encourage industry to follow the recommendations and standards contained in FDA guidances. After enlisting the help of the scientific community and industry, FDA published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guide (published in 1998) recommends GAPs and cGMPs that growers, packers, and shippers can take to address common risk factors in their operations. The guide was issued in several languages and FDA has conducted outreach, both domestically and internationally, to encourage its implementation. In September 2008, FDA published a *Federal Register* Notice soliciting comments and data to inform the agency in updating the 1998 guidance. We are currently drafting revised, proposed guidance based on these comments and other input. In addition, FDA has assisted industry in developing a number of commodity-specific food safety guidelines for the commodities most often associated with foodborne illness outbreaks. These include guidelines for lettuce and leafy greens, melons, and tomatoes. We will be working with industry on similar guidelines for herbs and green onions in the near future.

In 1999, there were six outbreaks and 390 reported illnesses associated with eating contaminated fresh sprouts. FDA published two guidance documents for seed and sprout producers that year. Following release of the sprout guidances, the number of outbreaks associated with the consumption of sprouts and the number of illnesses in an outbreak appeared to decline. There were no reported outbreaks associated with sprouts in 2005, 2006, or 2007. In late 2008, however, there was one sprout-associated *Salmonella* outbreak. In 2009, an ongoing *Salmonella* outbreak linked to sprouts has resulted in more than 200 confirmed cases of illness reported to CDC. Sprouts have also been linked to *Listeria* illnesses in 2009. On May 1, 2009, FDA issued a letter to seed suppliers, distributors, and sprouters urging them to review their operations in light of FDA's guidance and other available information. FDA will be conducting outreach to other industry members, retailers, consumer groups, and state partners. FDA intends to continue to work closely with all parties to identify, and promote adoption of, effective preventive controls.

FDA's efforts in this area are ongoing. In February 2008, FDA finalized its "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the Fresh-cut Guide). This guidance complements FDA's cGMPs for food processing facilities. It is intended to assist firms in minimizing the microbial food safety hazards of fresh-cut produce by providing recommendations specific to fresh-cut processing operations. In addition, FDA is leading an effort through the Codex Alimentarius Commission, the international food safety standards body, with support of the Food and Agriculture Organization/World Health Organization (FAO/WHO) to develop commodity-specific annexes to the Codex hygienic code for fresh fruit and vegetable production, starting with an annex for fresh leafy vegetables and herbs.

We will continue to work with Federal, state, local and international food safety partners and with industry to develop guidance, conduct research, develop educational outreach materials, and initiate other commodity- or region-specific programs to enhance the safety of fresh produce.

The close collaboration between Federal and state food safety officials in response to the *E. coli O157:H7* outbreak associated with fresh spinach is a good example of the effective working relationships we enjoy with our food safety partners. On March 23, 2007, FDA and California's Department of Health Services (CDHS) released a joint report on an extensive investigation into the causes of the 2006 *E. coli O157:H7* outbreak that was associated with contaminated Dole brand baby spinach and resulted in 204 confirmed illnesses and three deaths. The inquiry was conducted by the California Food Emergency Response Team (CalFERT), a team of experts from FDA's district offices in San Francisco and Los Angeles and CDHS. Potential environmental risk factors for *E. coli O157:H7* contamination identified in the report included the presence of wild pigs and the proximity of irrigation wells

to surface waterways potentially exposed to feces from cattle and wildlife. FDA has established agreements with six additional states to establish emergency response teams, similar to CalFERT, around the country.

Another important example of a food safety partnership we continue to enhance is the FDA/USDA Food Emergency Response Network (FERN). FERN is a network of Federal, state, and local laboratories capable of testing food samples for microbiological, chemical, and radiological threat agents. This partnership provides essential analytical expertise and surge capacity in case of emergencies. The number of participating laboratories has increased to 151 laboratories and 19 cooperative agreement laboratories in FY 2009, compared to 30 participating laboratories in March 2004 (near FERN's inception). The FERN network proved to be a critical asset in the *E. coli O157:H7* outbreak associated with fresh spinach. FERN analysts worked closely with CDC's Laboratory Response Network personnel to harmonize and approve a modified FERN method for detecting *E. coli O157:H7* in spinach. This method substantially improved the testing of spinach samples as it allowed for the detection of *E. coli O157:H7* at lower levels. FDA, with CDC, has provided technical assistance to USDA's Agricultural Marketing Service's Microbiological Data Program by providing information important to the planning of microbiological testing of fresh produce.

Legislative Initiatives

As noted earlier, the President has established a working group on food safety and asked that it make recommendations on updating our food safety laws, fostering coordination throughout the government, and enhancing enforcement. FDA's experience with recent foodborne disease outbreaks and related investigations and recalls have highlighted the need to enhance FDA's statutory authority to better protect consumers. We are reviewing with HHS, as well as other Federal and state food safety partners, prior requests to Congress to strengthen the Agency's ability to protect Americans from foodborne illness. At this time, we want to highlight the previously identified need for new or enhanced authority in several areas:

1. Authority for FDA to require preventive controls for foods;
2. Authority for enhanced access to records during routine inspections to ensure that inspectors have access to all information that bears on food safety; and
3. Authority for FDA to require food facilities to renew their registrations more often, and to allow FDA to modify the registration categories.

In addition, we note that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

Conclusion

FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, and international food safety partners, and with industry, consumers, and academia. As a result of this effective collaboration, the U.S. food supply continues to be among the safest in the world. We have made progress, but recent incidents of contaminated food demonstrate the challenges we face and the need to enhance our efforts. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible. Thank you for the opportunity to discuss FDA's continuing efforts to improve the safety of fresh produce. I would be happy to answer any questions.

The CHAIRMAN. Thank you, Dr. Acheson.

We are going to allow Mr. Shipman to briefly present his testimony. The bells have rung, although we didn't hear them in this room, and so there is a vote on so we are going to have break. There in fact are five votes. Mr. Shipman, if you could make your opening statement. Make sure you keep it within the allotted time. We have your full testimony in the record with your written copy, but I want to give you as much time as you need now, but unfortunately we may have to break and then come back. We will all ask questions after the votes. Mr. Shipman, please proceed.

STATEMENT OF DAVID R. SHIPMAN, ACTING ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Mr. SHIPMAN. Mr. Chairman and Members of the Subcommittee, good morning and thank you for the invitation to appear here today. I will just briefly cover the AMS programs and services. As you indicated, my written testimony provides more detail.

As you know, the Food and Drug Administration is a Federal agency with primary responsibility for food safety of fruits and vegetables. Within USDA the Food Safety Inspection Service holds similar responsibility for meat, poultry and egg products. The mission of the Agricultural Marketing Service is to facilitate the strategic marketing of agricultural products in the domestic and international market. AMS is not a food safety agency. We are an agency with a long, successful history of working with producers and processors on marketing programs that involve inspection of product quality, and verification of production processes. Some of these programs do incorporate food safety-related elements such as those involving the verification that growers, handlers and processors are following FDA guidance and commodity-specific agricultural best practices.

In the area of specialty crops, our program is carried out with a Federal workforce of 800 full-time and part-time employees plus an additional 3,500 federally licensed state employees. These individuals are highly trained professionals that adhere to strict ethical standards and have a proven record of providing impartial, high-quality service on a user-fee basis.

One example of an audit-based program fashioned around food-handling processes is our Good Agricultural Practices and Good Handling Practices Audit Verification program. This program verifies adherence of farms and packing houses to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. It also permits the use of an AMS seal as a marketing claim. It is a uniform nationwide program that is voluntary and it is run on a user-fee basis. The impetus of these programs originated because various state governments and industry organizations were seeking better ways to meet the increasing demand of retail customers for verification of product quality and safety. Participants in the program demonstrate control in several safety areas of their operation to minimize microbial hazards including: water supplies, manure management, worker health and hygiene, sanitation of facilities, field and packing area sanitation, transportation and product traceback. The minimum that we conduct audits under these programs is twice a year. Facilities failing an audit are subject to additional audits, and all facilities participating in the program are subject to unannounced audits.

Primary users of the program are fresh fruit and vegetable growers, packers, shippers and others in the marketing chain. For the Fiscal Year 2008, we conducted audits on 1,131 separate farms and facilities. The audits were performed in 36 states and in Puerto Rico. The trend for this program is increasing. In 2006 we did only 352, last year we did 400 audits and this year in the first 5 months we have done over 800. So the trend is continuing up.

Another example of an audit-based program that AMS runs is our Qualified-Through-Verification program. This one is used primarily by fresh-cut plants participating and we have seven of them. The QTV, or the Qualified-Through-Verification, is a voluntary, again, user-fee program that provides third-party verification of fresh-cut processors that they adhere to their own Hazard Analysis Critical Control Point, or HACCP plans. Under the program, processors identify and document critical points in their production process, measure performance of their operation at the critical points, and position themselves to detect and address the deficiencies.

Now I would like to look for a moment at our marketing orders and agreements. Under the authority of the Agricultural Marketing Agreement Act of 1937, marketing orders and agreements assist farmers and handlers by allowing them to collectively address marketing problems. Through an order or an agreement, farmers and handlers may set minimum quality requirements, standardize packaging, regulate the flow of product to the market, and implement other regulations including consumer education, research and advertising. Marketing agreements only apply to handlers who voluntarily sign an agreement, while marketing orders set regulations on handlers in a specific region once the program is approved in a grower referendum. We currently have 32 fruit and vegetable marketing orders.

Under the authority of the Act, the presence or absence of harmful pathogens, toxins or other contaminants is considered a quality characteristic. In response to producer requests, we have incorporated food quality-related requirements in the marketing agreements and marketing orders over many years. For example, testing for *Aflatoxin*, considered a possible human toxin, has been required for U.S.-grown peanuts since 1965. Beginning in 2005, pistachio handlers were required to test all nuts destined for human consumption for *Aflatoxin*, and then in the 2007 and 2008 crop almond handlers were required to treat almonds prior to shipment to reduce the chance of *Salmonella* contamination.

Following the September 2006 *E. coli* outbreak linked to fresh spinach, as you mentioned earlier, Mr. Chairman, the California Department of Food and Agriculture worked with the California leafy green market and they developed the California Leafy Greens Marketing Agreement in February. At the same time California was starting up their program——

The CHAIRMAN. Mr. Shipman, I apologize for interrupting you but we have less than 5 minutes left on the vote and the Members are going to need to get to the Floor to cast their votes. What I would like to do is call a temporary recess in the Committee proceedings. We will give you an opportunity to pick up right where you have left off and we will be back as soon as we conclude the five votes. It may be a while. This process does take a while on the Floor. We will try to make it as quick as possible.

[Recess.]

The CHAIRMAN. We will call the meeting back to order. I would like to let Mr. Shipman continue his testimony. Mrs. Schmidt is on her way and she will be here shortly, but we will make sure that it is in the record and that everyone gets a copy.

Mr. SHIPMAN. Thank you, Mr. Chairman. As I was saying, the California Leafy Greens Marketing Agreement was established in February 2007, and at that same time that the program was starting, we at AMS published an advanced notice of proposed rulemaking to assess the interest in a nationwide Good Agriculture and Handling Practice program. We received over 3,500 comments indicating strong support for the program but the comments also raised some challenges that needed to be addressed such as the cost and the impact on small entities.

A coalition of U.S. produce industry members began drafting a proposed national marketing agreement. Requirements implemented under the program would be science based, would conform to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* and would be subject to USDA inspection and audit verification and oversight. As a marketing agreement, the proposed rule would only be binding to handlers who voluntarily signed the agreement. In addition to the good handling practices, it is anticipated that the program would require signatories to verify that any product handled comes from producers or other handlers using verified good agriculture handling practices. The program would authorize unannounced audits and apply to imports, creating a need to audit growing facilities outside the United States.

The program would allow handlers to use an official mark to certify compliance with the program. Those found in violation of the agreement would be subject to withdrawal from the audit services, would lose the privilege to use the official mark and may be subject to misbranding or trademark violations. Any product deemed an immediate threat to public health by USDA inspectors would be reported to the Food and Drug Administration.

We anticipate receiving a proposal on a nationwide agreement to be submitted later this month. Once the request is received, AMS will proceed with conducting nationwide hearings to gather public information and any future program will include an extensive outreach effort to make businesses, especially small entities, aware of the marketing agreement and the audit requirements. Our 2010 budget request includes $2.3 million to support marketing agreements, some of which would be used for this national effort.

A final area I would like to highlight today involves our Microbiological Data Program, or MDP, a monitoring program to collect information regarding the incidence, number and species of foodborne pathogens and indicator organisms on domestic and imported fresh fruits and vegetables. The collection and analysis of these samples began in April 2001. The MDP program was established and helps establish benchmarks by which to evaluate the efficacy of procedures to reduce or eliminate harmful foodborne microorganisms. The data are provided to stakeholders for decisionmaking purposes such as the Federal and state public health agencies, growers, processors, retail stores and food handlers. Data collection and testing activities are carried out with the support of 11 states—California, Colorado, Florida, Maryland, Michigan, Minnesota, New York, Ohio, Texas, Washington, and Wisconsin—through cooperative agreements with us at AMS. AMS provides

quality assurance oversight and laboratory administrative support for the program.

Recent examples of the value provided by the MDP program occurred in April of this year during routine monitoring when *Salmonella* was found in alfalfa sprouts and spinach by the Ohio and Wisconsin laboratories testing samples collected by the program. The Centers for Disease Control and Prevention and the Food and Drug Administration, as well as health officials in both states, were notified. The MDP information was used for traceback and notification to customers who had received the affected products, and in both cases the affected products were voluntarily recalled.

To conclude, Mr. Chairman, I would like to reiterate that the Food and Drug Administration is the key agency with jurisdiction over food safety policies for fruits and vegetables. AMS has a nationwide network of skilled inspectors and auditors that both certify quality and verify product processes. We also incorporate food safety-related elements in several of our marketing programs to verify that industries adhere to FDA requirements and guidelines. I would be pleased to respond to any questions. Thank you.

[The prepared statement of Mr. Shipman follows:]

PREPARED STATEMENT OF DAVID R. SHIPMAN, ACTING ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Mr. Chairman and Members of the Subcommittee, good morning and thank you for the invitation to appear before you today. I appreciate the opportunity to share with you a brief overview of the U.S. Department of Agriculture's (USDA) activities and services that assist the fruit and vegetable industry in meeting U.S. Food and Drug Administration (FDA) and commercial marketplace requirements. The Agricultural Marketing Service (AMS) is the primary USDA agency working in this area.

As you know, FDA is the Federal agency with primary responsibility for the food safety of fruits and vegetables. Within USDA, the Food Safety and Inspection Service holds similar responsibility for meat, poultry, and egg products.

The mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency. The agency does respond to requests from producers to support their product quality control efforts for use as marketing claims. For example, producers have asked AMS to establish programs to provide independent verification that FDA guidance is being followed.

AMS Audit-Based Programs

AMS has significant experience in the design and delivery of marketing programs that involve inspections for product quality and verification of production processes. At industry's request, AMS has incorporated food safety-related elements into several of its marketing programs. AMS independent third-party audits provide impartial verification that growers, handlers and processors are following FDA guidance and commodity specific agricultural best practices. The Agency has developed the AMS Industry Services Audit and Accreditation Program to provide a range of audit and accreditation services. AMS auditor qualifications and training are based on International Organization for Standardization (ISO) auditing principles and activities with an emphasis on process-based auditing, program specific training, and annual program-specific refresher training. To maintain Agency credentials, each auditor must complete a minimum of 80 hours of continual professional development and course work every 3 years, plus meet annual performance criteria according to the U. S. Office of Personnel Management (OPM) Qualification Standards performance criteria as mandated by USDA.

AMS experienced staff in fruit vegetable inspection and agricultural practices have provided the foundation to evolve inspectors into International Standards Organization (ISO) trained auditors. The evolution of inspectors into auditors came at the request of the food industry that was in need of independent third-party verification. Plant sanitation surveys are one of the first audit-based services that assess food processing facility's compliance with FDA's current Good Manufacturing

Practices (GMP's), and ensures their ability to provide consistent quality and wholesome products by verifying food safety systems.

Audit-based programs focus on the management of production and handling systems. They provide a basis for third-party verification of conformance to production and handling standards, methods, or procedures. Through these programs, it is possible to verify that processes are working within established limits. Production and handling systems are documented, specific processes are monitored and measured, and product identity and traceability are required. Processes specifically relating to the management and minimization of food safety hazards may be included.

In the horticultural or specialty crops area, AMS product grading, plant sanitation review, and audit-based programs are conducted with a Federal workforce of some 800 full and part time employees. Additionally, AMS has cooperative agreements with nearly all State Departments of Agriculture, under which their fruit and vegetable inspectors receive training and are granted Federal licenses to assist in the delivery of AMS services and programs, adding another 3,500 skilled professionals to the agency's deployable workforce.

Good Agricultural Practices and Good Handling Practices Audit Verification Program

One example of an audit-based program fashioned around food handling processes is the Good Agricultural Practices and Good Handling Practices (GAP/GHP) Audit Verification Program. This program assists farms and packinghouses through verification of their adherence to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* to be used as a marketing claim. It is a uniform, nationwide program that is voluntary and funded by user fees.

The GAP/GHP Program originated from requests from various state governments and industry organizations. A program was sought that would enable growers and packers to demonstrate adherence to Good Agricultural Practices and Good Handling Practices, as was being required by their retail customers.

As identified in FDA's guidance materials, participants in this program demonstrate control in several areas of their operations to minimize microbial hazards, including water supplies, manure management, worker health and hygiene, sanitary facilities, field and packing area sanitation, transportation, and product traceback.

The minimum audit frequency for GAP and GHP audits is twice each season. Should a facility or growing operation fail to pass either the initial or subsequent audits, additional audits will be undertaken. In addition, in many instances, the same auditors are in and around these facilities in the course of other, routine quality grading activities. This provides many more opportunities to provide feedback on food safety problems that emerge between audits. The initial GAP or GHP audit is scheduled to ensure that the grower or packer has a clear understanding of when they need to have their operation in order. Subsequent audits are unannounced.

Primary users of this program include fresh fruit and vegetable growers, packers, shippers, and others in the marketing chain. For the 2008 Fiscal Year, AMS audited a total 1,131 separate farms or facilities with the total number of commodities audited being approximately 105. Audits were performed in 36 states and Puerto Rico. AMS staff and AMS-licensed and trained state employees perform the on-site audits.

Outreach to Small Farmers

In cooperation with the Department's Office of Civil Rights, AMS conducted three educational outreach sessions for small, disadvantaged farmers in March 2007. These sessions were held in Raleigh, North Carolina, Marianna, Arkansas, and Thomasville, Georgia and were attended by 20–25 farmers at each session.

The purpose of this outreach was to educate the participants in Good Agricultural Practices, Food Defense, and 3rd party audits, specifically the USDA–AMS GAP & GHP audit program. As a direct result of this effort, approximately 25 farms in Arkansas, Mississippi, Georgia, and North Carolina have successfully passed the USDA–AMS GAP & GHP audit over the past 2 years.

AMS staff also participated in training and outreach to small farmers in the New England and Mid-Atlantic regions at over 20 different grower meetings sponsored by the various state extension services over the past 3 years. These growers are generally participating in regional retail outlets "buy local" farm to store programs. Approximately 800 participants were given an overview of the USDA–AMS GAP & GHP audit program and had the opportunity to ask specific questions regarding the program.

Qualified-Through-Verification Program

Another example of an audit-based program offered by AMS is the Qualified-Through-Verification (QTV) Program. There are currently seven fresh-cut plants participating in the QTV program.

QTV is a voluntary, user-fee program that provides third-party verification of a fresh-cut processor's adherence to its Hazard Analysis Critical Control Point (HACCP) plan. Under the QTV program, processors identify and document critical points in their production process, measure performance of their operation at these critical points, and position themselves to detect and address any deficiencies as they might emerge.

Third-party verification by AMS involves initial document review and subsequent on-site audits. The frequency of audits begins at 2 week intervals, with reduced frequency possible based on a firm's performance. AMS auditors performing QTV audits must complete training in HACCP principles (including hazard analysis, preventive measures, critical control point determination, sanitation Standard Operating Procedures, critical limits, monitoring procedures, corrective actions, record keeping), in addition to AMS audit training requirements.

The QTV Program reflects the latest FDA guidelines. For example, with FDA's March 2007 release of its draft final *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (finalized in February 2008), AMS immediately modified its QTV program to incorporate this updated guidance regarding the identification and implementation of appropriate measures to minimize the hazard of microbial contamination during the processing of fresh-cut produce. In addition, participants in the QTV program will be required to source products only from growers that adhere to Good Agricultural Practices as outlined in FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.

Impartiality

All AMS' inspectors, including its Federal-licensed state partners, undergo an extensive combination of hands-on training and classroom instruction in commodity grading. In addition, inspectors receive training in ethics, conduct, and customer service. To ensure consistency and integrity in audit-based inspection services, AMS instituted minimum auditor requirements through its Industry Services Audit & Accreditation Program (ISAAP). The ISAAP requirements are based on internationally recognized standards for the training and evaluation of auditors.

Marketing Orders and Agreements

Authorized by the Agricultural Marketing Agreement Act of 1937 (the Act), marketing orders and agreements assist farmers and handlers by allowing them to collectively address marketing problems. These programs are initiated by industries that chose to have Federal oversight of certain aspects of their operations. AMS oversees marketing orders and agreements to ensure that they operate in the public interest and within legal bounds.

Marketing orders and agreements may set minimum quality requirements, standardize packaging, regulate flow of product to market, and implement other regulations including consumer education, research and advertising. Marketing agreements only apply to handlers who voluntarily sign an agreement, while marketing orders set regulations on all handlers in a specified region once the program is approved in a grower referendum. Fees are collected from handlers to cover the local costs of administering these programs. AMS currently administers 32 fruit and vegetable marketing orders, covering 25 specialty crop commodities.

Food Quality and Safety Issues Under Federal Marketing Orders

Section 608c(6) of the Act provides authority to regulate the quality of various commodities through Federal marketing orders and agreements. The presence or absence of harmful pathogens, toxins, or other contaminants is considered a quality characteristic. In response to producer requests, AMS has incorporated food quality-related requirements in marketing agreement and marketing order regulations for many years. For example, testing for *Aflatoxin*, considered a possible human toxin, has been required for U.S. grown peanuts since 1965, originally under a Federal marketing agreement and subsequently through separate legislation administered by AMS.

A large majority of the currently active Federal marketing order programs include minimum grade requirements with most U.S. grade standards having criteria related to food safety (e.g., lack of mold, insects, foreign material, *etc.*). Since 1961, for example, the marketing order for California prunes has had inspection and fumigation requirements relative to live insect infestations. Beginning in 2005, Pistachio handlers were required to test all nuts destined for human consumption for

Aflatoxin. Also, starting with the 2007–08 crop, almond handlers were required to treat almonds prior to shipment to reduce the chance of *Salmonella* contamination.

California Leafy Greens Marketing Agreement

Following the September 2006 *E. coli* outbreak linked to fresh spinach grown in the Salinas Valley (and subsequent collaboration among industry, FDA, and California Department of Public Health to enhance existing recommendations for the safety of leafy greens), the spinach and related leafy green industries collectively worked with the California Department of Food and Agriculture (CDFA) to begin designing a state marketing agreement that would require adherence to Good Agricultural Practices for most companies involved in shipping leafy greens in the state. The California Leafy Greens Marketing Agreement (Agreement) became effective in February 2007. Arizona implemented a similar program in October 2007.

The CDFA Agreement is a voluntary program. This program licenses signatory handlers to use a certification mark to certify the member's use of Good Agricultural Practices on all of the product handled. The use of the certification mark would be denied to those firms found in violation. The Agreement also mandates that handlers source their leafy greens produced in California from growers who comply with a specified set of Good Agricultural Practices. According to CDFA, to date, handlers representing more than 99 percent of the leafy greens produced in California have signed the Agreement.

AMS has cooperated with CDFA in the verification aspects of the Agreement, including the design and delivery of training for the California State auditors who monitor compliance.

AMS worked with the California and Arizona leafy greens industries, the California tomato industry, and the American mushroom industry to develop a framework for providing audit services. Each industry developed a "best practices" document and requested AMS to develop an audit protocol to monitor compliance with these practices. As a result, AMS is providing auditing services which recognize operator's adherence to industry-defined best practices and FDA guidance targeted to minimize food safety hazards. FDA specialists have interacted with industry as "subject matter experts" in the development of the best practices documents and AMS maintains an active working relationship with these same specialists.

Proposed National Marketing Agreement for Leafy Greens

In response to interests expressed by segments of the leafy green vegetable industries, AMS, in October 2007, published an advanced notice of proposed rulemaking (ANPR) that resulted in the submission and consideration of 3,500 public comments on the need and level of support for a nationwide good agricultural and handling practices program. In short, AMS' review of the comments received indicated public backing for such a measure could be favorable if certain issues, such as the cost and impact on small entities, the need for science-based guidelines and other factors, were addressed in the development and implementation of any Federal regulation.

Subsequent to the publication of the ANPR, a coalition of U.S. produce industry members began drafting a national marketing agreement proposal that would further minimize the hazards of foodborne contamination in leafy green vegetables. The purpose of the proposed marketing agreement would be to verify industry adherence to good agricultural and handling practices. Requirements implemented under the program would be science-based, would conform to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* and would be subject to USDA inspection audit verification and oversight. As a marketing agreement, the proposed program would only be binding to handlers who voluntarily sign the agreement. In addition to good handling practices, the program would require signatories to verify that any product handled comes from producers or other handlers using verified good agricultural and handling practices. The program would authorize unannounced audits and apply to imports, creating the need to audit growing facilities outside of the United States.

The program would license signatory handlers to use a certification mark to certify the member's compliance with the program. As a result of agreement violation, a signatory would be subject to withdrawal of audit services, would lose the privilege of the official certification mark, and may be subject to misbranding or trademark violations. Any product deemed an immediate threat to public health by USDA inspection would be reported by USDA to FDA.

Any requirements under a Federal marketing agreement for leafy greens would reinforce those industries' abilities to meet FDA requirements. Authorities and regulations under such a program would be consistent with FDA guidance and regulations.

AMS anticipates that proponents of the proposal will submit an official request for rulemaking in May 2009. Once the request is received, AMS will proceed with conducting nationwide hearings to gather evidence and advance the rulemaking process accordingly. This process will allow all interested parties the opportunity to provide input. Any future program would include an extensive outreach effort to make businesses, especially small entities, aware of the marketing agreement and audit requirements. AMS has requested $2.3 million in funding for 2010 to support the marketing agreement.

In both February 2008 and 2009, the Department of Agriculture-chartered Fruit and Vegetable Industry Advisory Committee, a group of 25 members of the U.S. produce industry, expressed strong support for making Federal marketing agreements and marketing orders available to industries to facilitate national adoption and compliance with food safety standards, such as GAPs, GHPs and Good Manufacturing Practices (GMPs).

Microbiological Data Program

In Fiscal Year 2001, AMS implemented the Microbiological Data Program (MDP), a monitoring program to collect information regarding the incidence, number, and species of important foodborne pathogens and indicator organisms on domestic and imported fresh fruit and vegetables. The collection and analysis of samples began in April 2001.

MDP was primarily designed to provide data on microbial presence in order to establish a microbial baseline to assess the risks of contamination, if any, in the domestic food supply. The data are used to establish "benchmarks" by which to evaluate the efficacy of procedures to reduce or eliminate harmful foodborne microorganisms. The data are provided to stakeholders for decision-making purposes (e.g., Federal and state public health agencies, growers, processors, retail stores, and food handlers).

Data collection and testing activities are carried out with the support of 11 states~California, Colorado, Florida, Maryland, Michigan, Minnesota, New York, Ohio, Texas, Washington, and Wisconsin~through cooperative agreements with their respective Departments of Agriculture. AMS provides quality assurance oversight and laboratory/administrative support to the program.

Recent examples of the value provided by MDP occurred in April this year during routine monitoring when *Salmonella* was found in alfalfa sprouts and spinach by the Ohio and Wisconsin laboratories testing samples collected by the program. The Centers for Disease Control and Prevention (CDC) and FDA as well as health officials in both states were notified. MDP information was used for trace back and notification to customers who had received the affected products and in both cases, the affected products were voluntarily recalled. The *Salmonella* strain found by Ohio was determined to be linked to a cluster of foodborne illnesses in Arizona and New Mexico. There are no reported illnesses linked to the spinach strain. Since spinach from this lot was distributed in Illinois, FDA is assisting in product recall for that state. Quick intervention by FDA and state officials and voluntary cooperation by distributors reduce risks to consumers' health and minimize economic impact on growers.

In the aftermath of these incidents, the FDA Associate Commissioner for Foods asked for a more interactive approach between the two agencies to develop plans and communication strategies for MDP. Building on their prior programmatic collaboration, FDA and AMS agreed to have designated points of contact always available so that FDA can respond quickly when MDP finds harmful pathogens during routine monitoring. CDC became actively engaged in MDP during the *Salmonella saintpaul* outbreak in 2008 and has continued participating in program planning by providing feedback on foods that need to be monitored by the program. The PFGE fingerprint patterns of enteric bacterial pathogens isolated by MDP are entered into CDC's PulseNet database to be compared with pathogens isolated from humans.

To conclude, Mr. Chairman, I would like to reiterate that Federal food safety policies for fruits and vegetables fall under the jurisdiction of the FDA. AMS has developed significant experience in the design and delivery of marketing programs, including those involving inspections for product quality and verification of production processes. At industry's request, AMS has incorporated food safety-related elements in several of its marketing programs to verify that industries adhere to FDA requirements and guidelines.

I would be pleased to respond to questions.

The CHAIRMAN. Thank you, Mr. Shipman.

Dr. Acheson, you testified that the President's budget request would allow FDA to increase the number of field staff working on

food by 404 full-time equivalents. I want to be clear on this number. Would those full-time equivalents, those 404 folks, conduct inspections for drugs and medical devices or will they be dedicated exclusively to food safety?

Dr. ACHESON. Currently, the intent is that those 400 or so individuals would be added to the Office of Regulatory Affairs from which my colleague, Steve Solomon, is here so he could provide you with more specifics. They would not all be inspectors because obviously there needs to be the infrastructure within Office of Regulatory Affairs to support what they are doing, but it would certainly be all devoted to foods, yes.

The CHAIRMAN. It would be all devoted to food?

Dr. ACHESON. Yes, but they would not all be inspecting. That is an important point, that you have to have personnel to support the infrastructure for the inspectors.

Dr. SOLOMON. If I could just add to that, 200 of those would be investigators all doing food and feed work.

The CHAIRMAN. Would you describe the types of activities these folks will do in the facilities? How does that process work? What are their protocols? Do inspectors review records or do they sample a product? Do they go out and verify the effectiveness of process controls? How do they conduct their activities?

Dr. SOLOMON. Thank you for the question. FDA investigators do a number of activities. They do routine inspections at facilities. They respond to consumer complaints. They conduct audits associated with recalls to evaluate the effectiveness of those recalls. So during a typical food inspection, say, of a processing facility that may be handling something like spinach, they are evaluating the facility. They do a walk-through of the facility to evaluate the entire facility. They look at records associated with that facility. They do specifically look at the processing equipment, the testings on hand at the processor to make sure there is adequate, say, chlorination if there is an issue about that. They also may be taking environmental samples at that facility to evaluate it.

The CHAIRMAN. Thank you, sir. I have two questions to follow up with that. What would you say the percentage of their time is looking at documents *versus* actually doing what I would call field inspections where they are in the plants? And as I recall the last time a number of you were here and we were talking specifically about peanuts, and we were also talking about the pepper and tomato issue at that time as well, one of the plants had not been looked at in 18 months or 2 years. How often is this protocol that these inspectors—how often would the average plant be inspected?

Dr. SOLOMON. It is difficult to say how much time is looking at records *versus* actually walking through and looking at the processing facility itself because it depends on what our interests are doing that period of time. So, for example, in a low-acid canned-food plant, looking at the historical records and processing during that facility is very critical. Other plants, they spend less time looking at records and more time actually in the facility. So there is no set time, no prescribed time. It depends on the circumstances, what the investigator is finding. We are spending more and more time doing more environmental sampling as part of our current protocols. And the frequency of inspection, we try to associate with

the risk associated with that so we try and get into high-risk facilities on a more frequent basis. And, then a facility like a warehouse or a lower risk facility we are going in less frequently. So in the higher risk facilities we have identified, we are trying to get in there as close to an annual basis as we can.

The CHAIRMAN. Thank you, Dr. Solomon. I regret to inform everyone assembled here that we have just been called to another vote, and so as of right now it is one vote. We will go cast our votes and come back as soon as possible. The Committee is temporarily adjourned.

[Recess.]

The CHAIRMAN. We will call the hearing back to order and resume questioning. Before I do that, I want to welcome three individuals to the Committee proceedings today. We have our newest Member with us, Mr. Scott Murphy from upstate New York. Thank you for being a Member of our Committee. We welcome you to our hearing and look forward to your input.

Also, I would like to recognize a former member of the state legislature who served with Mr. Costa and I. He was also the Director of Parks for the State of California, Mr. Rusty Areias. Welcome, Rusty, for being here. And he has with him his daughter, Alexis, and Alexis, welcome to you too. You come from a great political family. I am sure you will do wonderful things as you get older.

Okay. We stopped in the middle of question. Dr. Solomon, do you have anything further that you wanted to say in response? And then I have a few other questions.

Dr. SOLOMON. Thank you. I think we covered the two points about high-risk frequency of inspections, and what is covered during inspection.

The CHAIRMAN. Very good.

Dr. Acheson, does FDA currently have the data necessary to conduct risk assessment and modeling on products within its jurisdiction, and how is FDA using that data today?

Dr. ACHESON. FDA does not currently have enough data to adequately assess all the risk factors. I think it is very clear that the agency needs to gather more information, needs to be gathering that from multiple sources from working with the industry and working with the states, Federal partners, academia. Further, that information needs to be used for building more-sophisticated models of food safety because clearly we need a risk-based approach to make maximum use of resources. And while we, as Dr. Solomon says, use what we have to drive those inspectors into the facilities that are the greatest risk, there is more that needs to be done to gather information.

The CHAIRMAN. Very good. You testified in your budget request, which included that you needed more resources for FDA to work with Federal and state partners to measure the reduction of foodborne illnesses. Please describe this proposal, how the funding would be used, and if you have made a formal request to Ms. DeLauro's Committee. And I am going to ask you to be brief because we have a couple more questions and I want to allow time for my colleagues.

Dr. ACHESON. Are you talking about in the context of the 2010 budget?

The CHAIRMAN. Yes.

Dr. ACHESON. Well, clearly, that hearing hasn't occurred so I don't want to preempt anything that may be said there. But, let me speak to the importance of attribution and how states and locals as well as other Federal agencies, particularly CDC, play a key role there. This gets back to the risk. It is critical to know who is getting sick from what food and where on the production lifecycle is the problem occurring. If we stick with the example of fresh produce, is it at the farm, the processor, the distributor or the retailer, to be simplistic. That is what attribution is about. There are fairly sophisticated systems for simply measuring the number of O157 and *Salmonella* cases that are present but very limited sophistication in the information on the second part, which is critical if you are going to target your preventive strategies to the areas of greatest risk of exactly where is that contamination occurring and how. The states and the locals play a huge part in that because they are front and center, on the front line of investigations, where that information is usually the most easy to get.

The CHAIRMAN. In your testimony, you discussed the benefits of cooperation and coordination with the Federal and state industry partners. In fact, in the last hearing that we conducted I advocated for the same thing, indicating that I thought in California, for example, where nearly 50 percent of the fruits and vegetables in this country are grown, that CDFA does a fabulous job in what they do and the partnerships they worked out with growers. Can you envision a food safety framework in which FDA sets standards for fresh produce and USDA does the inspection and enforcement for those standards?

Dr. ACHESON. I can see part of that. I can certainly envision a situation where FDA sets the standards and the components of other regulatory bodies or potentially third parties would be undertaking some level of inspections. That is how I would see those partnerships working with other Federal colleagues and states and the locals. I believe that when it comes to enforcement, that is largely an FDA role, but I think that that would be a detail that would have to be worked out. But, unquestionably, the inspection part, the training part, the education, and as you pointed out, the relationships that many of those people already have with farmers is a huge piece of talent that we should build into any partnership.

The CHAIRMAN. I would like to submit this question to you, the one I just asked and the one I am going to ask, for follow-up and have you get back to me a written response. I think it really requires a lot of time for detailed thought and examination and sort of some soul searching within the organization. We are going to have to do the same thing in Congress to figure out what is the best role, who has the best expertise, who has the technical knowledge in whatever area. There has been some suggestion amongst Members that have discussed this topic of having a bifurcated system not crop by crop linearly up and down, but possibly side to side where FDA may establish standards, USDA would take those standards, and they would regulate field production generally. Then, processing above that level when you take the products and have a secondary process, that those might be legitimately and more properly regulated by FDA. I would like to have more discus-

sions where we can talk about those different potential models and see what makes the best sense, because certainly you want the folks with the most expertise and the most inspectors and the most ability to keep the public safety to do the regulatory response in those areas. So, I would like to pursue this with you in much greater detail.

Dr. ACHESON. We would certainly look forward to that. I think those are excellent points and I would be happy to engage in a dialogue with you on that.

The CHAIRMAN. Thank you. I have a number of questions that I want to ask you with regard to some other issues, specifically pistachios and leafy greens, but what I am going to do now is turn it over to my colleagues to ask their 5 minutes of questions, and then we will have a second round with you all.

So Mr. Costa, are you prepared for questions?

Mr. COSTA. Yes. You talk about risk assessment and risk management and you said you need more data. What in the way of data are you talking about? Are you talking about data that is contained where the products are grown? Are you talking about data in terms of your ability to have this information? Are you talking about the traceback ability that I mentioned in my opening commitments?

Dr. ACHESON. Are you addressing that question to me?

Mr. COSTA. Yes. You raised the issue that you need more data.

Dr. ACHESON. Absolutely, and I think is all of the above, because if you are truly going to do a risk-based approach, you need information. If you pick a specific commodity and you want to establish preventive controls, you clearly want to establish those based on risk, so——

Mr. COSTA. Right, but when you establish based on risk, you also make an assessment on risk, do you not?

Dr. ACHESON. Yes. It is a culmination——

Mr. COSTA. Between every part per billion or trillion when you may know that you have a much greater potential contamination because of other factors, you would go there first before you would—I mean, you don't have unlimited resources.

Dr. ACHESON. Absolutely, and that is the whole point of this, is that in order to make that judicious use of resources, you have to take them to the areas of greatest risk, and you can't do that without adequate data input in terms of where are those areas of greatest risk. For example, with leafy greens growing in a field, is it the water supply, is it the proximity of the cattle, is it the wild animals, is it the human contact, is it the machinery. Those sorts of data inputs are absolutely key in terms of making decisions about what you would inspect, what samples you would take and what preventative controls are going to work optimally.

Mr. COSTA. You had mentioned earlier in response to the Chairman's comment about cooperation and collaboration with state and local agencies. As you may know, we have a rather sophisticated, I would argue, maybe the most sophisticated food safety efforts in California because of our fruits and vegetables and our traceability effort. But we also have another program that we have worked with over the years on harmonization that is required for registration of herbicides and pesticides with the Federal Government.

That harmonization program historically had worked well. Is that what you are advocating here in terms of a harmonization, a hand in glove working with not only California but other major ag producing states?

Dr. ACHESON. I am not specifically familiar with the pesticide program that you referred to, but the concepts are probably very similar and would run in parallel. As we said earlier, it is using the expertise at the state, local and Federal colleague level, so that you are essentially not reinventing the wheel but you are building a seamless, integrated system that is going to allow you to build off that skill set.

Mr. COSTA. And so if you want to take advantage of that, the data and the other efforts to improve the programs, have you developed a matrix to see what best management practices are, taking a look at states like California and Florida and others so that we don't reinvent that wheel?

Dr. ACHESON. I think that is part of the process that we have to embark on. Over the last 12 months, there has been real movement in trying to engage more actively with the states in a number of areas. We held a meeting a year ago with all 50 states to begin to get into that information sharing, training, risk-based approaches and response elements. This is going to gain momentum, and if we get the money that we have asked for 2010, a portion of that would be used——

Mr. COSTA. Well, the money has been—well, we don't know if we will appropriate it but——

Dr. ACHESON. Well, that is what I mean.

Mr. COSTA.—the request has been made. My time is expiring so let me move on here. You talked about potential kill steps for fresh produce. What concerns do you foresee being raised on some of the new technologies that are being developed?

Dr. ACHESON. I think the concerns that we would have, if any, are, are they safe in terms of from a public health perspective. If it does the job and it is safe from a public health perspective, then I don't see that FDA would have a concern with that.

Mr. COSTA. And what criteria are we using to make that determination?

Dr. ACHESON. Well, I mean, if you pick an example like using polypropylene oxide as a treatment that has been used very successfully in almonds, can you apply that to pistachios, and do you use it at a level that is ultimately going to result in residue that could prove to be hazardous to health. That is the kind of assessment that would need to be done.

Mr. COSTA. Since you mentioned pistachios, I want to commend you for taking a more targeted approach as it relates to the most recent incident on the various brands. I think that is a part of making a risk assessment and targeting.

My time has expired, Mr. Chairman. I obviously have other questions and I will wait for the second round or submit them after the hearing.

The CHAIRMAN. Thank you, Mr. Costa.

Mrs. Schmidt, I would like to call on you for your questions and apologize to you. The culture of different committees—in this Committee we always recognize the Ranking Member first. In Rules

Committee, we do it the other way, and I have been on that committee more than on this Committee lately, and I called Mr. Costa first and I apologize, but thank you for——

Mr. COSTA. I apologize. I walked in late. I thought she had asked the last question.

Mrs. SCHMIDT. You know what, it doesn't matter as long as you get to the dinner table and you get some food, it is okay.

Dr. ACHESON. As long as that food is safe.

Mrs. SCHMIDT. Exactly. Growing up on a farm, our food was always safe.

Dr. Acheson, I have a couple of questions for you. First off, is it possible that irradiation could be used in the fresh fruit and vegetable industry, particularly with leafy greens, and what do you see as the pros and cons of using such technology?

Dr. ACHESON. Well, as I am sure you are aware, FDA has already approved the use of irradiation for certain types of leafy greens following a petition that was submitted several years ago. So that is already approved and FDA doesn't have a problem with it being used. So from a public health perspective, per the previous conversation, we don't have concerns that that will introduce a public health risk. There are obviously many other factors around whether or not such a technology would be used in terms of consumer acceptance, technological availability and economic impact.

Mrs. SCHMIDT. Okay. In previous testimony before the full Committee, sir, there was a call for the FDA to mandate HACCP for fresh fruits and vegetable growers. HACCP is a process control model typically applied to food processing. How do you see HACCP being applied on the farm?

Dr. ACHESON. I think HACCP is a very specific term that speaks to a very specific approach to preventive controls. We would see that while preventive controls are necessary on the farm, it needs to be done in a slightly broader way, again looking for what are the critical control points and how does one manage them. I could envision a situation on a farm where one wouldn't necessarily have all the mitigation practices be figured out to truly apply authentic, rigid HACCP. But the concept of risk-based approach in terms of preventive controls, which is the HACCP principle, absolutely, I think it could be used to great effectiveness on farms.

Mrs. SCHMIDT. Along the same lines, if HACCP were applied to the farm, what more are we going to get from this than from Good Agricultural Practices already in place?

Dr. ACHESON. What you get is, if it is mandatory and if it is enforced then there is verification that is being followed.

Mrs. SCHMIDT. And along those same lines, what kind of paperwork is going to be involved with the farmer to make sure that all of these things have been met?

Dr. ACHESON. I think that that would be a part of the discussion around such rulemaking if that was to proceed. I mean, I think reading between the lines of your question, what would be the economic impact and the paperwork impact on individual farmers, which could vary depending on the size of the facility and the level of sophistication and the demand for what is required. And, to be honest with you, I think that that would be part of the debate as one moves forward to actually putting this into practice.

Mrs. SCHMIDT. Do you see a difference between large farms, small farms, or would there be the same universal application across all farms, and then how do you mitigate the impact on the cost of doing business on a small farm *versus* the cost of doing business on a large farm?

Dr. ACHESON. I think again, that all has to be part of the economic analysis that is looked into when these things move into a rulemaking process. The impact on small business, whether it is a farm or a processor or what it is, is always a factor that is taken into account. But let us not lose sight of that argument that size does not equate with safety. Small facilities could clearly be a risk as we have seen over and over again, is it doesn't take much of a corner of a spinach field to cause havoc with spinach and create a lot of illnesses. We saw exactly the same with peanut butter earlier this year where a relatively small facility was distributing very widely. So, we have to be cautious about that, yet recognize that we have to also consider the economic consequences.

Mrs. SCHMIDT. And nobody should ever sacrifice safety for a dollar amount. I wasn't meaning to suggest that you would do that.

Dr. ACHESON. No, I didn't take it that way.

Mrs. SCHMIDT. Thank you. One more quick question. In the rulemaking process, what kind of input do you get from the farmers during the process, is it just behind closed doors?

Dr. ACHESON. No, it is very public, and this hasn't started yet, but I would anticipate this would be a very public process with public hearings, *Federal Register* notices. It is really a system that facilitates getting comment from everybody who has something to say.

Mrs. SCHMIDT. Thank you.

The CHAIRMAN. Thank you very much, Mrs. Schmidt.

We will continue with questions. Dr. Acheson, the recent recall of peanuts processed by the Peanut Corporation of America due to contamination with *Salmonella* was associated with over 700 serious illnesses, one of which was yours truly. There was also a recent recall of pistachios processed by Setton Farms due to contamination with *Salmonella*. How many illnesses have been linked to the recent recall of pistachios?

Dr. ACHESON. I am aware of one potential illness that was associated with pistachios, a young infant on the East Coast who reportedly consumed the product and became sick, and actually had the same serotype isolated from a stool sample as we had seen in the facilities.

The CHAIRMAN. I had not heard of that. I had heard that there was only one complaint but no serious illness. Is that what you mean?

Dr. ACHESON. No. I am aware of numerous complaints but the only one that looked like where there was actually a positive stool sample in a young infant. It doesn't mean that it was from pistachios.

The CHAIRMAN. I see. So you don't have a direct link there, it is a potential?

Dr. ACHESON. The infant reportedly consumed product that was part of the recall, got sick, had gastroenteritis, was positive for *Salmonella* with the same *Salmonella* strain that was found in the

pistachios. So is it an absolute dead-straight line? No, but it is suspicious.

The CHAIRMAN. Okay. Did the pistachio industry fully cooperate with FDA?

Dr. ACHESON. Absolutely, yes.

The CHAIRMAN. Given that there were few illnesses, as I said, there is this one, may consumers now safely eat pistachios that aren't subject to a recall?

Dr. ACHESON. Indeed. We recognized right from the beginning here that this was going to have an impact on pistachio consumption, and immediately within days worked with the pistachio industry to develop a tool that was on *pistachiorecall.org*. We were directing consumers to where they could look and determine that there was product that was not associated with the facility in which we had the concerns with ongoing recalls.

The CHAIRMAN. Has the FDA formally made that announcement in general to the public in press releases that pistachios are now safe to eat?

Dr. ACHESON. We have always said that pistachios that are not subject to the recall can be consumed. We said that right from the beginning. One of the challenges that we have right now is that we are still seeing pistachio products being recalled that are stemming back from that original recall, as we are still seeing peanut butter samples and peanuts, and that speaks to the complexity of the distribution systems and the difficulties with product tracking. One could ask, why don't people know where the product is coming from, and if they did and could do the recalls more quickly, we could shut these things down faster and get more positive consumer messages out there to protect the public and the industry.

The CHAIRMAN. I am somewhat concerned because about a 40 percent reduction in pistachio consumption occurred around that time. That is one of the devastating things that can happen to an industry. When one bad actor potentially has done something or missed something, it can just devastate the whole industry. Pistachios, have a little bit more shelf life than, say, a tomato does, but we certainly saw the effects to the industry of getting one incorrect. It wasn't the tomatoes, it was the jalapeños, as I recall. We have to be very judicious in how we protect the public, and at the same time, on how we don't devastate industries that are trying to be good participants with us in making their product as safe as possible. Balance is always difficult but it must be determined correctly. You might want to speak to that.

Dr. ACHESON. I agree with you. Our mission at FDA is to protect public health, and I think the pistachio situation was a great example of how the industry informed us of the problem. We tracked it back pretty quickly, again working with California, to a specific facility, and at that point we were able to work with the firm so they initiated recalls to get potentially contaminated product off the market. At the early stages of this, we knew that there were potentially millions of pounds of pistachios in the market, potentially, contaminated with *Salmonella*, and the prudent public health approach is to issue that information to consumers and to advise them to avoid consuming pistachios while this is gaining greater

clarity. That is the approach that is going to maximize public health protection.

The CHAIRMAN. Thank you.

I would now call Mrs. Lummis to ask her questions.

Mrs. LUMMIS. Thank you, Mr. Chairman. It is an honor to serve on this Subcommittee with you and Ranking Member Schmidt. I do have an opening statement that I would like to submit for the record.

[The prepared statement of Mrs. Lummis is located on p. 8.]

The CHAIRMAN. Without objection.

Mrs. LUMMIS. Thank you.

The first question I have is not leading, I am just curious. I have no opinions about this so don't feel like I am trying to lead you to something. I just have a genuine question here. Do you think it would be a better fit for the U.S. Food and Drug Administration to shift all responsibilities for food inspection to the USDA? That would allow the FDA to focus exclusively on drugs and consumer products. Since that is the big focus of the FDA, I wonder sometimes whether food gets lost in the FDA. It doesn't get lost in the USDA, so it is just an open-ended point of curiosity and I would like to start with Dr. Acheson.

Dr. ACHESON. I think that is an easy one to answer. In short, no. I think that would be a retrograde step for public health. The Food and Drug Administration obviously has oversight of medical products and foods for humans and for animals. It also has a great deal of expertise at the scientific level and the inspection level with regards to foods. Simply moving the inspection of foods from the Food and Drug Administration to the Department of Agriculture the way that you outlined it would, I believe, be a retrograde step for public health.

Mrs. LUMMIS. Dr. Solomon, do you agree with that?

Dr. SOLOMON. I do agree with that.

Mrs. LUMMIS. And Mr. Shipman?

Mr. SHIPMAN. I don't disagree with it, but I think that we need to recognize that the Administration has their food safety working group ongoing right now. Some of the issues that they are looking at is looking at the structure both from a statutory standpoint, a regulatory standpoint, and then how do you carry that out. I would defer answering specifically as to whether I agree or disagree until I see what that working group has to say.

Mrs. LUMMIS. Thank you. My next question is for Mr. Shipman. Have you seen a growth in participation in the Good Agricultural Practices and Good Handling Practices Audit Verification program and the Qualified-Through-Verification program?

Mr. SHIPMAN. Yes, we have since we put into place the Good Agricultural Practices and Good Handling Practices program. Just to give you an example, in 2006 we only did 52 audits, and in 2008 we did over 1,500 audits. So yes, we are seeing growth and we see that growth continuing this year.

Mrs. LUMMIS. And a second question, Mr. Shipman. Can you describe the relationship with the FDA when AMS incorporates FDA's guidance into verification programs and marketing orders and agreements?

Mr. SHIPMAN. Yes, we have a very close consultative process where if they are changing any of their requirements, our staffs are working together to ensure that we incorporate the latest requirements into the verification systems or programs that we have. We also have a standing Memorandum of Understanding, so that not only would these auditing programs but with our thousands of quality inspectors that are throughout the country, if they encounter anything that would be a violation of FDA requirements, action limits through that MOU, we notify the local FDA officials.

Mrs. LUMMIS. Thank you. Further, Mr. Shipman, when it comes to farm practices, I admit that I am skeptical of government mandates. That is why I am particularly interested in your testimony about voluntary marketing agreements. Do you have any data that would indicate how much a producer invests, on average, to comply with a marketing agreement?

Mr. SHIPMAN. I would have to get you for the record how much folks invest for that, but I would like to state that under the voluntary agreements, the uniqueness of those agreements is, that number one, they are voluntary, and number two, in the actual development of those programs, it is a collective input from all of the industry. We are going through one right now where we are addressing the leafy greens program on potentially a national basis. That is something that would be developed by bringing all parties to the table and working through whether an agreement is necessary, and then developing standards at a later time. That is not a one-size-fits-all program. It would be unique to the particular crops and, potentially, regionally.

Mrs. LUMMIS. My time is up, but Mr. Chairman, if would indulge one more follow-up question?

The CHAIRMAN. Yes.

Mrs. LUMMIS. Thank you.

Mr. Shipman, have you found that compliance with voluntary marketing agreements is high?

Mr. SHIPMAN. Again, I would have to get for you for the record the exact record of how many noncompliances, but it is my understanding that yes, when people sign up and they enter into these voluntary agreements, they are prepared to do what needs to be done to comply with it, and then the auditors are out there reviewing, I believe we do have a very high compliance rate but I would like to submit that for the record.

Mrs. LUMMIS. I would appreciate it if you would. Thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. Massa, this would be your appropriate time to ask questions.

Mr. MASSA. Thank you, Mr. Chairman. Good afternoon, gentlemen, and I approach these panels as an opportunity to be educated myself. I am from New York, where we have one of the highest concentration of family-owned and organic farms in the country. And it seems like almost every year for the past 6 or 7 years there has been at least one major, I call CNN moment, headline-grabbing food safety or food contamination news week-long issue—tomatoes, peanuts, pistachios as they are.

Dr. Acheson, could you please comment, have any of those been driven by small organic farms?

Dr. ACHESON. I am not aware that any of those have been driven by small organic farms, no.

Mr. MASSA. And if there are, feel free. I don't want to have a "gotcha" moment. If there is one, feel free to get back to me. It is not a rhetorical question. There is potential of significant pending legislation that will change how the locally sustainable grown foods and organic farm entities are looked at. I am relatively concerned that we don't drive them out of business, but that we also supply public safety. What issues are you looking at surrounding that segment of our farm economy?

Dr. ACHESON. I would have to get back to you with specifics on that, but my belief is that from a public health food safety perspective, we have not differentiated between farms that grow organic crops *versus* farms that grow conventional crops. We are looking at both in the context of how do you ensure that whatever is being grown is being grown in a way to ensure that it is safe.

Mr. MASSA. Can you commit to me as I report back to my constituents that one size does not fit all? There are a lot of regulations in the marketplace and in farm America. Some are much more easy to implement in large—I don't want to say factory farms, that is an improper characterization—but the smaller owned farms sometimes have a much harder time implementing these regulations. Can you commit to me that some measure of common sense will be, is and perhaps even has been applied with the formulation and implementation of these kinds of regulations?

Dr. ACHESON. I would certainly give you my commitment that as much common sense as can be brought to bear, hopefully, be brought to bear, as this dialogue continues. I think in answer to an earlier question is that this is typically a very public process which facilitates the opportunity for the very stakeholders you are concerned about to vocalize their concerns, whether they be economic or application. In that context, I think we have to be looking at as if it doesn't matter whether a product is organic is not, is there still a potential risk for the product to be contaminated by microbial pathogens or chemical agents, depending on the circumstance, and that preventive controls need to be in place whether you are an organic farmer or a regular farmer. One would certainly hope that during that public process, common sense will prevail and that the practical consequences of passing legislation that is non-implementable or non-enforceable are taken into account because that would be counterproductive.

Mr. MASSA. Last question, sir, and then I will ask if your associates would like to add to the conversation. You mentioned that there were problems in recalling products as far as tracing them back through processors towards point of origin. I am guessing that the focus of that comment really was on domestic produce. However, as you know much better than I, a large amount of the green leafy produce and citrus is now opened up to international markets. Are you equally or more concerned as I am about the traceability of foreign-produced food or that of domestically produced food?

Dr. ACHESON. We are concerned about both.

Mr. MASSA. Would you quantify the—I understand the concern about both but if you could offer me a quantification, I would appreciate it.

Dr. ACHESON. I would have to do that in writing, but I think that would be very difficult. The more complex a supply chain, the harder it is to track something back. We have already demonstrated that domestically the supply chain for certain types of fresh produce is incredibly complex, whereas on the other hand, the supply chain for certain imported products is relatively straightforward. So I don't think there is a clear rule of imports *versus* domestic. Having said that, if you are going to put in a system that is looking at how do you track a product back or forward rapidly, it cannot simply stop at the border. That would make no sense.

Mr. MASSA. And do your associates have any thoughts on these issues? Gentlemen?

Dr. SOLOMON. Nothing else. I agree.

Mr. SHIPMAN. Nothing else.

Mr. MASSA. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Massa.

I have further questions for acting Administrator Shipman. Some proposed food safety legislation envisions the use of third-party auditors to ensure compliance of foreign imports with regard to mandatory standards. Can you explain in greater detail AMS's industry audit and accreditation program, particularly its accreditation function?

Mr. SHIPMAN. In terms of the auditing programs I talked about today in terms of the GAP/GHP and the QTV, those are state employees and Federal employees that are doing those reviews and audits. We are not using an additional third-party accreditation system. We are using Federal employees or state employees that have been trained to certain specifications including ISO auditing practices.

The CHAIRMAN. You stated that once an official request for rulemaking is made, say in the case of national leafy green marketing agreements, you would conduct a nationwide hearing. How is the public comment obtained during these hearings used to inform and determine the requirements?

Mr. SHIPMAN. The public meetings that we would hold would be to gather further information in terms of the interest in and the structure of one of these marketing agreements. Once we have that, we would actually draft the agreement and it would be published in the *Federal Register* for a complete public comment.

The CHAIRMAN. You stated that AMS is not a food safety agency, and yet AMS has taken a leading role in developing and auditing microbiological data programs for the fruit and vegetable industry. For the Good Agricultural Practices and Good Handling Practices Audit Verification program, what training do AMS auditors receive?

Mr. SHIPMAN. We want folks that work for us that have a real background in quality determinations, so we typically work with our commodity graders or marketing specialists, they have a real strong understanding of quality assurance, quality control and food processing. They will receive, at a minimum, basic auditor's train-

ing and they will receive ISO 9001 lead auditor training as well as training in the Good Agriculture Practices (GAP) and Good Handling Practices (GHP). They work with a lead auditor for a while to ensure that they have adequate education before they provide auditing service. In addition, they are required to have 120 hours a year additional training and education to retain auditor status.

The CHAIRMAN. Mr. Shipman, I am very interested in the Microbiological Data program that you discussed, in light of the rapid identification of *Salmonella* in two products in April. Can you describe how the program works? Are samples taken and tested by AMS? Is it the state partners who do this work or is it by industry participants? And second, how and when do you communicate these results of the samplings with FDA and CDC?

Mr. SHIPMAN. The program involves 11 states, each with laboratories. USDA also has one laboratory. The states are partners. We will go out and sample. We collected, for example, last year 7,000 samples. In a typical year we try to collect in the neighborhood of 11,000 samples. They are collected at wholesale and retail locations. They are brought back, and tested in the lab. The results, if we have any sort of positive indication, are shared with CDC and FDA and confirmation testing has occurred because it is—you need to be careful about having false positives. So we want to ensure that they are accurate results so there is repeated testing and verification that occurs before those results are used for any sort of policy decision.

The CHAIRMAN. A follow-up to Dr. Acheson, does FDA have a parallel sampling program for fruits and vegetables, and if so, are the data from that program shared in the other direction with AMS?

Dr. ACHESON. FDA does not have the same level of surveillance that my colleague has just alluded to. What we have is assignments that are issued on a regular basis for different types of foods including fresh produce from time to time. It is usually targeted. It is usually based on the specific risk or concern, but it is not as extensive as the AMS program. In terms of whether that information is shared with AMS, certainly we are happy to do that. I don't know whether there is an active process to do that, and I will check into that and get back to you.

The CHAIRMAN. Please. I would like to have that information.

That concludes my questions. Mrs. Schmidt, do you have further questions?

Mrs. SCHMIDT. Thank you. Yes, I do.

This is for Mr. Shipman. Based on your testimony, sir, it appear AMS incorporates food safety under marketing orders and agreements as part of your authority to verify quality. Do you believe legislation is needed to allow for the implementation of food safety programs under marketing orders and agreements?

Mr. SHIPMAN. We have had that question posed to us. We have engaged our legal counsel at the Department and we have concluded that there is adequate authority now under the Marketing Agreements Act for us to incorporate quality related requirements.

Mrs. SCHMIDT. Thank you. And one more question, growers are usually quick to mention their concern about a one-size-fits-all approach to food safety. Given the variability of crops, climate, geog-

raphy and size of the farms, *et cetera*, can you explain how AMS accommodates commodity-specific approaches for food safety in various marketing orders and agreements?

Mr. SHIPMAN. Yes. Again, I want to make sure I emphasize that we are not a food safety agency. We don't set food safety policy. But we do work with producers, and if producers are interested in entering and establishing a marketing agreement or a marketing order, it is up to the producers to do so. Agreements are voluntary. And when we work with those producers, we bring them together. We will determine if it has a food safety element to it. We will look at Good Agricultural Practices and Good Handling Practices and the criteria for those and how they are adapted. The standards that would be developed would be done collectively, with a committee or a board that is overseeing those marketing orders or marketing agreements, and ensure it is the representation of the producers. So you naturally, out of the process, end up with regional commodity-specific criteria that you are working with in these agreements and orders.

Mrs. SCHMIDT. When you say the board makes the decision, sir, is there input from the community on it or is it just a straight board function?

Mr. SHIPMAN. There is an open, transparent process to collect the information and gather the information, and as far as actually setting up the order or the agreement, we go through the *Federal Register*. It is a regular rulemaking process. When you are actually working with standards and specifications, the board that is made under the order or under the agreement is participating in that process, but you are gathering information from the public at large.

Mrs. SCHMIDT. Thank you.

The CHAIRMAN. Thank you, Mrs. Schmidt.

I now recognize the gentlelady from Wyoming for 5 minutes.

Mrs. LUMMIS. Thank you, Mr. Chairman.

I am following up on Mr. Massa's questions, first of all to Dr. Acheson. If FDA were to make Good Agricultural Practices mandatory, would the agency enforce these requirements on farms operating in foreign countries? I thought I heard you say they would.

Dr. ACHESON. FDA's approach to preventive controls is that they need to be applied equally whether it be domestic or foreign. There aren't two sets of standards here, and I want to make that very clear.

Mrs. LUMMIS. Thank you. And further, your testimony mentioned the need for authority to require preventative controls for food. Would this authority extend to the farm or just within processing facilities?

Dr. ACHESON. That will ultimately depend on where Congress decides to take that point in terms of how far it extends. Our belief is that one has to look at preventative controls from one end of the food supply chain to the other. It starts at the farm and it ends at the retail, and you need to have adequate preventative controls from one end to the other in order to do the job appropriately to safeguard public health.

Mrs. LUMMIS. And Dr. Acheson, has there been an analysis of the costs of that to farmers, the cost of compliance?

Dr. ACHESON. I am not aware that there has been analysis of the cost because at this stage we don't know what the rule might look like or what the legislation would look like, but again, as part of the public process and the rulemaking process, economic considerations are taken into account. It is part of actually moving it through the public rule and comment period in which economic impacts on small and large businesses are examined and the economic impact on the business *versus* the economic gain from a public health perspective. So at this stage that process has simply not happened because we are not there yet, but it will.

Mrs. LUMMIS. Thank you. And finally, I am just curious about how would the FDA enforce its rules on another sovereign? If we are going to try to have a level playing field and mandatory rules, how could we apply them off our shores to food that is brought in?

Dr. ACHESON. I think that is a very important question, and it is a very complex one. We currently import foods from over 150 different countries all over the world, and the complex answer to that is that it is going to need a significant ramping up of approach as to how you do that. You have two bites of this. Essentially, you have oversight of what is happening in that foreign facility, whether it be a grower or a processor or manufacturer of some other food or food ingredient. That potentially is a combination of working with foreign governments, working with the industries. One of the suggestions it to appropriately use third-party inspections to inform that process, and the third element to that is FDA inspections themselves. We currently inspect a small number of foreign establishments. We are increasing that by about ten-fold over the next 2 or 3 years. So I would say that it would be a combination of those three elements. You then have the second level of control at the port of entry where all foods have to be—FDA has to be informed when a food is showing up. The system that I would see that we would try to build here is to use that information through foreign governments, FDA inspections, third parties to inform the risk-based decision making at the port of entry, and if you have concerns, you can hold a sample, hold the food, inspect it and potentially test it. That system is not currently in place, but if this is going to work, those are the types of models that one would have to use and it would require a lot of work and adequate resources.

Mrs. LUMMIS. So Dr. Acheson, I assume that that means that you would hold up food at the port that was not verified as having participated.

Dr. ACHESON. We would be looking to hold up food at the port if we had concerns about whether it was unsafe. I think that is the key criteria here is, what assurance do we have that it is safe, and if there are concerns, then it should be inspected and tested.

Mrs. LUMMIS. Thank you very much, Mr. Chairman.

The CHAIRMAN. I would like to thank the gentlelady.

At this point I would like to dismiss the panel. We look forward to your answers in writing that we have requested throughout the day's hearing. I would like to call up the witnesses in panel number two. While you are coming forward, I would like to introduce you all. We have with us today Joe Pezzini, Chief Operating Officer of Ocean Mist Farms, Castroville, California; Ron Ratto, President, Ratto Brothers Incorporated, Modesto, California; Phil LoBue,

President of LoBue Brothers Incorporated, Lindsay, California; Nicholas Maravell, Owner and Operator of Nick's Organic Farm, Potomac, Maryland; Steve Hirsch, Partner, Hirsch Fruit Farm Inc., on behalf of Ohio Producer Growers and Marketers Association and the Ohio Farm Bureau, from——

Mrs. SCHMIDT. Chillicothe, Ohio.

The CHAIRMAN. From Chillicothe, Ohio. Thank you, Mrs. Schmidt, for giving me the pronunciation of that community. We have also Charles Wingard, Director of Field Operations, Walter P. Rawl and Sons, Pelion, South Carolina; and Robert Stovicek, Ph.D., President and Chairman of Primus Group, Santa Maria, California.

Mr. Pezzini, are you in place and ready to go? Very good. I ask you and all of our witnesses today, we have received and reviewed your testimony in detail. We would like you to summarize, if possible, your information at this point because we anticipate that there is going to be additional votes. I am concerned about the length of the hearing going on throughout the day. We haven't had much actual testimony time. We have had a whole lot of time going back and forth to votes, which has cut into our hearing time. I am fearful that we are not going to be able to complete the hearing if we don't summarize. Also, we won't be able to ask an adequate number of questions. So please try and extemporaneously summarize your testimony, and Mr. Pezzini, we will begin with you.

STATEMENT OF JOSEPH PEZZINI, COO, OCEAN MIST FARMS, CASTROVILLE, CA; CHAIRMAN, CALIFORNIA LEAFY GREENS MARKETING AGREEMENT; ON BEHALF OF WESTERN GROWERS ASSOCIATION

Mr. PEZZINI. Thank you very much. Good afternoon, Mr. Chairman and Committee Members. My name is Joe Pezzini and I am the Chief Operating Officer for Ocean Mist Farms.

Ocean Mist Farms is a family-owned company based in Castroville, California, that has been producing vegetables since 1924. We are committed to both the art and science of agriculture and have invested heavily in the plant breeding, growing, harvesting, cooling and shipping operations which are all state of the art. I am also Chairman of the California Leafy Greens Marketing Agreement, the organization formed a little over 2 years ago to regulate the leafy greens industry in California and to verify that our growers are all implementing the highest food safety practices in growing, harvesting and handling of lettuce, spinach and other leafy green vegetables.

Two years ago to the day, I testified before this Subcommittee about a new public-private partnership created to verify that the best practices in food safety on the farm were being followed for the production of lettuce and leafy greens. At that time the program was just starting. Now I am here today to give you an update on the California Leafy Greens Marketing Agreement.

Let me start by providing some background. In September of 2006, an outbreak ultimately tied to California-grown spinach resulted in a national recall that brought our industry to a halt. The outbreak had huge financial costs but more important were the human costs. Over 300 consumers were ill from the tainted spinach, and tragically, three people died. Since that time outbreaks as-

sociated with other products have continued to keep a national focus on food safety policy. Given that debate, the steps we have taken in California to raise the bar for food safety may be instructive as we have created a program with strong government involvement to certify that our members are doing all they can to reduce the risk of foodborne illnesses in California's leafy green products.

Following the spinach outbreak in 2006, our industry joined with the California Department of Food and Agriculture and the U.S. Department of Agriculture to create the Leafy Greens Marketing Agreement. As an industry, our goals were to create a program with strong management oversight and involvement in order to rebuild confidence in our products, adopt of science-based food safety standards that would become a universal standard adopted by all leafy green growers in the state, incorporate government inspections to verify compliance with the new standards, and build a program with effective and transparent penalties for noncompliance.

It is important to note that the Leafy Greens Marketing Agreement is not industry self-regulation. Although membership in the organization is voluntary, once a company joins the requirements of the agreement, compliance is mandatory for all members and the results are backed by the force of law. As an industry, we insisted on the use of government agriculture inspectors who are independent, credible, unbiased rather than private company auditors.

Since its creation 2 years ago, the Leafy Greens Marketing Agreement has had several significant achievements. Almost 100 percent of the leafy greens products in our state are marketed by companies that are signatories to the marketing agreement, meaning that virtually all California leafy green are being shipped by companies inspected by USDA inspectors and certified to be in compliance with Good Agricultural Practices. In the past 2 years we have completed almost 1,000 food safety audits of our handlers and growers in California, all done by government inspectors, and those audits resulted in issuance of over 1,800 individual citations, mostly for fairly minor nonconformities. Since the marketing agreement requires corrective action on all of these nonconformities, we have required that our members undertake corrective action on any and all issues cited by inspectors. The Leafy Greens Marketing Agreement program does have teeth. We have not hesitated to punish through decertification with public notification of companies that commit flagrant penalties or fail to correct minor problems as required by the marketing agreement.

Let me give you some of my company's experience as a member of the Leafy Greens Marketing Agreement. Because the Leafy Greens Marketing Agreement audit standards are comprehensive and very specific, this has become the most rigorous inspection we face on the farm as we deal with many different audits for various companies. It can be tedious and very document-intensive. The other compelling feature is that we are subject to scheduled and unannounced audits as part of the program. This means vigilance must always be maintained as inspectors will show up at any time. And compliance is very real to us. If we lose our certification, not only is it made public, it has huge consequences to our business. We would not be able to sell our products to buyers in Canada or

Mexico and domestic customers like Markon Foodservice would stop doing business with us.

To conclude, we accept these responsibilities with a doubling of our resources and staff dedicated to food safety programs over the past 2 years, but no company can take food safety for granted. When an outbreak occurs, it impacts the whole industry. Our livelihoods and reputations depend on our ability to produce safe food, but most importantly we are committed to protecting public health as this is the same food we feed to our families.

I would like to thank the Committee for allowing my testimony and I am pleased to answer any questions you might have.

[The prepared statement of Mr. Pezzini follows:]

GOOD MORNING MR. CHAIRMAN....MY NAME IS JOE PEZZINI AND I AM THE CHIEF OPERATING OFFICER FOR OCEAN MIST FARMS. OCEAN MIST FARMS IS A FAMILY OWNED COMPANY BASED IN CASTROVILLE CALIFORNIA THAT HAS BEEN PRODUCING VEGETABLES SINCE 1924. WE ARE COMMITTED TO BOTH THE ART AND SCIENCE OF AGRICULTURE AND HAVE INVESTED HEAVILY IN OUR PLANT BREEDING, GROWING, HARVESTING, COOLING AND SHIPPING OPERATIONS WHICH ARE ALL STATE OF THE ART.

I AM ALSO CHAIRMAN OF THE CALIFORNIA LEAFY GREENS MARKETING AGREEMENT, THE ORGANIZATION FORMED A LITTLE OVER TWO YEARS AGO TO REGULATE THE LEAFY GREENS INDUSTRY IN CALIFORNIA, AND TO VERIFY THAT OUR GROWERS ARE ALL IMPLEMENTING THE HIGHEST FOOD SAFETY PRACTICES IN GROWING, HARVESTING, AND HANDLING OF LETTUCE, SPINACH AND OTHER LEAFY GREEN VEGETABLES.

TWO YEARS AGO TO THE DAY, I TESTIFIED BEFORE THIS COMMITTEE ABOUT A NEW PUBLIC-PRIVATE PARTNERSHIP CREATED TO VERIFIY THAT THE BEST PRACTICES IN FOOD SAFETY ON THE FARM WERE BEING FOLLOWED FOR THE PRODUCTION OF LETTUCE AND LEAFY GREENS. AT THAT TIME THE PROGRAM WAS JUST STARTING. NOW I AM HERE TODAY TO GIVE YOU AN UPDATE ON THE CALIFORNIA LEAFY GREENS MARKETING AGREEMENT. AND WITH OUR EXPERIENCE I AM EVEN MORE CONVINCED THAT THIS MODEL PROGRAM IS A "BEST IN CLASS" EXAMPLE OF A PUBLIC PRIVATE PARTNERSHIP ALLOWING INDUSTRY AND GOVERNMENT TO WORK TOGETHER TO ACHIEVE COMMON GOALS.

LET ME START BY PROVIDING SOME BACKGROUND.

IN SEPTEMBER OF 2006, AN OUTBREAK ULTIMATELY TIED TO CALIFORNIA-GROWN SPINACH RESULTED IN A NATIONAL RECALL AND BROUGHT OUR INDUSTRY TO A HALT. THE OUTBREAK HAD HUGE FINANCIAL COSTS, BUT MORE IMPORTANT WERE THE HUMAN COSTS. OVER 300

CONSUMERS WERE MADE ILL FROM THE TAINTED SPINACH, AND, TRAGICALLY, THREE PEOPLE DIED.

SINCE THAT TIME, OUTBREAKS ASSOCIATED WITH OTHER PRODUCTS HAVE CONTINUED TO KEEP THE NATIONAL FOCUS ON FOOD SAFETY POLICY. GIVEN THAT DEBATE, THE STEPS WE HAVE TAKEN IN CALIFORNIA TO RAISE THE BAR FOR FOOD SAFETY MAY BE INSTRUCTIVE, AS WE HAVE CREATED A PROGRAM WITH STRONG GOVERNMENT INVOLVEMENT TO CERTIFY THAT OUR MEMBERS ARE DOING ALL THEY CAN TO REDUCE THE RISK OF FOOD BORNE ILLNESS IN CALIFORNIA LEAFY GREEN PRODUCTS.

FOLLOWING THE SPINACH OUTBREAK IN 2006, OUR INDUSTRY JOINED WITH THE CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE AND THE US DEPARTMENT OF AGRICULTURE TO CREATE THE LEAFY GREENS MARKETING AGREEMENT. AS AN INDUSTRY, OUR GOALS WERE TO:

- CREATE A PROGRAM WITH STRONG GOVERNMENT OVERSIGHT AND INVOLVEMENT IN ORDER TO REBUILD CONFIDENCE AMONG BUYERS AND CONSUMERS ABOUT THE SAFETY OF LEAFY GREEN PRODUCTS FROM CALIFORNIA
- ADOPT A SET OF SCIENCE-BASED FOOD SAFETY STANDARDS THAT WOULD BECOME A UNIVERSAL SET OF STANDARDS ADOPTED BY ALL LEAFY GREEN GROWERS IN THE STATE
- INCORPORATE GOVERNMENT INSPECTIONS TO VERIFY COMPLIANCE WITH THE NEW STANDARDS
- BUILD A PROGRAM WITH EFFECTIVE AND TRANSPARENT PENALTIES FOR NON-COMPLIANCE

THE RESULT WAS THE CALIFORNIA LEAFY GREENS MARKETING AGREEMENT. IN ESSENCE A MARKETING AGREEMENT IS A LEGAL AGREEMENT THAT BINDS SIGNATORIES TO A COMMON PURPOSE. IN THE CASE OF THE CALIFORNIA LEAFY GREENS MARKETING AGREEMENT THAT PURPOSE IS TO CERTIFY THE SAFE GROWING AND HANDLING OF LEAFY GREEN PRODUCTS TO CONSUMERS.

IT IS IMPORTANT TO NOTE THAT THE LEAFY GREENS MARKETING AGREEMENT IS NOT INDUSTRY SELF-REGULATION. ALTHOUGH MEMBERSHIP IN THE ORGANIZATION IS VOLUNTARY, ONCE A COMPANY JOINS THE REQUIREMENTS OF THE AGREEMENT, COMPLIANCE IS MANDATORY FOR ALL MEMBERS, AND THE RULES ARE BACKED UP BY THE FORCE OF LAW. AS AN INDUSTRY WE INSISTED ON THE USE OF GOVERNMENT AGRICULTURAL INSPECTORS, WHO ARE INDEPENDENT, CREDIBLE AND UNBIASED, RATHER THAN PRIVATE COMPANY AUDITORS.

SINCE ITS CREATION TWO YEARS AGO, THE LGMA HAS HAD SEVERAL SIGNIFICANT ACHIEVEMENTS. ALMOST 100 PERCENT OF THE LEAFY GREENS PRODUCED IN OUR STATE ARE MARKETED BY COMPANIES THAT ARE SIGNATORIES TO THE MARKETING AGREEMENT, MEANING THAT VIRTUALLY ALL CALIFORNIA LEAFY GREENS ARE BEING SHIPPED BY COMPANIES INSPECTED BY THE USDA INSPECTORS AND CERTIFIED TO BE IN COMPLIANCE WITH OUR GOOD AGRICULTURAL PRACTICES. A COMPREHENSIVE SET OF FOOD SAFETY PRACTICES HAS BEEN DEVELOPED BY INDUSTRY EXPERTS, FOOD SAFETY SCIENTISTS AT MAJOR UNIVERSITIES AND OTHER FOOD SAFETY EXPERTS. THE CONSERVATION COMMUNITY HAS ALSO PROVIDED INPUT ON THE STANDARDS WORKING IN HARMONY WITH THE ENVIRONMENT. THESE STANDARDS ARE IMPLEMENTED THROUGH AND ENFORCED BY THE MARKETING AGREEMENT.

IN THE PAST TWO YEARS WE HAVE COMPLETED ALMOST 1,000 FOOD SAFETY AUDITS OF HANDLERS AND GROWERS IN CALIFORNIA – ALL DONE BY GOVERNMENT INSPECTORS. AND THOSE AUDITS HAVE RESULTED IN THE ISSUANCE OF OVER 1,800 INDIVIDUAL CITATIONS – MOSTLY FOR FAIRLY MINOR NON-CONFORMITIES. AND, SINCE THE MARKETING AGREEMENT REQUIRES CORRECTIVE ACTION ON ALL OF THESE NON-CONFORMITIES, WE HAVE REQUIRED THAT OUR MEMBERS UNDERTAKE CORRECTIVE ACTION ON ANY AND ALL ISSUES CITED BY THE INSPECTORS.

THE LGMA PROGRAM DOES HAVE TEETH. WE HAVE NOT HESITATED TO PUNISH, THROUGH DECERTIFICATION AND PUBLIC NOTIFICATION, COMPANIES THAT COMMIT FLAGRANT PENALTIES OR FAIL TO CORRECT MINOR PROBLEMS AS REQUIRED BY THE MARKETING AGREEMENT.

I AM HAPPY TO REPORT TO YOU, THEREFORE, THAT OUR INDUSTRY HAS FULFILLED THE PROMISES WE MADE TWO YEARS AGO. THIS PRIVATE PUBLIC PARTNERSHIP HAS RESULTED IN A STRONG SYSTEM FOR VERIFYING THAT LEAFY GREENS FARMERS ARE IMPLEMENTING ACCEPTED FOOD SAFETY PRACTICES AND PROTECTING PUBLIC HEALTH. AND, AS WE HAVE DONE THIS, WE'VE SEEN THE PROGRAM BECOME A MODEL FOR OTHER STATES AND INDUSTRIES. ALREADY, BOTH ARIZONA AND FLORIDA HAVE ADOPTED THE CALIFORNIA LEAFY GREENS STANDARDS AS THEIR OWN, AND WE'VE SEEN TOMATO AND MUSHROOM INDUSTRIES BUILD FOOD SAFETY PROGRAM MODELED ON OURS.

WE HAVE ALSO JOINED WITH AGRICULTURAL GROUPS FROM ACROSS THE COUNTRY TO WORK ON THE ESTABLISHMENT OF A NATIONAL LEAFY GREENS MARKETING AGREEMENT. THIS NATIONAL PROGRAM WILL BE BEST OVERSEEN BY THE USDA, WHO IS FAMILIAR WITH AGRICULTURE AND HAS THE ON FARM KNOWLEDGE TO INSPECT AND VERIFY GOOD AGRICULTURAL PRACTICES.

NOW, LET ME GIVE YOU SOME OF MY COMPANY'S EXPERIENCES AS A MEMBER OF THE LGMA.

BECAUSE THE LGMA AUDIT STANDARDS ARE COMPREHENSIVE AND VERY SPECIFIC, THIS HAS BECOME THE MOST RIGOROUS INSPECTION WE FACE ON THE FARM AS WE DEAL WITH MANY DIFFERENT AUDITS FROM VARIOUS COMPANIES. IT CAN BE A TEDIOUS PROCESS, VERY DOCUMENT INTENSIVE. THE OTHER COMPELLING FEATURE IS THAT WE ARE SUBJECT TO SCHEDULED AND UNANNOUNCED AUDITS AS PART OF THE PROGRAM. THIS MEANS VIGILANCE MUST ALWAYS BE MAINTAINED AS INSPECTORS WILL SHOW UP AT ANY TIME.

AND COMPLINACE IS VERY REAL TO US. IF WE LOSE OUR CERTIFICATION, NOT ONLY IS IT MADE PUBLIC, IT HAS HUGE CONSEQUENCES TO OUR BUSINESS. WE WOULD NOT BE ABLE TO SELL OUR PRODUCTS TO BUYERS IN CANADA OR MEXICO, AND DOMESTIC CUSTOMERS LIKE MARKON FOODSERVICE WOULD STOP DOING BUSINESS WITH US.

WE ACCEPT THESE RESPONSIBILITIES WITH A DOUBLING OF OUR RESOURCES AND STAFF DEDICATED TO OUR FOOD SAFETY PROGRAM OVER THESE PAST TWO YEARS. BUT NO COMPANY CAN TAKE FOOD SAFETY FOR GRANTED AND WHEN AN OUTBREAK OCCURS IT IMPACTS THE INDUSTRY AS A WHOLE. OUR LIVELIHOODS AND REPUTATIONS DEPEND ON OUR ABILITY TO PRODUCE SAFE FOOD. BUT MOST IMPORTANTLY WE ARE COMMITTED TO PROTECTING PUBLIC HEALTH, AS THIS IS THE SAME FOOD WE FEED TO OUR FAMILIES.

WHILE WE ARE PROUD OF THE PROGRESS WE HAVE MADE, WE REMAIN RESOLUTE IN OUR COMMITMENT TO DO EVERYTHING FEASIBLE TO PREVENT CONTAMINATION AND ILLNESS. WE LOOK FORWARD TO WORKING WITH THIS COMMITTEE TO ENSURE THAT WE ARE EMPOWERED TO MAKE CERTAIN WE DELIVER PRODUCTS THAT ARE SAFE, EVERY BITE, EVERY TIME.

I WOULD LIKE THANK THE COMMITTEE FOR ALLOWING MY TESTIMONY AND I AM PLEASED TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

The CHAIRMAN. Thank you, Mr. Pezzini. I appreciate you being here.

I would like at this time to take the witnesses out of normal order. I am told, by staff, that Mr. Hirsch, has an impending flight he needs to catch. I am going to ask you to summarize your testimony so that we can have time for Mrs. Schmidt to ask you some questions. We will give her her 5 minutes and then we will go back to regular order in the panel.

So Mr. Hirsch, would you please proceed?

STATEMENT OF STEVE HIRSCH, MEMBER, OHIO PRODUCE GROWERS AND MARKETERS ASSOCIATION; VICE PRESIDENT, OHIO FARM BUREAU FEDERATION; PARTNER, HIRSCH FRUIT FARM, CHILLICOTHE, OH

Mr. HIRSCH. Thank you, Mr. Chairman.

Good afternoon, Mr. Chairman and Members of the Subcommittee. Thank you for inviting me here to testify on the very important issue of food safety. My name is Steve Hirsch and my family and I operate Hirsch Fruit Farm in Chillicothe, Ohio, where we have raised both fruits and vegetables since 1872.

I am testifying today as a member of the Ohio Produce Growers and Marketers Association and as the Vice President of the Ohio Farm Bureau Federation. My family operates two farm markets, one located at the farm and a second several miles away. We sell 85 percent of our production directly to the public and the rest wholesale. We are members of the Chillicothe Farmers Market and buy and sell products at a local produce auction. We embrace a suite of food safety practices on our farm, in our markets, at the produce auction and at the farmers market. Though there are many common themes among these practices, they can vary because these environments differ and require food safety practices tailored to these different settings, and that is the theme of my testimony today.

In my view, compliance is the key component of any new food safety system and any new system should be flexible in nature so growers of all sizes can comply. The Ohio Produce Growers vary greatly in size, ranging from large operations that ship their produce both in state and across states to very small farmers that sell all their produce directly to the local public. Some are located in urban areas or near the shores of Lake Erie, while mine is in the hills of southern Ohio. Some irrigate from surface water, some use groundwater. Some are near livestock operations and some are nowhere near any livestock. My point is that a single national one-size-fits-all structure will not work and a national food safety system that allows for specific on-farm practices to be developed at the state level will achieve the best results.

To this regard, let me make several points: First, flexibility for on-farm practices. Flexibility regarding best management practices is key to the success of any new food safety system as different growing regions' practices vary significantly. Ohio Produce Growers, for example, tend to be involved in growing, packing and shipping of the product, and this may not be the case in other areas of the country. In Ohio, we have one of the largest concentrations of Amish farmers in the country. These growers do not use elec-

tricity and therefore must pick, pack and ship or sell all of their produce in one day. These are a few of the examples that highlight the need for flexibility.

There are several issues within the draft national Leafy Greens Marketing Agreement that are of concern to Ohio growers, such as: water use issues, animal intrusion issues and border distances surrounding crops. These specifics are designed around California's cultural practices and are not conducive to Ohio and many other states. The draft also subdivided the country into zones that have far too much variance and cultural practices. These vertical slices across the United States should be redefined to a state-by-state division which can better recognize more localized management issues.

Second, sound science: We believe any new practices should be based upon proven food safety practices and sound science. Currently, some of the science assumptions behind the California leafy greens approach are now being called into question. I would suggest the Federal Government take the time to fund and complete the science needed to determine the most appropriate practices to assure a safe food supply before moving forward with any new system.

Third, state coordination: Any new program should be coordinated with state departments of agriculture or other agencies responsible for food safety, inspection and enforcement. This coordination will be crucial to the success of new programs with any inspections conducted by and coordinated with state lead agencies *versus* an FDA inspector on the farm. The Ohio Farm Bureau office receives calls daily from small growers, organic growers and backyard hobbyists all very concerned with some of the legislative ideas in regard to new food safety systems. Flexibility would go a long way to addressing many of these concerns.

Fourth, economic impact: Any new system should consider the economic impact on various size operations across the country. Ohio, and likely other states, is at a distinct disadvantage regarding possible compliance costs because we must spread our costs over a shorter growing season, as opposed to states that can spread costs over the entire year given their longer growing season. A new system should be economically viable within existing industry structures that vary across the country.

I would like to note that this testimony only represents a portion of Farm Bureau's policy on food safety and that the American Farm Bureau will be following up with Committee Members regarding our complete position on these important issues. In closing, as we move forward in improving upon the safest, most abundant food system in the world, let us remember to be practical, cost effective, use sound science, allow flexibility for states to work with growers in developing best practices, and to recognize, embrace and build upon the diverse food production system that we have in this country.

Thank you, and I will be happy to take any questions.

[The prepared statement of Mr. Hirsch follows:]

PREPARED STATEMENT OF STEVE HIRSCH, MEMBER, OHIO PRODUCE GROWERS AND MARKETERS ASSOCIATION; VICE PRESIDENT, OHIO FARM BUREAU FEDERATION; PARTNER, HIRSCH FRUIT FARM, CHILLICOTHE, OH

Good morning Mr. Chairman and Members of the Subcommittee, thank you for inviting me here today to testify on the very important issue of food safety. I am Steve Hirsch, together with my family we operate Hirsch Fruit Farm in Chillicothe, Ohio where we raise both fruit and vegetables including asparagus, tomatoes, peppers, cucumbers, apples, peaches, berries and more. I am testifying today as a member of Ohio Produce Growers and Marketers Association (OPGMA) and as the Vice President of the Ohio Farm Bureau Federation.

The Ohio Farm Bureau Federation (OFBF) is the largest general farm organization in the state of Ohio with more than 200,000 members representing all of Ohio's 88 counties. Our members produce virtually every kind of agricultural commodity and as a result, OFBF is very interested in the nation's food safety policy.

The Ohio Produce Growers & Marketers Association (OPGMA) is an organization of produce growers and marketers whose goal is to produce exceptional quality crops, for consumers and processors, utilizing environmentally friendly practices.

My family operates two farm markets, one located at our farm and a second several miles away. We sell 85% of our produce and fruit directly to the public and the rest whole sale. We are members of the Chillicothe Farmers Market and buy and sell products at our local produce auction. We embrace a suite of food safety practices on our farm, in our markets, at the produce auction, and at the farmers market. There are many common themes among these practices but they can vary. They vary because these environments differ and require food safety practices tailored to provide the customer the safest and highest quality food possible per these different settings. Which is the theme of my testimony today.

In my view compliance is the key to the success of any new food safety system and any new system should be flexible in nature so growers can comply. Ohio produce growers vary in size ranging from larger operations that grow, pack, and ship their produce both in-state and across state lines, to very small farmers who sell all their produce directly to the local public. These farms are located throughout the state and are situated sometimes in the middle of suburbs to very rural areas. Some are located near the shores of Lake Erie, while mine is literally on a mountain top in southern Ohio. Some irrigate from surface water, others use ground water, some are near livestock operation and others nowhere near livestock.

My point, of course is that a single national, one-size-fits-all structure will not work and a national food safety system that allows for specific on-farm practices to be developed at the state level will achieve the best results. To this regard let me make several points:

First, State-by-State Flexibility Per On-Farm Practices. Flexibility per best management practices (BMPs) is key to the success of any new food safety system, as different growing regions on a national, even at a state level, vary significantly. For example, Ohio produce growers tend to be involved in growing, packing and shipping of the product, this isn't the case in other areas of the country. Different regions of the country use production land very differently as well, such as continual use of specific land for produce production *versus* shifting use of land between pasture, other crops and production of vegetables. One of our Ohio leafy green growers has noted that his production systems are vastly different from another grower just 50 miles away. A state-based program could better recognize more localized management issues such as the locations of feedlots, wildlife challenges and more.

To even more specifically illustrate this point there are several issues within the draft National Leafy Greens Marketing Agreement (NLGMA) that are of concern to Ohio growers such as several water use issues, animal intrusion and boarder distances surrounding crops. These specifics were designed around California's cultural practices and are not conducive to Ohio and many other state's accepted practices. The draft also subdivided the country into zones that are far too large with far too much variance in cultural practices between the northern and southern states which are all included in single zones. The zone that includes Ohio, for example, stretches as far north as Wisconsin and a far south as Alabama. These vertical slices across the U.S. need to be redefined to a state-by-state division.

Second, Sound Science. We believe any new practices should be based upon proven and effective food safety practices and sound science. Most of our produce is not produced in an indoor or enclosed environment and should not be regulated in a manner that is unrealistic to achieve. Currently some of science assumptions behind the California Leafy Greens approach are now being called into question. These challenges question the contamination threat related to water quality and animal intrusion. I suggest the Federal Government take the time to fund and com-

plete the science and research needed to determine the most appropriate and safe practices to assure a safe food supply before moving forward with any vast new system.

Third, State Coordination. Any new program should be coordinated with state departments of agriculture or other agencies responsible for food safety, inspection and enforcement. Such coordination will be crucial to the success of new programs and will prevent redundancy in programming. We need to bolster the funding, education and training for inspectors and when inspections are needed, such inspection should be conducted by and coordinate with state lead agency, such as the Ohio Department of Agriculture in Ohio, *versus* an FDA inspector on the farm. The Ohio Farm Bureau office receives calls daily from small growers, organic growers, backyard hobbyists and gardeners all very concerned, right or wrong, with some of the legislative ideas being proposed on Capitol Hill per new food safety systems. Flexibility would go a long way to addressing many of these concerns.

Fourth, Economic Impact. We emphasize the need for any new program to be organized in a manner that allows the strength of existing state-based systems to aid in the success of improved food safety, especially given the severe budget challenges that states currently face. Furthermore. the development of any new system should consider the economic impact on various size operations across the county. In Ohio, we have one of the largest, if not the largest, concentration of Amish farmers in the country. These produce growers do not use electricity and use horses in the fields to cultivate. They must pick, pack and sell their produce all in one day. They also keep horses outside the production areas during harvest time. These are a few of the many specific examples that highlight the need for flexibility. We also want to make it clear that Ohio, and likely other states, are at a distinct disadvantage per possible compliance costs because we must spread costs over a shorter growing season, as opposed to some states like California, that can spread costs over the entire year, given their longer growing season. Any new system should be economically viable within existing industry structures that vary across the country.

In closing, as we move forward in improving upon the safest, most abundant food system in the world, let's remember to be practical, cost-effective, use sound science, allow flexibility for states to work with growers in developing best practices and recognize, embrace and built-upon the diverse food production system we have in this county. Thank you. I'll be happy to take any questions.

The CHAIRMAN. Sir, you state that flexibility would go a long way in addressing the concerns of the small market and organic growers. What do you mean by flexibility?

Mr. HIRSCH. Well, as you will see from some of the other testimony, most of the growers in the panel other than the gentleman to my right are very large growers. They have the ability to comply with larger cost structure involved in complying with some of the regulations. We also process apple cider or apple juice, and we are federally regulated through the FDA. The Ohio Department of Agriculture, or ODA, actually does the FDA inspection on our food processing facility. We have a HACCP plan. It was 5 to 8 years ago when the FDA came out with their regs that you either had to develop a HACCP plan and have a 5-log kill step in your juice processing or you have to label your product with a warning label and can only sell it at the farm. We decided to go with that 5-log kill step because we sell at two different markets, a farmers market and other places. We do some wholesale. So we made that commitment. But it is still flexible enough that if you are a grower that makes cider at your market for 4 months a year, you can still sell it there, you would have to label it. So there is some flexibility in that program, you know. That would be an example of that.

The CHAIRMAN. Mrs. Schmidt, would you like to ask your questions of Mr. Hirsch at this time?

Mrs. SCHMIDT. Thank you.

Thank you so much for coming. There is some understanding that there are some ideas out there to move the new marketing

agreements forward. How involved have the midwestern growers been in this process?

Mr. HIRSCH. There has been some involvement but there are also some concerns with a number of growers that there hasn't been enough involvement. What we would like to see is the process work where we have the ability to make comments and to add some flexibility to a program that is based on what growers in the West are doing, and growers in the Midwest and the Northeast may not be doing those same type of cultural practices.

Mrs. SCHMIDT. I will shift gears just a second. There has been some talk of a greater role of the FDA in farming. Do you believe that the FDA has the resources and expertise to develop on-farm production practice standards, taking into account all the variables of crop diversity, climate, region and geography?

Mr. HIRSCH. They would have to develop some flexible standards because of that diversity that is inherent in American agriculture right now. You know, we have a lot of local food systems developing around the country, so they would have to be flexible. The diversity of crops in Ohio and California and Florida and those states is immense, and I think that some of the marketing agreements that are set up are just part of a food safety system that could be implemented, a flexible food safety system that could be implemented for all of those other crops.

Mrs. SCHMIDT. If we were to adopt the proposal of some in the fruit and vegetable sector and require the FDA to issue mandatory food safety standards for produce farmers, it will be necessary for the FDA or state regulators acting on this behalf to inspect farms for compliance. Considering the budgetary climate, are you prepared to pay for these inspections?

Mr. HIRSCH. Well, my feeling is that the food safety is for the public good and should be publicly funded.

Mrs. SCHMIDT. Mandatory FDA inspections on farms, do you have any support among your individual grower members for that? Is there support for that or is there a nervousness for it, or——

Mr. HIRSCH. I would imagine that there would be some trepidation toward mandatory FDA farm inspections.

Mrs. SCHMIDT. And finally, just to show the diversity of the United States, when the tobacco settlement was issued over 10 years ago, there was a push for tobacco growers to diversify into something else. Isn't that a reason why we have a stronger presence of farms like yours in Ohio?

Mr. HIRSCH. That is one of the reasons. I had mentioned the Amish communities and also the Mennonite communities. There are five or six produce auctions around the State of Ohio, most of them developed by the Amish or Mennonite communities. At each community, the one that we participate in, there are 70 Mennonite families that are in that area and probably 50 of those 70, the main thing that they do is raise fruits and vegetables and sell through those auctions to other smaller retailers, larger retailers. Jungle Jim's in Cincinnati buys at that produce auction.

Mrs. SCHMIDT. And I have the Kline family and one of the Miller families that left Amish to be Mennonites, so I have Amish and Mennonites in my own district as well.

Thank you so much for coming here. I really appreciate it.

Mr. HIRSCH. Well, than you for having me, and thank you, fellow panel members for indulging.

The CHAIRMAN. Mr. Hirsch, thank you as well, and you are excused so you can catch your plane.

Mr. HIRSCH. Thank you, sir.

The CHAIRMAN. Mr. Ratto, please proceed.

STATEMENT OF RONALD A. RATTO, PRESIDENT, RATTO BROS., INC., MODESTO, CA

Mr. RATTO. Mr. Chairman, Ranking Member Schmidt, thank you for the opportunity to appear today.

Ratto Brothers takes its origin from 1905 when my grandfather, Antone Ratto, quit school at the age of 16, much to the chagrin of his mother, and went to work full time in the vegetable gardens of Bay Farm Island in Alameda, California.

Today, we remain in the same kind of vegetable business doing basic food production. We grow food for people. We want to provide healthy, fresh, wholesome and low-cost vegetables to the communities where we live, to communities in California and beyond. We farm about 1,000 acres, growing a large variety of truck garden, leafy green, fresh vegetable crops such as beets, chard, dandelions, mustard greens, turnips, parsley, celery root, the leaf lettuces, and cabbages. Do we do anything unique? Well, we grow lots of different kinds of crops, 35 or 40. We plant many of the crops weekly. We have small fields, usually from a half acre to 3 acres in size, so we have lots of fields and lots of crops growing at any one time. This creates a very busy farm operation and lots of activity. We have customers of all sizes from the very large that order by the truckload to the very small ordering five to ten boxes at a time.

We do many things ourselves instead of hiring them out. We farm on land we own. We grow crops ourselves. We harvest the crops. We have our own cold storage, do our own sales, have our own mechanic shop, and we operate trucks for delivery. We are vertically integrated and a 100 year-newer version of how our ancestors operated. We bridge from the large to the small in many ways. We invest in facilities, equipment and people. We invest in capacity including food safety capacity, the ability of people to develop, implement, maintain, operate and improve food safety systems and in the system's infrastructure. If we are unique, it might be in the complexity of our operation due to the number and mix of crops we grow, the multitude of activities that we perform ourselves and the standards we hold ourselves to achieve.

Our predominant experience with food safety is with the California Leafy Greens Marketing Agreement, or LGMA, program. We believe the interest of food safety is implicit to our food production and must be an integral part of growing the vegetables that provide for our livelihood. We feel an obligation and responsibility to offer safe food products to our customers and to the consuming public. The food safety practices we follow do not occur without commitment and hard work, and as a company principal I have regular involvement in our food safety program. Commitment is essential, and we are committed.

The LGMA guidelines and requirements serve as the core of our food safety program. We think this public-private partnership be-

tween the leafy green industry and state and Federal Government brings the best from all realms to the program and government oversight provides a key feature to the program. Our approach is to fully integrate the LGMA program elements into our operational practices. A well-operating food safety program encourages communication between and among employees at all levels. Since food safety practices relate to all areas of our operation, employees in all areas are expected to contribute in their own particular way to the overall program.

Even though we grow food in the outdoors where there is the influence of wildlife, human life and weather, and where it is difficult to control external variables, there is much we can do and do do in the way of farm practices that contribute to safe food. We test water. We get ingredients documentation for soil amendments. We monitor surrounding lands and our own land for animals and environmental influences. We have health and sanitation standard operating practices for our workforce and we follow many other procedures, guidelines and requirements.

Our food safety program relies on people. We train and retrain employees. We check employees. We monitor internal systems. We self-audit. We talk about situations and we strive for perfection in our details. We can be perfect in what we do and we sometimes are perfect but we are not always. To attain perfection day after day, time after time is a challenge but that is what we strive for, and food safety seeks perfection.

The test of our performance is in the audit verification program. We are motivated to do well and our employees take pride in their food safety achievements. These mandatory audits are performed by government inspectors, sometimes announced in advance and sometimes unannounced and happen as a walk-in inspection. Both types of audits make sure that we are complying with the LGMA food safety standards. Implementation of the LGMA program has moved our food safety practices to a much higher level and we believe it has elevated the practices of others as well.

With that, Mr. Chairman, thank you very much for the opportunity to appear.

[The prepared statement of Mr. Ratto follows:]

PREPARED STATEMENT OF RONALD A. RATTO, PRESIDENT, RATTO BROS., INC., MODESTO, CA

Good morning, Mr. Chairman, distinguished Committee Members and the assembled public. My name is Ron Ratto, and I am with Ratto Bros., Inc. from Modesto, California. Thank you for the invitation to appear today.

1. So who are we?

Ratto Bros. takes its origin from 1905 when my grandfather Antone L. Ratto quit school at the age of 16, much to the chagrin of his mother, and went to work full time in the vegetable gardens of Bay Farm Island in Alameda, California. His father, uncles and grandfather were also all vegetables gardeners in the area of Alameda, West Oakland, East Oakland and Berkeley, and my grandfather spent his youth in their vegetable gardens and delivering produce with them.

2. What do we do today?

We remain in the same kind of vegetable business today, over 100 years later, doing basic food production. We grow food for people. We want to provide fresh, healthy, wholesome and low-cost vegetables to the communities where we live, to communities in California and beyond. We farm about 1,000 acres, growing a large variety of truck garden leafy green fresh vegetable crops such as Beets, Chard, Dan-

delions, Mustard Greens, Turnips, Parsley, Celery Root, Leaf Lettuces, and Cabbages.

3. Do we do anything unique?

We grow lots of different kinds of crops, 35–40. We plant many of the crops weekly. We have small field sizes, usually from ½ acre to 3 acres in size. We have lots of fields and lots of crops growing at anyone time. This creates a very busy and productive farm operation, with lots of activity. We have customers of all sizes, from the very large that order vegetables by the truck load, to the very small, ordering five to ten boxes at a time.

We do many things ourselves instead of hiring them out. We farm on land we own. We grow the crops ourselves, we harvest the crops, we have our own cold storage, we do our own sales, we have our own mechanics shop and we operate trucks for delivery. We are vertically integrated, in a 100 year newer version of how our ancestors operated. We bridge from the large to the small in many ways.

We invest. We invest in facilities, equipment and people. We invest in capacity. The last several years, we have invested in food safety capacity—the ability of people to implement, maintain, operate and improve food safety systems, and in systems infrastructure.

If we are unique, it might be in the complexity of our operation due to the number and mix of crops we grow, the multitude of activities we perform ourselves and the standards we hold ourselves to achieve.

4. Our experience, perspective and approach on food safety and the LGMA.

Our recent and current experience with food safety is with the California Leafy Greens Marketing Agreement program. Our company food safety program and systems today are much more comprehensive than they were before the establishment of the LGMA program.

We believe the interest of food safety is implicit to our food production and must be an integral part of growing the vegetables that provide for our livelihood. We feel an obligation and responsibility to offer safe food products to our customers and to the consuming public. The food safety practices we follow do not occur without commitment and hard work, and as a company principal, I have regular involvement in our food safety program.

Commitment is essential and we are committed.

We chose to commit to the LGMA program and to adopt the LGMA guidelines and requirements as the core of our food safety program. We think that the public-private partnership between the leafy green industry and state and Federal Government brings the best from all realms to the program. Government oversight of the program provides another key feature to the program.

The LGMA program is a substantial food safety program and we had to gear up to meet its challenges. We had to design and re-design our internal systems to link up to the program guidelines and requirements, and then disperse the responsibilities within our internal systems.

Our approach is to fully integrate the program elements into our operational practices. The development and operation of a food safety program encourages communication between and among employees at all levels. Since food safety practices relate to all areas of our operation, employees in all areas are expected to contribute in their own particular ways to the overall program.

Even though we grow food in the outdoors, where there is the influence of wild life, human life, and weather, and where it is difficult to impose control on external variables, there is much we can do and do do in the way of farm practices that contribute to the production of safe food. We test water, we get ingredients documentation for soil amendments, we monitor surrounding lands and our own land for animals and environmental influences. We have health and sanitation Standard Operating Practices for our work force. And we follow many other procedures, guidelines and requirements.

Our food safety program relies on people. There are many food safety routines that must be performed daily. We try to strengthen our routines so that they are an expected, embedded, re-occurring part of our employee's daily work life.

We train and re-train employees? we check employees, we monitor internal systems, we self-audit, we talk about situations and we strive for perfection in our details. We can be perfect in what we do, and we sometimes are perfect, but we are not always. To attain perfection day after day, time after time, is a challenge, but that's what we strive for. And food safety seeks perfection.

This is all part of the "food safety culture" we are building.

And the test of our performance is in the audit verification program. We are motivated to do well and our employees take pride in their food safety achievements.

These mandatory audits are performed by government inspectors, sometimes announced in advance, and sometimes unannounced and happen as walk-in inspections. Both types of audits make sure that we are complying with the program food safety standards.

Implementation of the LGMA program has moved our food safety practices to a much higher level, and we surmise it has moved higher the level of most others in the leafy green business as well.

5. Financial Burden

Is there a cost to food safety? Yes, of course there is. Should consumers have to pay extra for food safety? Maybe not, but the reality is that the cost of food reflects all the various costs that go into its production, and ultimately the consumer must bear the total cost of food production. The costs of food production are a constantly changing blend of increasing and decreasing cost components, the total of which seems to keep rising over time.

For us, examples of the costs of food safety include (1) supplies, such as gloves and hairnets and chlorine test strips, (2) equipment, such as a chlorine pump, an ORP meter and stainless steel work surfaces, (3) laboratory tests, such as for microorganisms, and (4) personnel, to administer and keep records of the food safety program.

Are the costs significant? Yes. Is it worth the expense? Yes, because we want to take extra steps to produce safe food.

And while the cost of food safety might be measured in dollars, the value of food safety is almost immeasurable as it affects so many people every day, both producers and consumers.

And with that, at this point I would like to stop. I hope this testimony is useful to the Committee, and I thank you again for the invitation to appear.

ATTACHMENT

Additional Comments To Submit As Written Testimony

Comments: Features of the LGMA program that could be considered in food safety legislation:

Food safety program guidelines and requirements are based on known scientific and academic work.

Program entities develop and operate their own food safety programs to attain the program requirements.

State inspectors under USDA overview compose the audit staff.

Program entities are subject to periodic audits.

Program entities are subject to unannounced audits.

If audit deficiencies are found, they must be corrected.

Corrections of deficiencies are audited.

If a program entity has serious violations, it is subject to disciplinary procedure, including suspension and termination from the program.

The program will name names—serious offenders that are de-certified are named as such.

Comments: Other points to consider in food safety legislation:

Governance of food safety programs:

- Authorize food safety programs with shared collaboration, involvement, participation and responsibility between Federal Government, state government and industry.
- Authorized national food safety programs to operate as U.S. wide.
- Prohibit individual state standards that would restrict the interstate movement or sale of food.

Scope of food safety legislation:

- Allow food safety programs for the production and harvest of food crops.
- Allow food safety programs for the handling and distribution of food crops.

Determination of who should be subject to food safety legislation:

- Encourage inclusion of all commercial food producers.
- Discourage exclusion or non-participation of selected groups of food producers.

Standards and requirements:

- Do not set food safety practices by Act of Congress.

- Allow food safety programs to establish processes to develop food safety standards that are flexible, efficient and open to industry and public participation.
- Allow food safety standards to be based on science and applied academic work.
- Allow processes for the flexible revision of food safety standards to enable the updating and changing of guidelines, standards and requirements based on new knowledge.

Food safety program elements:

- Regulates, inspects and enforces food safety standards.
- Provides training materials, resources and guidance to food producers on best practices and how to meet the standards or regulations
- Flexible implementation: Allow flexibility in how food producers meet food safety requirements.
- Audit function-verification of food safety practices by producers and handlers.
- Determine audit scheme and frequency.
- Establish process development, review and change to the audit scheme.
- Announced and unannounced audits.
- Timely follow-upon audit deficiencies.
- Supervise auditor staff.
- Set qualification and performance standards for auditors.
- Administer audit results to subject entities.
- Develop and administer consequences system to food producers with poor audit performances or deficiencies.
- Identify research needs.
- Investigate food contamination episodes and food related human illness outbreaks.
- Determine causes of outbreaks, write reports and make recommendations and changes to standards based on findings.

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

Mr. LoBue. Again, I would like to remind everyone to do their best to summarize their testimony. We now have votes that were just called. We are going to take your testimony, Mr. LoBue, and then we are going to see where we stand. I don't know how long we are going to be gone and I don't know how much time the Members are going to have. I will be informing you all as to how we are going to proceed as the votes progress. Mr. LoBue.

STATEMENT OF PHILIP LOBUE, PRESIDENT, LOBUE BROS., INC., LINDSAY, CA

Mr. LOBUE. Thank you, Mr. Chairman.

Good afternoon. My name is Philip LoBue and I am President of LoBue Brothers, a family-run citrus operation located in Lindsay, California, which is the heart of the fresh orange citrus industry. I am a second-generation producer and now a partner in our family growing, packing and shipping operation. What my father and his brothers started in 1932, my brother and I, along with my cousins, are now operating. We farm approximately 1,000 acres. We pack our own fruit along with that of another 150 growers, all of which manifest itself into four million cartons of fresh citrus sold domestically and internationally. During the peak season we employ approximately 250 people in the packing operation and another 100 plus in the field harvesting fruit. Collectively, the industry directly employs 12,000 people, sells an estimated $1.8 billion of product. We harvest fruit from trees that are 50 to 60 years old and in some cases over 100 years old. We and my former 3,500 farmer colleagues have done this without any food safety problems.

Believe me, we take our food responsibility seriously. We currently have a complete traceback system from the carton to the field, and soon data bar technology will allow for each piece of fruit to be identified and traced back to the field. Coupling this with GPS technology, we can get it pretty close to the tree. Our employees wear gloves in the field and at the packing house. Our fruit washing systems in the packing house are constantly monitored by a third party to ensure they are performing correctly. Field and packing house sanitary conditions are constantly monitored and recorded. The safety of our product is never taken for granted and the industry has an enviable food safety reputation.

Our industry certainly understands the concern and need for a viable food safety program. We believe any food safety program mandated by the government should be risk based and commodity specific. Citrus grows on a tree above the ground in a sealed package that is peeled before consumption. Our areas of vulnerability are entirely different and considerably less than that of other commodities. We shouldn't be saddled with a system that is more rigorous for a more risky commodity. Government-imposed costs are a pet peeve of ours as they now represent 25 percent of our farming costs as documented by Cal Poly, San Luis. Presently, our company incurs in excess of $50,000 of direct costs for two different audits. Every food safety audit company stresses different areas and they all seem to be trying to establish a name for themselves. We have shopped audit companies and have switched only to find that the next is worse than the one we had. Some of our customers specify certain audit companies and will not accept the results of others. Many of the things we do in the name of food safety I find hard to figure out the bearing on the safety of the product.

So we need to develop standards that are specific to the industry in order to harmonize the audits so that any third-party audit would produce the same results. So we would support this effort. If a food safety audit is necessary, then let us make it happen once and let us standardize it to the satisfaction of all concerned. I am sure the government has the resources current available to undertake this task. For us, because of the familiarity and the knowledge of the industry, we believe USDA is best suited to perform this task. This can be done with existing personnel. USDA already has contracts with CDFA, California Department of Food and Agriculture, who has agreements with the local farm advisors. It doesn't have to be an expansion of personnel. Just as I have learned new tricks, I am certain that within the existing government structure there are individuals who can be retrained or elevated to do the desired job.

Thank you for me allowing me this opportunity, and I look forward to answering any of your questions.

[The prepared statement of Mr. LoBue follows:]

PREPARED STATEMENT OF PHILIP LOBUE, PRESIDENT, LOBUE BROS., INC., LINDSAY, CA

Good afternoon, my name is Philip LoBue and I am President of LoBue Brothers, a family run citrus operation located in Lindsay California which is the heart of the fresh citrus industry. I am a second generation producer and now partner in the family growing, packing and shipping operation. What my father and his brothers started in 1932 my brother and I along with three cousins are now operating. We

farm approximately 1,000 acres; pack our own fruit and that of another 150 growers all of which manifests into four million cartons of fresh citrus sold domestically and internationally. We employ 250 people in the packing house and another 100 plus in the field harvesting fruit.

During my 30 years in the industry we have NEVER had a food safety issue. Never in my 30 years as a member of our industry have we had a food safety issue. The California citrus industry is the number one fresh citrus producing area in the nation. Each year an estimated $1.8b of product is sold which creates another $1.2b of economic activity. Collectively we employ 12,000 people and our activity supports another 13,000 jobs. And, again, we've never had a food safety issue. The safety of our product is never taken for granted and the industry has an enviable food safety reputation.

We do this without support payments or government assistance. We do this while facing tariffs approaching 54% and we do this while so many of our off shore competitors receive government assistance; in the EU the support level exceeds $lb. Our regulatory costs are over $400 per acre now.

Many years ago our own Citrus Research Board published a Food Safety directive for the industry at both the grove and packing house. In March 2007 they updated it with the statement Good Agricultural Practices are an insurance policy, not a burden. That's our belief, our responsibility and our commitment. We fulfill it every day.

This is the environment in which I and my family have farmed for almost 100 years. We harvest fresh fruit from trees that are 50–60 years old. We and my 3,500 farmer colleagues all do this without any food safety problems. I think we are a pretty good example of what sustainability is all about and yet we feel threatened by too much government involvement. Believe me Committee Members we take our food safety responsibility seriously. We have a complete traceback system from carton to field and soon data bar technology will allow for each piece of fruit to be identified and traced back to the block from which it was harvested. Add to that state of the art GPS technology and we will soon tell you what tree a piece of fruit came from. All this is being done without government rules, regs, mandates and costs. Our employees wear gloves in the field and at the packing house. Our fruit washing systems in the packinghouses are monitored by ourselves and a third party to insure they do the cleaning process necessary. Field and packing house sanitary conditions are constantly monitored.

Food safety begins at the grove as we producers are the first step in the farm to table food chain. It continues into the packing house with documentation, traceability, monitoring and communication. Our overall objective is to provide the public with a safe and nutritious product in a manner that sustains productivity and economic viability.

Our industry certainly understands the concern and need for a viable food safety program. We believe our industry's track record clearly supports my contention that we have a viable effort in place. Right now we are reviewing it to determine areas of vulnerability. We know things change, we know pathogens exist or change to create new challenges. We know we must be ever diligent to protect the consumer and our industry's integrity. We believe we do that. As an industry we should be willing to share our common program with the appropriate officials so that they may learn how one commodity accomplishes the desired objective.

We believe a food safety program mandated by government should be risk based. Committee Members, we are on a tree, above ground in a package that is peeled before consumption. Our areas of vulnerability are entirely different than other commodities. Not only are they different but there are considerably fewer areas of vulnerability as well. Government shouldn't impose a program on an entity that has demonstrated continued success towards the food safety objective. We should share, review and monitor. We shouldn't be told to change something that works and incur additional costs.

Government imposed costs are a pet peeve of ours. They now represent 25% of our farming costs. In the past few years as others set themselves up as the consumer protector, or to protect themselves from liability or choose a new marketing theme they have imposed marketplace mandates that are duplicative and expensive. Presently our company incurs $50,000 for two different audits. Every third party audit company and individual auditor stress different areas and it seems all of them are trying to establish a name for them by trying to out do the other. Many of our customers specify certain audit companies and will not accept results from others.

Many of the things we do in the name of food safety have no bearing on the safety of the product. Standards need to be developed that are specific to our industry in order to harmonize the audits so that any third party can conduct the audit. Finally we have to say enough is enough. On one hand we think a double standard exists

for what we must do to satisfy our customer *versus* what others are doing to protect the consumer. Second, we are asked to absorb these duplicative costs.

We have a saying in our industry, costs are fixed locally while prices are determined globally and the margin between the two is almost non existent. Imposing costs on us makes our product more expensive. Having those costs imposed more than once is doubling the expense without adjusting the margin as off shore competition can do everything for less expense. So we would support an effort to harmonize or standardize this cottage industry of food safety audits. If a food safety audit is necessary then make it happen once and make it standardized to the satisfaction of the government and the consumer.

Members of the Committee, I'm not so naïve to stipulate that a food safety problem will never occur in the citrus industry. We must maintain our standards. We must review them and we must improve them. But we shouldn't be saddled with a system that is more rigorous for a more risk prone commodity. We shouldn't be burdened with a multitude of audits so others can market their food safety awareness program. We shouldn't be burdened for a bureaucratic cost that cannot be passed on and we shouldn't be burdened by a program that buries our administrative staff in paperwork.

Allow me to conclude with one additional thought. I've been around to witness the formation of the Department of Education, Environmental Protection Agency and most recently Homeland Security. Before me USDA and FDA were developed. Surely you can't envision another government growth mandate. Existing agencies should be redirected to this mission. For us, because of familiarity and their knowledge of location, people and industry, we believe USDA is best suited to perform the food safety oversight tasks. This can be done with existing personnel. It can be done by contracting with state or local governments. It doesn't have to include an expansion of personnel. Just as I have had to learn new tricks on computers and electronic dissemination of information so should government personnel be retrained for today's needs.

Thank you for allowing me this opportunity and I look forward to answering any questions you may have.

The CHAIRMAN. Thank you very much, sir. At this time I am going to recess the hearing because we have three votes. This may take a bit of time. I have other commitments later this afternoon so I am checking with staff to determine how we to proceed with the question portion of the hearing. We want to make sure that your testimony is heard because we care very much about what you have to say. We will get back to you as things will be in flux here until we can get our schedules determined. We will be keeping you informed about how we are going to work everything out. I apologize for the inconvenience. The hearing is temporarily in recess.

[Recess.]

The CHAIRMAN. With apologies, I will reconvene the hearing. I am going to release Mr. Pezzini, Mr. Ratto and Mr. LoBue from further questions. We are going to submit our questions to the three of you in writing and circulate them with the rest of the Committee because of the situation we have had today with the impending votes. You are welcome to stay but I was going to release you in case you needed to catch flights. We are going to go to Mr. Maravell's statement and then we will have Mr. Wingard and Dr. Stovicek. I ask you once again to summarize and limit your testimony. We have them in writing and the Members of the Committee will in fact read them. We are intending to submit an extensive number of questions to you through written questions.

Mr. Maravell, please proceed with your testimony, and once again my apologies for the inconvenience.

STATEMENT OF NICHOLAS C. MARAVELL, OWNER AND OPERATOR, NICK'S ORGANIC FARM, LLC, POTOMAC, MD

Mr. MARAVELL. Thank you, Mr. Chairman.

Mr. Chairman, Mrs. Schmidt, my name is Nick Maravell. I have been an organic farmer for the past 30 years. I appreciate the opportunity to provide testimony regarding organic agriculture and food safety to an Agriculture Subcommittee.

I own and operate Nick's Organic Farm located in Montgomery and Frederick Counties, Maryland. I have 170 acres in production. I am a strong supporter of food safety. I will try to show how our farming practices, organic certification and direct marketing give us unique and effective built-in advantages in the area of food safety. And finally, I will offer a few recommendations. I hope will shape any Congressional changes to food safety policy.

We raise grass-fed Angus beef, pastured chickens and turkeys, free-range eggs. We grow various mixed hays. We maintain different types of pastures. We produce field corn, soybeans, barley, rye, hairy vetch. We grow fresh, edible vegetable soybeans. On the farm, we process and package our own chickens, turkeys, eggs, fresh soybeans, cover crop seeds and poultry feeds.

As a certified organic operation, we are part of the organic industry which is proactive and uniquely positioned on food safety in ways that are not standard in other food sectors. All of these provisions are required of organic operations, but not conventional operations. One, organic farmers and processors are required by law to maintain 5 year records that allow one-up, one-down traceability for all inputs and for all sales. From field to fork, every entity in the supply chain or in the stream of commerce must maintain an audit trail that permits full traceability and accountability. Two, raw livestock manure cannot be used on crops for human consumption without an extended waiting period before harvest. Three, compost made with animal manure must meet temperature, mixing and time requirements to ensure its safety or else be treated as raw manure.

I am going to summarize some other points in my testimony concerning issues that Congress should take into account when considering pending legislation regarding food safety. First, legislative measures should be appropriate to the size, scope and nature of an operation. The one-size-fits-all approach is fraught with unintended consequences, and in this case consumers could find it more difficult to obtain the products they want. Two, unless there is a specific, scientifically documented need to solve a clearly defined problem, solutions should not be imposed. Three, local—sorry. I am going to skip three. Four, the organic industry has in place legally mandated safeguards necessary to ensure food safety including full traceability and accountability of food products and strict controls on known potential sources of food contamination such as manure and pesticide residues. The organic certification system allows all producers and processors small and large the flexibility to maintain traceability records appropriate to the type and scale of operation.

Five, Congress should be very cautious in drawing organic food safety conclusions from studies that did not look at organic food production systems. For example, manure mineralization rates and counts of antibiotic-resistant bacteria on conventional farms and processing plants are not reliable indicators of what would be found on organic operations. The ecological science base for organic agriculture, in general, and for organic food safety, in specific, is ex-

panding rapidly. The organic community has begun advancing research proposals to Federal competitive grant programs, and we can expect to see appropriate organic food safety studies funded this year and in the coming years. These studies can both document the level of safety of the organic food supply and develop additional procedures and processes that can make organic products available to a wider audience at a more cost-effective price.

[The prepared statement of Mr. Maravell follows:]

PREPARED STATEMENT OF NICHOLAS C. MARAVELL, OWNER AND OPERATOR, NICK'S ORGANIC FARM, LLC, POTOMAC, MD

Mr. Cardoza, Mrs. Schmidt, and Members of the Committee, I am Nick Maravell, an organic farmer for the past 30 years.

I appreciate the opportunity to provide testimony regarding organic agriculture and food safety to an Agriculture Committee.

I own and operate Nick's Organic Farm, located in Montgomery and Frederick Counties, Maryland—not too far from here. It is a relatively small operation. I have 170 acres in production, the vast majority of which is in farmland preservation.

To give you an idea of where I am coming from, I thought a little background about myself would be helpful. Over the last 30 years, I have been active at the national and state level in establishing organic legislation and regulations, advancing scientific organic research, and increasing awareness of organic methods and improving markets for organic products. I have worked through such organizations as the Organic Trade Association, the Organic Farming Research Foundation, and the Maryland Organic Food and Farming Association. [As a life long member of the Organic Trade Association, I worked on a variety of policy and regulatory issues with the Farming Practices Committee. As a member of the Organic Farming Research Foundation, I have actively participated in the drafting of the National Organic Research Agenda, published in 2007. And I am a founding Board Member of our state association, the Maryland Organic Food and Farming Association, where I have worked in a variety of leadership capacities to advance the interests of organic farming and to expand markets for organic products.] Today I am testifying as an individual representing no organization.

I am a strong supporter of food safety, and I often think that I am more concerned about food safety than my customers are—and that is the way it should be—my customers should not have to worry about the safety of my products. I would like to explain to how various aspects of food safety are built into the way we farm and market our products. To do this I need to briefly tell you what we produce, how we produce it, how we market it, and generally what is behind our thinking.

Hopefully, I will be able to show that our farming practices, our organic certification, and our direct marketing give us unique and effective built in food safety advantages. And finally, I would like to offer a few observations which I believe should shape the Subcommittee's thinking regard changes to food safety policy, especially with regard to organic and family sized operations.

We raise grass fed Angus beef, pastured chickens and turkeys, and free range eggs. We grow various types of grass/clover and alfalfa/grass hays, and we maintain different types of pastures. We produce field corn, soybeans, barley, rye grain, and hairy vetch. We grow fresh edible vegetable soybeans, also known as edamame.

Our system of farming has evolved over the decades. We started with all vegetables, added small grains, then added large grains and hay, and finally added livestock. Our system is constantly gaining more diversity and complexity. We started with 2 year rotations, then 3 year, then 5 year, and now 8–12 year. We used to moldboard and chisel plow, now we rarely do either. Our earthworms and our mix of crops do the deep tillage.

As or system evolved, we recognized the tremendous gaps in scientific knowledge to help guide our future development. So we began experiments on the farm. Now we conduct ongoing long-term research on the farm in cooperation with USDA's Beltsville Agricultural Research Center and with personnel from the University of Maryland. We also cooperate in demonstrations with the Maryland Natural Resource Conservation Service.

We have found that by extending our rotations to include hay and pasture, we have been able to break weed, disease, and insect cycles in both our row crops and our forages. Consequently we use no insecticides, herbicides, or fungicides on our crops.

We have found that leaving our cattle on pasture, never putting them in inside, and feeding no grain, even during the cold winter months, results in an annual veterinary bill of zero. We have found that management intensive rotational grazing improperly used simply spreads intestinal parasites to all of our pastures. We have found that grazing poultry across our pastures, rotating pastures through hay and row crop cycles, and carefully selecting beef genetics for parasite resistance has resulted in never having to use parasiticides on any organic cattle born on our farm.

We have found that proper use of winter and summer cover crops can suppress weeds, increase nitrogen available for subsequent crops, add to soil organic matter, and improve soil tilth, and increase water penetration and moisture retention. We have found that multi-species cover cops with 2–4 different plant types are almost always better that single species covers.

We have found that virtually all of our fall and summer cover crops can be planted with organic no-till methods, helping to maintain good soil structure, reducing microbiological disruption and soil compaction, reducing organic matter depletion and CO_2 releases, saving energy, and making it more difficult for small seeded annual weeds to become established.

By using nitrogen fixing legumes such as soybeans, alfalfa, clover and hairy vetch in both our crop rotations and our cover crops, we do not need to purchase any nitrogen fertilizer. We add naturally occurring and slow release minerals, such as high calcium lime, rock phosphate, and potassium sulfate. The latter two minerals are added to selected fields maybe once every 10–20 years.

Pardon me if I have given you what appear to be random examples of how we farm. Now at the risk of using some jargon, I will attempt to explain how this fits together and is related to food safety.

We operate a diversified and integrated farm. This means we raise several types of crops and animals together. Generally our system demonstrates the advantages of encouraging diversity and decentralization, of fostering synergy and symbiosis, and of relying on nutrient recycling and self-regulating systems. These terms simply mean the parts of our system are designed to work well together and require little re-direction to maintain the system once it is established. Our crops and livestock are chosen only partially for economic marketability. More importantly the mix of plants and animals is intended to compliment each other as a self-sustaining system. People often ask me, what is the main thing that we do that makes our organic system work? My response is: "No one thing we do is very important—everything we do is important, each in its own small way."

I view half of our farm operation as living above the ground as crops and animals. I view the other half as living below the ground in the soil. While both halves are important, I begin constructing my farming system around the long term sustainability of the soil because it very often takes longer to produce desired changes in the soil than in crops and animals. A rich active living soil is a prerequisite to producing healthy plants and animals. As we will see, healthy plants and animals are a first step towards food safety.

In general, adding organic matter is a good way to achieve a biologically active and healthy soil because it feeds the microbiota, such as bacteria and fungi, and the macrobiota, larger organisms, such as earthworms. The micro biota are organisms, that are so small a million could live in a teaspoon of healthy soil rich in organic matter. These two types soil organisms digest decaying organic matter and release nutrients that plants use to grow. Quite simply, Feed the Earth and it will feed us.

So for example, we leave our corn stover and barley straw on the surface of the field and no-till our cover crops through it. When we later incorporate our cover crops into the soil, we use shallow tillage. This tillage leaves some organic matter on the surface to reduce soil erosion and run off and places the rest of the organic residues in the top 4 inches where air, moisture and temperature create ideal conditions for the soil biota to digest the organic matter quickly. From the mixture of mature plant matter with fresh plant matter, including legumes, the soil biota create longer lasting carbon compounds and associated stable plant nutrients which will not easily leach away. Stable soil nutrients mean less need to add additional fertility from organic sources, such as manure, and less run off to contaminate water, both leading to safer food crop production.

Our animals are not fed antibiotics, and our ground is not treated with pesticides. Both antibiotic and pesticide residues can impede the growth of certain species of micro and macro biota, thereby suppressing their activity. We are grazeirs. Our animals are managed to spread their own manure on an active soil with plenty of vegetative cover to take up the nutrients. Except in the coldest months of winter, manure breaks down quickly. We move our animals all the time. Water and feed for the animals is constantly moved so there are no concentrations of manure to collect large masses flies and diseases. We cannot collect manure, we do not spread ma-

nure, and our animals do not graze in areas that will be used for human crop production within the next year. These measures, designed to build a healthy soil, also help ensure the safety of food products by not encouraging antibiotic resistant bacteria in our animals and by preventing bacterial contamination of our food crops.

As a small diversified and integrated farm, our marketing strategy must add on farm value to our products to be economically viable. We do this by making the products organic and by selling most of them directly to the final user, either a consumer or another organic farm. About 90% of our sales are direct. For example, we process our chickens and turkeys, and pack our eggs, and clean and pack our fresh vegetable soybeans. Customers come to our farms and pick up our products and a small amount of our products are delivered to local retailers and regional wholesalers. In most cases, we are only one step down from the final consumer. This direct marketing system builds in ultimate accountability and traceability for the customer, another factor in food safety.

Unique Food Safety Characteristics of Certified Organic Food

However, the organic industry as a whole is proactive and uniquely positioned on food safety in ways that are not yet standard in other food sectors.

(1) Organic farmers and processors are required by law to maintain records that allow "one up, one down" traceability for all inputs and for all sales. From field to fork, every entity in the supply chain or in the stream of commerce must maintain an audit trail that permits full traceability and accountability.

(2) Raw manure cannot be used on crops for human consumption without an extended waiting period before harvest.

(3) Compost made with animal manure must meet temperature, mixing, and time requirements to ensure its safety or else be treated as raw manure.

(4) Synthetic pesticides are prohibited, reducing the risk of over-application or excessive pesticide residues.

(5) Antibiotics are prohibited in livestock feed and routine organic health programs. Organic farms do not increase the risk of creating antibiotic resistant bacteria.

(6) Organic livestock cannot be fed animal by-products, adding a layer of protection against the possibility of transmission of certain diseases. This prohibition exceeds current non-organic rules which, for example, allow nonmammalian animal by products to be fed to cattle and *vice versa.*

Recommendations for Future Congressional Action

Consumers over the past 2 decades have clearly exercised new choices with their food dollars. Witness the explosive growth of organic sales, the tremendous resurgence of farmer's markets, the continued growth of Community Supported Agriculture (CSAs), and the strong emergence of the Buy Local and Slow Food movements. Organic, direct marketing, and small family sized operations have almost exclusively met these consumer demands.

At the same time, I think it is fair to say that the pressing food safety concerns facing Congress today have not emerged from organic or family sized producers and processors. Consumers have, not surprisingly, gravitated to these areas that provide several unique characteristics, including certain food safety assurances. In devising changes to food safety laws, Congress should consider the specific impact these change could have on organic, direct marketing and family sized operations.

(1) Legislative measures should be appropriate to the size, scope and nature of an operation. The "one size fits all" approach is fraught with unintended consequences. And in this case, consumers could find it more difficult to obtain the products they want.

(2) Unless there is a specific scientifically documented need to solve a clearly defined problem, solutions should not be imposed. For example, while new technologies, like bar coding and electronically tracking palletized fresh products, may assist certain food sectors in attaining better food safety, these same measures may be burdensome, costly and unnecessary for smaller, direct marketing, and organic operations. Farmers say, "If it ain't broke, don't fix it."

(3) Local and state food safety laws currently regulate direct sales from farmers to consumers. Direct farmer to consumer sales are inherently traceable, and largely accountable, and should not require any further traceability measures. Special disposition should be afforded to clearly defined local markets which just happen to be multi-jurisdictional, such as my market which is a "tri-state" area, so that interstate commerce requirements do not automatically apply when they are clearly not appropriate or needed.

(4) The organic industry already has in place legally mandated safeguards necessary to ensure food safety, including full traceability and accountability of food products, and strict controls on known potential sources of food contamination such as manure and synthetic pesticide residues. The organic certification system allows all producers and processors, small and large, the flexibility to maintain traceability records appropriate to the type and scale of operation. The record keeping system is outlined in the organic system plan. Independent third party onsite inspections verify each of these organic system plans annually providing excellent accountability. These procedures should be left intact and should be allowed to satisfy any corresponding new requirements that Congress may institute on the larger food sector.

(5) Congress should be very cautious in drawing organic food safety conclusions from studies that did not look at organic food production systems. For example, manure mineralization rates and counts of antibiotic resistant bacteria on conventional farms and processing plants are not reliable indicators of what would be found on organic operations. The science base for organic agriculture in general, and for organic food safety in specific, is expanding rapidly. The organic community has begun advancing research proposals to Federal competitive grant programs, and we can expect to see appropriate organic food safety studies funded this year and in the coming years. These studies can both document the level of safety of the organic food supply and develop additional procedures and processes that can make organic products available to a wider audience at a more cost effective price.

The CHAIRMAN. Thank you very much, sir, for your testimony. I thought it was very interesting to hear how the organic community deals with some of their fertilizer issues. I don't know what Mrs. Schmidt would think of this, but I certainly would be prepared, since you just live down the road in Potomac, for you to come back and have a private meeting with us so that we can share, further, some of the concerns that you have as the legislation moves forward.

Mr. MARAVELL. That would be quite appropriate, and I can certainly work with staff to arrange that.

The CHAIRMAN. Excellent. We would love to do that, in addition to any answers to written questions that we will submit to you. Thank you.

Now I would like to introduce and ask Mr. Charles Wingard, Director of Field Operations for Walter Rawl and Sons from South Carolina, to please submit your testimony to the Committee.

STATEMENT OF CHARLES A. WINGARD, DIRECTOR OF FIELD OPERATIONS, WALTER P. RAWL & SONS, INC., PELION, SC

Mr. WINGARD. Thank you, sir. Good afternoon, Chairman and Ranking Member Schmidt. My name is Charles Wingard and I am Director of Field Operations at Walter P. Rawl in Pelion, South Carolina. This is a family-owned and operated business. I am one of nine who work there every day.

We grow a lot of different vegetables but we specialize in southern leafy greens which are sold fresh bulk and fresh cut processed. I brought with me a sample of a bag of collards for you to see. In addition to this, we control everything from seed all the way to delivery. I also have a sample of collard seed as well, and we do everything in between. I will get to what is in the middle of that in a second.

As a grower, we have watched with great interest over the last several years the debate in Washington on food safety laws and the changes to them, and we support many of those changes. Yet we are reminded every day that our produce is very, very safe with

over one billion servings being consumed daily here in this country, almost universally without any food safety incident. But it is still critical that the entire produce industry commit to ensuring that our products are grown and handled properly at every step of the way, all through the supply chain.

We have a very comprehensive food safety program at my company, and I am not going to go through all of that. I will highlight one point. At about 20 steps between seed and delivery, we keep records, manual records. In addition to the manual records, there are computerized records kept as well. It is about 35 sets of records kept in those 20 steps, and this is an example of what some would look like. It goes from this through this to that. And during the food safety audit, I could literally line up this entire table with three-ring binders. It would total about 50 or 60 three-ring binders of information that we keep non-computerized, and that would be in addition to our computer records. We do traceability. We do all kinds of tests and we have GAPs, SOPs, SSOPs, HACCP, GMPs, all that stuff. We have all that in place.

It is kind of interesting that about 8 years ago we had our first food safety audit, and we spent about $100,000 that year on food safety, and we scored a 900. In those 8 years our company has grown in size about three times, yet our food safety spending has grown almost ten fold, and we just had an audit 5 weeks ago, and we didn't score but 930. It sort of seems the more you do, the more you have to do.

There are challenges for us today in food safety. We have multiple audits from different customers. We have third-party auditors that come in to audit us against their standards, not necessarily the government's, and we have about nine or ten audits a year from three or four different third-party auditors, and that is down from about 15 three years ago. We see a big problem with consistency of different auditing companies and inconsistency of different inspectors within one auditing company. The cost varies tremendously, even though that is not the big portion of our food safety budget, but the cost varies tremendously, and we don't get to choose who we want to audit us because our customers tell us which audit they will recognize. It is sort of like a little monopoly going on, and it is not a very good situation at times.

We need to work a little bit better within our industry, but it is going to take Federal oversight to make sure that everybody in the industry is committed. I know of producers who don't do the steps that we do in food safety and then they end up with an economic advantage at the end of the day. We must allow Federal oversight, must allow for clear commodity-specific approaches based on the best available science. It must be consistent and applicable to the entire commodity or the commodity sector regardless of where it is grown or packed. It can vary in production techniques, but it must apply to the entire commodity and it must be federally mandated, it must be credible enough and fair enough to the growers yet maintain consumers' confidence in our food supply.

Thank you again for the opportunity to participate in this hearing, and I look forward to answering any questions.

[The prepared statement of Mr. Wingard follows:]

PREPARED STATEMENT OF CHARLES A. WINGARD, DIRECTOR OF FIELD OPERATIONS, WALTER P. RAWL & SONS, INC., PELION, SC

Introduction and History of Walter P. Rawl & Sons

Good morning Chairman Cardoza, Ranking Member Schmidt and Members of the Subcommittee. My name is Charles Wingard and I am Director of Field Operations for Walter P. Rawl & Sons in Pelion SC. Three generations of our family have farmed in this area since the 1920s, and nine family members oversee our operations today in a hands-on manner. We specialize in southern leafy greens such as collards, kale, mustard & turnip greens, and also produce a variety of summer vegetables in season along with a few other year round vegetable crops.

We have farm operations in several South Carolina counties and have farming relationships in Florida, Virginia, & New York. Our produce is marketed and delivered throughout the Eastern United States, and about ½ of our leafy greens are washed and packaged in our own facility and sold as fresh-cut chopped greens, with the rest sold in bulk.

We are also active in our industry's national association to lead efforts to help bring safe, healthy, affordable and great-tasting fruits and vegetables to the public. My cousin serves on the Board of Directors of the United Fresh Produce Association, and I serve as a member of its Government Relations Council.

General Thoughts on Food Safety and Produce

As a grower member of that council, I have watched with great interest over the last several years the policy debate here in Washington, D.C. about potential changes in our food safety laws. We support many of those changes. Yet, I am reminded everyday that produce consumed in the United States is an extraordinarily safe and healthy food! Every major worldwide public health authority advises that the health benefits of eating produce far outweigh risks; and over one billion servings of produce are consumed daily in the U.S., almost universally without a food safety incident. These statistics do not lie, but we also must recognize that consumer confidence in their food is at an all-time low. According to a recent survey conducted for United Fresh Produce Association, 88% of the respondents indicated they are at least somewhat concerned about the safety of produce while 21% are at least very concerned about food safety and produce. This must change as fear has no place in the fresh produce department.

Ensuring the safety of fresh produce is an ongoing and integral focus for the entire industry. With a product that is grown in a natural environment and usually eaten raw, it is critical that the produce industry take every opportunity to ensure that our products are grown and handled properly at every step of the supply chain From grower to retailer, the produce industry is making tremendous investments to assure that the highest quality and safest produce is available to consumers to enjoy everyday.

Our Current Food Safety Practices

As our farm has evolved over 80+ years, so have the food safety challenges. My family and our employees take food safety seriously and are dedicated to providing our customers with the safest produce possible, as well as trying to help advance food safety issues within our industry. The following list gives you an idea of our company's commitment to food safety:

- approximately $750,000 invested every year for food safety and quality assurance.
- Intensive, bi-lingual food safety & food security training for all harvesters.
- Comprehensive production records kept.
- Good Agricultural Practices & HACCP plans in place.
- Periodical microbial testing of all water sources.
- Use of chlorinators for surface water irrigation sources when appropriate.
- Production inputs such as ag chemical are kept secure and applied with all appropriate controls.
- Records kept documenting food safety compliance at approximately 20 steps between field production and distribution of fresh products.
- Daily sanitation & testing prior to startup.
- Traceability for all of our products to the farm.
- Collaboration with the leafy greens industry across the country to develop national standards and metrics that could be applied through a National Leafy Greens Marketing Agreement (NLGMA) or potential regulation.

Challenges for Food Safety

- **Multiple food safety audits from customers—**One of our greatest challenges today is the lack of a consistent and agreed-upon standard for Good Agricultural Practices. Without that government endorsed standard, different customers demand different food safety audits which are burdensome to our company. My food safety personnel could do a better, more efficient job if they had one standard to adhere to instead of trying to make sure that our controls will meet the nuances of several sets of metrics.
- **Consistency of auditing and inspections—**Although many of the metrics in different audits are identical, we have found it difficult to deal with multiple third party auditors due to the fact that different auditors focus on different parts of the metrics. This would be a challenge for either third-party auditors or government inspectors. For example, one third party auditor will focus heavily on land use and water quality while another third party auditor will focus heavily on paperwork, & records. I was told during a recent audit that my portable toilet facility (PTF) was located at the wrong place and lost points. The inspector suggested that I place it in a particular area. Six months later, during another audit by the same third party company but by a different inspector, the second inspector suggested that my PTF go back to where the first inspector said to move it from.
- **Cost—**Range of cost varies tremendously when all audits intend to do about the same thing. I believe that with a consistent and agreed-upon government standard, the cost of food safety inspections should be borne by the general public since it is the general public's health that is being protected. The current system without that government standard allows the private auditing industry to charge whatever they can, especially when customers dictate to producers which third party audit they will accept. There are no checks and balances in place to prevent price gouging.
- **Industry commitment—**The produce industry is committed to food safety. Our company has been involved in proactive industry-wide efforts to improve our country's food safety system to include all the supply chain and to reinstall consumer confidence in the produce industry. Personally, I invest hundreds of thousands of dollars into food safety programs so that our consumers will have confidence in my brands. However, our industry is only as strong as our weakest link, and unfortunately, one bad actor can cost an entire industry millions of dollars. The produce industry needs Federal food safety oversight to boost consumer's confidence and to level the playing field for all producers.

Key Recommendations for Food Safety Reform

Put simply, we are at a point where we must 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 airplane knowing that next flight is inordinately safe—just as spinach, tomatoes, or peppers from thousands of farms were safe on the day of the tragedy in our industry, and the next day, and the next day. Therefore the industry has focused on three major policy principles that are aimed to protect public health and ensure consumer confidence.

1. *Must allow for a commodity-specific approach, based on the best available science*—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 food borne disease. In fact, a recent FDA *Federal Register* notice in 2007 confirmed that five produce commodities have been associated with 90% of all food borne disease outbreaks in the past 10 years, and that is where we must direct our resources.

2. *Must be consistent and applicable to commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country*—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. I want to know that if I am required to comply with food safety requirements, my competitors are complying with the same standard.

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 surface water and flowing rivers. 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 sources of irrigation water must meet safety standards that protect the product. That must be true whether the produce is grown in South Carolina, California, or Mexico.

3. *Must be federally mandated with sufficient Federal oversight of compliance in order to be most credible to consumers*—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. 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 other stakeholders. For this work, FDA must also have strong relationships with the USDA, state agriculture and regulatory officials, and foreign governments 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.

Conclusion

None of us can deny that our fresh produce industry faces a different business world today than we did before September 2006. Each time any fruit or vegetable is implicated in a food borne illness outbreak, we all suffer from lost consumer confidence in our industry as a whole. In the long run, this simply is not sustainable and certainly not acceptable. In turn, the fresh produce industry must continue to take responsibility to do all we can on our own. As has been mentioned today from my industry colleagues, stakeholders should continue developing commodity specific best practices and marketing agreements such as the LGMA and self-imposed regulation is an important positive step. Industry action is our most important defense. At the same time a Federal food safety system must also be elevated that maintains the confidence in eating healthy fresh fruits and vegetables; can deal with the rare problems without destroying public confidence; and doesn't kill the industry or sweep all products into the same bucket.

Thank you again for the opportunity to participate in this hearing and look forward to answering your questions.

The CHAIRMAN. Thank you, sir. I will tell you that I consume your product. It is of extremely high quality. My grandma taught me to eat greens a long time ago, and I think it is a fabulous product that you provide and I couldn't agree more with your testimony.

Mr. Robert Stovicek, Ph.D., President and Chairman of Primus Group from Santa Monica, California, welcome, sir. I would ask the same thing of you, to summarize your testimony and we will in fact be in contact with you to provide you with written questions.

STATEMENT OF ROBERT F. STOVICEK, PH.D., PRESIDENT AND CHAIRMAN OF PRIMUS GROUP, INC., SANTA MONICA, CA

Dr. STOVICEK. Thanks for the invitation. Thanks for letting me speak.

The auditing companies are quite often managing auditing companies managing auditors. One of the statements that we put in the first page of our audit is, when laws, commodity-specific guidelines or best-practice recommendations exist and are derived from reputable sources, then these practice parameters should be used. There is a way to set up an audit so you are taking into account both commodity differences and regions. But, you have to have auditors who understand the commodity groups that they are dealing with, and must understand the culture and languages where they are auditing.

Primus audits throughout the Western Hemisphere. Last year, 2008, we audited over 10,000 operations. We operate and have companies in Chile and Mexico. We have laboratories in Florida, Arizona, two in California, one in Mexico. We are audited ourselves by ANSI in the United States under the ISO 65 guidelines, in Mexico by EMA under ISO 65, which is an auditing scheme that audits auditors. We have over 2,000 paying clients in the fresh produce industry. We are a company that has existed for 20 years. We have one sole function: we service the fresh produce industry and we service it with regards to food safety.

If this is a crisis that needed to be dealt with fast and you brought the military in, they would outsource portions of what they had to do to a Blackwater or someone like that. Instead, what you hear is discussion after discussion, decade after decade, about how are we going to get it here, how are we going to get it there, how are we going to deal with commodities that are different, *et cetera*. Perhaps if you outsourced it to somebody you could fire at the end of the day if they didn't do their job, then it would get done, and that is my abbreviated presentation. Thank you.

[The prepared statement of Dr. Stovicek follows:]

PREPARED STATEMENT OF ROBERT F. STOVICEK, PH.D., PRESIDENT AND CHAIRMAN, PRIMUS GROUP, INC., SANTA MARIA, CA

Chairman Cardoza and Members of the Subcommittee:

On behalf of myself and my staff, I would like to thank you for the invitation and opportunity to address this Subcommittee.

Introduction. Few industries have gone through as radical a change as the fresh produce industry in the past 10 to 15 years. Fresh produce's image as the most wholesome of the food categories has evolved to one that is repeatedly associated with disease outbreaks. Considering how natural it is to resist change, no one should be blamed for asking how responsive the fresh produce industry has been to the issue of foodborne illness.

Studying the history of a firm that limits its service to providing the fresh produce industry technical assistance in the area of food safety would provide a measure of the industry's responsiveness. Primus Group, Inc. is just such a firm.

Primus Group, Inc. recognized in the early 1990s that the consumer perspective of fresh produce was going to change. New technologies in microbial testing, telecommunications and computerization enhanced the health official's investigative capabilities enabling them to identify what acts as vectors of human pathogens despite the fact that the foods themselves provide a poor medium for pathogen growth. Health officials had been speculating since at least the mid 1980s that fresh produce was vectoring human pathogens. These new tools have provided the data to prove the theory.

Primus' anticipation of these changes and the firm's success in selling services designed to address food safety is a reflection of the fresh produce industry's receptiveness to acknowledging its need to change.

History. Less than a year from incorporation in 1988, Primus hired a young doctoral candidate from Michigan State University majoring in Crop Science and Environmental Toxicology to assist in a shift from clinical services to agricultural testing. Prior to 1989, the firm had discontinued all clinical services and focused 100% on providing pesticide residue tests for the fresh produce industry.

In response to the early 1990s cantaloupe industry crisis, which resulted in 30,000 to 40,000 mid-westerners developing salmonellosis, Primus expanded its laboratory capabilities. These included human pathogen testing and assistance to fresh produce processors in developing their Hazard Analysis Critical Control Point (HACCP) programs and Good Manufacturing Practices (GMP). As the 1990s progressed, Primus expanded its consulting services from facilities to developing what we initially called Good Farming Practices, which now is referred to as Good Agricultural Practices (GAP).

Recognizing that in the process of consolidating, the fresh-cut produce industry was becoming too sophisticated to hope to build a business providing consulting assistance. Primus converted what intellectual material we felt was of value to Internet-based interactive training and safety manual development programs and offered them for free. At the same time, while continuing to offer microbiological and pesticide residue testing, Primus shifted resources into the realm of third party auditing. Since just before 1998, Primus has been auditing fresh produce operations with regards to their safe production and handling practices. Primus supported this third party auditing development by providing all the auditing checklists, guidelines and self-audit tools via the Internet, again free of charge.

Current. After over 20 years, Primus Group, Inc. remains a firm providing the fresh produce industry with food safety services. In 2008, Primus Group, Inc. invoiced over 2,000 fresh produce companies operating throughout the supply chain (see Flow Diagram). Services range from extensive food safety programs to individual audits or tests. Primus has grown to include subsidiaries in Mexico and Chile; Primus Laboratorios de Mexico, Azzule, and PrimusLabs.com Chile. Primus operates laboratories in Lakeland-Florida, Yuma-Arizona, Culiacan-Sinaloa, Mexico as well as in Salinas and Santa Maria, California. Within Primus' databases are the auditing results of more than 11,000 unique fresh produce growing and handling operations (see Chart). We work extensively throughout the Western Hemisphere, and on rare occasions, in Asia, Europe and Africa (see Map).

Value. With well over a billion servings of fresh produce per day, adverse events are actually rare when viewed on a per serving basis. Frequently, fresh produce operations are complex organizations consisting of numerous independent firms. Any given brand may have dozens or even thousands of growers. Commonly, the brand owner will subcontract with an independent harvesting company to harvest, and then with another independent firm, to cool and provide cold storage. Last, an independent trucking company is hired to transport the fresh produce to the retail or food service distribution center. Each of these operations has the potential to contribute to an adverse event (see Flow Diagram). Finding and acting to prevent a contamination in such a complex system is a challenge. A failed audit within such a complex system is far less meaningful than how the auditee responds to the nonconforming responses (NCR) (see Table). NCRs bring to attention issues that may become possible sources of contamination. Reducing the number of outbreaks in fresh produce will depend on how players within the supply chain react to the NCRs within the audits.

Cost. Implementing a food safety program is the major expenditure, while actual audit costs are a fraction of the food safety investment. For example the California Leafy Greens Marketing Agreement (LGMA) provides the best general sense for the cost of fresh produce auditing. The LGMA imposed a $0.02 per carton charge on the suppliers to pay for the Federal and State of California Inspection Program. The participants then requested that the fresh produce buyers pay an additional charge of approximately $0.30 per carton to cover the costs associated with changing the growing practices required to audit successfully. Primus has estimated the cost of our auditing program at approximately $0.005 per carton. Either way the auditing cost is a fraction of the cost of changing farming practices to assure successful auditing results.

Quality Control. Primus' United States based laboratories each participate in state administered accreditation programs. Our Culiacan, Sinaloa Mexico laboratory, in addition to participating in the state of Sinaloa's accreditation program, is also an ISO 17025 accredited laboratory. Furthermore, each laboratory participates in independent proficiency sample testing programs.

Primus Group, Inc. is the first firm to gain approval in the USDA National Organics Program (NOP) without being "grandfathered" in. Primus was the first EUREPGAP certification body in North America (2002) and remains the only North American based certification body. Primus is also a certification body under the MexBest auditing program. The EUREPGAP (now renamed GlobalGAP) auditing program and the MexBest auditing program require the certification body to be ISO 65 accredited. On an annual basis, Primus' food safety testing and auditing services are reviewed by four states, two accreditation bodies (*i.e.,* American National Standards Institute (ANSI) and Entitad Mexicana de Acreditación (EMA)). The USDA review of Primus' certification program is done once every 5 years. In 2008, Primus began the process of benchmarking our auditing program against the Global Food Safety Initiative (GFSI). On the 20th of May, the technical committee will review Primus' auditing program. When Primus achieves recognition from GFSI, it will be our firm's third ISO 65 auditing system.

All of these quality review systems help Primus understand how differently government, private sector, Europeans, Americans, Latin Americans and others set their priorities. While these formal auditing systems provide an excellent guide for expectations and have helped us understand expectations from other cultures, it is Primus' aggressive use of the Internet and commitment to transparency in all processes of the business, which encourages a plethora of quality reviewers. This reviewing emanates from all levels of the supply chain including clients and supporters in the buying community. Establishing systems that are auditee-friendly invite a universe of opinions but over time it is the frontline feedback that makes a responsive innovative firm successful. These folks come at us from so many varied perspectives that it would be cost prohibitive to hire the in-house equivalent.

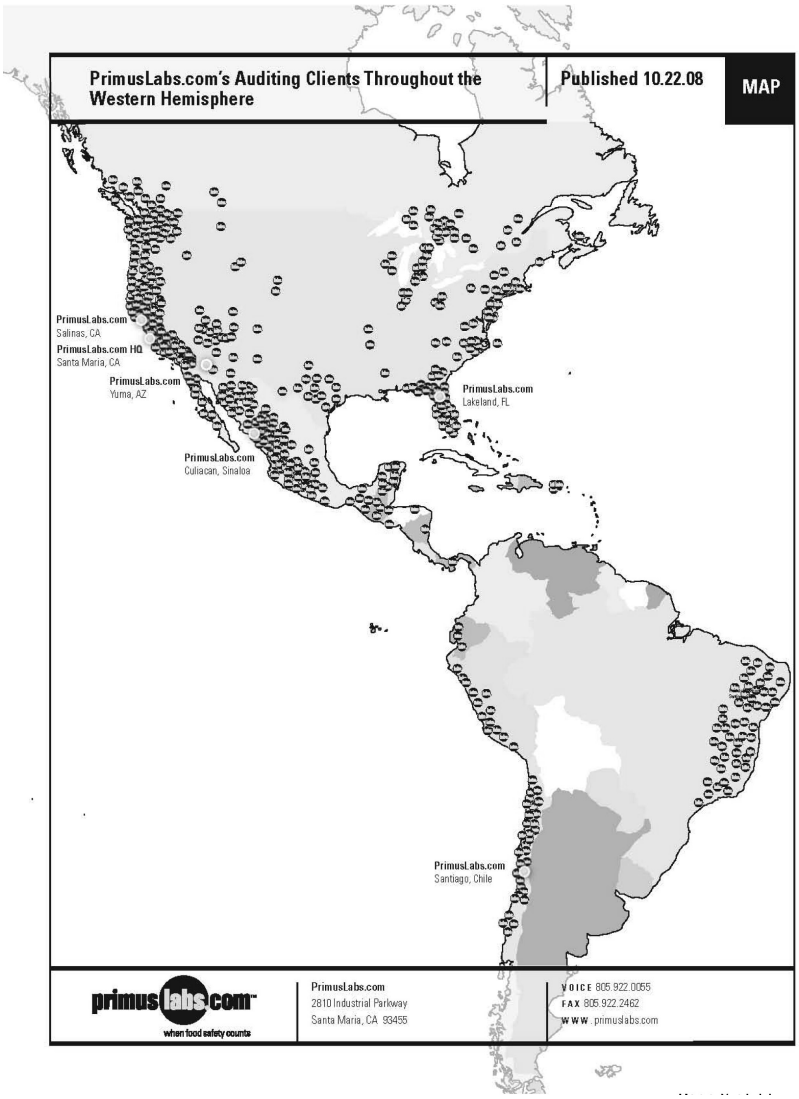
Who's Story. Primus' success is appropriately attributed to our rapid response. Response to suppliers and buyers that recognized the need to change years before fresh produce safety issues became routine news stories. Primus' success is a direct result of fresh produce suppliers and buyers who have been working with us for over a decade to perfect the ability to convey their concerns to their growers and handlers. Working together, we refine computer-based systems that accurately convey back to the buyers the supplier's acknowledgement of their expectations and implementation of corrective actions.

While this has been Primus' story, the reality is that this is the fresh produce industry's story. It represents only one service provider's (Primus) effort to address the challenge of food safety. There are even more compelling stories being carried out daily at different fresh produce companies throughout North and South America. Stories that one would assume to be a pleasant surprise for many American consumers.

On behalf of myself and my staff, again, thank you for this opportunity to make this presentation.

Corporate Website: *www.primuslabs.com*

ATTACHMENT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PrimusLabs.com - GMP* Non-Conforming Responses (NCR) By Count Compliance Ratios

TABLE

GMP* Non-Conforming Responses (NCR) By Count Compliance Ratios

	2005		2006		2007		2008		2009‡	
Number of Audits	859		941		1067		1316		336	
	Integer	% Breakdown	Integer	% Breakdown	Integer	% Breakdown	Integer	% Breakdown	Integer	% Breakdown
Full Compliance	109,235	84%	121,824	86%	138,001	86%	174,583	88%	46,864	87%
Less Than Full Compliance	20,409	16%	20,024	14%	22,132	14%	24,377	12%	7,191	13%
Average NCR's per Audit	24		21		21		19		21	

*** Good Management Practices**
‡ Up To May

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PrimusLabs.com - Annual Volume of Third Party Audits Uploaded

CHART

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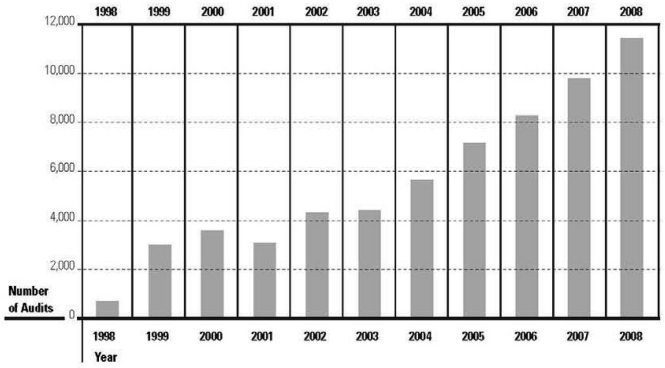

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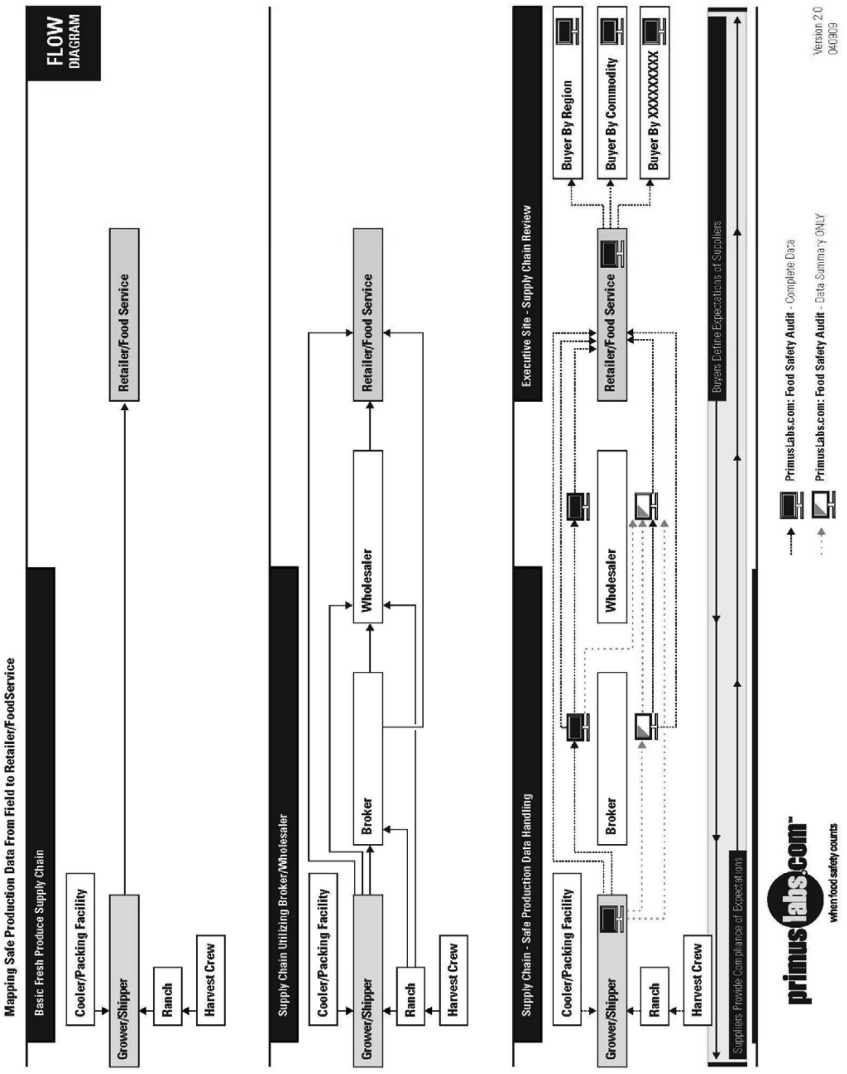
Mapping Safe Production Data From Field to Retailer/FoodService
FLOW DIAGRAM
Basic Fresh Produce Supply Chain
Cooler/Packing Facility
Grower/Shipper
Ranch
Harvest Crew
Retailer/Food Service
Supply Chain Utilizing Broker/Wholesaler
Cooler/Packing Facility
Grower/Shipper
Ranch
Harvest Crew
Broker
Wholesaler
Retailer/Food Service
Supply Chain - Safe Production Data Handling
Executive Site - Supply Chain Review
Cooler/Packing Facility
Grower/Shipper
Ranch
Harvest Crew
Broker
Wholesaler
Retailer/Food Service
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The CHAIRMAN. Thank you very much to all the panelists for providing your testimony today. We very much appreciate your time and we very much appreciate the fact that you have accommodated us on this difficult day that has been interrupted numerous times by votes. That is not unusual here, but today, I think it affected our hearing more than is regularly the case. So for that, I want to apologize even though I had nothing to do with the schedule.

Before we adjourn, I will briefly allow the Ranking Member to give any closing remarks she would like to do before I adjourn the hearing.

Mrs. SCHMIDT. Thank you so much, and I thank everyone for this wonderful testimony on this very important subject. Like the Chairman, I apologize for the disruption. Some days are smoother than others and today you hit one of those rocky roads, but we managed to get the people's work done here both here in Committee as well as in the full House, and we will break. Thank you very, very much. I look forward to Mr. Maravell coming to my office, and if any other individual wishes to come to my office, please feel free. We can teleconference or whatever. Thank you so much and good luck.

The CHAIRMAN. Thank you. Under the rules of the Committee, the record of today's hearing will remain open for 10 calendar days to receive additional material and supplementary written responses from the witnesses to any question posed by a Member. This hearing of the Subcommittee on Horticulture and Organic Agriculture is hereby adjourned.

[Whereupon, at 2:45 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUBMITTED STATEMENT OF LONNIE J. KING, D.V.M., DIRECTOR, NATIONAL CENTER FOR ZOONOTIC, VECTOR-BORNE & ENTERIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Findings from CDC's Foodborne Diseases Active Surveillance Network (FoodNet)

Introduction

Thank you for the opportunity to submit testimony for the record on CDC's activities related to the prevention of foodborne disease and CDC's role in collecting and reporting FoodNet data.

Background

Diseases spread by contaminated foods continue to challenge the public health system. Large foodborne outbreaks are often attributed to fresh produce and processed foods, as well as foods of animal origin. Numerous factors are responsible for these large outbreaks such as changing production systems, changing ecologies, and changing food consumption patterns.

As an agency within the Department of Health and Human Services (HHS), CDC leads Federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC relies on local and state health departments, which have varying capacity to detect and respond to food-related illnesses.

CDC is not a food safety regulatory agency, but CDC works closely with the food safety regulatory agencies, in particular with HHS' Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the United States Department of Agriculture (USDA/FSIS). CDC also plays a key role in building state and local health department epidemiology, laboratory, environmental health, and communication capacity to support foodborne disease surveillance and outbreak response. CDC surveillance data can help attribute the burden of foodborne illness to specific food commodity groups to support regulatory risk-based inspection efforts and help document the effectiveness of prevention interventions.

Much of what CDC does to detect and monitor foodborne illness depends on critical partnerships with state and local public health departments that collect surveillance data, conduct laboratory testing, investigate most outbreaks, and take public health action. CDC has worked with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE) to develop networks for foodborne disease surveillance. For example, PulseNet, the national network for molecular subtyping of foodborne bacteria coordinated by CDC, allows every state health laboratory to test strains of bacteria from sick persons in that state and to compare them with DNA "fingerprint" patterns in the national database at CDC. This has greatly improved the ability to detect clusters of illness that may be related, even if they are dispersed across multiple states. Similarly, other related networks [OutbreakNet team] help coordinate the investigation of the large, multi-state clusters detected by PulseNet, facilitate state reporting of outbreaks to CDC [National Outbreak Reporting System], develop baseline information on what foods are commonly consumed and trends in foodborne illness [FoodNet], and assess policies and practices of retail foodservice establishments that could lead to or prevent foodborne outbreaks [Environmental Health Specialist Network]. These networks and systems, among others, provide data to help CDC and our regulatory partners better understand foodborne disease in the United States.

CDC also works with a broad range of other partners to improve capacity and knowledge regarding foodborne disease control and prevention. In collaboration with the National Environmental Health Association (NEHA), CDC conducts team training programs for local and state health department officials including specialists in environmental health, laboratory science, and epidemiology. CDC works with the World Health Organization (WHO) and a variety of other international partners to conduct similar training programs in other countries. CDC supports the Council to Improve Foodborne Outbreak Response (CIFOR), which was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CSTE and the National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR, and it includes representatives from CDC, FDA, USDA, APHL, NEHA, the Association of State and Territorial Health Officials, the Association of Food and Drug Officials, and industry.

FoodNet

The Foodborne Diseases Active Surveillance Network (FoodNet) of CDC's Emerging Infections Program collects data from ten U.S. sites, representing approximately 15 percent of the U.S. population. Sites locations include Connecticut, Georgia,

Maryland, Minnesota, New Mexico, Oregon, Tennessee, and selected counties in California, Colorado, and New York. FoodNet is an active, population-based surveillance system for laboratory-confirmed infections caused by pathogens transmitted commonly through food. Preliminary data for 2008 were released last month and show that the estimated incidence of infections caused by *Campylobacter, Cryptosporidium, Cyclospora, Listeria,* Shiga toxin-producing *Escherichia coli* (STEC) O157, *Salmonella, Shigella, Vibrio,* and *Yersinia* did not change significantly when compared with the preceding 3 years.

The lack of significant change in recent years is in contrast to trends from 1996, when FoodNet surveillance began, to 2004. Models show that rates of infection with *Yersinia, Shigella, Listeria, Campylobacter,* and STEC O157 had decreased 25 to 48 percent. However, *Vibrio* had increased 47 percent. The estimated incidence of infection with *Cryptosporidium* and *Salmonella* did not change significantly over this period.

Despite ongoing activities aimed at preventing foodborne human infections, progress toward the national health objectives has plateaued, suggesting that fundamental problems with food contamination persist. Although significant declines in the incidence of certain pathogens have occurred since establishment of FoodNet, these all occurred before 2004. The lack of recent progress toward national health objective targets and the occurrence of large multi-state outbreaks caused by *E. coli* in shredded lettuce, frozen pizza, and ground beef; *Salmonella* in tomatoes, peanut butter, cantaloupe, and jalapeños; and botulinum toxin in carrot juice and canned chili sauce point to gaps in the current food safety system and the need to continue to develop and evaluate food safety practices as food moves from the farm to the table.

Enhanced and food-specific measures are needed to (1) control or eliminate pathogens in domestic and imported food; (2) reduce or prevent contamination during growing, harvesting, and processing; and (3) continue the education of restaurant workers and consumers about risks and prevention measures. In particular, continued efforts are needed to understand how contamination of fresh produce and processed foods occurs and to develop and implement measures that reduce it. More outbreaks can be recognized and their causative foods identified with rapid and complete subtyping of pathogens and with rapid standardized interviews of ill persons and appropriately selected controls.

Consumers can reduce their risk for foodborne illness by following safe food-handling and preparation recommendations and by avoiding consumption of unpasteurized milk, raw or undercooked oysters, or other raw or undercooked foods of animal origin such as eggs, ground beef, and poultry. Risk also can be decreased by choosing pasteurized eggs, high pressure-treated oysters, and irradiated meat and produce. Everyone should wash hands before and after contact with raw meat, raw foods derived from animal products, and animals and their environments.

Conclusion

There is a continued need for robust public health surveillance at all levels—local, state, and Federal—to ensure prompt recognition, response, and investigation of foodborne illness. CDC will continue its efforts to:

- focus on research, education, and training that will assist with Federal strategies to prevent foodborne illnesses;
- incorporate food industries into prevention, response and information sharing; and
- bolster state health infrastructures to effectively and promptly identify and respond to outbreaks.

This will entail continued cooperation between regulatory authorities, state and local partners, food and environmental microbiologist scientists, and the food industry to prevent future foodborne illness outbreaks. CDC is working closely with the White House Food Safety Working Group established by President Obama and is strongly committed to strengthening our national food safety system. President Obama established the working group to coordinate the efforts of Federal agencies and to advise the President on improving coordination throughout the government. Thank you again for the opportunity to submit written testimony for the record.

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