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HEARING TO REVIEW CURRENT ISSUES IN FOOD SAFETY

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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HEARING TO REVIEW CURRENT ISSUES IN FOOD SAFETY

THURSDAY, JULY 16, 2009

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The Committee met, pursuant to call, at 10:08 a.m., in Room 1300, Longworth House Office Building, Hon. Collin C. Peterson [Chairman of the Committee] presiding.

Members present: Representatives Peterson, McIntyre, Boswell, Baca, Cardoza, Scott, Herseth Sandlin, Cuellar, Costa, Walz, Kagen, Halvorson, Dahlkemper, Bright, Markey, Kratovil, Schauer, Kissell, Boccieri, Minnick, Goodlatte, Moran, Johnson, King, Neugebauer, Conaway, Fortenberry, Schmidt, Smith, Latta, and Luetkemeyer.

Staff Present: Andy Baker, Robert L. Larew, Nathan Fretz, Chandler Goule, Alejandra Gonzalez-Arias, Tyler Jameson, Scott Kuschmider, James Ryder, April Slayton, Rebekah Solem, Patricia Barr, Tamara Hinton, John Goldberg, Pam Miller, and Pete Thomson.

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

The CHAIRMAN. The Committee will come to order. This hearing of the Committee on Agriculture today is to review the current issues on food safety and will come to order.

I am going to be brief in my statement. I welcome everybody to the Committee. I welcome our witnesses.

There is a lot going on with food safety right now, both in policy and legislation. The President's Food Safety Working Group has been working on policies to improve food safety. The House Energy and Commerce Committee has approved legislation related to food safety at the FDA, and this is the fourth hearing this year held by this Committee to look at this topic. And I can tell you that it won't be the last hearing we have on the subject either. It is a complicated issue with a lot of interacting and moving parts; so I want to be sure that our Members have a clear understanding of what is going on and what we can do to play a role in the process.

So I hope Members are ready to get involved. We all want to do whatever we can to make our food safety system better. We have the safest food in the world, but it can always be better and that is a priority of this Committee, and we will do whatever we can to facilitate that process.

So I am going to do something a little out of the ordinary here. I have constituent, sort of, from Minnesota here and I wanted to recognize him. His mother was in my district and passed away because of the peanut situation that happened here not too long ago, and he has joined us today. So I just want to give the rest of my time to him to tell us a little bit about his mother and the situation, and he is also an accountant so we are brothers that way as well. So Jeffrey Almer from Minnesota, you are recognized.

STATEMENT OF JEFFREY ALMER, MEMBER, S.T.O.P.—SAFE TABLES OUR PRIORITY, SAVAGE, MN

Mr. ALMER. Thank you, Mr. Chairman. I thank everyone for inviting me. I am just, very obviously, interested in how this progresses. I know it is a long process. My main reason to be here is to let you folks know that—and you probably do know this already—things can be done so much better, and I know there has been some rumors going around on the Internet and things like that about how it will affect small farmers and things like that. I just want to see that we turn food safety in this country around and make it safe like it needs to be. I don't want to have any political parties influenced one way or the other. I just want to have it done right.

But my mother Shirley, she was a business woman and she had defeated cancer twice, lung cancer 1 year and brain cancer the next year. She overcame a lot of struggles and was in a rehab facility for a urinary infection, a simple infection. And she consumed some peanut butter that was in an industrialized container, and that took her. It is very hard to imagine to see somebody struggle to get that far beat cancer and then have something as simple as peanut butter take her life. She had a lot more life to live and was loved by all of us.

So I am here in her honor, I am here on her behalf and for the other people that have been affected by food, and there are quite a few people. One out of four every year will be affected by food illness. So I have joined up with S.T.O.P.—Safe Tables Our Priority. They have done expert work. I am not an expert by any means but just as an average layman I can see we can do better. I know we can. So I appreciate your time thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much for taking time to be with us and for honoring your mother. We sympathize with your situation and I can assure you this Committee will do whatever we can to improve the food safety system in this country. Thank you.

[The prepared statement of Mr. Peterson follows:]

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

Good morning and welcome to today's hearing of the House Agriculture Committee. Because we have a lot to get to today, I am going to keep my remarks brief.

There is a lot going on with food safety policy and legislation right now. The President's Food Safety Working Group has been working on policies to improve food safety. The House Energy and Commerce Committee has approved legislation related to food safety at FDA. And this is the fourth hearing this year held by this Committee to look at this topic. It won't be the last hearing we have on this subject either. This is a complicated issue with a lot of interacting and moving parts, so I want to be sure that our Members have a clear understanding of what is going

on and what we can do to play a role in this process. I hope that Members of the Committee are ready to roll up their sleeves, learn all that they can, and ask the questions that need to be asked.

I want to thank all of our witnesses for being here today, and I look forward to their testimony.

The CHAIRMAN. I now recognize the gentleman who is sitting in today as the Ranking Member, former Chairman of the Committee, former Ranking Member of the Committee and my good friend, Mr. Goodlatte from Virginia.

OPENING STATEMENT OF HON. BOB GOODLATTE, A REPRESENTATIVE IN CONGRESS FROM VIRGINIA

Mr. GOODLATTE. Thank you, Mr. Chairman. I very much appreciate that this Committee is continuing to devote its attention to such an important issue as the safety of our food supply. Every Member of this Committee recognizes that food safety is approximately the single most important issue for which we have jurisdiction. Likewise, I don't think there is a single member of this panel who wouldn't support reasonable proposals that improve the safety of what is already the safest food supply in the world. It is unfortunate that the legislation passed out by the Energy and Commerce Committee, H.R. 2749, the Food Safety Enhancement Act of 2009, does so little to enhance food safety. Most observers agree that to improve food safety, we must focus on preventing contamination and cross contamination during food processing and preparation. However, it appears that the overwhelming majority of this bill seems to misdirect the attention of the regulatory agency to reacting after a foodborne illness outbreak in punishing those who may or may not have anything to do with it.

Another area of considerable concern with this legislation is that the authors seem to believe that the Food and Drug Administration has the resources and expertise to be able to implement and enforce regulations on the more than 2.2 million farms in this country. Section 103 of this legislation will direct the FDA to issue mandatory on-farm food safety performance standards. Due to severe resource constraints within the FDA, this will undoubtedly ignore the complexity and diversity of farming operations. Section 103 will direct the FDA to adapt a food processing regulatory model to agricultural production practices.

Let me be clear about the consequences of this legislation. Directing the Food and Drug Administration to tell farmers how to farm will make food more expensive. It will threaten our food security. It will increase our reliance on foreign food. It will not make our food supply safer.

The FDA does have the expertise, and if this legislation is crafted correctly, will have the resources to facilitate the processing, distribution and preparation of safer food. That to me is where we need to be directing our attention to avoid the kind of tragedies that some have experienced. But a live animal, a plant actively growing in a field, or a piece of fruit developing high up in a tree, is not yet food and is therefore beyond the expertise of the FDA to oversee its production.

I am continually frustrated by advocates who believe that Congress should enact legislation that attempts to extend the food processing regulatory model to agricultural production practices.

This is simply not the way to go, no matter how good the intentions.

On this Committee and at the USDA, our colleagues understand the nature of farming in America. We know about the complexity and diversity of our farming operations and fully appreciate that a one size fits all regulatory model would be a disaster. The Committee can take pride in the fact that our country is blessed to have farmers who continually produce the safest, highest quality, most abundant and affordable food supply in the history of the world. We must make clear one important fact regarding a recent incident of foodborne illness that seems to be driving this legislation.

That incident was not the result of inadequate legal authority or even inadequate regulation. It was the result of intentional disregard of food safety standards by the food processor and a complete failure of the FDA to enforce its own regulations.

As we consider this legislation, I will be evaluating this and any other proposal on three key principles: One, does the legislation make food safer? Two, does the legislation hold the regulator accountable? And three, does the legislation adequately account for geographic differences and weather differences in food production, as well as the diversity of the crops being grown?

Mr. Chairman, again, I thank you for this hearing and I look forward to today's testimony and the considerate informed debate that will follow.

The CHAIRMAN. I thank the gentleman for his statement. All other Members are advised that they can submit statements for the record.

[The prepared statement of Mr. Walz follows:]

PREPARED STATEMENT OF HON. TIMOTHY J. WALZ, A REPRESENTATIVE IN CONGRESS FROM MINNESOTA

Mr. Chairman, Mr. Ranking Member, Members of the Committee, our witnesses here, thank you for this very important hearing.

A series of high-profile outbreaks of foodborne illness over the past 3 years resulting in thousands of individuals sickened and multiple deaths has demonstrated the need to improve food safety. I am glad that we are here today looking at legislation to improve our food safety system. We have an obligation to our children to address this problem, to set an example for the world, and to strengthen our economic security and energy independence. However, we must do it wisely, it must make sense, and it must not do more harm than good.

I do have concerns about certain provisions in H.R. 2749, the Food Safety Enhancement Act of 2009. It is important that Congress get it right. Mr. Chairman, I thank you for bringing together these experts to address food safety legislation as it relates to the agriculture community.

So far, USDA has set a good example as a regulating agency. It is important to use their expertise to help shape any food safety legislation that affects our producers.

I know the farmers in my district in southern Minnesota want to be part of the solution and want to assure the public that they are doing everything possible to keep our food safe. They understand we need new mechanisms to stop the bad actors. However, we need mechanisms that work, not mechanisms that simply add heavy-handed regulation to low-risk commodities.

Mr. Chairman, I look forward to the opportunity to hear the testimony of our witnesses today and the chance to ask them questions about how they believe food safety regulation should be addressed.

The CHAIRMAN. And we will move to the witnesses.

We would like to welcome them all again to the witness table. Mr. Larry Wooten, the President of the North Carolina American Farm Bureau Federation. Welcome, Larry.

Mr. WOOTEN. Glad to be here.

The CHAIRMAN. Patrick Boyle, President of the American Meat Institute. Ms. Carol Tucker-Foreman, Distinguished Fellow with the Food Policy Institute, Consumer Federation of America. Dr. Sam Ives, Director of Veterinary Services and Associate Director of Research for the Cactus Feeders, Limited, on behalf of the National Cattlemen's Association. Mr. Kent Peppler, President of the Rocky Mountain Farmers Union. Mr. Bob Reinhard, Director of Food Safety for Sara Lee and Chairman of the Technical and Regulatory Committee of the National Turkey Federation. Mr. Nicholas Maravell, Owner and Operator of Nick's Organic Farm in Potomac, Maryland. And Mr. Drew McDonald, Vice President of National Quality Systems, Taylor Farms, Salinas, California.

So welcome all to the Committee. Mr. Wooten you are on first. Your full statements will be all made part of the record. And we have votes coming up at 11:30; so we are going to try to move this. So we would like to have you observe the 5 minute rule and your full testimony will be made part of the record. So welcome to the Committee.

STATEMENT OF LARRY B. WOOTEN, PRESIDENT, NORTH CAROLINA FARM BUREAU FEDERATION; MEMBER, BOARD OF DIRECTORS, AMERICAN FARM BUREAU FEDERATION, RALEIGH, NC

Mr. WOOTEN. Thank you very much. Good morning, Chairman Peterson, Mr. Goodlatte, and Members of the Committee. I am Larry Wooten, a tobacco and grain producer from North Carolina. I am President of the North Carolina Farm Bureau and testifying today as a Member of the Board of Directors of the American Farm Bureau Federation. We appreciate your scheduling this hearing to review the current food safety issues.

As the nation's largest general farm organization and the representative of farmers and ranchers in every state in the nation, Farm Bureau has a vital interest in how food safety is practiced, perceived, and regulated. We represent growers of virtually every commodity from apples to zucchini and pigs to peanuts. My home State of North Carolina is a microcosm of Farm Bureau's diversity as we proudly claim the nation's third most diversified agricultural economy. North Carolina's rural landscape is made up of many small farms due to our state's history with the Federal tobacco and peanut programs. North Carolina is a perfect example of the need for any food safety legislation to recognize the different needs of farmers based on the size and scope of their operations. One size does not fit all. Regional differences in production and cultural methods must certainly be considered.

Farm Bureau supports efforts to strengthen the country's food and animal feed safety systems utilizing sound science in a risk-based approach. We also recognize the importance of providing adequate resources in a manner that increases efficiencies. The nation's food safety system must have the capacity, the authority, and the structural organization to safeguard the health of American

consumers against foodborne illness. Evaluating food safety laws to determine whether they have kept pace with significant changes in food production is a priority both for agriculture and the food industry, as well as for government.

However, there is concern that too many new standards will unnecessarily complicate the marketplace without increasing the overall safety of the food supply. While we understand the need for continuous food safety improvement, the farm level impact on producers must certainly be considered in any new initiatives. Legislation currently pending in the House of Representatives contains some very troubling provisions that could undermine our ability to provide a safe, affordable and abundant food supply. Although numerous bills have been introduced in Congress to address a variety of food safety-related issues, we will focus our comments today on the Food Safety Enhancement Act. Farm Bureau supports of goal of H.R. 2749 to provide additional food safety resources both internally and through cooperative relationships.

We appreciate the bill's requirement that FDA establish a program to recognize laboratory accreditation bodies and encourage that third-party certification be extended to domestic testing and inspections. Much of the additional research required in this legislation has been necessary for several years and is critical to any effective food safety initiatives in the future. Bipartisan negotiations that took place prior to the Committee passage of H.R. 2749 to address numerous concerns raised by the Farm Bureau and other groups was important. Most notably livestock operations and the livestock portion of diversified farming operations are generally exempted from the bill. Despite substantial and significant progress from the legislation's original discussion draft, unresolved issues that could increase costs and increase paperwork burdens on farmers and ranchers remain.

As approved by the full Committee on June 17, H.R. 2749 would significantly expand authorities for FDA to regulate and oversee on-farm production practices. Farms are explicitly included in extensive new record-keeping, reporting and traceability measures which may not be feasible or practical for many of our producers. FDA does not have the personnel, the funding, the expertise or the time to regulate agricultural production practices particularly given its overall volume of increased responsibilities contemplated in H.R. 2749.

Mr. Chairman and Members of the Committee, we thank you for arranging—again, for arranging this public hearing to better understand food safety issues, and for allowing us to share producers' views of the current legislation. We are committed, at American Farm Bureau, to improving food safety in a targeted scientific and risk-based manner, and we stand ready to work with Congress in that effort. Thank you very much.

[The prepared statement of Mr. Wooten follows:]

PREPARED STATEMENT OF LARRY B. WOOTEN, PRESIDENT, NORTH CAROLINA FARM BUREAU FEDERATION; MEMBER, BOARD OF DIRECTORS, AMERICAN FARM BUREAU FEDERATION, RALEIGH, NC

Good morning, Chairman Peterson, Ranking Member Lucas and Members of the Committee. I am Larry Wooten, a tobacco and grain producer from North Carolina.

I am President of the North Carolina Farm Bureau and testifying today as a Member of the Board of Directors of the American Farm Bureau Federation (AFBF).

On behalf of Farm Bureau's more than six million members, thank you for your dedication and commitment to farmers, ranchers and the related industries that provide the U.S. with the world's most abundant, affordable and safe food supply. We appreciate you scheduling this hearing to review current food safety issues. AFBF is pleased to present producers' perspectives on this issue and we thank you for inviting us to share our views on a topic that is important to our members, producers and consumers alike.

As the nation's largest general farm organization and the representative of farmers and ranchers in every state in the nation, AFBF has a vital interest in how food safety is practiced, perceived and regulated. We represent growers of virtually every commodity, from apples to zucchini and pigs to peanuts.

My home State of North Carolina is a microcosm of Farm Bureau's diversity, as we proudly claim the nation's third most diversified agriculture economy. Agriculture is North Carolina's number one industry accounting for about $70.8 billion in annual economic activity and just under ⅕ of our state's jobs.

North Carolina's rural landscape is made up of many small farms due to our state's history with the Federal tobacco and peanut programs. It is a perfect example of the need for any food safety legislation to recognize the different needs of farmers based on the size and scope of their operations. One size does not fit all, and agencies with experience in the diversity of farming operations—including USDA—appreciate regional differences in production and cultural methods.

The Safety of the U.S. Food Supply

American consumers deserve to have confidence that their food is safe and that the best science is used to ensure that the most wholesome product possible is produced and offered. Consumers reasonably expect that their food is safe, whether grown domestically or imported.

By their nature, food systems are biological and thus, not failsafe nor can they ever be "zero risk." However, food today is safer than in the past and food safety is constantly improving, particularly through reporting and tracing when food problems occur. In 1996, the Centers for Disease Control (CDC) improved its data collection of foodborne illnesses. The results since then indicate a 25 percent decline in *E. coli* ailments, *Campylobacter* cases are down 32 percent, and *Listeria* has shown a 36 percent decrease in illnesses. Other bacterial infections are down by about 33 percent.

These improvements have occurred despite new challenges for food safety, such as changes in the typical American diet to include more imported foods and more food consumed away from home. The U.S. now imports food from more than 150 different countries through more than 300 ports of entry. About half of fresh fruits eaten in America are grown outside of the country, and if you've ever been to a mid-Atlantic farmers market in January an explanation of why this happens becomes clear—these imports allow us to enjoy our favorite produce year-round. Trade in food permits a more varied and customized diet suited to today's consumer preferences. It permits our farmers and other food producers to sell their goods abroad. Yet, it also means that food safety requires enhanced attention to the global food supply.

Adding to the complexity presented by increased food sources, the number of people involved in preparing the food we consume has also increased. Approximately 50¢ of every food dollar today is spent on foods prepared outside the home in places like restaurants, vending machines, and schools. This development increases the need to ensure adequate training for food service workers across the country and to consider the potential widespread impact of deliberate contamination of the food supply. As the supply chain gets longer, there are more opportunities (both accidental and intentional) for the introduction of public health threats.

Though the U.S. food production system is among the best in the world, producers and consumers agree that improvement is always an important goal. In addition to the new trends previously noted, recent food recalls have increased consumer awareness of food safety. The nation's food safety system must have the resources, authority and structural organization to safeguard the health of American consumers against foodborne illness. Evaluating food safety laws to determine whether they have kept pace with significant changes in food production, processing and marketing—such as new food sources, advances in production and distribution methods, and the growing volume of imports—is a priority for the agriculture and food industry, as well as government.

However, there is concern that too many new standards will unnecessarily complicate the marketplace without improving food safety overall. While we understand

the need for continuous food safety improvement, the farm-level impact on producers must be considered in any new food safety regulations or legislation.

Farm Bureau Policy

AFBF supports:

- Adequate funding of the government's food and feed safety and protection functions;
- Increased education and training for inspectors;
- Additional science-based inspection, targeted according to risk;
- Research and development of scientifically based rapid testing procedures and tools;
- Increased funding for the Food Animal Residue Avoidance Databank (FARAD);
- Accurate and timely responses to outbreaks that identify contaminated products, remove them from the market and minimize disruption to producers; and
- Indemnification for producers who suffer marketing losses due to inaccurate government-advised recalls or warnings.

Farm Bureau strongly opposes efforts to eliminate years of food safety expertise by creating a new, single food safety regulator. Rather than streamlining authorities, the result would be less organization, more energy expended in transition than inspections, and the cumulative loss of valuable technical knowledge.

While we believe that import inspections must be increased in a risk-based manner, we have concerns about food safety bills which could threaten trade. Port closures and discriminatory treatment of international products are especially problematic.

Food Safety Responsibilities

Food safety is a shared responsibility of everyone in the food chain, from producer to consumer and each step in between. The government also plays a vital oversight and regulatory role.

It Starts with the Producer

America's farmers and ranchers are committed to producing safe and affordable food for consumers in the U.S. and around the world. There are several reasons for their strong support for food safety. They have the same desire as other consumers to have a safe, abundant and affordable food supply. They also have an economic interest because the demand for their products is determined by consumer confidence that food is safe.

Food safety is paramount for everyone involved in the agriculture industry. We have an obligation to produce a safe, nutritious product for domestic and international consumers, and that obligation is at the core of all that we do.

Government Role

The Government Accountability Office (GAO) has identified 15 Federal agencies that administer at least 30 laws related to food safety. The Food and Drug Administration (FDA) within the Department of Health and Human Services and the Food Safety Inspection Service (FSIS) within the Department of Agriculture (USDA) handle most of the government's food safety regulatory system.

FDA regulates 80 percent of the food supply. The agency is responsible for ensuring that all domestic and imported food products—except for most meat and poultry derived from the major animal species—are safe, nutritious, wholesome and accurately labeled. FDA share responsibility for the safety of eggs with FSIS.

FSIS regulates 20 percent of the food supply, ensuring the safety, wholesomeness and proper labeling of most domestic and imported meat and poultry and their products sold for human consumption. FSIS inspects all cattle, sheep, swine, goats and horses before and after they are slaughtered. FSIS also maintains oversight during meat and poultry processing into food products.

Among the other agencies that play a role in food safety are USDA's Agricultural Research Service, the Center for Disease Control, the Environmental Protection Agency, the National Marine Fisheries Service and the Department of Homeland Security (DHS).

Consumers are the Ultimate Step

Once a safe food product leaves the retail shelf, the final responsibility for safe storage, handling and preparation ultimately rests with the consumer. The amount of time (less) and methods used (more) to prepare food have changed considerably, requiring consumers to increase their knowledge and vigilance.

Yet, consumers' knowledge about food storage and preparation has declined markedly in the past 30 years. This results in greater chance for human error in food choices and preparation. Many of the estimated 76 million cases of foodborne illnesses in the U.S. each year are contracted in the home, and many can be prevented through proper kitchen health, storage and cooking.

The entire food industry is committed to not only offering a safe product to consumers, but also doing all that we can to ensure the safety of that product until it is consumed. On February 10, AFBF launched a consumer website, *Your Agriculture,* at *www.fb.org/yourag,* which includes safety guidelines for food preparation, cooking, serving and storage in the home. Our biannual publication "Farm Facts," dedicated to educating the public about all facets of agriculture in layman's terms, details the four simple food safety steps: clean, separate, chill and cook. Last year, we began publishing a monthly e-newsletter, "Foodie News." AFBF also produces a brochure, "Farmers Provide Safe and Abundant Food," to help educate the public about food safety.

It is important to note that everyone plays a role in food safety, including the food industry and regulatory agencies. Therefore, we support Congress' efforts to strengthen the country's food- and animal feed-safety systems utilizing sound science and a risk-based approach. We also recognize the importance of structuring and providing adequate resources to our food- and feed-safety systems to increase efficiencies. However, legislation currently pending in the House of Representatives contains some very troubling provisions that could undermine our ability to provide a safe, affordable and abundant food supply.

Legislative Action in the House of Representatives

Although numerous bills have been introduced in Congress to address a variety of food safety related issues, we will focus our comments today on the Food Safety Enhancement Act (H.R. 2749) as it appears to be the primary vehicle for food safety reform in the House. We appreciate the interest of both the majority and minority Members and staff of the Energy & Commerce Committee in learning about how and why we do what we do to produce safe food. We remain engaged in ongoing discussions to continue improving H.R. 2749 before it comes to the House floor for a vote.

Farm Bureau is encouraged by several provisions in H.R. 2947 to increase FDA resources, both internally and through cooperative relationships. We support the goal of the legislation to strengthen and provide additional resources for food safety functions. We appreciate the bill's requirement that FDA establish a program to recognize laboratory accreditation bodies and encourage that third-party certification be extended to domestic testing and inspections. Much of the additional research required in the legislation—to develop efficient rapid methods for detecting contaminants; determine the sources of contamination; identify common and emerging zoonotic diseases; and develop methods for destroying pathogens—has been necessary for several years and is critical to any effective food safety initiatives in the future.

Bipartisan negotiations took place prior to House Energy and Commerce Committee passage of H.R. 2749 to address numerous concerns raised by Farm Bureau and other agriculture groups. Most notably, livestock operations and the livestock portion of diversified operations are generally exempted from the bill. Other improvements include the removal of troubling restrictions on modified atmosphere packaging and clarification that country-of-origin labeling (COOL) requirements not conflict with what is already required by the USDA program.

Despite substantial and significant progress from the legislation's original discussion draft, unresolved issues that could increase cost and paperwork burdens on farmers and ranchers remain. As amended and approved by the full Committee on June 17, H.R. 2749 would significantly expand authorities for FDA to regulate and oversee on-farm production activities. Farms are explicitly included in extensive new record-keeping, reporting and traceability measures which may not be feasible or practical for many producers.

Furthermore, H.R. 2749 paints the entire food supply system with a very broad brush. As you know, each segment of the food and agriculture spectrum is unique.

The bill would for the first time permit the Food and Drug Administration (FDA) oversight of many on-farm production activities with which it has little to no experience and which have not traditionally been under its jurisdiction on a routine basis. Many of these authorities are duplicative and overlapping with the jurisdiction of the U.S. Department of Agriculture and the Congressional Agriculture Committees.

Not only are the authorities redundant with existing USDA authority, but FDA does not have the personnel, funding, knowledge, expertise or time to regulate agricultural production practices—particularly given its overall volume of increased re-

sponsibilities contemplated in H.R. 2749. While that view is certainly widely held within the agriculture community, it is not limited to the production audience. Even the National Federation of Independent Businesses noted the business impracticalities in a letter on June 17 which noted that H.R. 2749 "will do little to improve food safety but (would) impose significant costs on small farms and food producers."

Last month, Farm Bureau and a coalition of 18 other agriculture organizations expressed written concerns about the scope of H.R. 2749 on production agriculture activities. As currently written, H.R. 2749 would:

- Expand FDA's on-farm authorities to potentially include production practices;
- Lower the existing on-farm inspection trigger threshold from the 2002 Bioterrorism Act which requires that FDA have a reasonable belief that a product presents threat of serious adverse health consequences of death to humans or animals;
- Require additional record-keeping, including new requirements for farms;
- Increase FDA's access to records without sufficient guarantee of confidentiality;
- Require FDA to create a food traceability system which could include farms (except most direct sales and farmers markets);
- Greatly expand FDA authority to quarantine geographic areas for food safety problems; and
- Delegate to FDA District Offices the authority to issue subpoenas and mandatory recalls, including to farms.

A more detailed discussion of these specific concerns follows.

Safety Standards for Agricultural Commodities:

The bill (Sec. 104) would require FDA to promulgate science and risk-based safety-standard regulations for seven activities, including the safe growing, harvesting, packing, sorting, transporting and holding of raw agricultural commodities. The performance standards are not limited to produce, but extend to any plant or fungus.

"Reasonably necessary" regulations would be determined at FDA's discretion for both broad and specific safety standards, including manure use, water quality, animal control and temperature controls. These types of activities are all outside of FDA's realm of expertise, and most are redundant with existing USDA, EPA and Interior Department jurisdiction. While FDA would be required to consider impacts on small-scale and diversified farms and on a variety of environmental criteria, there is no guarantee that FDA will produce fair or necessary standards that ultimately result in safer food.

Recordkeeping:

The bill (Sec. 106) would require farmers to keep records regardless of the commodity they are producing and its associated risk profile, or lack thereof. FDA has unprecedented routine access to business records without justification of cause. Producers are required for the first time to allow a Federal official to access and copy all records, including production and sales records that may be related in any way to food or feed safety. By deleting the farm exemption in the Bioterrorism Act of 2002, each farmer would be required to maintain records showing every buyer to which the farm's products are sold (except products sold directly to final consumers or restaurants). Further, the bill would allow FDA to require that farmers retain records for up to 2 years.

In a change from traditional practice dating back to 2002, FDA is not required to show cause prior to requesting records. Indeed, the bill would delete the current Bioterrorism Act threshold that requires that FDA first have a "reasonable belief" that a food article "is adulterated and presents a threat of serious health consequences or death to humans or animals" before having the authority to access records.

Finally, confidentiality remains a serious concern in the Committee-passed bill. The ability of FDA to appropriately protect the privacy of producers' information from unauthorized release and/or access is unclear, at best, and not explicitly guaranteed.

Food Traceability:

FDA is required (Sec. 107) to create a new system to track any food or feed contamination incident to its source within 2 business days. Because this provision exceeds the current Bioterrorism Act requirements to trace "one-step-forward/one-step-back," it could require producers to maintain a complete history of where farm inputs originated and where farm-production outputs are sold. Electronic record-keep-

ing is not specifically required, but farm records would likely need to be electronic to facilitate traceability in the specified time frame.

This system would increase production costs for diversified farmers and grain farmers, most of whom operate small businesses. The requirement is overly burdensome considering the plethora of records that producers currently maintain. Yet, most farms do not have the technical or financial resources to make their record-keeping systems interoperable with others in the food chain. According to USDA Census of Agriculture data, less than 60 percent of farmers and ranchers have a computer, and only ⅓ have high-speed Internet access.

Quarantine Authority:

The quarantine authority (Sec. 133) is broad and far exceeds the authority granted to USDA. If FDA had this authority and had chosen to utilize it in 2008—when it erroneously suspected, based on what it believed at the time was "credible information" that tomatoes were a source of *Salmonella* contamination—entire regions of the country could have been quarantined, further decimating a sector of agriculture that already had suffered severe economic damage. Although livestock are exempt, it is unclear if the bill would allow FDA to conduct an on-farm inspection of or quarantine the livestock side of a diversified operation that has a food-safety issue with the grain side of its business. Unlike USDA, FDA is not required or even able to provide any indemnification, whether a quarantine is justified or erroneous.

Penalties:

FDA is required (Sec.134 and 135) to issue fines for criminal and civil penalties. Unintentional as well as intentional violations may be fined, including up to $20,000 per individual for a record-keeping mistake. Each violation cited and each day during which it continues shall be considered to be a separate offense. Although penalties per event are capped, the cap is high enough ($50,000 for individuals for unintentional violations) to severely damage producers financially or put them out of business.

Delegation of Authority:

The bill (Sec. 311, 418 and 420) gives wide latitude to the discretion of district office personnel for many authorities, including the right to recommend prescriptive preventive controls and the authority to issue mandatory recalls and subpoenas. This empowerment at the FDA District Office Director level is particularly troubling given the removal of the previous threshold for FDA action and records access. We strongly urge that authorities with broad and significant impact on the regulated entities be non-delegable beyond, at a minimum, the Center Director level and ideally retained within the office of the Secretary or Commissioner.

Trade Impacts:

The latest version of H.R. 2749 removes the separate user registration for importers and production facilities, a very positive development. However, several provisions of the bill still violate U.S. trade commitments and would invite retaliation by our trading partners against exports of U.S. agricultural products.

The food safety regime should be science based and flexible enough to recognize equivalence between food safety authorities. For example, there is no need for redundant inspections between countries like the U.S. and Canada. In addition, the frequency of inspections does not seem to be scientifically justified. The bill sets an arbitrary timeline for recurring inspections.

There is serious concern that the user fee currently in the bill does not provide enough additional service to justify the fee. User fees that do not generate additional benefit for the importer may be trade restricting.

As Congress works to finalize this legislation, Farm Bureau urges lawmakers to remain conscious of the international implications that food safety regulations have. Congress should ensure that the mechanisms put in place to regulate food safety do not treat importers more harshly than domestic facilities. To do so would be a violation of our World Trade Organization obligations.

Conclusion

Thank you again for arranging this public hearing to better understand food safety issues, and for allowing us to share producers' views of current legislation. We are committed to improving food safety in a targeted, scientific, and risk-based manner, and we stand ready to work with Congress in that effort. We look forward to working with you and your colleagues as food safety legislation continues to be developed.

The CHAIRMAN. Thank you, Mr. Wooten. That was a good job, 4 seconds over, so you get an A+.

Mr. Boyle, welcome to the Committee.

STATEMENT OF J. PATRICK BOYLE, PRESIDENT AND CEO, AMERICAN MEAT INSTITUTE, WASHINGTON, D.C.

Mr. BOYLE. Thank you, Mr. Chairman, and I appreciate the opportunity to provide perspective upon, and hopefully insight, into the Federal inspection system for meat and poultry products. Food safety is the institute's number one priority. For the past 10 years, it has been addressed by AMI members in a noncompetitive manner by sharing best practices and new technologies to improve food safety for the good of the industry and our customers.

Today with the accompanying PowerPoint presentation, I would like to discuss the important oversight role of the Food Safety and Inspection Service as well as highlight the significant food safety improvements in meat and poultry products.

The 8,000 field employees of FSIS inspect approximately 6,300 domestic meat and poultry operations. An additional 2,000 Federal employees provide supervision and support services at a total annual cost of $1.1 billion. Plants processing animals are not inspected during all hours the plant is operating. Plants processing meat and poultry products are inspected at least daily. For imported meat and poultry products, Federal law requires the foreign countries' inspection system to be equivalent to the U.S. system. Currently 33 foreign countries are approved to ship products to the U.S. and each foreign inspection system is audited annually. All meat and poultry products arriving at our borders are also subject to reinspection and laboratory analysis.

Seventy-five import inspectors conduct these activities at 150 official import establishments. More than a decade ago, FSIS and the industry embraced a major shift in the approach to food safety programs by adopting the principles of prevention embodied in HACCP. In fact, in 1993 AMI petitioned USDA to mandate HACCP to modernize the meat and poultry food and safety inspection system. FSIS oversight does not stop with HACCP regulations. FSIS assures processes are scientifically validated. Teams of expert auditors conduct periodic in-depth food safety assessments which can take days or weeks to complete and may involve extensive microbiological sampling of the plant's environment and finished products. Annually, FSIS conducts more than 8,000 microbiological tests to verify the production processes are under control. This is in addition to the several million microbiological tests that industry conducts each year.

In addition to process control programs, the plant is required to have written standard sanitation operating procedures that prescribe how the operating environment will be maintained in a sanitary condition.

Mr. Chairman, I ask your consent that we insert in the record a book entitled *Protecting Consumers,* which provides a more detailed oversight of FSIS in the meat and poultry industry.

The CHAIRMAN. Without objection.

Mr. BOYLE. Thank you, Mr. Chairman.

We clearly have an intensive meat and poultry inspection system, but it is important to recognize that only industry can produce safe food, and we have been making noteworthy progress. Since 2000 the industry has reduced the prevalence of *E. coli O157:H7* in ground beef by 45 percent to less than ½ percent. The prevalence of *Listeria monocytogenes* in ready to eat products has been reduced by 69 percent to 4/10 of 1 percent. We have seen similar improvements in the incidence of foodborne illness reported by the CDC. Since 2000 illnesses caused by *E. coli* are down by 44 percent. Listeriosis is down by three percent, though with much greater reductions occurring before the year 2000. In fact, we have not had a single product recall associated with an outbreak of listeriosis in the last 6 years.

As Congress considers various bills to reform FDA oversight, additional regulatory authorities are being proposed for FDA. AMI believes that many of them are unnecessary if applied to the FSIS inspection regimen. First, user fees are inappropriate. AMI does not support funding a $1 billion federally mandated inspection program by imposing fees on the regulated industry. Second, HACCP programs should be designed by food companies, not by the government, and then subjected to the review of the regulatory agency as is currently the situation with FSIS. Third, microbiological performance standards can be effective if properly constructed to achieve a public objective and are scientifically based to measure food safety. Our experience with FSIS performance standards is that those related to *E. coli* and LM have worked to improve public health. On the other hand, the *Salmonella* performance, while dramatically reducing the incidence on chicken, pork and beef has not reduced the number of cases of salmonellosis.

Fourth, mandatory recall for meat and poultry products is needlessly redundant. Industry has every incentive to remove contaminated products from the marketplace to reduce potential liability, and the detention and seizure authority of FSIS provides the agency with more than sufficient leverage to compel the so-called voluntary recall.

And fifth, civil money penalties within a continuous inspection program like FSIS are unnecessary. As noted on this slide, severe penalties are already in place for meat and poultry plants.

Finally, AMI looks forward to working with this Committee and the Obama Administration's Food Safety Working Group about food safety initiatives that benefit consumers, the food industry, and the regulatory agencies that oversee the nation's food supply.

Thank you very much, Mr. Chairman.

[The prepared statement of Mr. Boyle follows:]

PREPARED STATEMENT OF J. PATRICK BOYLE, PRESIDENT AND CEO, AMERICAN MEAT INSTITUTE, WASHINGTON, D.C.

Good morning Mr. Chairman, Ranking Member, and Members of the House Committee on Agriculture. Thank you for allowing me the opportunity to appear before this Committee. My name is Patrick Boyle and I am the President and CEO of the American Meat Institute (AMI). AMI has provided service to the nation's meat and poultry industry—an industry that employs more than 500,000 individuals and contributes more than $832 billion to our nation's economy—for more than 100 years.

AMI's 200 members include the nation's most well-known meat and poultry food manufacturers. Collectively, they produce 90 percent of the beef, pork, veal, and lamb food products and 75 percent of the turkey food products in the U.S. AMI's

membership is extremely diverse, ranging from large, publicly traded companies that employ thousands to very small companies with as few as two employees. Indeed, more than half of AMI's members are small, family-owned businesses employing fewer than 100 individuals. We have one member company with just three employees. These companies operate, compete, sometimes struggle, and mostly thrive in one of the toughest, most competitive and certainly the most scrutinized sectors of our economy: meat and poultry packing and processing.

AMI appreciates the opportunity to provide perspective and hopefully insight into our nation's food safety inspection system for meat and poultry products. Food safety is the Institute's number one priority. Each year, the AMI Board of Directors establishes priorities to direct the Institute. Food safety has topped the list for the past decade. In 1999, food safety was made a non-competitive issue by the organization which provided top management commitment to share best practices and new technology to improve food safety for the good of the industry.

We all know that food safety has been in the news and because of that publicity a common refrain heard in Washington and other venues is that the U.S. food safety regulatory system is broken and has failed the American people. Indeed, a great deal of attention has been devoted to what is wrong and the changes needed to assure us that the food we consume is safe. Although some of the criticism may be warranted, a closer look at our meat and poultry food safety systems yields a different conclusion.

Illnesses associated with meat and poultry consumption have declined. Nearly one billion meals are consumed each day in the United States without incident (*Slide 1*). For context, human illness statistics published by the Centers for Disease Prevention show that the pathogens most commonly associated with meat and poultry make up only a fraction of the total foodborne illnesses and deaths in the U.S. (*Slide 2*). These statistics are not provided to minimize each and every illness, hospitalization, or death associated with food consumption, but to put the risk into proper context.

Is the sky falling? No, but most rational individuals still believe that food safety can be improved. I would like to discuss with you today some of the real improvements the meat and poultry industry has made and the important role government oversight plays in assuring that the industry meets its responsibility to produce safe food.

First, the meat and poultry industry supports a strong Federal oversight system—and we have a strong system. The approximately 8,000 employees of USDA's Food Safety Inspection Service (FSIS) inspect approximately 6,300 domestic meat and poultry operations and an additional 2,000 Federal employees provide supervision and support services, at a total cost of more than $1 billion. Plants processing animals are inspected during all hours the plant is operating. Plants preparing meat and poultry products are inspected at least daily (*Slide 3*).

For imported meat and poultry products, Federal law requires the foreign country's inspection system to be equivalent to the U.S. system. Thirty-three foreign countries are currently approved to ship products to the U.S. and each foreign inspection system is audited annually. All meat and poultry products arriving at our borders also are subject to reinspection and are routinely inspected and sampled for laboratory analysis. Seventy-five import inspectors conduct these activities at 150 official import establishments (*Slide 4*).

Another comment often heard is that the food safety system must be preventative. We agree. More than a decade ago FSIS and the industry embraced a major shift in the approach to food safety programs by adopting the principles of prevention embodied in the Hazard Analysis and Critical Control Point, or HACCP. In fact, in 1993 AMI petitioned USDA to mandate the implementation of HACCP in federally-inspected plants in an effort to modernize the meat and poultry food safety inspection system (*Slide 5*).

Mandatory HACCP provides a framework for identifying potential hazards and implementing measures to control those potential hazards during the production process. The process is continually monitored to assure that critical food safety standards are met. Pre-planned corrective actions are prescribed if critical limits are not met. Records are kept and available to FSIS inspectors for review and procedures are established to verify that the system is working properly. However, AMI believes that this prevention and control system must be uniquely suited to address the hazards specific to any facility. Uniform government controls are detrimental to individualized HACCP planning, thus food safety planning must remain the responsibility of the producing company. The proper role of the government in a HACCP-based food safety system is to verify that companies have conducted a proper hazard analysis, identified the hazards reasonably likely to occur in their operation, and have developed and implemented an appropriate HACCP plan to control those haz-

ards. We do not believe it is the proper role of the government to establish hazards that are reasonably likely to occur and mandate preventive controls, as these vary by establishment.

FSIS oversight does not stop at mandatory HACCP. FSIS assures processes are scientifically validated. Teams of expert auditors conduct periodic in-depth food safety reviews to complement the activities performed by the FSIS inspectors permanently stationed at the plant. These food safety assessments, or FSAs, can take days or weeks to complete and may involve extensive microbiological sampling of the environment and product (*Slide 6*).

During the course of a year, FSIS conducts more than 80,000 microbiological tests to verify that federally inspected establishments' production processes are under control. FSIS conducts these verification tests in addition to the several million microbiological tests the industry does each year (*Slide 7*).

There is no finished product testing regime, however, that can guarantee that food products are pathogen-free or that they can be mishandled and remain safe to eat. Finished product testing is an important tool because it can show that process controls are effective and working, but it cannot eliminate every risk to a meaningful degree of certainty.

In addition to process control programs, the plant is required to have written standard sanitation operating procedures that prescribe how the operating environment will be maintained in a sanitary condition. FSIS monitors plant sanitation before operations begin and while the plant is operating. Any deficiencies noted require immediate corrective action and failure to react appropriately can result in the plant being shut down by FSIS officials until the deficiencies are corrected (*Slide 8*).

We have a strong Federal meat and poultry inspection system, but it is important to recognize that only the industry can produce safe food. Although food processors and handlers can minimize risks through the use of systems discussed above and other good management practices, there can be no absolute certainty that all food products are free from all risks. Notwithstanding that caveat, progress has been and is being made.

Specifically, government data show a decline in pathogen prevalence on meat and poultry products. Since 2000, the industry has reduced the prevalence of *E. coli O157:H7* in ground beef by 45 percent to less than ½ percent (*Slide 9*). The prevalence of *Listeria monocytogenes* in ready-to-eat products has been reduced by 69 percent to less than 0.5 percent (*Slide 10*). We have seen similar improvement in the incidence of foodborne illness reported by the Centers for Disease Control and Prevention. In that regard, since 2000, illnesses caused by *E. coli O157:H7* are down by 44 percent and listeriosis is down by three percent with much of the improvement occurring before 2000 (*Slides 11–12*).

A question often debated is whether microbiological performance standards are needed to improve public health. To answer that question, it is instructive to look at the existing *Salmonella* performance standards that are codified in the meat and poultry regulations.

Since the performance standards were promulgated, the prevalence of *Salmonella* in chicken is down by 63 percent, in pork it is down by 70 percent, and in ground beef it is down by 68 percent (*Slides 13–15*). Looking at these numbers one might conclude the *Salmonella* performance standards are a great success. Of significance, however, is the fact that the incidence of foodborne illness associated with *Salmonella* has actually increased slightly over the same time period (*Slide 16*).

One might ask whether microbiological performance standards are a useful tool. The answer is they can be if properly constructed to achieve a public health objective and if they are scientifically based to measure whether food is safe and not injurious to public health. Conversely, I would suggest that a performance standard based solely on achieving an arbitrary outcome that yields no public health benefit is inappropriate.

As the food safety debate heats up, some Congressional Members and others have called for enhancing the enforcement powers of the inspection agencies, including civil monetary penalties and other sanctions. For meat and poultry plants, however, very severe penalties already are in place.

Specifically, FSIS can detain and seize adulterated products in commerce, as well as retain product at the plant thereby preventing it from entering commerce. Federal inspectors also have the authority to shut down a plant at a moment's notice if food safety violations such as insanitary conditions are identified. More serious violations can result in Federal inspectors being withdrawn from the plant, which results in the plant not being able to operate. And, plant management can be criminally prosecuted for food safety violations. It is difficult to comprehend how additional remedial penalties would improve food safety.

Another subject of some controversy is mandatory recall. The cry for mandatory recall ignores a simple fact: Industry has every incentive to remove contaminated product from the marketplace to reduce potential liability. Experience shows us that the speed with which contaminated meat and poultry product is removed from the market will not improve with mandatory recall. In most cases, meat and poultry products are recalled within hours after a problem is discovered. And industry cooperation to execute recalls has been excellent (*Slide 17*).

To date, no meat company has ever refused to conduct a warranted recall and in the highly unlikely event such a circumstance ever were to occur, the previously mentioned threat of FSIS product detention and seizure, coupled with the agency's ability to directly inform the public not to consume the product because the company refused to recall the affected product, not to mention the ramifications for the company at the producing plant, is more than sufficient leverage for FSIS. To my knowledge, such a situation has never occurred. In short, the concept of mandatory recall is a solution in search of a problem.

A final concern as it relates to food safety is the imposition of a user fee that would be paid by the regulated industry for food safety inspection services. Similar proposals for meat and poultry inspection at USDA have been rejected by Congress annually for nearly 30 years. USDA inspection services have long been paid for with government funds because those inspections are activities that benefit of the general public. Inspection activities should be funded not from user or registration fees that, in effect, are a food tax, but from monies appropriated out of the general treasury.

Earlier in the year, President Obama formed the White House Food Safety Working Group to recommend a new, public health-focused approach to food safety based on prevention, strengthening surveillance and enforcement, and improving response and recovery. We appreciate the recommendations put forth by the Working Group to date, and we reemphasize that any changes in our food safety system must show measured improvements in public health. AMI looks forward to working with the Obama Administration on implementing effective programs that benefit consumers, the industry, and our public institutions that safeguard the nation's food supply.

Let me conclude with some suggestions on what will improve food safety.

(1) With respect to government inspection programs the focus must be on systems designed and implemented to protect public health. Inspection activities that do not have a direct impact on public health waste scarce resources and divert attention from issues of public health importance.

(2) Continual improvement of preventive process control systems is needed. Mandatory HACCP and SSOP that focus on prevention *versus* detection is critical and the rigor of the control system should be proportional to the public health risk.

(3) Government agencies must be fully funded to help assure the safety of domestically produced and imported food.

(4) Resources should be allocated based on the public health risk posed by a particular food and the control measures that are used during the manufacturing and distribution process to control such risk.

(5) Objective and achievable food safety standards that are scientifically determined to measure whether the food is safe, not adulterated, and non-injurious to public health are needed. Food safety standards must be based on quantifiable, measurable criteria and have a direct impact on public health.

(6) The U.S. must assure that such standards are compatible with internationally recognized standards, such as *Codex Alimentarius,* to protect the health of consumers, ensure fair trade practices, and promote the coordination of food standards development by the international community.

(7) Efforts should be focused on conducting a more thorough analysis to identify how and why a foodborne disease outbreak occurred. Each government agency involved in investigations of foodborne disease outbreaks or product recalls should be required to report the reasons such incidents occurred and those reports should focus on how the food product was harvested, processed, distributed, prepared, and consumed to provide detailed information that will assist food handlers in preventing future occurrences.

(8) Rigorous government inspection and testing is needed to verify that consumer-ready products are safe. Test results should be performed under accepted sampling and analytical protocols and should meet objective food safety standards. Testing to determine the adequacy of process control at interim points during harvesting, manufacturing, and distribution should be conducted by the industry.

(9) Establishment of a public-private partnership to design and implement a comprehensive research program to improve food safety is needed. The research program should be directed by a board of qualified food safety experts from government, academia, and industry. The program should focus on developing risk mitigation and intervention strategies to prevent foodborne disease outbreaks.

Let me provide some parting thoughts. It is indisputable that producing safe food is good for customers and good for business. To that end, the meat and poultry industry has been working to meet the challenge of continuously improving the safety of the products produced, but the job is not done. Industry pledges to cooperate with all parties to ensure that the U.S. maintains the safest meat and poultry supply in the world.

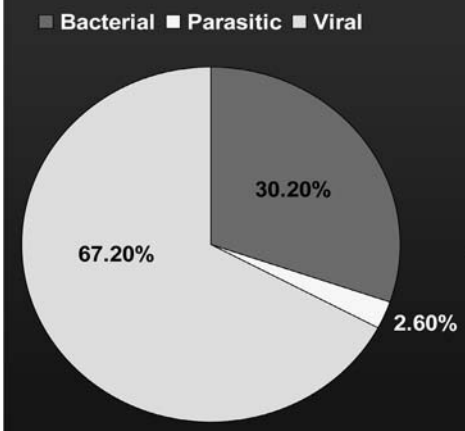
Thank you for the opportunity to testify before the Committee today. I am happy to answer any questions that Members may have regarding my testimony and the food safety system for meat and poultry products.

ATTACHMENT 1

Review of the Federal Food Safety System

Testimony of J. Patrick Boyle
President and CEO
American Meat Institute
Before the
House Committee on Agriculture
July 16, 2009

Percentage of Illnesses by Foodborne Pathogens



66.6% - Norwalk-like Viruses

14.2% - *Campylobacter* spp.

9.7% - *Salmonella*

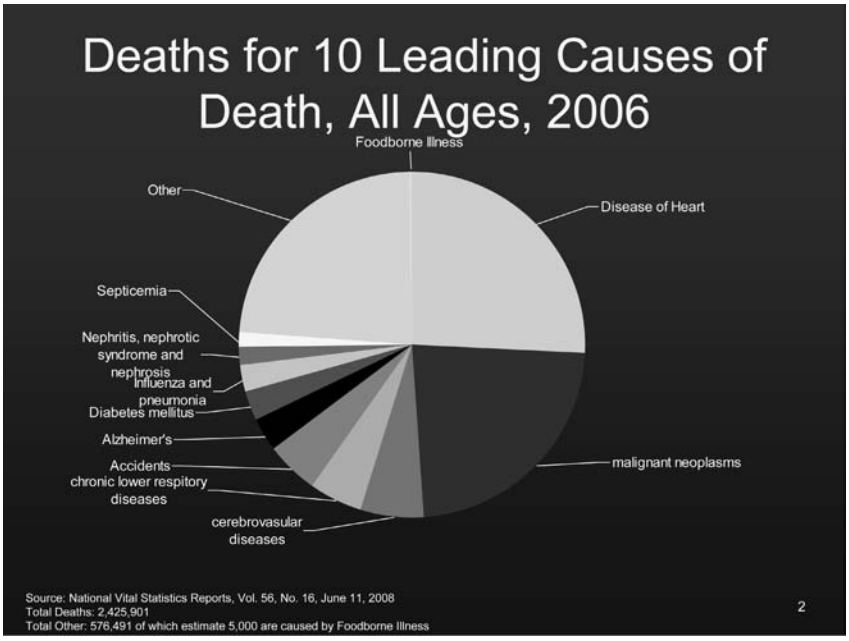
0.5% - *E. coli* O157:H7

0.3% - *E. coli*, non-O157:H7 STEC

0.0% - *Listeria monocytogenes*

Mead et al. (1999)

1



A Comparison of Resources for Food Oversight Agencies

	Food Safety and Inspection Service	Food and Drug Administration (Foods Only)
Funding (FY09)	$1.11 billion	$649 million
Staff (est. field only)	8,000	1,900
Domestic Facilities	6,300 slaughter and/or processing establishments	136,000 facilities

3

Robust FSIS Import Inspection

- 33 foreign countries equivalent
- Annual foreign audits
- 75 import inspectors at 150 official import establishments
- Routine product inspection and analysis

4

Strong Preventative Measures

Mandatory Hazard Analysis Critical Control Points Programs

- Hazard analysis
- Critical Control Points
- Critical limits
- Monitoring
- Corrective actions
- Recordkeeping
- Verification

5

FSIS Assures Processes Are Validated

- In-depth Food Safety Audits
- Environmental sanitation monitoring
- Extensive product sampling

6

FSIS Microbiological Tests

Salmonella	
Raw Products	41,805
RTE Products	11,651
E. coli O157:H7	
Ground Beef	11,607
Beef Products	2,836
Listeria	
All Products	12,665
Total Micro Tests:	80,564

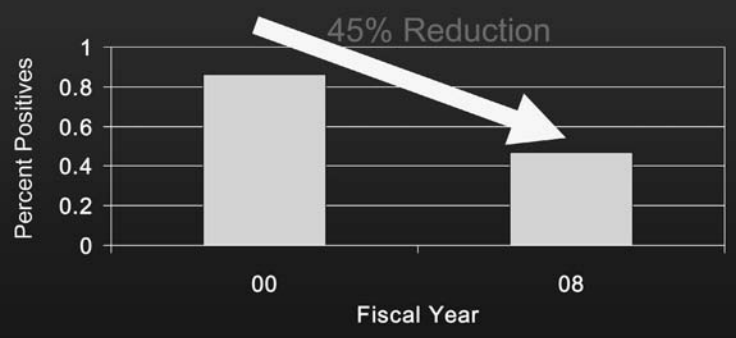
7

FSIS Continuously Monitors Plant Sanitation

- SSOP Programs
- Immediate corrective action

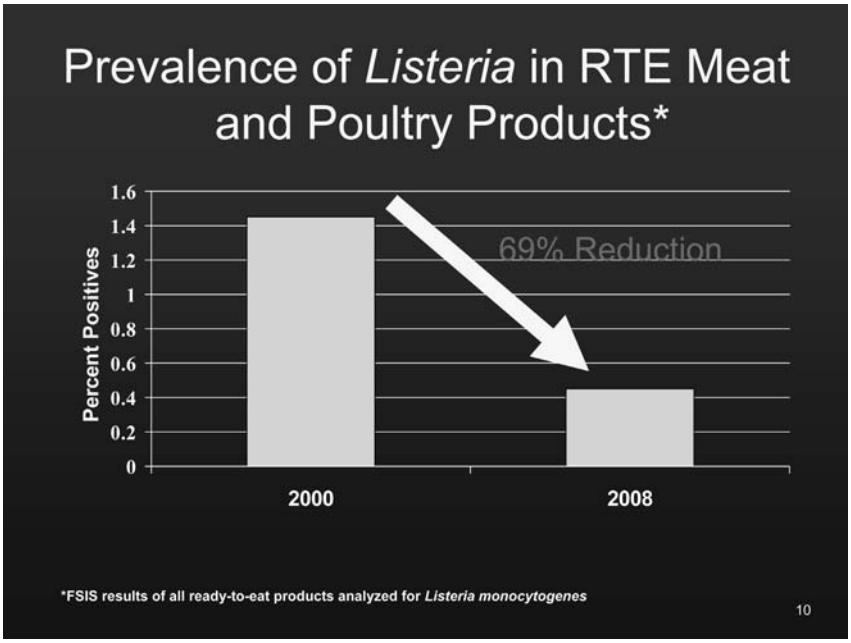
8

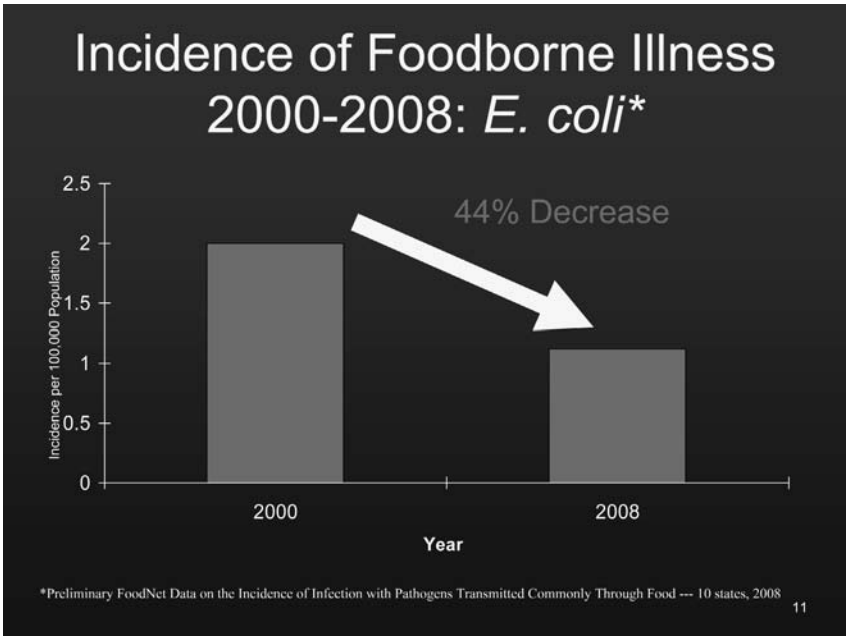
Prevalence of *E. coli* O157:H7 in Ground Beef*

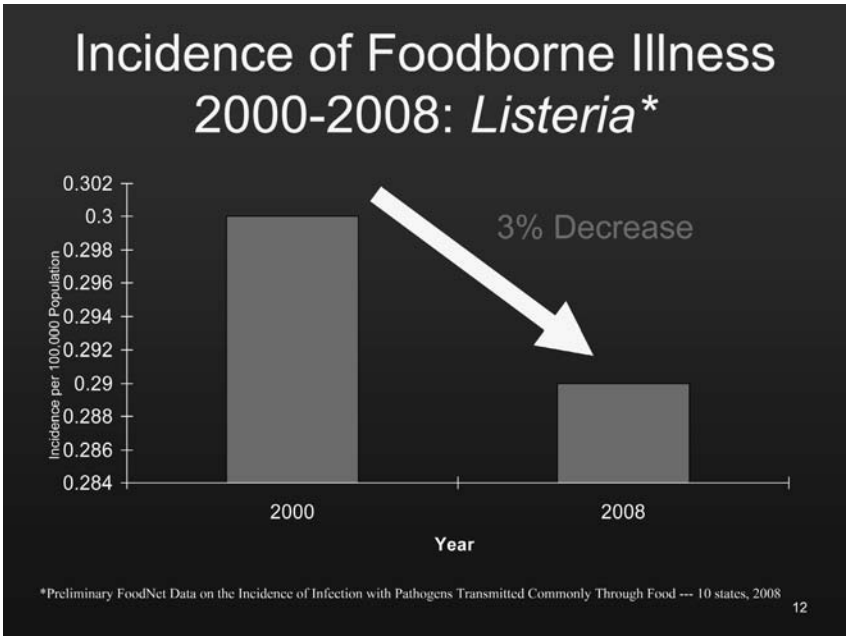


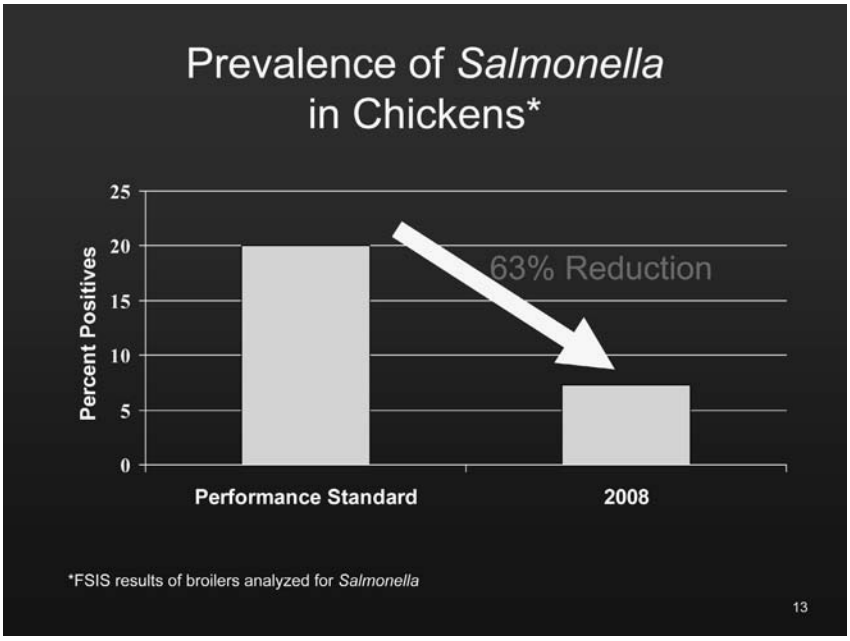
* Results of raw ground beef products analyzed for *E. coli* O157:H7 in federal plants.

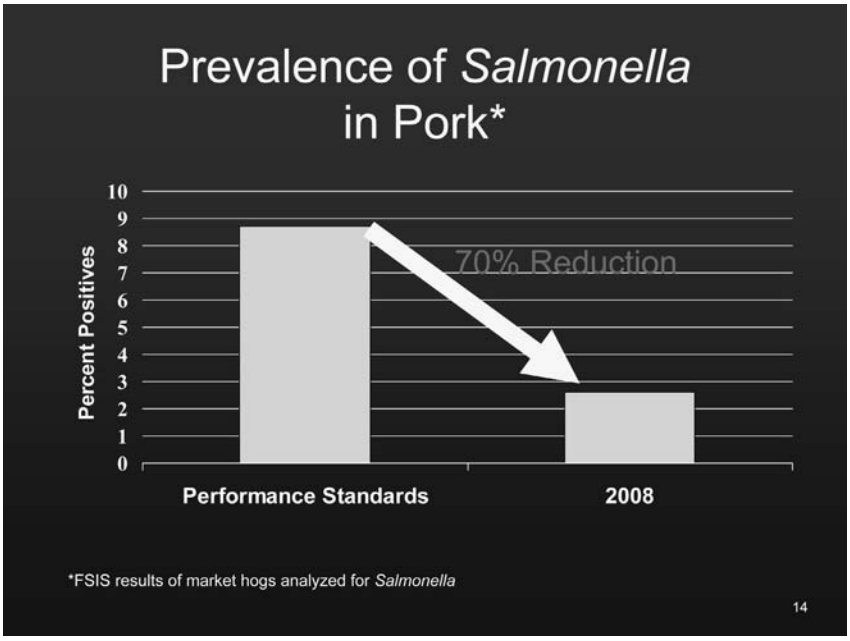
9

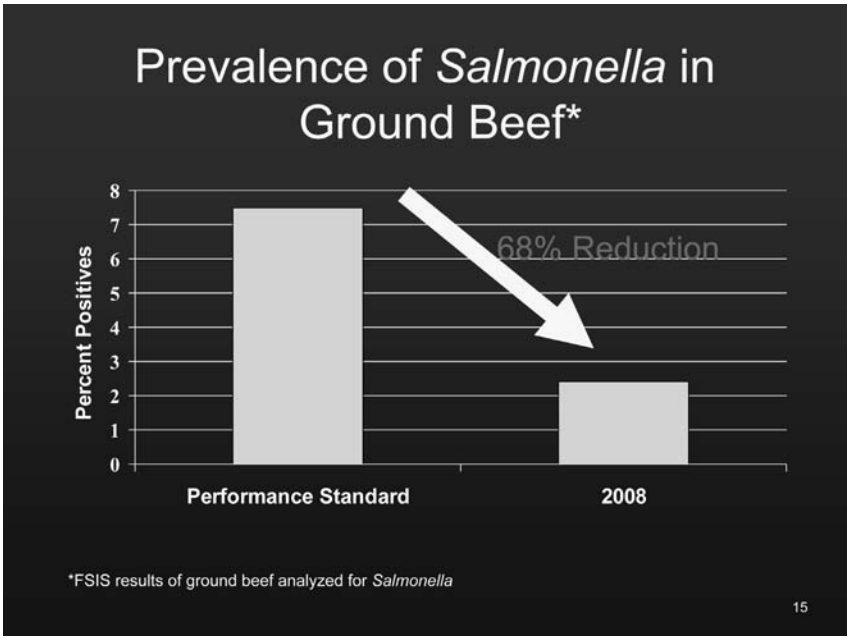

Prevalence of *Listeria* in RTE Meat and Poultry Products*
Percent Positives
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
69% Reduction
2000
2008
*FSIS results of all ready-to-eat products analyzed for *Listeria monocytogenes*
10


Incidence of Foodborne Illness 2000-2008: *E. coli**
Incidence per 100,000 Population
2.5
2
1.5
1
0.5
0
44% Decrease
2000
2008
Year
*Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food --- 10 states, 2008
11


Incidence of Foodborne Illness 2000-2008: *Listeria**
0.302
0.3
0.298
0.296
0.294
0.292
0.29
0.288
0.286
0.284
Incidence per 100,000 Population
3% Decrease
2000
2008
Year
*Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food --- 10 states, 2008
12


Prevalence of *Salmonella* in Chickens*
25
20
15
10
5
0
Percent Positives
63% Reduction
Performance Standard
2008
*FSIS results of broilers analyzed for *Salmonella*
13


Prevalence of *Salmonella* in Pork*
Percent Positives
10
9
8
7
6
5
4
3
2
1
0
70% Reduction
Performance Standards
2008
*FSIS results of market hogs analyzed for *Salmonella*
14

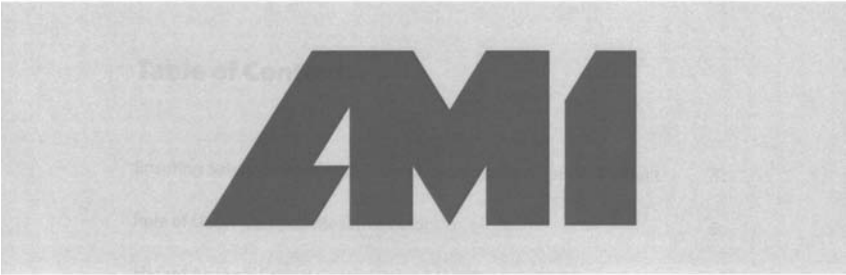

Prevalence of *Salmonella* in Ground Beef*
Percent Positives
8
7
6
5
4
3
2
1
0
68% Reduction
Performance Standard
2008
*FSIS results of ground beef analyzed for *Salmonella*
15

Will More Enforcement Authority Spur Improvement?

- FSIS can detain and seize products
- FSIS can condemn products
- FSIS can shut down plant
- FSIS can withdraw inspection
- FSIS can criminally prosecute management

17

ATTACHMENT 2



PROTECTING CONSUMERS:

ACCOUNTING FOR FOOD SAFETY IN THE MEAT & POULTRY INDUSTRY

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PROTECTING CONSUMERS:
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For more information please visit:
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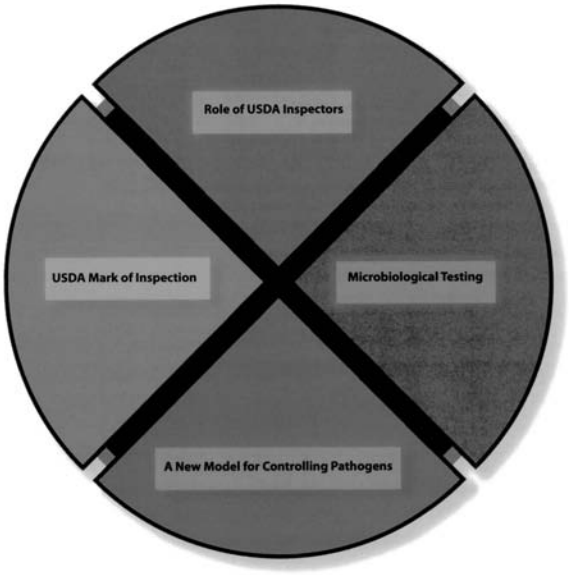
Ensuring Safety of Domestically Produced Meat and Poultry Products

A Series of Interlocking Steps to Ensure Consumer Protection

Background

USDA's inspection of U.S. meat and poultry products and the process to produce them are designed to augment industry efforts to protect consumers and assure the marketing of safe and nutritious meat and poultry products that are accurately labelled.

Under the Federal Meat Inspection Act, (21 U.S.C. 601 *et seq.*), and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), the USDA's Food Safety and Inspection Service (FSIS) routinely issues regulations governing the production of meat and poultry products prepared for distribution in commerce. FSIS and its nearly 10,000 employees inspect 6,500 establishments producing meat, poultry and egg products. USDA veterinarians examine animals before and after slaughter, examining more than 5 billion poultry carcasses and 130 million livestock carcasses each year.



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(SOURCE: USDA, 2008)

Ensuring Safety of Domestically Produced Meat and Poultry Products

A Series of Interlocking Steps to Ensure Consumer Protection

CONTINUED

Role of USDA Inspectors
Federal meat and poultry inspectors monitor products during processing, handling, and packaging to ensure that they are safe and accurately labeled. Federal inspectors have the authority to retain or detain products, or shut plants down for food safety violations, by withholding the mark of federal inspection on products.

USDA Mark of Inspection
Companies under federal inspection apply the USDA mark to all products. The mark contains an establishment number, which indicates the facility that produced the product. The presence of the mark indicates that the product was produced in compliance with one of the most comprehensive set of regulations applied to an industry.

A New Model for Controlling Pathogens
In the late 1990s, the industry and USDA undertook a major shift in its food safety program by adding microbiological interventions and adopted a model of food safety to make maximum advances in eliminating the risk of microbial pathogens. This major shift began in 1996, with the promulgation of the Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Rule.

Under HACCP, each plant must analyze the processes used to make each type of product and must identify 1) where problems may occur and; 2) which hazards are reasonably likely to occur. Food safety resources are then concentrated at these points. HACCP is built on a strategy of preventing problems before they occur rather than detecting them after the product is made. Federal inspectors are present in the plants to determine adherence to the HACCP plan and that the product being produced meets federal standards.

Microbiological Testing.
Across the country, FSIS collects samples of meat and poultry products to verify adherence to microbiological performance standards, test for drug residues and to estimate the national prevalence and levels of bacteria of public health concern. FSIS uses data to inform its regulatory oversight and publishes it on its website.

USDA often uses its regulatory authority to respond to emerging issues.

In 2007, the Food Safety and Inspection Service issued:

4 Final Rules
20 New or Updated Directives
51 Notices

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(SOURCE: USDA, 2008)

Role of a USDA-certified Meat Inspector

In-Plant Inspection

A Meat Inspector's job is to identify meat as:

- **Fit for consumption**
- **Sound (clean, sanitary)**
- **Wholesome (non-adulterated)**
- **Properly Labeled (accuracy, suitability, safety)**

Functions of Meat Inspection:

- **Detection and destruction of diseased meat and/or contaminated meat**
- **Assurance of clean and sanitary handling and preparation**
- **Minimization of microbiological contamination of meat**
- **Prevention of adulteration (the addition of harmful substances or products considered improper in certain specified quantities) and the detection of chemical or drug residues**
- **Prevention of false labeling or economic adulteration**
- **Application of inspection legend**

The Function of USDA Inspection:
Federal meat inspection occurs when meat is to be sold in interstate or foreign commerce. USDA inspectors are responsible for overseeing food production, distribution, procurement and preparation and have the authority to seize any product deemed unfit to enter commerce.

Areas of responsibility for meat inspection:

- **Construction of facilites and operational sanitation**
- **Antemortem inspection - Inspection of animals before slaughter, in pens on the premises, on the day of slaughter, in motion and at rest**
- **Animal welfare responsibilities including insuring the humane handling and treatment of all animals on the premise**
- **Postmortem inspection - Inspection after slaughter of head, viscera and carcass. Inspection proceeds simultaneously with slaughter and dressing**
- **Product inspection**
  - Reinspection privilege - To assure that a previously acceptable cut, carcass or product has not become sour, rancid, tainted, spoiled or adulterated.
  - Inspection of imported meat products - All meats are thoroughly inspected in the country of origin and representative samples (determined statistically) are tested at the port of entry for cleanliness, labeling, water content, wholesomeness, net weight and fat percentage.
  - Processed products inspection - Supervision of manufacturing procedures. Inspectors must be fully informed of recipes, manufacturing processes to prevent adulteration, false labeling and to assure sanitary handling.
  - Inspection of boneless manufacturing beef - Statistically sample boneless manufacturing beef boxes.
- **Laboratory determinations and assays**
- **Control and restriction of condemned products**
  - Once inspectors condemn an animal, a carcass, a cut or a product, it must be identified as U.S. Condemned and held under lock key or in suitably marked containers and disposed of.
- **Marking, labeling and application of inspection legend**
- **Hazard Analysis and Critical Control Point (HACCP)**
  - A systematic approach to hazard identification, assessment and control.
  - A HACCP plan is implemented by plant personnel and monitored for effectiveness by inspectors.
  - HACCP is a preventative system intended to keep microbiological, chemical and physical hazards from entering the meat or poultry product at critical places along the production line at the processing facility.

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(SOURCE: USDA, 2008)
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Hazard Analysis Critical Control Point
(HACCP)

Seven Principles

1. **Potential hazards to food safety are recognized and measures to regulate and control the hazards are identified (hazards can be physical, chemical, and/or microbiological)**

   Example: Microbiological contamination (e.g. Salmonella) in an undercooked deli ham

2. **Identification of critical control points (CCPs) for minimizing or eliminating the hazards throughout the production process of the product**

   Example: Establishing an appropriate cooking temperature for deli hams that has been scientifically validated to eliminate possible pathogens

3. **Establish preventive measures with critical limits for each CCP**

   Example: Establish a minimum cooking temperature for deli hams

4. **Establish procedures to monitor the CCPs**

   Example: Utilize computer controlled thermocouples that monitor and record cooking temperatures for each batch or lot of deli hams

5. **Establish corrective actions to be taken when monitoring shows that a critical limit for a CCP has not been met**

   Example: If the cooking temperature is not met for a particular batch, an alarm is sounded and that batch will be diverted and reprocessed or destroyed.

6. **Establish effective recordkeeping to document the HACCP system (for FSIS examination)**

   Example: Maintain thorough records of each lot of product, temperature checks for each lot, and what actions were taken with lots that were produced outside of the established critical limit

7. **Establish procedures to verify that the system is working properly**

   Example: Calibrate thermometers at specific times during the day to verify their accuracy and double-check cooking temperatures with a handheld thermometer daily to verify the computer system is performing correctly. Also, ensure that batches of deli hams that are produced outside the established critical limit are being diverted from the rest of the batches and properly reprocessed or destroyed.

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(SOURCE: USDA, 2008)
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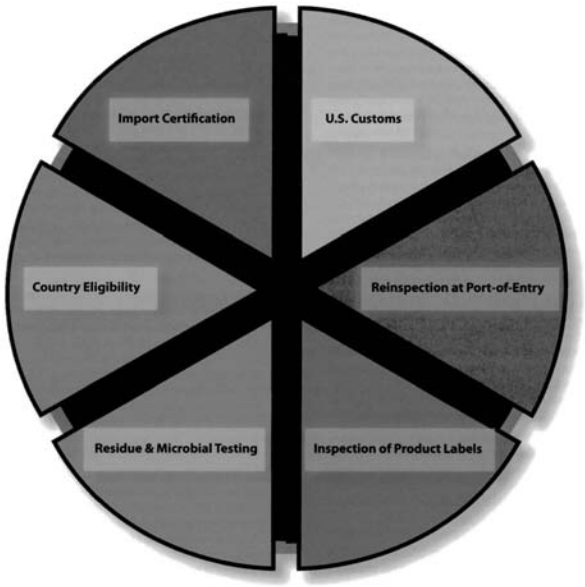
USDA Import Procedures

Background

Foreign countries that export meat, poultry and egg products to the United States are required to establish and maintain inspection systems that are equivalent to those of the United States. The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) audits foreign inspection systems and reinspects meat and poultry at the port-of-entry to ensure that foreign countries have maintained equivalent inspection systems.

FSIS makes two types of equivalence determinations: **(1)** determinations of initial equivalence (termed "eligibility") for countries that are not yet trading partners and **(2)** determinations of whether equivalence is being maintained by countries that are currently eligible.



(SOURCE: USDA, 2008)

USDA Import Procedures

Country Eligibility

Countries are required to have inspection systems equivalent to the U.S. The evaluation of a country's inspection system to determine eligibility involves two steps: a document review and an on-site audit.

The document review is an evaluation of the country's laws, regulations and other written information, focusing on five risk areas: sanitation controls, animal disease controls, slaughter and processing controls, residue controls and enforcement controls.

If the document review process shows the country's system to be equivalent, a technical team will visit the country to evaluate the five risk areas as well as other aspects of the inspection system including plant facilities and equipment, laboratories, training programs and in-plant inspection operations. These on-site audits are used to verify that countries have implemented inspection programs properly, and if not, resolve differences and clarify requirements.

If FSIS deems the inspection system to be equivalent to the U.S. system, a proposed rule is published in the *Federal Register* announcing the determination and the intent of FSIS to list the country as eligible to export meat, poultry or egg products to the United States. After considering public comments, a final decision is made on country eligibility and, if favorable, a final rule is issued. That foreign country's inspection system is then responsible for certifying individual exporting establishments to FSIS and for providing annual re-certification documentation. FSIS regularly conducts on-site audits of the eligible foreign inspection systems to ensure they remain equivalent to the U.S. system.

Import Certification

Foreign inspection certificates are required to accompany all imported meat, poultry and egg products. These certificates must indicate the product name, establishment number, country of origin, name and address of the manufacturer or distributor, quantity and weight of contents, list of ingredients, species of animals it was derived from and identification marks. The certificate must also bear the official seal of the foreign government agency responsible for the inspection along with the signature of an agency official. This certificate must be in English and the language of the foreign country.

U.S. Customs

Importers of any merchandise into the United States must file an entry form with the U.S. Customs Service prior to the shipments arrivel at a U.S. port-of-entry. For meat and poultry shipments, FSIS requires two additional documents the original certificate from the country-of-origin indicating the product was inspected and passed by the country's inspection service and is eligible for export to the United States as well as an import inspection application and report. The Customs Service also requires the importer to post a bond, usually an amount to cover the value of the shipment plus duties and fees. Meat and poultry shipments remain under bond and subject to recall by the Customs Service until FSIS notifies them of the results of the reinspection.

Reinspection at Port-of-Entry

Upon arrival at a U.S. port-of-entry, all meat and poultry shipments must be reinspected by an FSIS import inspector before they are allowed into this country. All containers are visually inspected for appearance and condition and checked for certification and label compliance. In addition, the Automated Import Information System (AIIS) assigns various other types of inspection, including product examinations and microbial and chemical laboratory analysis. Egg products are reinspected at the facility where they are taken for further processing. About 75 FSIS inspectors carry out reinspection at approximately 150 official import establishments.

Shipments that pass reinspection are allowed to enter U.S. commerce and are treated as domestic product. Shipments from all countries except Canada are stamped with the official USDA mark of inspection. Canadian shipments carry the Canadian mark of inspection and an export stamp. If a shipment does not meet U.S. requirements, the containers are stamped "U.S. Refused Entry," and within 45 days must be exported, destroyed, or converted to animal food, if an appropriate request for diversion is approved by FDA.

Residue & Microbial Testing

In order to export to the United States, a foreign country must have a residue control program with standards equivalent to U.S. standards. Statutes require that foreign residue control programs include: random sampling of animals at slaughter, the use of approved sampling and analytical methods, testing of appropriate target tissues for specific compounds and testing for compounds identified by the USDA or the country-of-origin as potential contaminants.

Microbial testing is also conducted on imported meat and poultry products. The microbial testing plan for imported products, like that for residues, is modeled after the microbial testing plan for domestic products. If a residue or microbial violation occurs in meat, poultry or egg products, the frequency of inspection is increased for all shipments of similar product from the violative foreign establishment until a record of compliance is re-established.

Inspection of Product Labels

FSIS import inspectors check labels on both shipping containers and retail-size packages. Labels on retail packages of meat or poultry shipped to the United States must meet U.S. labeling requirements. Product labels must be in English and must include:

- product name;
- foreign establishment number and country-of-origin shown directly under the product name;
- name and address of the manufacturer or distributor;
- net quantity of contents in pounds and ounces or liquid measure;
- list of ingredients; and
- if applicable, safe handling instructions and nutrition information.

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(SOURCE: USDA, 2008)

Countries with Equivalency * Agreements with United States

* = "The United States makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. FSIS evaluates foreign food regulatory systems for equivalence through document reviews, on-site audits and port-of-entry reinspection of products at the time of importation." (USDA/FSIS website)

* = The Peoples Republic of China has equivalency for poultry only with the U.S., but is prohibited by statute from importing any products into the U.S.

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(SOURCE: USDA, 2008)

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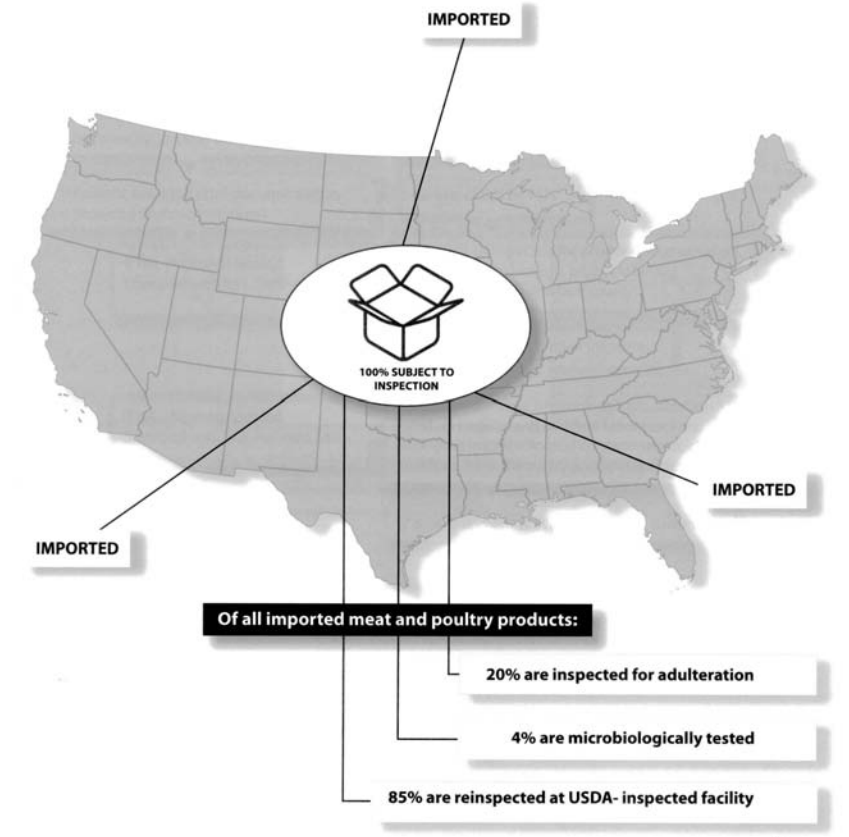
USDA Border Inspection

100% of all Imported Meat and Poultry Shipments are Subject to Inspection



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(SOURCE: USDA, 2008)
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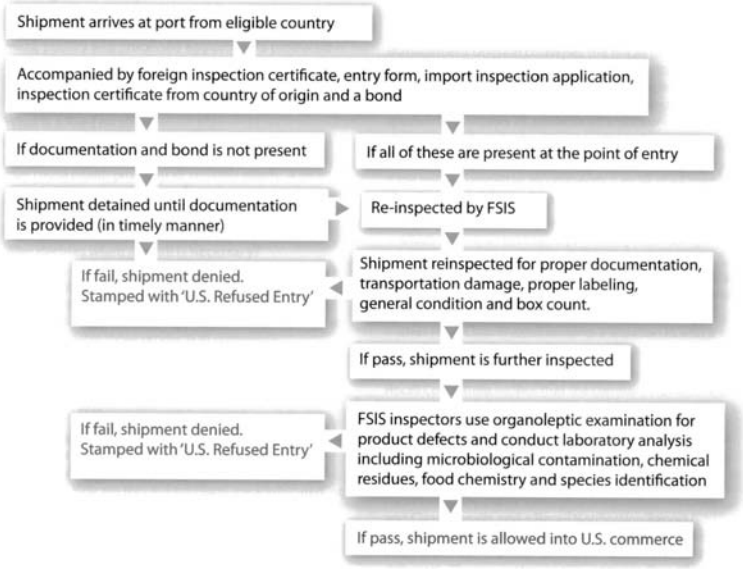
Import Flow Chart for USDA-Inspected Products



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(SOURCE: USDA, 2008)

FSIS Recall Procedure

Who regulates food products?
The Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture inspects and regulates meat, poultry and processed egg products produced in federally inspected plants. FSIS is responsible for ensuring that these products are safe, wholesome and accurately labeled.

What is a food recall?
A food recall is a voluntary action by a manufacturer or distributor to protect the public from products that may cause health problems or possible death. A recall is intended to remove food products from commerce when there is reason to believe the products may be adulterated or misbranded.

Who decides when a recall is necessary?
Recalls are initiated by the manufacturer or distributor of the meat or poultry, sometimes at the request of FSIS. All recalls are voluntary. However, if a company refuses to recall its products, then FSIS has the legal authority to detain and seize those products in commerce.

How are unsafe products discovered?
There are four, primary means by which unsafe or improperly labeled meat and poultry products come to the attention of FSIS:

- The company that manufactured or distributed the food informs FSIS of the potential hazard;
- Test results received by FSIS as part of its sampling program indicate that the products are adulterated, or, in some situations, misbranded;
- FSIS field inspectors and program investigators, in the course of their routine duties, discover unsafe or improperly labeled foods; and
- Epidemiological data submitted by State or local public health departments, or other Federal agencies.

As soon as FSIS learns that a potentially unsafe or mislabeled meat or poultry product is in commerce, the Agency conducts a preliminary investigation to determine whether there is a need for a recall.

What is FSIS' role during a recall?
When there is reason to believe that adulterated or misbranded product has entered commerce, the FSIS Recall Management Division convenes the Recall Committee, a standing committee within FSIS. The Committee, consisting of FSIS scientists, technical experts, field inspection managers, enforcement personnel and communications specialists, evaluates all available information and then makes recommendations to the company about the need for a recall.

If the Recall Committee recommends a recall, the Committee classifies the recall based on the relative health risk, as follows:

- **Class I** - A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.
- **Class II** - A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.
- **Class III** - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.

In addition to determining the class of the recall, the Recall Committee verifies that the company has identified production and distribution information to facilitate the recall. The Recall Committee advises the company of its recommendation and also provides an opportunity for the firm to offer any information it wishes FSIS to consider regarding the recall after completing its investigation.

FSIS notifies the public through a press release for Class I and Class II recalls, and a Recall Notification Report (RNR) for Class III recalls (The RNR provides substantially the same information as the press release; however, the format is different). The press release is issued to media outlets in the areas where the product was distributed, and is also distributed through an email listserv.

How does FSIS ensure that a recall is effective?
FSIS field enforcement personnel conduct **"effectiveness checks"** to ensure that the recalling firm makes all reasonable efforts to notify the consignees of the recalled product that there is a need to remove the product from commerce. FSIS conducts a sufficient number of effectiveness checks to verify that the recalling firm is contacting its consignees. If FSIS determines that the recalling firm has contacted its consignees, or has made all reasonable efforts to do so, the Agency notifies the firm that the recall is complete and no further action is expected.

(SOURCE: USDA, 2008)
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The CHAIRMAN. Thank you Mr. Boyle.

Ms. Tucker-Foreman, welcome back to the Committee. We appreciate your testimony.

STATEMENT OF CAROL L. TUCKER-FOREMAN, DISTINGUISHED FELLOW, THE FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA, WASHINGTON, D.C.; ON BEHALF OF CENTER FOR FOODBORNE ILLNESS RESEARCH & PREVENTION; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; CONSUMERS UNION; FOOD & WATER WATCH, GOVERNMENT ACCOUNTABILITY PROJECT; NATIONAL CONSUMERS LEAGUE; THE PEW CHARITABLE TRUSTS; SAFE TABLES OUR PRIORITY; TRUST FOR AMERICA'S HEALTH; AND THE UNITED FOOD & COMMERCIAL WORKERS INTERNATIONAL UNION

Ms. TUCKER-FOREMAN. Thank you, Mr. Chairman and thank you as well for allowing Mr. Almer to address the Committee. I am Carol Tucker-Foreman with Consumer Federation of America. I was, formerly, Assistant Secretary of Agriculture with responsibility for meat and poultry inspection. I am testifying today on behalf of ten consumer public health and trade union organizations representing millions of Americans who are concerned about the safety of the food we eat every day.

Foodborne illness has reached near crisis proportions in this country. It kills Americans at the rate of one every 2 hours every day of the year, and that is likely to continue until you tell the Food and Drug Administration to institute a preventative program and give them the authority to do it. Foodborne illness outbreaks hit everybody in the food chain. The Kellogg Company reports that the Peanut Corporation of America outbreak cost them $65 to $70 million. Sales of peanut butter have been down ever since. The *E. coli* outbreak from bagged spinach cost the leafy greens industry more than $350 million, and last year Florida tomato farmers were devastated when they were incorrectly—when tomatoes were incorrectly implicated in an outbreak of *Salmonella saintpaul.*

You have heard from Jeff Almer today. I would like to introduce you to two other families who are here today. First, Robin and Jeff Allgood from Chubbuck, Idaho, and Nancy Donley from Chicago.

Would you all stand up, please.

Robin and Jeff have come from Idaho today. Their son Kyle, a mischievous and energetic 2 year old, died of *E. coli* poisoning after his mother gave him a smoothie that contained bagged spinach, that was contaminated with that deadly pathogen. Nancy Donley's only child, 6 year old Alex, also died of *E. coli* poisoning after eating contaminating ground beef. Since then, Nancy has taken the time that she would have spent raising Alex helping other families deal with their loss and trying to persuade the government to institute additional protections to prevent others from suffering.

Thank you all.

Americans are very aware that people are dying from foodborne illness. Two weeks ago, IBM announced a poll that showed that 60 percent of Americans are concerned about the safety of the food they purchase. Less than 20 percent trust food companies to develop and sell food products that are safe and healthy for them-

selves and their families; 63 percent confirmed that they would not purchase a food until the source of—recalled food until the source of contamination was found; and 57 percent said they had stopped purchasing foods, even for a short time within the past 2 years, because of safety considerations.

These illnesses are almost completely preventable if you have a good preventative health system. And the GAO and the NAS have listed key elements for such a preventative system including process—company process control and regular inspection, better controls over imported foods. These provisions and additional ones are all included in H.R. 2749. It gives FDA—it requires FDA to begin a preventative program that will stop these problems. The agriculture community has objected to a number of items in the legislation, and the Energy and Commerce Committee has heard you and made major changes in the legislation to address your concerns, including keeping all jurisdictions as they are now and requiring the Secretary of HHS to coordinate with the departments of agriculture in the states in setting up regulations.

Frankly, consumer groups have chosen not to oppose a number of requirements in the legislation that we think limit its full protection of consumers. We are very sympathetic to the concerns of those in the food industry who may have to change the way they do business. It is clear that the legislation has been structured to assure it doesn't place an undue burden on small farms and businesses. On behalf of all the families here today and the others around the country who suffered because of outmoded food safety law that has failed to protect consumers. We think that a reasonable and appropriate balancing of interests has been worked out. We urge you to please act on this legislation quickly and provide additional protection. Thank you.

[The prepared statement of Ms. Tucker-Foreman follows:]

PREPARED STATEMENT OF CAROL L. TUCKER-FOREMAN, DISTINGUISHED FELLOW, THE FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA, WASHINGTON, D.C.; ON BEHALF OF CENTER FOR FOODBORNE ILLNESS RESEARCH & PREVENTION; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; CONSUMERS UNION; FOOD & WATER WATCH; GOVERNMENT ACCOUNTABILITY PROJECT; NATIONAL CONSUMERS LEAGUE; THE PEW CHARITABLE TRUSTS; SAFE TABLES OUR PRIORITY; TRUST FOR AMERICA'S HEALTH; AND THE UNITED FOOD & COMMERCIAL WORKERS INTERNATIONAL UNION

Chairman Peterson, Ranking Member Lucas and Members of the Committee. I am Carol Tucker-Foreman, Distinguished Fellow in the Food Policy Institute at Consumer Federation of America (CFA). From 1977–1981, I was Assistant Secretary for Food and Consumer Services at the United States Department of Agriculture. My responsibilities included oversight of the nation's meat, poultry and egg inspection and food assistance programs.

I am testifying on behalf of eleven consumer, public health and trade union organizations representing millions of Americans who are concerned about the safety of the food their families eat every day. A list and description of the organizations supporting this testimony is attached. We commend the Committee for holding this hearing to explore current congressional efforts to address the serious food safety problems that confront the country.

Mr. Chairman, foodborne disease kills one American every 2 hours, every day of the year.[1] The vast majority of these deaths are preventable. There has been limited progress in reducing the toll because the Food Drug and Cosmetic Act (FDCA), which governs the safety of over 80 percent of the food we consume, was designed

[1] Based on Centers for Disease Control and Prevention estimates that foodborne disease kills 5,000 people each year.

to address problems prevalent at the beginning and middle of the last century and hasn't been amended to keep up with changes that have altered the way we live and eat today. In 1906 the primary food safety danger arose from companies adding dangerous chemicals to meat to mask decay and substituting cheap ingredients to defraud consumers. The FDCA provisions don't adequately address the most pressing current food safety problem, protecting consumers from illness caused by food contaminated with disease-causing bacteria.

Current law does not give the Food and Drug Administration (FDA) specific authority to establish requirements to prevent foodborne illness. As a result, the Agency's program is almost entirely reactive. FDA often doesn't act until after there are confirmed reports of illness and death. That system doesn't work in a global marketplace where food is mass produced and travels around the world in a matter of hours. By the time we know a contaminated product is on the market, it is too late to keep people from getting sick.

Our country has experienced an almost constant stream of foodborne illness outbreaks traced to FDA regulated foods over the past few years, including:

- June 2009—*E. coli O157:H7* contaminated Nestle chocolate chip cookie dough has made 72 people in 30 states sick.
- September 2008–March 2009—*Salmonella* contaminated peanut products from Peanut Corporation of America sickened 691 people and caused nine deaths in 46 states and Canada.
- April to August 2008—Imported Jalapeño and Serrano peppers, contaminated with *Salmonella saintpaul* sickened 1,442 people in 43 states, the District of Columbia and Canada. Originally thought to be caused by contaminated tomatoes, the outbreak virtually destroyed the market for summer tomatoes in several states.
- June 2007—Veggie Booty snacks contaminated with *Salmonella* caused 65 illnesses in 20 states.
- February 2007—Peter Pan Peanut Butter contaminated with *Salmonella* sickened 425 people in 44 states.
- Dec. 2006—*Salmonella* found in tomatoes sickened 183 people in 21 states.
- August–September 2006—*E. coli O157:H7* in bagged spinach sickened 204 people in 26 states and killed three.

(Source—CSPI Building a Better Food Safety System)

All of these outbreaks were the result of poor sanitation or mishandling at some point in the food chain. None resulted from consumer mishandling.

In addition, we have been threatened by high levels of drug residues and toxic chemicals in fish and dairy products imported from South East Asia.

Some food industry representatives insist we are on the way to solving the problem of foodborne illness. In support of this claim, they cite reductions in illnesses caused by some pathogens since the Centers for Disease Control first began tracking illnesses through the FoodNet system and comparing the base years 1996–1998 to the most recent year. However, the CDC acknowledges that, after initial reductions, progress has stalled and there has been virtually no further decline in the last 5 years.[2]

The CDC is reviewing the data but has not reduced the annual total of 76 million cases of foodborne illness each year, 350,000 hospitalizations and 5,000 deaths. That means someone dies every 2 hours. The best estimate for the human illness costs of foodborne pathogens for all CDC estimated cases is $357 billion each year in medical costs, lost productivity, and pain and suffering.[3]

It is hard to comprehend numbers this large. Millions of illnesses and billions of dollars seem unconnected to what goes on in our daily lives. It is important to remember that these enormous numbers represent individual Americans whose lives have been altered forever by the simple act of having consumed common, everyday foods that appear regularly on family dinner tables—beef, chicken, spinach, lettuce, tomatoes, peppers and peanut products—that were contaminated with deadly pathogens.

The victims of foodborne illness live in your states and congressional districts. They are your friends and possibly members of your family. The *known* victims of the Peanut Corporation of America outbreak included 100 Ohioans; 76 Californians;

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[2] CDC, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2008" MMWR, 58(13), 333–337, April 10, 2009.

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

43 Minnesotans. The 2008 *Salmonella saintpaul* pepper outbreak hit 559 Texans, 120 people in Illinois, 42 in Georgia, 59 in Arizona. Last April, 84 Nebraskans, 27 Iowans, and five Kansans and South Dakotans were among the victims of a *Salmonella saintpaul* outbreak traced to eating contaminated fresh sprouts. And these cases are just the tip of the iceberg—for every reported illness, there are far more that the CDC never knows about.

In the hearing room today are representatives of three families for whom the foodborne illness numbers are crushingly real. Jeff Almer has come here from Perham, Minnesota. Jeff's mother Shirley Almer had run the family business for years after the death of her husband in 1990. When she retired, she remained active in her bowling league, continued to garden and bird watch, and spent time with her five children and four grandchildren. In October last year Shirley was declared cancer free after fighting off both brain and lung cancer. Two months later, on December 21, 2008, she was dead at age 72. Cancer did not kill Shirley Almer. According to the Minnesota Department of Public Health, the woman who fought off cancer died as a result of eating *Salmonella* contaminated peanut butter.

Robyn and Jeff Allgood have come here from Chubbuck, Idaho. Their son, Kyle, was a mischievous and energetic 2 year old whose favorite T-shirt read, "I do all my own stunts." Eager to meet her children's nutritional needs, Robyn often mixed fresh spinach and other vegetables into fruit smoothies. In September 2006, she unknowingly used spinach contaminated with *E. coli O157:H7*. Kyle became sick the next day. A week later he was dead from a heart attack after the *E. coli* poisoning developed into Hemolytic Uremic Syndrome (HUS).

Nancy Donley's only child, 6 year old Alex, also died of *E. coli O157:H7* poisoning he contracted after eating contaminated ground beef. After Alex's death, Nancy decided to invest the time she would have spent raising Alex in comforting other victims, informing the public about HUS and educating public officials about the need to make basic changes in the nation's food safety system to prevent others from suffering the same loss.

These are four courageous Americans. None is a public person. None has great resources. They decided not to take the easy way out and nurse their grief in private. You hear every day from representatives of the food industry and farm organizations. Today, the Almers, Allgoods and Donleys are here to ask you to consider the millions of foodborne illness victims whose concerns they represent. All bring you the same message. Congress must act now to prevent more and more illnesses and deaths.

They would welcome the opportunity to meet with Members of the Committee after the hearing to respond to your questions and will take questions from the media and interested people, as well.

The problems that robbed the Allgoods and Nancy of their children and the Almers of their mother and grandmother have caused Americans to become increasingly aware of and anxious about the weaknesses of our current food safety system.

Two weeks ago the technology giant IBM published the results of a new survey they sponsored, showing:

- *60 percent of consumers are concerned about the safety of the food they purchase.*
- *Less than 20 percent of consumers trust food companies to develop and sell food products that are safe and healthy for themselves and their families.*
- *83 percent of consumers were able to name a food that had been recalled in the last 2 years. 63 percent confirmed they would not purchase a food until the source of the contamination was found, and* ***57 percent said they had stopped purchasing foods, even for a short time, within the past 2 years because of safety considerations.***[4]

The failure of our food safety system and the increasing loss of public trust and confidence is bad for the food business and for farmers. The CEO of Kellogg's told the House Energy & Commerce Committee that the Peanut Corporation of America recall cost the company $65–$70 million.[5] Although no major brands of jarred peanut butter sold at retail were involved in the PCA outbreak, sales of those products also plunged after the outbreak became known.

Foodborne illness outbreaks can be disastrous for farmers who grow the crops implicated. Florida tomato farmers were devastated by the connection of their product to the *Salmonella saintpaul* outbreak that came at the height of their growing sea-

[4] IBM, Food Safety Awareness Survey, June 2009.

[5] Statement of David Mackay, President & CEO, Kellogg Company, before the House Committee on Oversight and Investigations, "The *Salmonella* Outbreak: The Role of Industry in Protecting the Nation's Food Supply." U.S. House of Representatives, March 19, 2009.

son. Spinach and lettuce farmers experienced a drop in demand after their products were implicated in 2006 outbreaks and, 3 years later, sales of these products have yet to recover.

Perhaps the greatest tragedy here is that foodborne illnesses are almost completely preventable if farmers, food companies and government exercise some care. Congress can reduce the toll—both physical and economic—by substantially modernizing outmoded laws that are part of the problem, starting with passing H.R. 2749.

Congress Must Begin Now to Create a 21st Century Food Safety System

The need to revise the Food Drug and Cosmetic Act has been documented in reports to Congress by the GAO, in studies by the National Academy of Sciences, and in a dozen hearings before the Energy and Commerce Committee.

Nearly a dozen bills to improve food safety have been introduced this year, some by Members of this Committee. All the bills embrace at least some of the common elements identified by the NAS and GAO as necessary for securing the safety of both domestic and imported foods.

H.R. 2749, reported unanimously by the House Energy and Commerce Committee, includes the key elements most frequently noted by experts as essential to an effective food safety system. The bill:

- Focuses on preventing FDA regulated foods from causing foodborne illness.
- Requires food companies to develop and implement process controls to assure that the food they sell is safe.
- Requires the FDA to establish and enforce microbial performance standards that will reduce pathogens to a minimum and assure an acceptable level of public health protection.
- Assures the integrity of the food system and the food supply through comprehensive enforcement, including regular oversight (inspection) conducted by public officials and based on the risk presented by the product; sampling and testing for pathogens and reporting; access to company food safety records; and mandatory recalls of contaminated food.
- Ensures the food we import is as safe as that produced and processed here.
- Provides a research capacity to develop the best means to address current and emerging pathogens.
- Assures continuing revenue to support part of the program costs by instituting a $500 annual registration fee for all food processing companies, with no company required to pay more than $175,000 annually. While some of us have long harbored reservations about any kind of fee to support food safety activities, we are convinced that, given large budget deficits for the foreseeable future, this fee is a modest request and justified by the pressing need for stronger Federal oversight and the benefits of reduced illness and death.

We think the legislation would be more effective if it included detailed language and resources to ensure data collection, sharing and analysis necessary for developing robust food attribution models.

In recent weeks some concerns have been raised about H.R. 2749, many on the Internet, suggesting almost apocalyptic outcomes for farmers if the bill becomes law. While our groups originally had some disagreement about the impact that the discussion draft might have had on small farmers, the Energy and Commerce Committee amendments went a long way to addressing concerns that provisions would disadvantage small farmers, especially organic farmers. We also have chosen not to oppose some provisions, made to address farmer concerns, that we think compromise the bill's ability to fully protect consumers.

Further, before reporting the bill, your colleagues on the Energy and Commerce Committee met with Members of this Committee and with farm and industry groups and made numerous changes to address the concerns raised by farmers and food processors. These changes:

- Exempt from provisions of H.R. 2749 the parts of food facilities and farms regulated by USDA.
- Provide that nothing in this bill changes existing jurisdictional lines between FDA and USDA.
- Require the Secretary of HHS to coordinate with USDA and the states in setting commodity-specific standards for the safe growing, harvesting and packaging of fruits and vegetables.
- Require the Secretary of HHS, before issuing any proposed regulations establishing new traceability requirements, to conduct information gathering to de-

termine the feasibility and cost/benefit of the system. Previous prescriptive requirements have been moved to the information gathering process.

- Exempt farmers who sell direct to consumers, such as at roadside stands, from the traceability requirements of the legislation.
- Limit the FDA's authority to restrict the movement of food in interstate commerce *only* if the food presents an *imminent threat of serious adverse health consequences or death. The language was changed to address farmer and processor concerns by limiting the FDA's actions to situations where there is an imminent threat and providing that the authority can only be exercised by the Commissioner. It cannot be delegated to lower officials.*
- Require the FDA to consider the impact of regulations on small businesses and organic farmers.
- Require the FDA to take into account the impact of produce regulations on small-scale and diversified farms, wildlife habitat, conservation practices, watershed protection efforts, and organic production methods.

Mr. Chairman, your Committee has oversight over the USDA's meat and poultry inspection program, which emphasizes inspection, requiring the USDA to be in every meat and poultry processing plant at least once a day and to examine all slaughtered carcasses to assure they do not have animal disease or visible problems that would make them dangerous to serve the family for dinner. Our groups tend to support the far more intensive inspection regime that USDA applies to both domestic and imported meat and poultry products. The FDA, notably, does not conduct regular, onsite inspection of the companies it regulates. We believe intensive inspection by Federal officials, coupled with appropriate corporate process controls and Federal standards, offers the best protection for the future.

Despite the fact that the Energy and Commerce Committee has made changes to address legitimate concerns, the Internet and some print media are full of specious charges against the bill. It is clear the legislation has become a target for people who are angry and frustrated about a multitude of other problems that would not be affected by the law.

For example, on Monday, July 13, the *San Francisco Chronicle* ran a long article charging that farmers are being forced to dismantle important conservation practices and destroy wildlife habitat. The article was passionate, but not accurate, in suggesting that H.R. 2749 is responsible for these changes. H.R. 2749, of course, has not passed Congress and is not in effect. Moreover, provisions of H.R. 2749 protect against the gross actions described in the article. The bill requires the FDA, if it promulgates produce safety regulations, to use science based standards that take into account the impact the regulations would have on small-scale and diversified farms, wildlife habitat, conservation practices, watershed protection efforts, and organic production methods.

The problems cited by the *Chronicle* reporter and the people she interviewed arise from private, not government, actions. Private customers—food processors and supermarkets—have imposed contractual requirements on their suppliers to create sterile borders. If the farmer wants to sell to the companies, he has to meet his customer's requirements. Private contractual requirements do not have to be science-based or consider environmental impact.

Some who oppose efforts to improve food safety law have larger concerns about the global and industrial nature of our current food system. The IBM survey shows that people increasingly want to know where their food comes from. Other polls indicate people would like to buy locally produced food. That yearning is reaching levels that may require Congress to address these more basic issues.

However, it has taken many years for the current system to build to this point. The changes that many seek would alter farming and food processing completely. That kind of change is not likely to come quickly or easily. Today we have a global food system and most of us, now and for the foreseeable future, will continue to purchase at least some mass produced food from enormous corporations at major supermarkets, many of them owned by foreign corporations. The immediate need, therefore, is for Congress to take steps to make our existing food supply safe. This requires giving the FDA the authority and the resources to address the problems created by a modern, mass production, international food system.

The need is now and the need is urgent. While we are sympathetic to the concerns of those in the food industry who may indeed have to make some changes in the way they do business, it is clear that H.R. 2749 has been structured to assure it does not place an undue burden on small farms or businesses. On behalf of the families here today and all the others who have suffered because of an outmoded food

safety law that has failed to protect American consumers, we suggest that a reasonable and appropriate balancing of interests has been worked out in H.R. 2749.

The time has come for Congress to act responsibly, consider the interests of those who consume food as well as those who produce and process it, and pass the Food Safety Enhancement Act promptly.

ATTACHMENT

Supporting Organizations

Center for Foodborne Illness Research & Prevention was founded in 2006 to promote science-based solutions for the food safety challenges of the 21st Century. CFI is a national, nonprofit health organization dedicated to preventing foodborne illness through research, education, advocacy and service. CFI's co-founders, who have advanced degrees in biostatistics and education, were personally impacted by foodborne illness and have dedicated themselves to improving food safety for the past 7 years.

Center for Science in the Public Interest, founded in 1971, has been a strong advocate for nutrition and health, food safety, alcohol policy, and sound science. Its award-winning newsletter, *Nutrition Action Healthletter,* is the largest-circulation health newsletter in North America, providing reliable information on nutrition and health. CSPI manages *Outbreak Alert,* the most comprehensive foodborne illness attribution database, listing over 5,000 outbreaks.

Consumer Federation of America is a nonprofit association of 300 local, state and national consumer groups, consumer cooperatives, public health organizations, farm groups and trade unions, representing more than 50 million Americans. CFA was established in 1968 to advance the consumer interest through research, education and advocacy. The organization's policy positions are established by vote of member representatives attending the annual meeting or by the board of directors elected at the meeting.

Consumers Union, publisher of *Consumer Reports,* is an independent, nonprofit testing and information organization serving only consumers. Consumers Union is a comprehensive source for unbiased advice about products and services, personal finance, health and nutrition, and other consumer concerns. Since 1936, CU's mission has been to test products, inform the public, and protect consumers.

Food & Water Watch is a nonprofit consumer organization that works to ensure clean water and safe food. Food & Water Watch works with grassroots organizations around the world to create an economically and environmentally viable future. Through research, public and policymaker education, media, and lobbying, FWW advocates policies that guarantee safe, wholesome food produced in a humane and sustainable manner and public, rather than private, control of water resources including oceans, rivers, and groundwater.

Government Accountability Project was founded in 1977 in response to White House scandals in the United States. From the beginning GAP has focused upon the unique contributions of employees of conscience within governments, large corporations, and international institutions. GAP's mission is to protect the public interest by promoting public accountability at workplaces and advancing the rights of employees to speak out about serious problems. These employees are often the most credible witnesses to corruption, public health dangers, and environmental threats.

National Consumers League seeks to protect and promote social and economic justice for consumers and workers in the United States and abroad. NCL is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. It is the nation's oldest consumer organization.

The Pew Charitable Trusts, an independent nonprofit, is the sole beneficiary of seven individual charitable funds established between 1948 and 1979 by two sons and two daughters of Sun Oil Company founder Joseph N. Pew and his wife, Mary Anderson Pew. Pew applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. Pew's Health and Human Services Policy program seeks to improve the health and well-being of all Americans. Based on research and critical analysis, the program advocates policies that reduce unacceptable health risk, focusing on areas that include consumer, medical and food safety.

Safe Tables Our Priority (S.T.O.P.) is a national nonprofit public health organization dedicated to preventing illness and death from foodborne pathogens. S.T.O.P. supports its mission by advocating public health-based changes in public policy, educating and conducting outreach and providing victim assistance. S.T.O.P. was founded in 1993 in the aftermath of the Jack in the Box *E. coli O157:H7* epidemic.

Trust for America's Health is a nonprofit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

United Food and Commercial Workers International Union is the largest private sector union in North America. With over 1.3 million members, UFCW represents workers in every state and community in the United States. The majority of UFCW members work in the retail food stores and meatpacking and food processing sectors. The UFCW is committed to continuing and building upon its long history of involvement in food safety and regulatory issues.

The CHAIRMAN. Thank you very much for your statement, Carol. Dr. Ives, welcome to the Committee.

STATEMENT OF SAMUEL E. IVES, D.V.M., PH.D., DIRECTOR OF VETERINARY SERVICES AND ASSOCIATE DIRECTOR OF RESEARCH, CACTUS FEEDERS, LTD., AMARILLO, TX; ON BEHALF OF NATIONAL CATTLEMEN'S BEEF ASSOCIATION

Dr. IVES. Good morning, Chairman Peterson, Mr. Goodlatte, and Members of the Agriculture Committee. I am Sam Ives and I am the Director of Veterinary Services and Associate Director of Research for Cactus Feeders. Cactus Feeders is headquartered in Amarillo, Texas, and we have nine large-scale cattle feedyards across the Texas High Plains and southwest Kansas where we produce one million head of cattle annually for slaughter. A subsidiary to our feeding operations includes three ranches in Texas and New Mexico. The ranches produce 30,000 stocker calves annually and maintain 2,000 mama cows. I appreciate the opportunity to represent the National Cattlemen's Beef Association at today's hearing to discuss the beef industry's commitment to beef safety. I would like to start out by emphasizing that everyone plays an important role in the safety of food. And it starts with producers raising healthy cattle. Cattlemen are committed to producing the safest, most wholesome nutritious and affordable beef products in the world.

There is no question that the United States has the safest food supply in the world and other countries consider the U.S. the gold standard. Cattle producers support the establishment of realistic food safety objectives designed to protect public health to the maximum extent possible. Several food safety bills that have been introduced in the Congress, and one in particular, H.R. 2749 is of interest to beef producers. We appreciate the willingness of the Energy and Commerce Committee to discuss and learn more about how meat and poultry products are regulated by USDA, and we understand the intent of the bill is to exempt livestock and poultry from this FDA-focused bill.

However, we are concerned the current bill language does not go far enough to ensure Congressional intent is not misinterpreted. The bill must contain clear legislative language to ensure that FDA is not granted the authority to regulate livestock on-farm by mandating production standards for cattlemen across the country. Live animals are not food until the point of processing, and we would like to see language that explicitly excludes livestock and poultry from the definition of *food* under this bill and the Federal Food Drug and Cosmetic Act. Additionally, exempting livestock and poultry from food would also clarify the record-keeping requirements of this bill and their application to food. Under the Federal Food Drug

and Cosmetic Act, farms are exempt, but this legislation eliminates that exemption. H.R. 2749 raises concerns about the treatment of state-inspected facilities as the bill only exempts official establishments as defined by this legislation. Many beef producers, especially in rural areas, rely on state-inspected facilities to process their cattle. The definition needs to be expanded to ensure state-inspected facilities are included in the exemption of this bill. Section 133 of the bill grants FDA with a redundant authority regarding quarantine of a geographical area where food presents serious adverse health consequences to humans and animals. This new responsibility of FDA is concerning, as under the Animal Health Protection Act, USDA can impose a Federal quarantine for animal health reasons when they deem necessary and work closely with state authorities. Under the Animal Health Protection Act the government is mandated to pay indemnity to producers when the government takes the animal. This provision does not require the FDA to pay indemnity.

Again, we appreciate the willingness of the Energy and Commerce Committee to work with the livestock groups to address some of the duplicative and unnecessary regulatory authority this bill's grants the FDA. We urge both the Agriculture and Energy and Commerce Committees to ensure the true intent of the bill is made very clear before any further action is taken on the legislation. My written testimony provides more information about the concerns that I, and my fellow cattle producers, have with this bill.

In closing, the U.S. has the safest food supply in the world which is an achievement worth noting. Science is a critical component of the beef industry, and through science-based improvements and animal genetics, management practices, nutrition and health, beef production per cow has increased from 400 pounds of beef in the mid 1960s to 585 pounds of beef in 2005. As beef producers, we have our work cut out for us in order to feed our ever-growing population. Cattlemen will continue to increase efficiencies based on science in order to produce high-quality beef with fewer resources being consumed. The beef industry will continue to dedicate time and resources to ensure the safety of beef. We look forward to working with the Committee to ensure Congressional intent of this bill is not misunderstood.

Many thanks for the opportunity to testify here today, and I look forward to answering any questions that you may have.

[The prepared statement of Dr. Ives follows:]

PREPARED STATEMENT OF SAMUEL E. IVES, D.V.M., PH.D., DIRECTOR OF VETERINARY SERVICES AND ASSOCIATE DIRECTOR OF RESEARCH, CACTUS FEEDERS, LTD., AMARILLO, TX; ON BEHALF OF NATIONAL CATTLEMEN'S BEEF ASSOCIATION

Chairman Peterson, Ranking Member Lucas and Members of the Committee, I'm Sam Ives and I am the Director of Veterinary Services and Associate Director of Research for Cactus Feeders. Cactus Feeders is headquartered in Amarillo, Texas and we have nine large-scale cattle feedyards across the Texas High Plains and Southwest Kansas where we produce 1,000,000 head of cattle for slaughter annually. A subsidiary to our feeding operations includes three ranches in Texas and New Mexico. The ranches produce 30,000 stocker calves annually and maintain 2,000 mother cows. My responsibilities are focused on animal health and well-being of the cattle in our operations. These responsibilities include advising the feeding and ranching operations on best practices for preventing, controlling, and treating diseases that occur in the cattle during the feeding period. Much time is spent training employees

and evaluating our health programs to assure that we are providing cattle that will become a safe and wholesome meat product for our consuming public. Many of the recommendations used in our operations are supported by studies conducted at Cactus Research which I manage along with Dr. Spencer Swingle. Cactus Research is managed as a 12,000 head research feedlot in the Texas panhandle. Together Dr. Swingle and I are responsible for investigating and coordinating sponsored and internal research studies including diet formulation, growth promoting technologies, direct-fed microbials, feed additives, the incidence and control of important food safety pathogens, and medications for control and treatment of cattle diseases.

I appreciate the opportunity to represent the National Cattlemen's Beef Association (NCBA) at today's hearing to discuss the beef industry's commitment to beef safety. NCBA is the oldest and largest national trade association for cattle producers and represents over 230,000 cattle producers through direct membership and state and breed affiliates. Cattlemen are committed to producing the safest, most wholesome, nutritious and affordable beef products in the world. There is no question that the United States has the safest food supply in the world and other countries consider the U.S. the "gold standard." Science is a critical component of the beef industry and through science-based improvements in animal genetics, management practices, nutrition and health, beef production per cow has increased from 400 pounds of beef in the mid-1960s to 585 pounds of beef in 2005.[1] As beef producers we have our work cut out for us in order to feed our ever growing population. In 1960 there were 3.9 million farms feeding a U.S. population of 183 million and in 2005 there were 2.1 million farms feeding an estimated population of 296 million—a population increase of 61 percent.[2] In 1960 the average farmer fed 25.8 people. Today's American farmer feeds about 144 people worldwide.[3] Cattlemen will continue to increase efficiencies based on science in order to produce high-quality beef with fewer resources being consumed. In addition, our industry continues to focus on our long-term efforts to improve our knowledge and ability to produce healthy cattle, which are the foundation of a safe food supply.

Since 1993, cattle producers have invested more than $27 million in beef safety research and the beef industry as a whole spends approximately $350 million every year on beef safety. It is important to note that **everyone** plays an important role in the safety of beef. It starts with producers raising healthy cattle, and everyone who plays a role in the production chain is committed to producing safe beef products. Consumers also play a critical role to ensure the safety of their meat products by using safe storage, handling and preparation techniques.

All beef is subject to strict government oversight by the U.S. Department of Agriculture (USDA) and every meat processing facility undergoes on-going USDA inspection. The inspection process includes review of their Hazard Analysis Critical Control Point plans also known as HACCP plans. HACCP plans were pro-actively developed by the food industry as a method to identify potential hazards and prevent them. In 1996, USDA's Food Safety and Inspection Service (FSIS) enacted a rule requiring HACCP plans for all beef processing plants.

In 1997, the Beef Industry Food Safety Council (BIFSCo) was formed to coordinate a broad effort to solve pathogen issues, and to focus on research and consumer education. Representatives from all segments of the beef industry belong to BIFSCo and work together under the founding principles that safety is a non-competitive issue to develop industry-wide, science-based strategies to address safety challenges, particularly *E. coli O157:H7*. Cattlemen and the entire beef industry have dedicated significant time and resources to a variety of research areas including building our knowledge of *E. coli O157:H7* by identifying where, why and how it survives from pre- to post-harvest; the relationship between the live animal and the pathogen in order to develop pre-harvest interventions; and the impact that production practices, processing systems and interventions have on the pathogens.

NCBA continues to evaluate how to optimize food safety systems not only for the current safety challenges but also for any potential future ones. Cattle producers and our partners will continue to dedicate time and resources to reduce the incidence of pathogens and other food safety issues. The beef industry and our government share the common goal of producing safe beef products. With the current budget and economic situation there has never been a more important time for our government and the industry to work together to achieve this goal.

NCBA supports the establishment of realistic food safety objectives designed to protect public health to the maximum extent possible. It is vital that the objectives be based on sound science with the realistic understanding that even under the best

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[1] Cattle-Fax: *http://www.beefusa.org/uDocs/cattlenumbersandbeefproduction347.pdf.*
[2] NASS: *http://www.nass.usda.gov:8080/QuickStats/PullData_US.jsp.*
[3] ACA: *http://www.agday.org/media/agfactsheet.htm.*

science-based operating procedures achieving zero risk is not possible. However, utilizing science-based principles and validating interventions used throughout the process will effectively control the associated risks of pathogens like *E. coli O157:H7*. In addition, it is more important to focus resources on the validation of process controls rather than testing as a means to protect public health. Beef packing plants and processors vary in size and design, and their safety plans must be tailored to their set-up. Nearly 100 percent of beef establishments use one or more of the post-harvest safety interventions the beef industry has helped research, implement and validate.

NCBA's members remain committed to beef safety, we take a lot of pride in the amount of time and resources we have dedicated to making beef an even safer product. As Congress continues to debate food safety legislation we encourage you to continue working with all relevant stakeholders to increase efficiencies and the effectiveness of our food safety system. There are several food safety bills being discussed that would result in unintended consequences for cattlemen as well as other livestock and poultry producers.

As legislation is developed, it is important to understand the Food and Drug Administration's (FDA) role in food safety and how their role differs from USDA's Food Safety Inspection Service (FSIS). H.R. 2749 passed the House Energy and Commerce Committee on June 17, 2009. There are several sections of this bill of concern to cattle producers and we appreciate the Energy and Commerce Committee's willingness to discuss and learn more about how the meat and poultry industries are regulated. We understand the intent of the Committee is to exempt livestock and poultry from this bill as meat and poultry products are already regulated by USDA with the authority granted to them by Congress in the Federal Meat Inspection Act, the Poultry Inspection Act and the Egg Products Inspection Act.

However, we are concerned the current bill language does not go far enough to ensure Congressional intent. The bill must contain clear legislative language ensuring that FDA is not granted the authority to regulate livestock on-farm by mandating production standards for cattlemen across the country. Live animals are not "food" until the point of processing, which is why this bill needs to clarify that the FDA does not have regulatory authority on our farms, ranches or feedlots. Cattle producers support language that explicitly excludes livestock and poultry from the definition of "food" under this bill and the Federal Food Drug and Cosmetic Act (FFDCA). This important change is essential to resolve the ambiguity to keep the more than century old and successful animal health and meat, poultry, and egg inspection a functioning partnership between USDA and state authorities.

The exemption of livestock and poultry from "food" would also clarify the record-keeping requirements and their application to "food". Under the FFDCA record-keeping requirements apply to "food," the FFDCA also exempts "farms" but this legislation eliminates that exemption. It is our concern the "livestock" exemption from the definition of "farm" in this bill is not clear. The exemption of "livestock" should also apply to "food" as the record-keeping requirements of this bill are applicable to "food". We urge the Committee to exclude livestock from the definition of "food" under the FFDCA and modify the facility requirements of this bill to ensure "preventative controls" and "inspections" requirements of this bill are not applicable to USDA regulated facilities. In addition, cattle producers are concerned with the definition of "facility" as the "preventative controls" and "inspections" requirements of this bill will apply to USDA facilities with FDA operations. For example, a beef slaughter facility with a rendering operation would be subject to FDA preventative controls and inspections for all aspects of their operations. This is unnecessary and duplicative as USDA has regulatory authority now. We ask the Committee to modify the definition of "food" and to modify the facility requirements of this bill to ensure "preventative controls" and "inspections" requirements of this bill are not applicable to USDA regulated facilities. H.R. 2749 raises concerns about the treatment of state inspected facilities as the bill only exempts "official establishments" as defined by this legislation. This definition refers to the "regulations promulgated under this subchapter" and does not include state inspected facilities. Many beef producers, especially in rural areas, rely on state inspected facilities when processing their cattle. State inspected facilities are not "official establishments" and the definition needs to be expanded to include these facilities in the exemption.

Section 133 of the bill grants FDA with another redundant authority regarding quarantine of a geographical area where food presents serious adverse health consequences. This new responsibility of FDA is unnecessary, confusing and will disrupt the decades of cooperative efforts between USDA and state authorities. Currently, under the authorities of the Animal Health Protection Act (AHPA), USDA can impose a Federal quarantine for animal health reasons when they deem necessary and USDA works very closely with state agencies. Additionally, under AHPA

statute USDA must provide indemnity to affected producers when the Federal Government "takes" an animal. In this bill FDA would not be required to pay indemnity or even have a qualified reason to extend the quarantine to the live animal area. USDA has the expertise, resources and current regulatory authority to impose an animal health quarantine, and granting this authority to FDA is unnecessary. As pointed out in the full Committee markup this provision would extend to retailers and there is no indication in the bill as to how the quarantine would be removed once put into place. As written this provision creates confusion between the roles of USDA and FDA and needs to be thought through carefully so there are not any unintended consequences created by this bill. Again, specifically exempting livestock and poultry in these new regulations would eliminate duplication into current USDA authority.

We appreciate the Energy and Commerce Committee working with the livestock groups to address some of the duplicative and unnecessary regulatory authority this bill grants the FDA. We look forward to working with both the Energy and Commerce and Agriculture Committees to add clarifying language to ensure there is not any confusion as to Congress' intent of this bill.

While I have this opportunity to address the Committee on food safety, I would like to discuss several topics that are being linked to the food safety debates. First is the misconception that an animal identification system is a necessary component for food safety. Animal identification programs are tools to help monitor and trace disease in the event of an animal health emergency. Animal identification systems do not enhance food safety, nor were they ever intended to. In addition, animal identification systems do not prevent animal disease; they are only a tool to help trace and contain them. Producers currently utilize animal identification for herd management, genetic improvement and as a positive tool for their operations' marketing program.

Another topic that is receiving a lot of interest from the media and activist groups is the use of antibiotics in the beef industry. Animal health and well-being are top priorities for cattle producers across the country. Without healthy animals, we do not have healthy food for American families, so we judiciously utilize important tools like vaccines, antimicrobials, and other drugs to control disease, treat disease, and provide a higher quality of life for our cattle while keeping the food supply safe. Additionally, all products approved by FDA for use in food producing animals must first pass significant human food safety benchmarks. It is also important to recognize that animal drugs go through a rigorous, science-based testing process before they are approved for use. FDA, USDA, veterinarians, animal health companies, producer organizations, and other stakeholders have implemented several layers of human health protections. The issue of antimicrobial resistance is very concerning to cattle producers. To date extensive international research on the topic of antimicrobial resistance shows no link between antimicrobial use in livestock and antimicrobial resistance in humans. NCBA producers and The Beef Checkoff proactively work to increase our knowledge of antimicrobial resistance in both animals and humans. We encourage and advocate for judicious use of all medications. In fact, NCBA producer-made policy supports the *Producer Guidelines for Judicious Use of Antimicrobials* which have been in place since 1987. In addition, NCBA participates in the Codex Alimentarius Task Force on Antimicrobial Resistance.

Antimicrobial resistance is not a black and white issue. It is a multi-faceted and extremely complex issue that cannot be solely focused on the use of drugs in animal agriculture. Unfortunately, animal agriculture has been a primary target in this fight, with little or no consideration given by the public to the use, misuse, and mishandling of human drugs by the general population. To ensure that the issue of antimicrobial resistance is properly addressed, it is imperative that we gather accurate, appropriate, and complete data to identify any problems and all contributing factors. To date, only limited data exists. These data need to be gathered and scientifically evaluated without bias or a pre-determined agenda before any further action is taken by Congress.

Cattle producers have a long history of proactively providing solutions to issues when science-based evidence shows there is an issue that needs to be addressed. Again, to date there is no scientific evidence linking the judicious use of antimicrobials in the beef industry to antimicrobial resistance in humans. The international scientific community continues to actively research and discuss this issue. It is important that we have strong conclusive science-based information before any legislative actions are taken that could impact the health of our animals and food supply.

In closing, I would like state again, that the U.S. has the safest food supply in the world, which is an achievement worth noting. The beef industry will continue to dedicate time and resources to address food safety issues to ensure the U.S. main-

tains the safest food supply in the world. It is imperative for our government to use sound science when evaluating the effectiveness of our food safety systems, and to realize the differences between FDA's and USDA's regulatory authority of food safety. Science-based intervention and management strategies coupled with safe food handling techniques, will help our industry maintain its goal of providing a safe, high-quality product for the consumer. Everyone plays an important role in food safety and our industry will continue our research and educational outreach efforts to consumers.

I appreciate the opportunity to testify today about the beef industry's role in food safety and some of our areas of concern with H.R. 2749. Cattle producers are concerned that unnecessary duplication of USDA's regulatory authorities will undermine our common goal of creating a more effective and efficient food safety system. We are happy to provide additional information and look forward to working with both the Energy and Commerce and Agriculture Committees to clarify some of the provisions so there is not any misunderstanding of Congressional intent.

The CHAIRMAN. Thank you, Dr. Ives, for your statement.

Mr. Peppler, welcome to the Committee.

STATEMENT OF KENT PEPPLER, PRESIDENT, ROCKY MOUNTAIN FARMERS UNION, MEAD, CO; ON BEHALF OF NATIONAL FARMERS UNION

Mr. PEPPLER. Good morning, Mr. Chairman, and Members of the Committee. My name is Kent Peppler. I am President of Rocky Mountain Farmers Union, which represents family farmers and ranchers in Colorado, Wyoming, and New Mexico. I am here today on behalf of Rocky Mountain Farmers Union and National Farmers Union, and I am also a fourth generation farmer in northern Colorado and we have also fed cattle and sheep and hogs in the past.

As a farmer, it is my best interest to maintain the confidence of American consumers that the food on our supper table is safe. About 3 weeks ago, USDA announced that JBS Swift Beef Company, based in my neighborhood in Greeley, Colorado, was voluntarily recalling approximately 380,000 pounds of assorted beef products that may have been contaminated with *E. coli*. Unfortunately, USDA has wasted time, attention, and efforts on this recall by focusing on the origin of the cattle. This reminds me of the story of the guy who loses his wallet on the east side of the street and decides to look for it on the west side of the street because the light is better.

I urge you not to get distracted in this debate by those who argue that it is the farmers who are the problem. Farmers are the first line of defense in addressing food safety issues, and I would argue that we have done a heck of a job. You don't see headlines of food contaminated when it's going straight from the farm to the consumer. The headlines we have been seeing too often lately typically appear with the logos of big corporate vertically integrated ag processors. Placing unnecessary, onerous, costly and burdensome regulations on farmers will not yield the results we all need and want in this issue. The lack of outreach to the independent farm production sector by those in Congress, who are intent on moving food safety legislation forward, is problematic.

Provisions that adversely impact independent family farmers and ranchers will be counterproductive in improving the safety of our food. A punitive or one-size-fits-all approach for traceability, penalties or other efforts seeking to improve food safety will not yield successful results. Specifically, small and mid-size operations that focus on sustainable and organic production methods are concerned

with potentially excessive burden and expense associated with legislative efforts on food safety. Congressional leaders must do a better job in reaching out to our producer community. You might be surprised with what you find, common sense solutions and ideas for achieving better food safety that those inside the beltway hadn't considered. NFU's policy supports two key components for improving food safety: One, creating a new regulatory body, single food agency to oversee the entire U.S. food system including imports, and two, providing the regulator with mandatory recall authority.

My written testimony details additional policy suggestions. Concerns we have with the Food Safety Modernization Act of 2009, include the following: Traceability requirements have been improved by allowing producers to maintain records either electronically or on hard copies for 6 months; however, the focus of improving food safety should not be misdirected on independent farmers and ranchers. Registration fees are woefully deficient in recognizing the difference between small processors and large corporate multi-national processors. The legislation needs to recognize the uniqueness of small processing facilities and exempt those from any fees, so as not to discourage those facilities from participating in an already consolidated and concentrated food processing system.

Unintentional barriers to producers interested in transitioning into organic production methods: Requirements or encouragement of producers to eliminate certain environmental practices under the guise of safer food production. The FDA has no background, knowledge, or expertise of real world environmental practices by farmers, and I strongly urge this Subcommittee, and others who understand the benefits of environmental practices like buffer strips, to engage your colleagues to articulate the consequences of pursuing this misdirected path.

Farmers are the first link of the food safety chain and can be a valuable resource as Congress determines what policies will yield the greatest results. As an organization that represents independent family farmers and ranchers, RMU and NFU are eager to provide an on-farm real-world perspective to the food safety debate.

[The prepared statement of Mr. Peppler follows:]

PREPARED STATEMENT OF KENT PEPPLER, PRESIDENT, ROCKY MOUNTAIN FARMERS UNION, MEAD, CO; ON BEHALF OF NATIONAL FARMERS UNION

Good morning, Mr. Chairman and Members of the Committee. My name is Kent Peppler, I serve as the President of Rocky Mountain Farmers Union, which represents family farmers and ranchers in Colorado, Wyoming and New Mexico. I am a fourth generation farmer from Mead, Colo., my operation consists of 500 acres of corn, wheat, alfalfa hay and barley. In the past my family raised sugar beets and sunflowers; we also fed cattle, sheep and hogs. I am here today on behalf of Rocky Mountain Farmers Union and National Farmers Union (NFU)—a nationwide organization representing more than 250,000 farm, ranch and rural residents.

There is no question that doing more to protect our food supply is necessary. The solutions to achieving this goal are as diverse as the perspectives of impacted communities. America's farmers and ranchers are the best in the world at what they do; it is in our best interests to maintain the confidence of American consumers that the food on their supper table is safe.

Many in agriculture would agree that food safety concerns could be addressed at minimum by adequate and appropriate enforcement of existing regulations. A vast array of regulations and laws exist today, yet the Federal agencies tasked with enforcing those laws are not given adequate resources to accomplish the job. I must also note that existing regulations, even when enforced, have not yielded appropriate protections for consumers—as demonstrated by the recent cookie dough and

peanut butter outbreaks. The failure to inspect and regulate food processing facilities is a concern held by producers across the country. However, adding additional mandates from Congress, without equipping the agencies to do the job, will yield the same failed results we are experiencing today.

The complexities of our modern food supply system have outpaced the ability of regulators to sufficiently address supply safety controls. Last summer, during the *Salmonella saintpaul* outbreak, Rocky Mountain Farmers Union called on consumers to demand more local and seasonal food production rather than rely upon the *status quo* of food distribution. In response to other recent food safety outbreaks, some have suggested the solution is nationwide marketing orders. Our members have worked to prevent such regulations being imposed on family farmers because of evidence from the Food and Drug Administration (FDA) that demonstrates *E. coli O157:H7* outbreaks have been associated with products coming from processing facilities, not the farm. Efforts to establish a nationwide set of mandatory food safety marketing orders for all produce farms is the wrong approach to addressing food safety concerns.

A growing concern with the direction of legislative food safety action is the impact on farmers' environmental practices. Attached to my testimony is a July 13, 2009 article published in the *San Francisco Chronicle* titled, "Crops, Ponds Destroyed in Quest for Food Safety." If producers are required to eliminate environmentally beneficial practices based upon no evidence the revised production practices will yield safer food, the consequences will be severe. The FDA has no background, knowledge or expertise of real-world environmental practices by farmers and I strongly urge this Subcommittee and others who understand the benefits of environmentally beneficial practices like buffer strips, wildlife habitat and water quality protection to engage your colleagues to articulate the consequences of pursuing this misdirected path.

Three weeks ago yesterday, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) announced that JBS Swift Beef Company, based in my neighborhood of Greeley, Colo., was voluntarily recalling approximately 380,000 pounds of assorted beef products that may have been contaminated with *E. coli 0157:H7.* While not the largest beef recall our nation has faced, it serves as an unwelcome reminder that the time to act on food safety is now. Unfortunately, time, attention and focus have been wasted by USDA on this recall by focusing on the origin of the cattle. It reminds me of the story of the guy who loses his wallet on the east side of the street, and decides to look for it on the west side because the light is better. Consumers and producers would be better served if slaughterhouses are no longer allowed to self-regulate and the entire regulatory system is updated to reflect the complexities of today's modern food supply.

NFU's policy has called on Congress to create a new regulatory body to oversee the U.S. food system. In order to be successful, such a system must be adequately funded to carry out its mission. This will require the Federal Government to make food safety a fiscal priority and not demand user fees or registration fees to cover the entire cost of providing safe food to American consumers.

Our members also support the creation of a single food agency to regulate the food supply as a whole, including increasing amounts of imported foods. The agency should be granted authority for issuing a mandatory recall in the event of a food safety outbreak. With the recent voluntary beef recall in my state, we know the meat was processed approximately 65 days prior to the voluntary recall and distributed to at least 13 states and international markets. The inability to issue a mandatory recall perpetuates both consumer fear and depressed product sales. Mandatory recall authority should also include a requirement for timely notification at points of sale to minimize distribution of product to consumers. Reduced product sales lead to lower market prices received by producers and can last for weeks or months, devastating producers' income. Mandatory recall authority could mitigate the economic impact on producers while at the same time containing consumer fear.

Any food safety legislation must recognize implications for farmers and their ability to continue to provide an affordable, safe and abundant food supply. Farmers are the first link of the food safety chain and can be a valuable resource as Congress determines what policies will yield the greatest results. As an organization that represents independent family farmers and ranchers, RMFU and NFU are eager to provide an "on-the-farm," real-world perspective as the food safety debate proceeds. An aggressive outreach and education effort must be made to producers regarding food safety measures that can be implemented on the farm. An affiliate of NFU, the Community Alliance with Family Farmers based in Davis, Calif., has been developing an educational outreach campaigned, geared toward producers, to mitigate food safety concerns on the farm. Their efforts should be replicated across the country and would require no legislative action.

We are concerned with the lack of outreach to the independent farm production sector by those in Congress who are intent on moving food safety legislation forward. Provisions that adversely impact independent family farmers and ranchers will be counterproductive in improving the safety of our food. A punitive or one-size-fits-all approach for traceability, penalties or other efforts seeking to improve food safety will not yield successful results. Specifically, small and mid-sized operations focused on sustainable and organic production methods are concerned with potential excessive burden and expense associated with legislative efforts on food safety. While the language in the Food Safety Enhancement Act of 2009 (H.R. 2749) to account for organic production methods and size are needed, more must to be done to address these concerns. Congress must ensure new food safety legislation does not prescribe a separate set of standards that would unintentionally discourage producers from transitioning to organic production methods. I encourage this Subcommittee to reach out to all food producers, including small scale and organic producers, to ensure legislative efforts do not disproportionately burden these good actors.

Traceability

H.R. 2749 includes language to establish a higher standard of traceability of food in order to quickly identify and contain the source of an outbreak. While working through the Energy and Commerce Committee process, the bill was improved to provide an accommodation for producers that sell directly to grocery stores, restaurants or consumers. The modified section allows producers to maintain records either electronically or in hard copy format for a 6 month period. This section was also improved by requiring a cost/benefit analysis, public hearings, a pilot project and information gathering effort prior to publishing regulations.

Imports

According to an April 2009 Congressional Research Service report, the FDA physically inspects approximately one percent of all imported food items with 450 inspectors covering more than 300 ports of entry. According to USDA's Economic Research Service, the value of agriculture imports went from approximately $37 billion in 1998 to $80 billion in 2008. Combined with frequent headlines of tainted imports such as pet food ingredients, baby formula, shrimp—our food safety efforts cannot continue to fail to acknowledge the increasing amount of food entering our country from places around the globe that either have no food safety standards or standards in name only.

Registration Fees

As currently drafted, H.R. 2749 does not appropriately recognize the differentiation between small and large processors. To require all food facilities, regardless of size, pay an annual registration fee of $500 demonstrates a deficiency in the legislation. Congress should recognize the uniqueness of small processing facilities and exempt such facilities from this fee so as not to discourage small-scale processors from participating in an already consolidated and concentrated food processing system.

Additional Policy Suggestions

In order to maintain the high quality of our food supply, NFU supports the following standards for production, processing and transportation of food products:

- Vigorous action by U.S. regulatory agencies to prevent the introduction of bovine spongiform encephalopathy (BSE) into U.S. livestock and livestock products;
- A moratorium on mechanical de-boning until the process can be improved to ensure that no undesired portions of the carcass are present in the final product;
- Labeling of irradiated products and further research on its long-term effects on human health;
- Opposition to the transportation of food in containers that have carried incompatible substances;
- Protecting our nation's food supply and the rigorous inspection of all imported food, fiber, Milk Protein Concentrate (MPC), animal products and by-products to ensure they meet our nation's sanitary and phyto-sanitary standards including safe pesticide levels. USDA inspection stamps/seals should be placed only on the individual items inspected;
- Permitting states to implement food safety regulations more stringent than comparable Federal regulations where states deem consumer health and safety to be at risk or when individual agricultural producers strive to set a higher bar for the safety of food products destined for specialty or export markets; and

- Labeling the use of all additives, such as carbon monoxide injected in meat and seafood or packaging for appearance or shelf-life purposes.

Labeling

Thorough and accurate food labels are an important tool that help consumers make informed decisions and allows producers to differentiate their products. We support mandatory labeling for food products to include all ingredients, additives and processes such as:

- Carbon Monoxide;
- Artificial growth hormones;
- Products derived from cloned animals;
- Irradiation;
- The identity of the parent company; and
- Country-of-origin.

Agri-Terrorism

With increased attention and focus on potential agri-terrorism attacks on our nation's food chain, rural America must be educated, prepared and vigilant of all potential circumstances. National Farmers Union supports:

- The Department of Homeland Security (DHS) and USDA immediately developing mechanisms to combat agro-terrorism with full funding provided by DHS. Such mechanisms should ensure the safety of the consumer and agricultural industry;
- Increased cooperation between USDA, DHS, Department of Health and Human Services (HHS) and the Federal Emergency Management Agency (FEMA) to establish, expand and continue to determine vulnerabilities within the agricultural and food industries;
- Establishing a USDA public awareness and education campaign for producers;
- Providing Federal guidance and funding to states and localities to develop and implement plans for agricultural disease prevention, recovery and response, based upon already established state animal response activities; and
- A requirement of representatives of Federal, state and county agencies to notify landowners prior to non-emergency access of their private property. Representatives and vehicles used for access should also display appropriate agency signage and identification.

I thank you for the opportunity to testify today and look forward to responding to any questions Committee Members may have.

ATTACHMENT

San Francisco Chronicle

Crops, ponds destroyed in quest for food safety

CAROLYN LOCHHEAD, *Chronicle* Washington Bureau

Monday, July 13, 2009

(07–13) 04:00 PDT Washington—Dick Peixoto planted hedges of fennel and flowering cilantro around his organic vegetable fields in the Pajaro Valley near Watsonville to harbor beneficial insects, an alternative to pesticides.

He has since ripped out such plants in the name of food safety, because his big customers demand sterile buffers around his crops. No vegetation. No water. No wildlife of any kind. "I was driving by a field where a squirrel fed off the end of the field, and so 30 feet in we had to destroy the crop," he said. "On one field where a deer walked through, didn't eat anything, just walked through and you could see the tracks, we had to take out 30 feet on each side of the tracks and annihilate the crop."

In the verdant farmland surrounding Monterey Bay, a national marine sanctuary and one of the world's biological jewels, scorched-earth strategies are being imposed on hundreds of thousands of acres in the quest for an antiseptic field of greens. And the scheme is about to go national.

Invisible to a public that sees only the headlines of the latest food-safety scare—spinach, peppers and now cookie dough—ponds are being poisoned and bulldozed. Vegetation harboring pollinators and filtering storm runoff is being cleared. Fences and poison baits line wildlife corridors. Birds, frogs, mice and deer—and anything

that shelters them—are caught in a raging battle in the Salinas Valley against *E. coli O157:H7*, a lethal, foodborne bacteria.

In pending legislation and in proposed Federal regulations, the push for food safety butts up against the movement toward biologically diverse farming methods, while evidence suggests that industrial agriculture may be the bigger culprit.

'Foolhardy' approach

"Sanitizing American agriculture, aside from being impossible, is foolhardy," said UC Berkeley food guru Michael Pollan, who most recently made his case for smaller-scale farming in the documentary film "Food, Inc." "You have to think about what's the logical end point of looking at food this way. It's food grown indoors hydroponically."

Scientists do not know how the killer *E. coli* pathogen, which dwells mainly in the guts of cattle, made its way to a spinach field near San Juan Bautista (San Benito County) in 2006, leaving four people dead, 35 with acute kidney failure and 103 hospitalized. The deadly bug first appeared in hamburger meat in the early 1980s and migrated to certain kinds of produce, mainly lettuce and other leafy greens that are cut, mixed and bagged for the convenience of supermarket shoppers. Hundreds of thousands of the bug can fit on the head of a pin; as few as ten can lodge in a salad and end in lifelong disability, including organ failure.

Going national

For many giant food retailers, the choice between a dead pond and a dead child is no choice at all. Industry has paid more than $100 million in court settlements and verdicts in spinach and lettuce lawsuits, a fraction of the lost sales involved.

Galvanized by the spinach disaster, large growers instituted a quasi-governmental program of new protocols for growing greens safely, called the "leafy greens marketing agreement." A proposal was submitted last month in Washington to take these rules nationwide. A food safety bill sponsored by Rep. Henry Waxman, D-Los Angeles, passed this month in the House Energy and Commerce Committee. It would give new powers to the Food and Drug Administration to regulate all farms and produce in an attempt to fix the problem. The bill would require consideration of farm diversity and environmental rules, but would leave much to the FDA.

An Amish farmer in Ohio who uses horses to plow his fields could find himself caught in a net aimed 2,000 miles away at a feral pig in San Benito County. While he may pick, pack and sell his greens in 1 day because he does not refrigerate, the bagged lettuce trucked from Salinas with a 17 day shelf life may be considered safer.

The leafy-green agreement is based on available science, but it is just a jumping-off point. Large produce buyers have compiled secret "super metrics" that go much further. Farmers must follow them if they expect to sell their crops. These can include vast bare-dirt buffers, elimination of wildlife, and strict rules on water sources. To enforce these rules, retail buyers have sent forth armies of food-safety auditors, many of them trained in indoor processing plants, to inspect fields.

Keeping children out

"They're used to working inside the factory walls," said Ken Kimes, owner of New Natives farms in Aptos (Santa Cruz County) and a board member of the Community Alliance With Family Farmers, a California group. "If they're not prepared for the farm landscape, it can come as quite a shock to them. Some of this stuff that they want, you just can't actually do." Auditors have told Kimes that no children younger than 5 can be allowed on his farm for fear of diapers. He has been asked to issue identification badges to all visitors.

Not only do the rules conflict with organic and environmental standards; many are simply unscientific. Surprisingly little is known about how *E. coli* is transmitted from cow to table.

Reducing *E. coli*

Scientists have created a vaccine to reduce *E. coli* in livestock, and a White House working group announced plans Tuesday to boost safety standards for eggs and meat. This month, the group is expected to issue draft guidelines for reducing *E. coli* contamination in leafy greens, tomatoes and melons.

Some science suggests that removing vegetation near field crops could make food less safe. Vegetation and wetlands are a landscape's lungs and kidneys, filtering out not just fertilizers, sediments and pesticides, but also pathogens. UC Davis scientists found that vegetation buffers can remove as much as 98 percent of *E. coli* from surface water. UC Davis advisers warn that some rodents prefer cleared areas.

Produce buyers compete to demand the most Draconian standards, said Jo Ann Baumgartner, head of the Wild Farm Alliance in Watsonville, so that they can sell their products as the "safest."

State agencies responsible for California's water, air and wildlife have been unable to find out from buyers what they are demanding.

They do know that trees have been bulldozed along the riparian corridors of the Salinas Valley, while poison-filled tubes targeting rodents dot lettuce fields. Dying rodents have led to deaths of owls and hawks that naturally control rodents.

Unscientific approach

"It's all based on panic and fear, and the science is not there," said Dr. Andy Gordus, an environmental scientist with the California Department of Fish and Game. Preliminary results released in April from a 2 year study by the state wildlife agency, UC Davis and the U.S. Department of Agriculture found that less than ½ of 1 percent of 866 wild animals tested positive for *E. coli O157:H7* in Central California. Frogs are unrelated to *E. coli*, but their remains in bags of mechanically harvested greens are unsightly, Gordus said, so "the industry has been using food safety as a premise to eliminate frogs."

Farmers are told that ponds used to recycle irrigation water are unsafe. So they bulldoze the ponds and pump more groundwater, opening more of the aquifer to saltwater intrusion, said Jill Wilson, an environmental scientist at the Central Coast Regional Water Quality Control Board in San Luis Obispo.

Wilson said demands for 450 foot dirt buffers remove the agency's chief means of preventing pollution from entering streams and rivers. Jovita Pajarillo, associate director of the water division in the San Francisco office of the Environmental Protection Agency, said removal of vegetative buffers threatens Arroyo Seco, one of the last remaining stretches of habitat for steelhead trout.

Turning down clients

"It's been a problem for us trying to balance the organic growing methods with the food safety requirements," Peixoto said. "At some point, we can't really meet their criteria. We just tell them that's all we can do, and we have to turn down that customer." Large retailers did not respond to requests for comment. Food trade groups in Washington suggested calling other trade groups, which didn't comment.

Chiquita/Fresh Express, a large Salinas produce handler, told the advocacy group Food and Water Watch that the company has "developed extensive additional guidelines for the procurement of leafy greens and other produce, but we consider such guidelines to be our confidential and proprietary information."

Seattle trial lawyer Bill Marler, who represented many of the plaintiffs in the 2006 *E. coli* outbreak in spinach, said, "If we want to have bagged spinach and lettuce available 24/7, 12 months of the year, it comes with costs."

Still, he said, the industry rules won't stop lawsuits or eliminate the risk of processed greens cut in fields, mingled in large baths, put in bags that must be chilled from packing plant to kitchen, and shipped thousands of miles away.

"In 16 years of handling nearly every major foodborne illness outbreak in America, I can tell you I've never had a case where it's been linked to a farmers' market," Marler said. "Could it happen? Absolutely. But the big problem has been the mass-produced product. What you're seeing is this rub between trying to make it as clean as possible so they don't poison anybody, but still not wanting to come to the reality that it may be the industrialized process that's making it all so risky."

Some major recent outbreaks of foodborne illness

The Food and Drug Administration lists 40 foodborne pathogens. Among the more common: *E. coli O157:H7, Salmonella, Listeria, Campylobacter,* botulism and hepatitis A.

June 2009: *E. coli O157:H7* found in Nestle Toll House refrigerated cookie dough manufactured in Danville, Va., resulted in the recall of 3.6 million packages. Seventy-two people in 30 states were sickened. No traces found on equipment or workers; investigators are looking at flour and other ingredients.

October 2008: *Salmonella* found in peanut butter from a Peanut Corp. of America plant in Georgia. Nine people died, and an estimated 22,500 were sickened. Criminal negligence was alleged after the product tested positive and was shipped.

June 2008: *Salmonella saintpaul* traced to serrano peppers grown in Mexico. More than 1,000 people were sickened in 41 states, with 203 reported hospitalizations and at least one death. Tomatoes were suspected, devastating growers.

April 2007: *E. coli O157:H7* found in beef, sickening 14 people. United Food Group recalled 5.7 million pounds of meat.

December 2006: *E. coli O157:H7* traced to Taco Bell restaurants in New Jersey and Long Island, N.Y. Green onions suspected, then lettuce. Thirty-nine people were sickened, some with acute kidney failure.

September 2006: *E. coli O157:H7* found in Dole bagged spinach processed at Earthbound Farms in San Juan Bautista (San Benito County). The outbreak killed four people, sent 103 to hospitals, and devastated the spinach industry.

E-mail Carolyn Lochhead at *clochhead@sfchronicle.com.*

http://sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/07/13/MN0218DVJ8.DTL

This article appeared on page A–1 of the ***San Francisco Chronicle***

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

Mr. Reinhard, welcome to the Committee.

STATEMENT OF ROBERT G. REINHARD, DIRECTOR OF FOOD SAFETY AND REGULATORY AFFAIRS, SARA LEE CORPORATION; CO-CHAIRMAN, TECHNICAL AND REGULATORY COMMITTEE, NATIONAL TURKEY FEDERATION, DOWNERS GROVE, IL

Mr. REINHARD. Good morning, Chairman Peterson, Congressman Goodlatte, and the Members of the House Agriculture Committee. My name is Bob Reinhard, and I will be testifying on behalf of the National Turkey Federation. In the interest of time, I will abbreviate my opening comments to a few short remarks and ask that my entire testimony be accepted for the record.

The National Turkey Federation is a nonprofit trade association representing nearly 100 percent of the U.S. turkey industry. We greatly appreciate the opportunity to provide comments today.

Federal inspection of turkey and other meat and poultry products by the USDA Food Safety Inspection Service has undergone major changes in the last 13 years. The collaborative efforts of the industry and FSIS have resulted in major accomplishments related to food safety and pathogen reduction. Both government and industry have shown they are capable of implementing scientific food safety programs and that a modern science-based inspection service, within the framework of the existing statutes, can be effective.

However, work remains to be done on all sides and there should be a role for Congress to play in this process. Yet, we believe the mindset and commitment that has been established by both the regulators and the regulated has created a foundation for continuous improvement of meat and poultry inspection.

On March 14, 2009, President Obama announced the creation of the Food Safety Working Group to focus on food safety based on the need to improve the existing food safety system. The Food Safety Working Group is chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture. The purpose of the Food Safety Working Group is to provide information to the President on how the food safety system can be modified for the 21st century, a system fostering coordination on food safety issues throughout all government, and to work to ensure the existing food safety laws are enforced.

In the last week, the Food Safety Working Group announced several new initiatives founded on three core principles: prevention, strengthening surveillance, and improving response and recovery. The National Turkey Federation supports and believes in these same principles. The use of scientific data analysis is particularly critical in making informed decisions towards the improvement of

our food safety system. To that end the agencies need to continue to strive to have more specific information about attribution, as well as work together to share data, not only with each other, but more broadly with the regulated industry and other interested parties.

HACCP is a science-based food safety system, first implemented in 1998, that clearly has enhanced food safety and public health. HACCP implementation was not always pretty and might not have been so successful without the extensive meetings and consultations between FSIS, industry, and consumers during implementation, along with the effective oversight of this Committee. We bring this up to only caution that any changes to the existing laws and regulations should be done so carefully and all due diligence should be exercised.

Given the nature of this hearing it would not be appropriate to close without discussing H.R. 2749, the Food Safety Enhancement Act of 2009, recently passed by the Energy and Commerce Committee. One thing of note in the bill is the exemption in section 5 regarding products that are inspected under the Meat and Poultry Inspection Acts and the farms raising these products. We applaud the efforts of Chairman Waxman, Ranking Member Barton and the entire Energy and Commerce Committee to include this exemption, and we would encourage Congress to preserve and, if possible, strengthen this exemption as the bill moves through the legislative process.

The opportunity for Congress to pass significant food safety legislation rarely comes along. It is NTF's position that with an opportunity that is presented, legislation should give USDA and FDA additional tools to collaborate with industry, consumers, academia and all other stakeholders to prevent food safety problems from occurring in the first place. Before adding new regulations we strongly encourage this Committee and all Members of Congress to consider whether those—whether that legislation provides measurable public health outcomes.

In closing, it should be reiterated that the U.S. meat and poultry supply is one of the safest in the world; however, the turkey industry recognizes changes could be made to further enhance confidence to the consuming public. As the food safety reform debate moves to the forefront in the Congressional agenda, any changes that are enacted should ensure demonstrable improvements in food safety and public health.

Mr. Chairman and other Members of the Committee, again, let me thank you for allowing the National Turkey Federation the opportunity to provide testimony today. The number one goal of the U.S. turkey industry is to provide safe, wholesome nutritious quality products at an affordable cost to our customers. Thank you very much, and I will be happy to answer questions.

[The prepared statement of Mr. Reinhard follows:]

PREPARED STATEMENT OF ROBERT G. REINHARD, DIRECTOR OF FOOD SAFETY AND REGULATORY AFFAIRS, SARA LEE CORPORATION; CO-CHAIRMAN, TECHNICAL AND REGULATORY COMMITTEE, NATIONAL TURKEY FEDERATION, DOWNERS GROVE, IL

Good morning Chairman Peterson, Ranking Member Lucas, and Members of the House Agriculture Committee. My name is Bob Reinhard and I am the Director of Food Safety and Regulatory Affairs for Sara Lee Corporation. Today I will be testi-

fying on behalf of the National Turkey Federation, as Co-Chairman of the federation's Technical and Regulatory Committee, which oversees all scientific and technical food safety activities for the federation. The National Turkey Federation is a nonprofit, U.S. trade association located in Washington, D.C., representing the entire turkey industry, including local farmers, processors, marketers, retailers and industry allied services. Currently, NTF represents nearly 100 percent of the U.S. turkey industry and we greatly appreciate the opportunity to provide comments today.

The U.S. turkey industry raises more than 260 million turkeys, which after processing represents approximately 6 billion pounds of safe, wholesome, nutritious protein products for domestic and international consumers. Food safety is NTF's number-one priority and federation members' future success is directly linked to customer confidence in the safety of the food supply and turkey products. Since the inception of the National Turkey Federation in 1940, science-based food safety has been an industry priority and over the years the membership has agreed food safety is an issue on which they would cooperate, share best practices, and developing science-based, state-of-the-art food safety interventions from the farm to the consumer.

Federal inspection of turkey and other meat and poultry products by the USDA Food Safety Inspection Service (FSIS) has undergone major changes in the last 13 years, and the collaborative efforts of industry and FSIS have resulted in some major accomplishments related to food safety and pathogen reduction. Both the government and industry have shown they are capable of implementing scientific food safety programs and that a modern, science-based inspection system within the framework of the existing inspection statutes can be effective. However, work remains to be done on all sides, as we will discuss momentarily, and there should be a role for Congress to play in this process. Yet, we believe that the mindset and commitment that has been established by both the regulators and the regulated has created a foundation for the continuing improvement of the meat and poultry inspection.

Going back more than a decade, it was a coalition from the food industry that included the National Turkey Federation, which petitioned the USDA's FSIS for a preventive, science-based food safety system and in 1996 FSIS promulgated the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) requirements. With this "HACCP rule," which was implemented by industry in 1998, certain naturally occurring pathogens in raw meat and poultry products were identified as potential food safety hazards and if those hazards were likely to occur, process controls to eliminate or control those hazards were implemented at the production facility. Further, a processing establishment was also required to have programs for ensuring they maintain the highest sanitary conditions in their facility, known as Sanitation Standard Operating Procedures (SSOPs). We feel these programs have been highly successful, but again recognize that further progress is and can be accomplished.

On March 14, 2009, President Obama announced the creation of a Food Safety Working Group (FSWG) to focus on food safety based on the need to improve the existing food safety systems. The FSWG is chaired by the Secretaries of the Department of Health and Human Services and the Department of Agriculture. The purpose of the FSWG is to provide information to the President on how the food safety system can be modified for the 21st century, assist in fostering coordination on food safety issues throughout all of government, and to work to ensure that existing food safety laws are enforced.

In the last week, the FSWG announced several new initiatives, founded on three core principles: prevention, strengthening surveillance, and improving response and recovery.

Examples fostering these principals, which were shared by the Secretaries included:

- Preventing harm to consumers;
- Food safety inspection and enforcement dependent on data and analysis; and
- Outbreaks identified quickly and stopped.

Industry supports and believes in these same principles. The use of scientific data analysis is particularly critical in making informed decision towards the improvement of our public health system. To that end, the agencies need to continue to strive to have more specific information on attribution, as well as work together to share data, not only with each other but more broadly with the regulated industry and with other interested parties.

The industry is confident and optimistic that the White House FSWG, the Secretary of Agriculture, and the Secretary of Health and Human Services will con-

tinue to take a leadership and preventive role on food safety issues and work to break down barriers in working across different government agencies. The FSWG should monitor implementation of their recommendations, as well as ensure coordination of food safety policies between the different parties overseeing the implementation of recommended measures.

At this point, it is very important to note, HACCP and SSOPs have yielded significant and measurable successes, as shown by USDA FSIS pathogen testing data. Specifically, on an annual basis, the Office of Public Health and Science analyzes more than 125,000 products and conducts more than 650,000 combined analyses on these meat and poultry products and in the processing environment in federally inspected establishment. These FSIS analyses include testing for chemical and biological food safety hazards, including pathogens of public health concern like *Listeria monocytogenes* and *Salmonella*. Using this scientific quantitative data as a benchmark, since turn of the century (2000 to 2007) we have seen a 74 percent reduction in the incidence of *Listeria monocytogenes* in ready-to-eat meat and poultry products. Additionally, since an initial baseline study by FSIS in 1996 on *Salmonella* prevalence on raw turkey carcasses, we have seen a 64 percent reduction in this pathogen's presence. However, we need better attribution data to confirm what our best instincts tell us—that these food safety improvements have a correlation to the decline in foodborne illness. The development of attribution information will be of critical importance as we continue to make improvements in food safety.

We share this information to show that we are not in need of re-building a system, but in need of enhancing a system that is already working. Everyone wants to do better, but we need to build on our successes and use data with attribution information to drive the changes that will lead to improvements in public health.

Modernization

HACCP is a science-based proven food safety system that has enhanced the safety of the meat and poultry products produced in the United States. And since initial implementation in 1998, there have been ongoing efforts to improve the way regulatory oversight is executed and how a processing establishment performance is measured. During HACCP's implementation period in 1998, FSIS hosted numerous public meetings across the country and provided countless supporting documents to assist the regulated entities in achieving compliance with the new requirements. The process was phased-in based on plant size, with specific focus on small and very small establishments. Today, all federally inspected meat and poultry establishments have implemented a hazard analysis and preventive control system.

We bring this up to only caution that any such changes to the existing laws and regulations should be done carefully and all due diligence should be exercised. Any changes to the existing statue should be done with a scalpel, not an axe, to ensure that the current level of inspection is not compromised.

When the current food safety statutes were passed, no one envisioned HACCP, yet the law proved flexible enough to accommodate it. As science and technology improves, it is highly plausible that the food safety inspection process would and should be improved as well. Changes to FSIS and FDA statutory authority should not be so prescriptive that they stifle innovation and prevent industry, the Secretary of Agriculture, or the Secretary of Health and Human Services from making science-based improvements with definable public health outcomes that are deemed appropriate. Currently, as reiterated by the White House FSWG, FSIS has embarked on further refining its inspection process using science, risk and other appropriate data. The agency has been moving to utilize public health risk in determining how to best utilize their inspection resources. In today's economic environment, it is prudent that the government and industry focus more of their limited resources toward processes to prevent food safety concerns and that we focus specifically on interventions that have a measurable outcome related to public health. This clearly is the way of the future. FSIS' efforts offer instructive lessons for anyone interested in food safety. All food safety systems should be designed to manage and reduce risk to the food supply. Congress may want to consider giving FSIS expanded authority to allocate inspection resources according to risk so that inspectors are focused most closely on those tasks that will have the biggest impact on food safety. For example, federally inspected establishments could be allowed to share bird-by-bird inspection duties in a joint effort, working with and under the close supervision of FSIS employees to assure the safety of poultry caresses. Such a system would permit inspection resources to be shifted to inspection processes that have a higher risk related to food safety and a measurable public health outcome.

Current Legislation

Given the nature of this hearing, it would not be appropriate to close without discussing H.R. 2749, the "Food Safety Enhancement Act of 2009" recently passed by the Energy and Commerce Committee.

One thing of note is the exemption in Section 5 regarding products that are inspected under the Meat and Poultry Inspection Acts and the farms raising these products. We applaud these exemptions and the efforts of Chairman Waxman, Ranking Member Barton and the entire Energy and Commerce Committee to include this exemption, and we would encourage Congress to preserve and, if appropriate, strengthen the exemption as the bill moves through the legislative process.

The opportunity for Congress to pass significant food safety legislation rarely comes along. It is NTF's position that with an opportunity like what is presented; legislation should give USDA and FDA additional tools to collaborate with industry, consumers, academia and all other stakeholders to prevent food safety problems from occurring in the first place. Before adding new regulations, we strongly encourage this Committee and all Members of Congress consider whether legislation provides measurable public health outcomes.

In closing, it should be reiterated that the U.S. meat and poultry supply is one of the safest in the world. However, the turkey industry recognizes changes could and should be made to further enhance confidence in the consuming public. As the food safety reform debate moves to the forefront of the Congressional agenda, any changes that are enacted should ensure demonstrable improvements in food safety and that a measurable public health outcome is achieved.

Mr. Chairman and other Members of the Committee, again, let me thank you for allowing the National Turkey Federation the opportunity to provide this testimony today. The number one goal of the U.S. turkey industry is to provide safe, wholesome, nutritious, quality products at an affordable cost to our customers. Thank you very much and I will be happy to answer any questions.

The CHAIRMAN. Thank you very much, Mr. Reinhard, for your testimony.

Mr. Maravell, welcome to the Committee.

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

Mr. MARAVELL. Thank you, Chairman Peterson and Members of the Committee. I am Nicholas Maravell, an organic farmer for the past 30 years. I appreciate the opportunity to provide testimony on H.R. 2749 especially with regard to organic, sustainable, and family-sized operations and on-farm value-added processing. I own and operate Nick's Organic Farm located in Montgomery and Frederick Counties, Maryland. I have 170 acres in production. We raise grass fed Angus beef, pastured chickens and turkeys, free range eggs. We sell various types of mixed hays. We produce field corn, soybeans, barley, rye grain, and hairy vetch. We grow fresh vegetable soybeans.

We operate a diversified and integrated farm, raising several types of crops and types of animals together. As an ecologically-based operation, we rely on crop and animal diversity and longer and more varied crop rotations to build a farming system that stands up to the test in good times and in bad, while maintaining or improving the quality of our soil and our environment. We are not highly concentrated in one product. Our diversity allows us to design a system where the parts work well together. Our marketing strategy must complement our production diversity. Given our small size and our varied product mix we must add value on the farm to be economically viable.

We do this by making the products organic, by selling about 90 percent directly to the final user and by on-farm processing. We process our own organic chicken and turkeys, pack our eggs and

vegetable soybeans, condition organic seed, and grind our grains into poultry feed. In most cases, we are only one step down from the final consumer. This direct personal marketing relationship allows us to develop trust with our customers based on full accountability and traceability. The customer has no doubt where to find accurate information about our operation or products.

What concerns me most about this bill is that could be perilously close to making our nation's food safety more difficult to achieve in the long run. While the Food Safety Enhancement Act of 2009 will have some positive impacts it will also have unanticipated consequences. In my opinion, as a farmer, this legislation needs more refinement before going forward. Over the last 30 years I have seen tremendous growth and vitality in small and diversified farms, in on-farm value-added processing, and in decentralized direct to consumer marketing channels. None of these growth areas have been associated with major food safety issues. These innovations and alternatives to the mainstream food system have already implemented transparency and connection between the producer and the consumer. As long as they provide safe food these approaches should be given incentives, not barriers, to continue their growth by adding new entrepreneurs and expanding existing operations.

As a certified organic grower and on-farm processor, I already meet the major concerns raised in this bill. To have to meet them again would be cost and time prohibitive. I have attached an analysis of the food safety aspects of the organic certification program.

To the extent that this bill does not recognize and encourage diversity in our food system; to the extent this bill economically favors further industry consolidation and centralization, because smaller more diverse operations cannot efficiently meet the added regulatory costs, restrictions and burdens; then our food supply becomes more susceptible to large shocks whether from unintended contamination or from bioterrorism.

Another concern with this bill is its one-size-fits-all solution to food safety. The flat $500 registration fee is an example. For modest family-sized operations that may conduct only minimal and occasional processing, the cost and ensuing paperwork are very burdensome. Estimates indicate the vast majority of fees to be generated under this bill would come from facilities with gross sales of under a million dollars. And yet the vast volume of food with potential safety weaknesses is concentrated in operations generating more than $1 million in sales. If true, then smaller operators are being asked to disproportionately pay for the monitoring of larger operations. This is fundamentally unfair, I repeat, fundamentally unfair.

I have specific recommendations in my written testimony on, one, a revised fee structure; two, taking into account fees already paid and data already collected; three, the need to make explicit all of the exemptions that would apply to farms; four, the need to specify explicit coordination with the USDA Secretary in certain sections; and, five, additional language for safety standards to ensure small scale diversified and organic producers would be able to continue their practices in a safe economical and responsible manner.

[The prepared statement of Mr. Maravell follows:]

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

Mr. Peterson, Mr. Lucas, and Members of the Committee, I am Nick Maravell, an organic farmer for the past 30 years.

I appreciate the opportunity to provide testimony on H.R. 2749 regarding food safety to an Agriculture Committee.

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, and in all my years of organic production and on-farm processing, I have never had a food safety issue or problem arise. I would like to offer a few observations and recommendations which I believe should shape the House Member's thinking regarding changes to the food safety policy contained in H.R. 2749, especially with regard to organic, sustainable, and family sized operations and on-farm value added processing.

We raise grass fed Angus beef, pastured chickens and turkeys, and free range eggs. We grow and sell various types of mixed 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.

We operate a diversified and integrated farm, raising several types of crops and types of animals together. As an ecologically based operation, we rely on crop and animal diversity, and longer and more varied crop rotations, to build a farming system that stands up to the test in good times and bad, while maintaining or improving the quality of our soil and environment. We are not highly concentrated in one product, such as beef or dairy, or in two or three main cash crops. Our diversity allows us to design a system where the parts work well together and require little re-direction once the system is established.

Our marketing strategy must complement our production diversity. Given our small size and our varied product mix, we must add value on-farm to be economically viable. We do this by making the products organic, by selling about 90% directly to the final user, either a consumer or another farm, and by on-farm processing. We process our own organic chickens and turkeys, pack our eggs and vegetable soybeans, condition organic seed, and grind our grains into poultry feed. Our beef is processed off the farm under USDA inspection. In most cases, we are only one step down from the final consumer. This direct personal marketing relationship allows us to develop trust with our customers through accountability and traceability. The customer has no doubt about where to find accurate information about our operation or products.

Observations on Food Safety Provisions in H.R. 2749

What concerns me most about this bill is that it could be perilously close to making our nation's food safety more difficult to achieve in the long run. While the Food Safety Enhancement Act of 2009 will have some positive impacts on the safety of our nation's food supply, it will also have some unintended consequences. In my opinion as a farmer, this legislation needs more refinement before going forward. I do not make this statement lightly or out of self-interest, but out of deep concern for the ultimate safety and security of our country's food supply.

Over the last 30 years, I have seen tremendous growth and vitality in small and diversified farms, in on-farm value added processing, and in decentralized direct to consumer marketing channels. Growth of farmers markets, community supported agriculture (CSAs), the Buy Local and Slow Food movements, and the expansion of organic and sustainable food and farming practices have given the consumer many choices. None of the growth areas, especially those direct-to-consumer areas, have been associated with major food safety issues. Part of the reason for this safety record has to do with the approaches they take to producing, processing, and marketing food. These approaches represent innovations and alternatives to the mainstream food chain because, at the core, they have already implemented transparency and connection between the producer and the final consumer. As long as they provide safe food, these approaches should be given incentives, not barriers, to continue their growth by adding new entrepreneurs and expanding existing operations.

To the extent that this bill does not recognize and encourage the diversity in our food system, to the extent this bill economically favors further industry consolidation and centralization because smaller more diverse operations can not efficiently meet the added regulatory costs and burdens, then our food supply becomes more susceptible to large shocks—whether from unintended contamination or from bioterrorism.

In my case, as a certified organic grower and on-farm processor, I already meet the major concerns raised in this bill. To have to meet them again through an addi-

tional program would be cost and time prohibitive. I have attached a detailed analysis prepared by the Organic Trade Association which shows the food safety aspects of the USDA organic certification program that are already in place.

Fees and Registration

Another of my concerns with this bill is that it proposes to legislate a "one size fits all" solution to food safety. The flat $500 registration fee structure is one good example of this approach. For larger corporate facilities, this fee may be insignificant. For modest family sized operations that may conduct only minimal and occasional processing, the cost and the ensuing paperwork are very burdensome. Estimates indicate the vast majority of fees to be generated under this bill would come from facilities with gross sales of under $1 million, and yet the vast volume of food with potential safety weaknesses is concentrated in operations generating more than $1 million in sales. If the Committee can determine that this situation is true, then smaller operators are being asked to disproportionately pay for the monitoring of larger operations. This is fundamentally unfair. I repeat, fundamentally unfair. My recommendation is to charge no registration fees for operations with sales less that $500,000, to charge a $250 fee for facilities with sales between $500,000 and $1million, and to charge appropriately scaled fees for facilities with sales of over $1 million.

In my case, I already pay modest fees and am already registered for most aspects of my food production and on-farm processing operations with the Maryland Agriculture and Maryland Health Departments and with the Federal level through my USDA organic certification program. Again, treating all operations as "one size fits all" ignores other state and Federal programs already in place and leads to potentially unnecessary costs and paperwork burden. I recommend the Secretary of HHS, with explicit coordination with the USDA Secretary, be directed to take into account fees already paid and data already collected to accomplish the purposes of registration and data collection wherever feasible.

Exemptions

In an attempt to make policy appropriate to the type and scale of food production and processing activity, the bill provides for some exemptions, particularly for farms that meet certain conditions and for livestock programs administered by USDA. I know the exemption provisions rely on the definitions of "facility" contained in the Bioterrorism Act of 2002 and regulations at 21 CFR 1.226 and 227. I also know that, in at least one instance, a Federal court has interpreted the definition of food to apply to livestock, creating a fuzzy line between USDA and FDA program jurisdiction. I am not sure what aspects of my farm production and on-farm processing will be exempt from Sec. 414—Maintenance and Inspection of Records (including Tracing System for Food); Sec. 415—Registration of Food Facilities; Sec. 418—Hazard Analysis and Risk-Based Preventative Controls; Sec. 418A—Food Safety Plan (and associated compliance with Sec. 419—Performance Standards). I recommend that the language of this bill make all the exemptions explicit so that farmers and processors know what exactly to expect. I further recommend that this bill state explicitly that the definition of "food" in the Food, Drug, and Cosmetic Act (FDCA) does not apply to livestock. This latter recommendation is made notwithstanding the jurisdictional division already contained in the FDCA and this bill regarding USDA's livestock inspection programs.

Explicit Coordination With USDA

As a farmer, I am concerned that the bill does not seem to utilize the expertise of other agencies, especially the USDA. Vast new authority is given to the Secretary of HHS regarding areas in which USDA has relevant expertise:

Sec. 403 (i)—Quarantine of Geographic Location

Sec. 414(c)—Tracing System for Food

Sec. 419A—Safety Standards for Produce and Certain other Raw Agricultural Commodities

I recommend that the bill specify that the Secretary of HHS explicitly coordinate policy in these areas with the Secretary of USDA.

Safety Standards

I strongly endorse the language in 419A(b)(7), (8) and (9) which permits flexibility, coordination, and could prevent duplicative efforts by (i) recognizing the special impacts on small-scale and diversified farms, wildlife habitat, and organic production methods, (ii) allowing coordination for education and training with other entities that have experience working directly with farmers, and (iii) allowing the HHS Sec-

retary to recognize other publicly available procedures and practices to implement safety standards. I would recommend adding the words "direct farmer to consumer distribution channels" to the impacts listed in paragraph (7). If combined with explicit coordination with the USDA Secretary, these provisions would help ensure small scale, diversified and organic producers would be able to continue their practices in a safe, economical, and responsible manner.

ATTACHMENT

Organic Production and Handling – Food Safety Reform:

An emphasis on avoiding both chemical contaminants & pathogens

July 13, 2009

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy (www.ota.com).

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Fact Sheet: Introduction to Organic Production and Handling

All products that are marketed and sold as "certified organic" in the United States must meet the requirements of the Organic Foods Production Act of 1990 (OFPA),[1] This statute, part of the Farm Bill of 1990, required the U.S. Department of Agriculture (USDA) to published regulations governing the entire system of organic production and processing. The regulations cover crops and livestock on the farm and any processing and handling of products to create a far-reaching and innovative set of regulations. Organic producers and handlers are also required to comply with all local, state and federal laws and regulations.

Organic refers to how farm products are grown, processed and handled, and use of the term *organic* on the label of a food or beverage product denotes that it meets or exceeds U.S. national organic standards. Organic producers and processors must adhere to rigorous growing and processing standards, and farms and processors must have their organic system plans and their facilities inspected at least annually by an agent of the USDA, an accredited certification agent. There are 98 accredited certification agencies in operating globally.

All certified organic farms and production facilities are registered with the U.S. Department of Agriculture, and USDA accredits third party certifiers to the National Organic Standard/Program.

As labeling terms, *organic* and *natural* are not interchangeable.

As noted, all applicable local, state and federal requirements for food safety are followed on organic farms and processing facilities, additionally, there are some unique processes required in organic farming and manufacturing that could assist in consideration of food safety legislation:

There are some unique perspectives and points of organic farming and manufacturing that deserve consideration when food safety legislation is being crafted.

- The organic system is built on third-party certification, audit trails/ traceability and inspections.
- The organic regulation includes a process to review and approve or disapprove new materials, processes and methods as they come to market.
- Organic compliance begins on the farm, and any processing or handling must maintain that integrity all the way through the food chain to the consumer.
- Manure use on organic farms is strictly regulated by the organic standards to substantially minimize the potential for contamination of crops.
- Organic farms build healthy soils without the use of toxic and persistent pesticides and chemical fertilizers, and without the use of sewage sludge.

[1] USC Code

Fact Sheet: Unique Food Safety Characteristics of Certified Organic Food

The organic industry takes food safety seriously and embraces Congressional efforts and their intended outcome of a safer food supply.

As a certified process, the organic food industry is uniquely positioned to respond to food safety requirements in ways that are not in effect in other food sectors. The organic foods industry has legally mandated safeguards that contribute to food safety for consumers, including full food product traceability, accountability of food production methods, and strict controls on known potential sources of food contamination such as manure and toxic, synthetic pesticide residues. Organic producers and handlers are already familiar with planning, regulatory oversight, third-party certification, and independent inspections. Certified organic growers follow strict guidelines for organic food production and, as with all food producers, they must comply with local, state and federal food safety and health standards. Familiarity with these requirements positions the organic sector well in terms of complying with future efforts to improve food safety systems in the U.S.

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, i.e. manually or electronically. The record keeping system is outlined in the organic system plan. Independent third-party onsite inspections verify each of these organic system plans and their implementation annually, thus providing excellent accountability. Ultimately, regardless of scale or type of farming operation, every operation must understand and addresses its specific on-farm risks.

1) **All organic farmers and processors are registered with the U.S.D.A.**

   As required by the National Organic Program regulation sub-section §205.100 – What has to be certified, each production or handling operation or specific portion of a production or handling operation that produces or handles organic products must be certified according to the provisions of the certification section. Certification agents are accredited by the U.S.D.A.

2) **Third-party oversight. All organic producers and handlers are subject to oversight by third-party certifiers accredited by the U.S.D.A.**

   As required by the general requirements for certification sub-section §205.400 – Any entity seeking to maintain organic certification must comply with "the act" and establish and implement, and update annually an organic production and/or handling system plan that is submitted to an accredited certifier.

3) **Inspections of organic operations**. All organic producers and handlers are subject to initial and annual on-site inspections. Additionally certifiers may conduct additional announced or unannounced inspections to determine compliance with the governing organic standards.

As required by the general requirements for certification sub-section §205.403 – On site inspections.

4) **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. Authorized entities, accredited certifiers, maintain and have access to full chain traceability.**

As required by the National Organic Program regulation sub-section §205.103– recordkeeping, all certified operations must maintain records pertaining to the production, harvesting and handling of agricultural products intended to be sold as organic. Records must document all activities and transactions in sufficient detail to be audited and must be maintained for a minimum of five years. Records must be made available for inspection (announced or unannounced) by representatives of the Secretary of Agriculture, applicable State program's governing official, or the certifying agent. 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.

5) **Organic is the only segment of agriculture that has rigorous national regulations regarding the application of manure on farms.**

Organic food production is the only segment of the food industry where animal manure is strictly regulated as an input to agriculture for purposes of safety. The U.S. regulations for organic production impose strict requirements for the use of animal manure if it is used on the farm. The regulations require that raw animal manure must be composted unless it is applied to land used for a crop not intended for human consumption; or is incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with soil; or is incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles. See 7 CFR 205.203 (c) (1) and (2). The purpose of these restrictions is to substantially minimize the potential for contamination of organic crops by raw manure.

6) Compost made with animal manure must meet temperature, mixing, and time requirements to ensure its safety.

The requirements for making compost are well regulated and are designed to encourage soil health while minimizing risks to human health or the environment. The National Organic Program Rule defines compost (7 CFR 205.2) as follows:

Compost: The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial Carbon:Nitrogen ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 deg. F and 170 deg. F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 deg. F and 170 deg. F for 15 days, during which time the materials must be turned a minimum of five times. The purpose of these requirements is to substantially minimize the ability of human pathogens to survive the composting process and pose a food safety problem with the organic crop.

7) Organic farmers are required to maintain or improve soil and water quality.

As required by the National Organic Program regulation sub-section §205.200 - Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality. Additionally, sub-section §205.203 soil fertility and crop nutrient management practice standard requires a producer must manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

8) Organic production permits anti-microbial steps to be taken to lower pathogen contamination

Pasteurization, restricted use of chlorine and hydrogen peroxide, equipment sanitation, and other food safety practices are also utilized by organic food producers and handlers to assure the safety of organic foods. These processes are permitted under the National Organic Program.

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

As required by the Organic Production and Handling Requirements sub-section §205.238 – Livestock healthcare practice standard, healthy living conditions and attentive care are considered first steps in the prevention of illness. Therefore, animals must not be overcrowded, and must be allowed periodic access to the outdoors and direct sunlight. Antibiotics are not used to treat organically raised animals in the United States, and if, for humane reasons, an animal must be treated with an antibiotic, then it is removed to a conventional herd, and not returned to organic status.

10) **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 non-mammalian animal by-products to be fed to cattle and vice versa.

Steps taken to ensure regulatory compliance can be considered "organic control points" similar to the "critical control points" considered in hazard analysis. Some of these are detailed and directly transferable to food safety issues, such as the documentation of the non-use of prohibited materials and the plans for compost and manure management. With these systems and documentation protocols in place, the organic system offers an integrated process approach to preventive food safety practices that could stand as a national model for both farming and manufacturing operations. The organic process already contains many steps that contribute to food safety processes and it can be easily integrated into a more elaborate food safety system – especially in processing.

Fact Sheet: Food Safety Legislation and the Organic System

The Organic Trade Association (OTA) fully supports reform in food safety. The organic system includes accredited third-party oversight and audit-trail systems, and OTA fully supports the use of these practices in food safety protocols.

There are some unique perspectives and points of organic farming and manufacturing that deserve consideration when food safety legislation is being crafted.

Concerns

1) **Legislation should not require materials or processes that are prohibited for use in organic production**

   Any new food safety legislation should avoid prescriptive requirements that could mandate use of materials or technologies that are prohibited for use in organic agriculture and processing, such as irradiation. A focus on outcome goals will allow organic farmers and processors to meet both important food safety standards and the standards set by the National Organic Program.

2) **Legislation should not disproportionately affect small businesses**

   Like agriculture as a whole, many organic farmers are small farmers. Many problems in food safety occur at the national or international level. Legislators should be careful in assessing the root causes of food safety problems when crafting legislation. Similarly, protocols such as costly tests that work for organizations that are able to fund major programs might not be feasible for the large number of small farmers in the country. See OTA's comment on the Leafy Greens Marketing Agreement: (http://www.ota.com/pp/otaposition/frc/amsleafygreens.html).

   Another issue within this concern is how to handle sales that are directly from the farmer to the consumer as in farmer's markets, Community Supported Agriculture (CSA) or on the farm sales. Additionally these small farms are supplying regional supermarkets, restaurants, and processors. This is an area of trade that is more and more integrated into the overall food supply, and supports a growing number of organic farmers, and legislation should not put excessive burdens on this avenue to local economic development.

Organic farmers and processors are permitted to keep records in hard copy or electronically, and small operations may not even own a computer. Therefore, solely electronic record keeping could be a strong deterrent to organic production.

3) **Legislation should focus on prevention through process controls rather than post-contamination remediation**

Although we applaud the current draft pieces of legislation for including this perspective, there may be those who find business easier to manage through promotion of, for example, irradiation to ensure the safety of beef products. Not only is this an approach which is not geared to preventing contamination, irradiation is prohibited in organic production, so this approach would not work for the growing organic meat sector.

The same point should be applied to the use of sterilizing materials to clean up prior contamination—the emphasis should be on preventive process controls.

4) **User fees would add to the financial burden of prior compliance with the organic regulation and could be largely duplicative in the case of organic operations, most of which spend considerable money to be certified**

Again, many organic farmers are small farmers, and many organic processors are small businesses. If user fees are included, consideration should be given to the existing system of organic regulatory compliance, which includes inspections. Organic operations should not pay twice for oversight that could include both organic certification and food safety inspections.

5) **Registration for certified organic farmers would be duplicative; any such requirement should simply direct FDA to consult with USDA regarding certified organic operations**

The certification and inspection of organic operations is a complex and demanding process, well beyond simple registration. OTA urges legislators to require cooperation between FDA and USDA to minimize the regulatory burden on small organic businesses, whether farms or manufacturers. Organic operations should not pay twice for organic certification and food safety registration.

6) **Traceability requirements for organic farmers and processors would also be duplicative.**

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. Authorized entities, accredited certifiers, maintain and have access to **full chain traceability**.

> As required by the National Organic Program regulation sub-section §205.103– recordkeeping, all certified operations must maintain records pertaining to the production, harvesting and handling of agricultural products intended to be sold as organic. Records must document all activities and transactions in sufficient detail to be audited and must be maintained for a minimum of five years. Records must be made available for inspection (announced or unannounced) by representatives of the Secretary of Agriculture, applicable State program's governing official, or the certifying agent.

7) Food safety issues are not limited to microbial contamination

> Consumer concerns regarding safety of the food supply are broader than microbial contamination. They include heavy metals, pesticide residues, the use of synthetic hormones and antibiotics in livestock production and various other substances. A full assessment of the safety of the food supply should address non-microbial contamination as well as microbial contamination as they relate to public health.

The CHAIRMAN. Thank you very much, Mr. Maravell. We appreciate your being with us.

Mr. McDonald, welcome to the Committee.

STATEMENT OF DREW McDONALD, VICE PRESIDENT, NATIONAL QUALITY SYSTEMS, TAYLOR FARMS, SALINAS, CA

Mr. MCDONALD. Good morning, Chairman Peterson, Mr. Goodlatte, and Members of the Committee. My name is Drew McDonald, and I am Vice President of the National Quality Systems for Taylor Farms in Salinas, California. Thank you for allowing me the opportunity to testify today.

We are the world largest salad and fresh cut vegetable processor, with ten processing plants operating in seven states and Mexico. Taylor's valued network of local, independent family-run farms who supply produce to extend across more than a dozen states as well as from outside the United States, in Canada, Chile, and Mexico. We provide fresh healthy products to a hundred million Americans, to provide enjoyment and promote healthy lifestyles. We are also active in the major produce trade organizations, including United Fresh Produce, Western Growers, and Produce Marketing Association.

I want to start out by saying that the fresh produce industry has been at the forefront of developing comprehensive food safety programs for many years. The industry has worked side by side with Federal Government regulators and scientists as well as academia to develop best practices and extensive commodity-specific guidelines for various produce items. My written statement outlines a number of challenges that are important for the Committee to consider.

Today I would like to focus on three areas of great concern. First of all, audit cost and consistency. One of our greatest challenges is agreed-upon standards for food safety audits. Without a government-endorsed standard the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. In addition, many producers are financially challenged to comply with these requirements, and perhaps most importantly, it's not clear that the increased cost of these audits result in better compliance or safer food.

Next, under the topic of accountability and transparency, over the last few years regulatory requirements have spurred industry improvements in the areas of prevention and traceback. The primary focus has been on prevention of foodborne disease and experts agree this is the most important investment. The key to this has been stronger industry-government collaboration. One very good example of this is the California Leafy Greens Marketing Agreement. This was implemented following the spinach outbreak a few years back. It provides an excellent model that achieves a HACCP-like risk-based approach. It enforces measurable food safety mitigation steps from growing to processing.

Under the program produce handlers are audited by USDA trained inspectors to ensure that they are complying with the standards. It is a model approach that involved industry coordination with FDA, CDC, CDFA, and university food safety experts. It is not an easy, task but it is a critical in preventive measures and

provides assurance to the public that our industry is doing everything we can to make our products safe.

Now, concerning the current Congressional efforts on food safety, the fresh produce industry has been a leading proponent of strong, credible food safety standards. In fact as you know, the industry has developed a set of policy principles that call for mandatory, science based, and commodity specific standards. We are pleased that the consensus in Congress has grown in support of these principles. In particular, the Food Safety Enhancement Act, passed by the House Energy and Commerce Committee, addressed a number of critical issues related to produce, but there are still several issues that Congress needs to consider which will provide a strong foundation for the legislation.

Regarding finished product testing, as someone who deals with testing on a regular basis, I continue to be concerned with the concept of trying to test our way to a safe product. Testing has very process specific implications and the Committee-passed bill contains language on testing that, if implemented, will not improve food safety, but will generate confusion and ultimately costs that do not correspond to enhanced food safety.

Scientists and FDA continue to recommend a HACCP approach with finished product testing as a prudent validation that the process and associated HACCP plan is working. Taylor Farms—we utilize the HACCP plan throughout all our plants and it includes various testing points along the way. The goal must always be on preventing food safety issues during the process rather than trying to detect them after the process. As such, the Federal Government should not rely on testing as a cornerstone for the improvement of safety in our food supply.

Concerning traceback and outbreak investigation, as discussed earlier, efforts to date have focused on prevention. What we have not done enough of is spend time on how to investigate and manage an outbreak when it does occur. FDA and its stakeholders must figure out how we can better address a foodborne illness outbreak to protect both public health and maintain consumer confidence.

Regarding the geographic quarantine, based on recent outbreaks and actions by FDA, we would have serious reservations about the impact that the quarantine power would have on a particular commodity sector or region, and how that impact would do little to actually enhance food safety.

In conclusion, it's in everyone's interest to maintain a safe supply of healthy fruits and vegetables, and starting with the fresh produce industry, we must continue to take responsibility to do all we can. We must provide safe food. Each time any fruit or vegetable is implicated in a foodborne illness outbreak, industry suffers from lost consumer confidence in our industry as a whole and consumer health suffers due to a reduction in the consumption of healthy fresh produce. In the long run this is simply not sustainable and certainly not acceptable. A Federal food safety system must be elevated that maintains the confidence in eating healthy fresh fruits and vegetables, and, yet, can deal with the rare problems without destroying public confidence.

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

[The prepared statement of Mr. McDonald follows:]

PREPARED STATEMENT OF DREW MCDONALD, VICE PRESIDENT, NATIONAL QUALITY SYSTEMS, TAYLOR FARMS, SALINAS, CA

Introduction and History of Taylor Farms

Good morning Chairman Peterson, Ranking Member Lucas and Members of the Committee. My name is Drew McDonald and I am Vice President of National Quality Systems for Taylor Farms Salinas California. We are the world's largest salad and fresh cut vegetable processor with ten processing plants operating in six states and Mexico. Taylor's valued network of independent, family-run farms who supply produce to us extend across more than nine states including California, Arizona, Oregon, Washington, Colorado, New Mexico, Michigan, New Jersey, Florida as well as other countries such as Canada, Chile, and Mexico. We provide fresh healthy products to 100 million Americans each week to provide enjoyment and promote healthy lifestyles.

We are active in the major produce trade organizations including serving on the board of directors for United Fresh Produce Association, Western Growers, and Produce Marketing Association. These organizations have help lead industry efforts to bring safe, healthy, affordable and great-tasting fruits and vegetables to the public.

Taylor Farm Food Safety Investment

Taylor Farms is committed to the development of processes and systems that promote the prevention of product failure. It is our belief that it is both impossible and impractical to inspect quality into a product. As such, we employ a three-stage approach to assure product performance. We start with a development process that clearly defines the requirements of the product. The product is then integrated into our established quality systems where each key step of the process is carefully monitored and controlled. Finally, the product is subjected to a rigorous hazard analysis and incorporated into our company wide HACCP program to insure food safety. Before any product is processed for commercial distribution, quality control points and food safety critical control points have been thoroughly documented and shown to be effective. Subsequent periodic audits and verification of key finished product attributes are conducted to assure the on-going adequacy of the procedures and systems. Together, these programs assure that the products packaged and distributed by Taylor Farms meet our exacting standards for quality, customer performance and food safety day in and day out.

Over the last few years we have invested over $100 million in new, state-of-the-art processing facilities. The Taylor Farms' facilities, operations and work practices have been developed according to Good Manufacturing Practices. These FDA regulations cover the design, maintenance and sanitary operation of our facilities, equipment, processes, storage areas and distribution practices. Each of these areas is audited and results documented on a daily basis by Taylor Farms' staff. These daily audits include both visual inspections as well as random microbiological sampling of equipment surfaces. On a monthly basis, environmental samples are taken throughout the facility to verify the effectiveness of our overall sanitation program. Additionally, Taylor Farms commissions audits by accredited independent auditors to insure a fresh look at our sanitary practices.

What are Some of our Food Safety Challenges

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

Despite this ongoing industry commitment, there continue to be significant challenges associated with preventive control practices along with how the government responds to outbreaks once they occur. Below are few of examples of challenges we continue to see related to food safety.

Audit Consistency and Cost—One of our greatest challenges today is the lack of a consistent and agreed-upon standard for food safety audits. Without that government endorsed standard, different customers demand different food safety audits which are burdensome to our company. Today, the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. Most buyers will only accept the results and certification of certain certification bodies, thus leading to a proliferation of different audits for different buyers. In some cases, the same auditor will visit a facility multiple times to perform different audits to verify compliance with different and potentially conflicting standards. In addition, inconsistencies in audit standards among the different certification bodies have created frustration and confusion, have unnecessarily increased operational costs, and may create an obstacle to training in food safety practices. To date, every effort to create a harmonized set of produce food safety audit standards has only added another set of standards to the list. If third-party certification programs are to be successful, there must be a system in place that requires buying companies to recognize and approve the results of these audits without requiring their own duplicative audits to recognize the same results.

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

Need for Improved Accountability and Transparency—The produce industry has a decades-long history of implementing food safety improvements to prevent both deliberate and unintentional contamination of produce as it makes it way from the field to the retail store or restaurant. We have a commercial interest in ensuring that only safe wholesome fresh fruits and vegetables are delivered to our customers' tables. As a result, industry is driven to constantly improve and refine its own food safety programs and food safety defense capabilities.

In addition, there are legal requirements, such as the Perishable Agricultural Commodities Act, the Bioterrorism Act, and new governmental mandates that call for industry action including the FDA Produce Safety Action Plan and the more recent Food Protection Plan. These Federal actions have spurred industry improvements in the areas of prevention and trace back; each integral parts of comprehensive food safety programs. These efforts, conducted in cooperation and consultation with FDA, DHS, USDA, state departments of health and agriculture and food safety experts, have also resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, and the ability to respond more quickly to outbreaks of foodborne illness.

Yet, as I look at all of the work that has gone into industry driven initiatives along with our collaborations with the government, I am left with an observation that our priority has been almost exclusively on *prevention* of foodborne disease from the farm up through the distribution chain. This is a good thing as both the industry and FDA agree that the most important investment in food safety is on prevention. Accordingly, the industry has implemented best agricultural practices for tomatoes, leafy greens, and other products to prevent contamination, and devoted extensive resources to auditing systems to measure compliance against these standards. However, we also need to focus on the management of outbreaks after they occur. As the industry and government work towards enhancing food safety, what we have *not* done, is spend a commensurate amount of time on how best to investigate and manage an outbreak when it does occur. It is time for government, industry and all stakeholders to figure out how we can better fight a foodborne disease outbreak to both protect public health and minimize damage to consumer confidence and industry profitability. Let me provide some examples.

In recent experiences with outbreaks and during the investigations, it has become clear that no one is in charge, leaving local, state, and Federal officials vying for leadership; various agencies pursuing different priorities; and well-meaning individuals reacting independently to events rather than as part of a coordinated investigation moving forward in a logical and expeditious direction. Local and state governments are usually first to discover illnesses, and are free to draw their own conclu-

sions and issue press releases at any time. But how can CDC or FDA stand by when a state seems to be "more protective" of its citizens? Yet, not just today's experience but past history shows us that premature mistakes have consequences. When local officials first blamed strawberries for a cyclospora outbreak in the mid 1990s, their advice may have actually pushed consumers to eat more raspberries that were eventually found to be the cause.

The government's failure to use industry's expertise in outbreak investigations is one of the most important problems we have today. There is an abundance of knowledge in the industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves.

Finally, every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing." In the cases such as spinach in 2006 and then tomatoes/peppers from last summer, it seems that internal agency decisions on when to warn the public, how broadly to make a warning, and what specifically to advise, are based as much on fear of being second-guessed rather than careful risk analysis. That inevitably leads one toward extreme measures—in effect banning all spinach, tomatoes or peppers—in the quest for zero risk of immediate illness. But, is such a consumer message truly without risk, when it needlessly scares the public away from a healthy food that may help prevent disease? We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot.

Stronger Industry/Government Collaboration—No company can take food safety for granted because when an outbreak occurs it impacts the industry as a whole, and we all suffer. It is incumbent upon us as an industry to do all we can to prevent these outbreaks and to ensure that our products are safe every bite, every time. That is why we should support strong industry and government collaboration to prevent outbreaks from occurring. One example that we think is very important is the California Leafy Greens Marketing Agreement.

The California Leafy Greens Marketing Agreement serves as a means of setting rigorous measurements of safety for leafy greens from this major production region. These science-based standards include careful attention to site selection for growing fields based on farm history and proximity to animal operations, appropriate standards for irrigation water and other water sources that can come in contact with crops, prohibition of raw manure with use of only certified safe fertilizers, good employee hygiene in fields and handling, and of course, strong food safety controls in all processing plants. The program is based on GAPs and essentially serves as a standard risk assessment similar to HACCP. Hazards in the growing and harvest operations have been identified and specific control points have been established. Under the Leafy Greens Agreement, produce handlers are required to ensure that their product is meeting these standards. They are audited by the California Department of Food and Agriculture to ensure that they are complying with these standards. It should be noted that not only are the auditors CDFA employees but they are USDA trained and the process by which they audit is USDA-certified. And, the produce suppliers will face penalties if found not to be in compliance, with the ultimate consequence of not being allowed to sell product if they cannot do so safely. Taking this risk-based process approach involved industry coordination with FDA, CDC, CDFA and university food safety experts was not an easy task for the private industry sector. But we believe this is a critical step in continuing to assure the public that our industry is doing everything we can to make our products safe.

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

tant, and we urge Congress to include a robust research agenda when considering reforming our nation's food safety laws.

We believe that boosting produce safety research is a vital part of reducing risk in the future but we are not waiting for the government to act. Taylor Farms contributed $2 million to the creation of the Center for Produce Safety at the University of California at Davis. This is a public-private partnership that funds applied research directed at the most acute needs of the produce industry's food safety agenda. The food safety regulatory body not only needs to be able to address food safety today but also food safety in the future. This means they need be able to understand the economic and market impacts of food safety, have the means to develop meaning advances in food safety while supporting the industry in commercializing these advances. They must also be a vocal national and international advocate of the safety of the U.S. food supply. Any enhancement of the U.S. regulatory scheme must be driven by a central focus to insure that the U.S. food supply remains the preeminent example of safety and wholesomeness.

Current Legislation Before Congress

Over the past several years, you know that the fresh produce industry has been a leading proponent of strong, credible food safety standards. In fact, the industry has developed a set of policy principles that call for mandatory, science-based and commodity-specific standards. We are pleased that the consensus in Congress has grown in support of these principles, which have largely been incorporated into all major food safety legislative vehicles before the House and Senate.

Let me now turn specifically to the Food Safety Enhancement Act of 2009 which the House Energy and Commerce Committee passed in June. During the debate on this legislation, the Committee addressed a number of critical issues including commodity specific produce standards, flexibility for industry to utilize best practices/innovation in traceability programs, and allowing individual experience for fresh produce processors in developing HACCP based food safety programs. However, there are several issues that Congress needs to continue to consider which will provide a strong foundation for this legislative proposal.

Finished Product Testing—The Committee-passed bill contains language on testing that, if implemented, will not improve food safety but will generate confusion and costs. First, the bill requires that companies include a description of the facilities' environmental and product testing programs. Second, the Secretary would be required to conduct a pilot project and a study to evaluate the feasibility, benefits and costs of collecting finished product testing results from Category 1 facilities that are required to comply with Good Manufacturing regulations. After completion of the study, the Secretary could require the submission of finished product test results of Category 1 facilities that must comply with Good Manufacturing regulations.

As someone who deals with testing on a regular basis, I continue to be concerned that one cannot test their way to a safe product. A 1985 National Academy of Science report came to that conclusion when they recommended HACCP as an alternative to product acceptance testing. Since then, scientists and FDA have recommended finished product testing as a prudent validation that the process and associated HACCP plan is working; neither recommended it as a routine measure of lot safety.

Taylor Farms employs and rigorously maintains a HACCP program for all of our products at all of our facilities. As part of this program, Taylor Farms periodically verifies compliance with and the validity of our Critical Control Points and Pre-Requisite Programs by sampling for indicator microorganisms. It is Taylor Farms' belief that HACCP provides greater security of control over product safety than is possible with traditional product testing. The Taylor Farms' HACCP program was independently developed along the guidelines established by the National Advisory Committee on Microbiological Criteria. This plan is periodically re-evaluated and validated for changes and/or newly available information. All HACCP documentation is maintained at the production site for a period of 365 days after the end of shelf life of the product. When FDA inspects us, which is at least once per year per plant, these programs are review. The Taylor Farms' position on HACCP and finished product testing is consistent with the recommendations of the Joint FAO/WHO Codex Alimentarius Commission, the USDA and the U.S. Food and Drug Administration.

Companies with good food safety plans may decide to do finished product testing for this purpose but, again, this doesn't improve food safety, just verifies the plan is working, and punishes good companies for their surveillance when a positive is found. The bill requires rigorous food safety plans, but I believe the inclusion of finished product testing runs counter to the rest of the bill and will actually discourage

testing. *Where to test, when to test, what to test, and what to test for, are very much product and process specific questions.* There is no blanket answer other than to say do not expect testing in and of itself to distinguish safe food products from unsafe food products. In some instances testing of raw materials may provide more insight into the safety process than finished product testing.

The goal must always focus on preventing food safety issues during the process rather than trying to detect them after the process. From this perspective one might say that finished product lot testing has little to no benefit in an ongoing food safety program. Even the most rigorous microbiological testing programs as outlined by the International Commission on Microbiological Specifications for Foods can only ensure the detection of contamination 95% percent of the time when that adulterant has contaminated over 5% of the lot in question. Traceback on recent foodborne illness outbreaks consistently tell us that contamination levels far lower than 5% are involved, suggesting that finished product testing would have absolutely no impact on the rate of future foodborne illness outbreaks. Congress or the Federal Government should not rely on testing as a cornerstone for the improvement of our food supply's safety.

Funding of Food Safety Requirements—Food safety is a public health issue affecting our entire society and accordingly the cost of any increased Federal regulatory oversight should be borne by U.S. general revenues. Public funding will have the advantage of making consistent funding available for food safety oversight and not be subject to the same inconsistent production that the produce industry faces. The funding structure for the Committee-passed bill uses a both appropriations and mandatory fee-based structure. While the fee structure is more reasonable than where it started, fee increases are pegged to inflation and FDA compensation shortages. The appropriations funding is not. One can envision that, very quickly, facility fees will become the funding vehicle for food safety, shifting fruit and vegetable production in favor of larger, more complex farming operations and away from many smaller operations. This shift could work against product diversity and support for local agriculture, and act as a barrier to entry for smaller operations that today already contribute substantially to the safe and wholesome supply of fruits and vegetables.

Geographic Quarantine—This section gives FDA the power to restrict the movement of food from states or regions if it believes that the type of food presents an imminent threat of serious adverse health consequences or death. While the bill demands that the commissioner or deputy commissioner may take this action only when a food may cause serious adverse health impacts, that evidentiary standard applies only to the particular food. As written, the bill provides no evidentiary finding that comparable food within that region or state carries that a risk of adverse health impacts. Based on recent outbreaks and actions taken by FDA, we would have serious reservations about the intent of this provision and the impact it could have on particular commodity sectors or regions. In particular tomatoes would have qualified under this scenario last summer and thus the entire domestic tomato industry would have been under a nation-wide quarantine. What is more, the bill elsewhere allows FDA to stop distribution of product based on a reasonable belief that it may cause serious adverse health effects, which makes the quarantine language unnecessary. The produce industry supports reasoned action based on science and evidence but we must object to quarantining all growers based on nothing more than conjecture.

In addition, FDA currently, has a number of actions available to them such as a *Public Health Advisory, Import Alert, Detention without Examination* that would allow them to alert the public, if that is necessary. For instance, last year's *Public Health Advisory* press release from FDA recommended consumers not eat tomatoes was strong enough guidance for consumers to stop eating tomatoes while the entire distribution chain to stop moving tomatoes throughout the country. Similar actions occurred in the 2006 spinach outbreak. As discussed above, the bill's mandatory and emergency recalls provisions along with administrative detention authority empower FDA to stop movement of a food product quickly and efficiently. Further, with the new mandate that food companies must incorporate traceability systems, one would conclude that effective traceback/tracefoward system will be implemented to render the need for a Geographic Quarantine Authority unnecessary.

Finally, by providing FDA with the ability to "quarantine" a particular food in a geographic region would be extremely harmful to a multitude of the innocent producers, handlers, distributors, and packers of a particular commodity under this authority and could have a long-term impact on consumer confidence of that region's ability to produce or process safe food. Again, we would cite the tomato situation from last summer and what that could have done for the tomato industry of this country had this been in effect.

Need for Improved Accountability, Transparency, and Industry Partnership—I have already described the need for improved accountability and transparency by FDA during its foodborne illness outbreak responses and recovery activities, and the need for FDA to use industry's expertise in outbreak investigations. None of these is addressed in the Committee-passed bill.

Conclusion

It is in everyone's interest to maintain a safe supply of healthy fruits and vegetables and starting with the fresh produce industry we must continue to take responsibility to do all we can on our own. Each time any fruit or vegetable is implicated in a foodborne illness outbreak, industry suffers from lost consumer confidence in our industry as a whole and consumer health suffers due to a reduction in the consumption of healthy produce. In the long run, this simply is not sustainable and certainly not acceptable. 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. Given the ongoing discussions on health care reform the benefits of fresh produce to the American diet cannot be stressed enough. How many lives can be extended with increased consumption? Imagine how regular consumption of fresh fruits and vegetables can extend quality of life in old age? What if fruits or vegetables are removed from the diet out of fear the consequences will be the cost to society?

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

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

We thank all of the witnesses for their testimony. I would like to announce that we are going to try something new here as of today, because of some—I keep getting tons of questions every time we have been doing things, based on who gets here, and concerns about where you are on the list and whether you got counted on time or not.

So, from now on, or at least for the time being, we are going to recognize Members by seniority, and we will see how that works for a while.

Mr. KRATOVIL. In reverse order.

The CHAIRMAN. You know, I am up for maybe every once in a while reversing the order. I am not opposed to that; I am just trying to make it a little more predictable.

But anyway, Ms. Tucker-Foreman, I was struck—you made a statement that has been made to me by Mr. Dingell that he did not want FDA on the farm, and he did not want to get into our jurisdiction. But having read this bill, there is no way for me to come to any conclusion but the way the bill is in the current form; despite their efforts to try to clarify this, they are clearly, in my opinion, going to be on the farm.

And Dr. Ives, sitting next to you, I think if I heard you correctly, you came to that conclusion, and others brought this up.

So—you are sitting next to each other, so let's try to get to the bottom of this. Why do you think I am wrong? You know, it just—it is kind of like what we have been involved in here with the SEC and the CFTC, where these folks that want to take the CFTC that never caused any problem at all—that didn't have any collapses in this financial crisis—and give them to the SEC, which screwed everything up.

Now, I would not say that FSIS is perfect or that the work that we have done is perfect, but I would argue it is a heck of a lot better than what FDA has been doing. So, where we are coming from here is, we want to be helpful to make FDA more productive, but we think if it gets—if it muddles up the situation, we are actually going to be worse off.

I am going to be meeting with Mr. Dingell and Mr. Waxman tomorrow to propose some language to them to clarify this, and we will see whether we can do that.

But would you support further efforts to clarify that?

Ms. TUCKER-FOREMAN. Mr. Chairman, I would not support ever giving FDA any of the authority that USDA currently has to inspect and regulate meat and poultry, the safety of meat and poultry products.

I think their system of HACCP-plus-inspection works reasonably well.

You know that there are other things we want there. FDA has had some authority for on-farm activities as long as I can remember. If they think, for example, that drugs, animal drugs, are being misused, they can go on the farm. There is a reason and they have some expertise at FDA to have them involved in produce safety.

The Agricultural Marketing Services and the Leafy Greens Agreement are completely voluntary. If somebody doesn't want to follow the rules, the only penalty is they don't get to use the label anymore. David Shipman, the acting Administrator of the agency, was before this Committee a month ago saying FDA is the food safety agency and FDA ought to have the primary responsibility for assuring the safety of produce on-farm. And they do have the expertise; they developed draft guidance documents, two of them now over the past several years to do this.

I don't think anybody anticipates that FDA is going to have a flock of personnel out on farms. They have spoken about working with state agencies to enforce these regulations when they get them, and I think that is entirely appropriate.

The CHAIRMAN. Well, thank you.

What I am going to suggest to them is to clarify this in terms of livestock and grain. The food and vegetable people acknowledge there is a place for FDA, and they actually, as part of what we are going to suggest, in making sure that we get that in the legislation. It is a combination of clarifying it for grain farms, livestock farms, and then having the regulation that the food and vegetable people want brought into the legislation in a way that they think is workable. So that is what we are going to try to achieve.

And, I just hope that people will work with us and the Committee will, because if they don't fix this, I am thinking about having a markup and reporting this bill unfavorably if we don't get this resolved.

I don't see any reason why we can't get this resolved. Mr. Dingell seems to want to work with us on this, and we will try to do that.

But, from my reading of this at the present time, in terms of livestock and grain farms, I think there is a potential problem; and we would like to get it clarified.

Ms. TUCKER-FOREMAN. I certainly thought the language was dispositive in maintaining current jurisdiction and exempting any-

thing that is regulated by the Federal Meat and Poultry Inspection Acts.

So I am curious to know what the problems are.

The CHAIRMAN. Well, we can visit about that.

Ms. TUCKER-FOREMAN. Okay. Thank you.

The CHAIRMAN. But my time has expired.

The gentleman from Virginia, Mr. Goodlatte.

Mr. GOODLATTE. Thank you, Mr. Chairman. I would like to follow up on that with the entire panel.

I think everybody agrees that there are some things that can and should be done here to improve food safety. A lot of things are being done, and it is important that the public know that we have, based upon the statistics on foodborne illness, the safest food supply in the world. But there are always going to be ways you can improve on that and help to avoid more of the families that we are seeing here today. So I don't think there is anybody who would disagree that we can do more.

My question to each and every one of you is—and we will start with you, Mr. Wooten—do you support the bill that was reported out of the Energy and Commerce Committee, the Waxman bill, in its current form? Not how you would like it to be, not with some changes you would like to see; do you support it or oppose it in its current form?

Mr. WOOTEN. In its current form, we really have some reservations about supporting it. There are questions that we feel need to be resolved before American Farm Bureau could support this bill.

Mr. GOODLATTE. In its current form then, I take it you would oppose it.

Mr. Boyle?

Mr. BOYLE. Mr. Goodlatte, we have expressed concerns to the Committee, prior to the markup, about a number of the provisions, not so much because of how they would apply to the companies we represent, who are regulated under FSIS authorities, but because of the precedent that they may establish that may one day apply to the companies that we represent.

And I articulated my concerns in both my written and oral testimony. They concern the very prescriptive nature of the HACCP authority that is in that bill, the availability of civil penalties that FDA could apply to food companies under its regulations, mandatory recall.

The user fee precedent is extremely troubling.

Mr. GOODLATTE. I am going to cut you off because I don't have very much time. I have to go all the way down the line, and I have some other questions I want to ask, too.

So in your current form, do you support it or oppose it?

Mr. BOYLE. We have not taken a position in favor or opposition, but we do have concerns about the precedent.

Mr. GOODLATTE. Ms. Tucker-Foreman?

Ms. TUCKER-FOREMAN. The ten organizations I am here representing support the passage of the bill.

Mr. GOODLATTE. Dr. Ives?

Dr. IVES. NCBA does not support the current bill.

Mr. GOODLATTE. Mr. Peppler?

Mr. PEPPLER. National Farmers Union has not taken a position on the bill. And as it is right now, we have some severe reservations on it.

Mr. GOODLATTE. So you would not support it in its current form?

Mr. PEPPLER. Probably not.

Mr. GOODLATTE. Mr. Reinhard?

Mr. REINHARD. The National Turkey Federation has concerns with the bill as it exists and thinks it could be strengthened, but we have not taken an official position to support or oppose the bill.

Mr. GOODLATTE. But you would not support it in its current form?

Mr. REINHARD. We would like to work with the Committee and Congress.

Mr. GOODLATTE. I am not taking that away from you at all. I know that is a concern each and every one of you has. But you don't support it the way it is right now?

Mr. REINHARD. That is correct.

Mr. GOODLATTE. Mr. Maravell?

Mr. MARAVELL. I can speak just for myself, so this is easy.

I have severe reservations about the bill, and I could not support it as is. And I have communicated some of those reservations with my fellow farmers, and tried to communicate those with the Committee and Committee staff as well.

Mr. GOODLATTE. Mr. McDonald?

Mr. MCDONALD. There has definitely been great improvement in it, but at this point we are not in a position to support it.

Mr. GOODLATTE. Okay. All right. Thank you very much.

Let me ask Mr. Wooten, representing the Farm Bureau, is it appropriate for the Food and Drug Administration to establish mandatory food production practices on the farm? And if so, what resources and expertise does the FDA need in order to set and enforce such standards?

Mr. WOOTEN. Well, the FDA obviously is not equipped at this point to look at agricultural practices. We certainly think they ought to work, as one of the witnesses said, closer with those folks that are on the ground, the state agencies, in some type of partnership with the state agencies and, where appropriate, the private industry to make it work.

Mr. GOODLATTE. In your testimony about record-keeping, you expressed concerns about the lack of confidentiality protections in H.R. 2749. What sorts of information are farmers typically worried about being disclosed?

Mr. WOOTEN. It would be difficult. I mean, the types of information that may be disclosed would be production methods, some costs, types of products used. I mean, there would be some real questions there.

Mr. GOODLATTE. Okay.

Dr. Ives, I am concerned about the Waxman proposal for FDA to establish mandatory on-farm production practices.

Is it fair to say that there is a great deal of variety among cow/calf operations? Is it possible for the FDA to write a one-size-fits-all standard for cattlemen?

Dr. IVES. No. You are exactly right, there is a tremendous amount of diversity within our organization, all the way from the

cow/calf through the stocker phases into the feed yard. And there is absolutely no way one size will fit all.

Mr. GOODLATTE. Mr. Chairman, if I might, I have one more question I would like to ask to Mr. Peppler.

In your testimony, you refer to a lack of resources hampering the effectiveness of our Federal food safety system. To the best of your knowledge, has the FDA or the USDA been receiving less funding than they have requested for food safety activities?

Mr. PEPPLER. Could you repeat it again, sir?

Mr. GOODLATTE. Sure.

The question is, you refer to a lack of resources hampering the effectiveness of our Federal food safety system; and I am wondering if you can help us quantify that.

To your knowledge, has the FDA or the USDA been receiving less funding than they have requested for food safety activities?

Mr. PEPPLER. I can't answer that. But I am working off the statistic that on the imported food we are only inspecting one percent of it.

Mr. GOODLATTE. I saw a chart that was put up by Mr. Boyle that showed there were about 8,000 workers inspecting 6,300 facilities related to meat processing, and 1,800 inspectors, less than a quarter, inspecting 136,000 nonmeat or other food processing plants.

Would you say that the biggest disparity, the biggest problem here, exists on the FDA side of not adequately providing the number of inspectors that are needed for those types of facilities?

Anybody else want to try that one?

Ms. TUCKER-FOREMAN. If I could, sir, we certainly agree that the FDA needs additional resources. And in the last year, Congress has begun—in the last 2 years, Congress has begun to give them additional resources.

The biggest problem is that FDA has no specific responsibility to prevent foodborne illness, and they do have an arrangement under law where they have to provide services to meet the user fees that are collected under the drug and device laws.

So part of the reason they don't have the resources is that Congress has set up a system that has sucked the resources out of FDA. But until they have a responsibility to prevent, I don't know that just resources will fix the problem.

Mr. GOODLATTE. Well, I agree that resources alone will not fix the problem. But if you have one inspector responsible for 60 or 70 food processing facilities, it is awfully hard for them to either play a role in food prevention or inspection.

So it is certainly a key ingredient. And, you and I could probably agree on some other things that could be done as well.

Where you and I would disagree is whether that FDA inspector of any kind would be in any way fit to go onto farms and set up systems that would in any way be effective at preventing food illness.

I yield back, Mr. Chairman.

Mr. HOLDEN [presiding.] I thank the gentleman.

Mr. McDonald, there is a company in my home State of Pennsylvania, Hanson Technologies, that has developed technology that can test the wash water of produce for *Salmonella* and *E. coli* at the processing level. Their technology has the ability to perform

screening of the entire produce lot, without culturing, in 2 hours or less after sample collection, which is the fastest, most comprehensive testing available.

And, Mr. McDonald, in your testimony you seem to disagree with final product testing. But do you think that the produce processing industry would benefit from being able to rapidly test for common pathogens? And do you think they should be required to do so in order to verify that their food safety plans are working?

Mr. MCDONALD. Thank you for the question, Mr. Holden.

I actually have pretty intimate knowledge of their process. We have a research facility that we set up with them, and spent more than a month; and I am actually on their advisory board as a technical—in a technical capacity.

And it is a great concept. It is essentially using a biotracer to identify in a very rapid manner.

It is not as simple as a finished product test. In fact, what it really is testing is the water, the wash water, which I agree with to some extent; technically, it is in the right direction. It is a great example, though, where the technology is not quite ready yet for prime time, so to speak.

So we absolutely are looking at those kinds of approaches. Is it the answer that is going to solve it? Any finished product testing, again, it is going to tell you what happened already; and it may have some preventative components, but really what you have to do is go to the process before that.

Mr. HOLDEN. Thank you.

I have one more question for members of the panel. I think Mr. Peppler might have referred to this in his testimony.

Some recommended food safety practices on the farm may be in direct contradiction with good conservation practices. For example, removing wildlife habitat from around farm fields to reduce the possibility of animal contact with produce might be encouraged for food safety purposes, but runs directly counter to environmental conservation principles.

I am just wondering if anyone on the panel has any opinion about that.

Ms. TUCKER-FOREMAN. If I could, sir, there has been some criticism of that in the media just this week.

The complaints that are being made about the sterile borders around fields are steps that have been taken solely in response to private contractual obligations; that is, if you want to sell to a particular company, the farmer says you got—the company says you have to take these steps to make sure that your field is sterile.

We favor a science-based system there. And in fact, one of the requirements in H.R. 2749 is that the FDA establish science-based requirements. That they take into consideration the environmental impact, and that they consult with the USDA in the development of these activities. So this is something we have been extremely sensitive to, because none of us has any interest at all in encouraging practices that would take away important wetlands or wildlife habitat.

But what is happening right now is happening as a result of private contracts. If FDA set standards, it might encourage a change in those private contracts.

Mr. HOLDEN. Anyone else? Mr. Peppler or anyone?

Go ahead, sir.

Mr. MARAVELL. Okay. Thank you, sir.

With regard to organic and various types of sustainable production, we have to have a diversity of habitat in our production system, which would include both wildlife and, for insects, beneficial insects.

So our system is based upon bringing in natural elements that keep pathogens and destructive pests in balance. And if we have to take away those purposefully kept wildlife habitat areas, it would decrease—I mean, we would have to find another way to control pathogens and pests.

Mr. HOLDEN. Mr. Peppler, were you trying to respond?

Mr. PEPPLER. Yes, sir.

I believe in my written testimony there is a copy of an article that talks about exactly what you are talking about, concerning a farmer in California that had a private marketing order and was forced to destroy his environmental buffers around his field.

So, definitely, that would be a concern.

Mr. HOLDEN. Thank you.

Mr. MCDONALD. May I? Is the time up?

Mr. HOLDEN. Briefly.

Mr. MCDONALD. Just very briefly, I agree with Ms. Tucker-Foreman and the other comments.

I will say, having been involved in the Leafy Greens Marketing Agreement, this issue did come up very much in the beginning and quite aggressively. And a lot of it was left, because of misinterpretation of the standards, the marketing agreement went above and beyond that to kind of address it.

It is probably a small percentage at this point. It is something that needs to be addressed, but there is no reason that they can't be—they shouldn't contradict each other. Environmental policy and food safety buffer zones, these kinds of things, should not be in conflict.

Mr. HOLDEN. Thank you.

The gentleman from Kansas, Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you. I yield my time to the gentleman from Texas, Mr. Conaway, who believed he had arrived prior to me, and was entitled to my time.

Mr. CONAWAY. I did point that out to him. I hope that the Chairman will be open to some conversation about his unilateral decision to alter the Committee rules, because it is nice to be able to get here, on time, and sit through the witnesses and listen, and not have some ranking———

Mr. MORAN. Reclaiming my time———

Mr. CONAWAY. Ms. Foreman, in all seriousness, thank you for bringing three examples of heartbreaking stories of where the system either didn't work or couldn't have worked, showing how important it is for us to get this right and setting a backdrop for us to have this conversation. If we have disagreements as to how we get to where we want to get to, it is not because we are callous and heartless and insensitive to the heartbreaks that these three families have suffered as a result of these tragedies, but it will be legiti-

mate differences of opinion between informed individuals where we might wind up.

I am concerned, as some of the others have testified, that particularly when you use the word "anticipate" having a legion of FDA folks running around—legislation doesn't really allow you to write in anticipations. I am worried about the unintended consequences this legislation may have by having FDA reach into the farm prior to conversion of farm products into food, that would be detrimental to the system and the overall regulatory impact that has.

I was curious, Mr. McDonald, you mentioned there weren't any audit standards for the industry to comply with; and yet later on in your conversation, you said the industry had in fact come up with some standards in other areas. And I am curious as to why the processors, the growers, the producers of a particular product that wanted to have an audit system in place so that the buyers could use it and rely on it, wouldn't come up with a voluntary set of standards that the collective group could agree to, and then have that rolled out, as opposed to each company that buys setting up its own standards.

Is it not a possibility for something like that to occur, where the industry itself could self-regulate the process?

Mr. MCDONALD. Yes. Thank you for the question. It is absolutely possible. And that is the example I gave in the Leafy Greens Marketing Agreement.

There is a perfect example where actually not only industry, but industry and government came together, along with academia, to develop standards. Essentially, they took the FDA guides, existing guides, that are very good, and came up with specific metrics that everyone agrees upon, and then using government auditors to actually inspect against.

Mr. CONAWAY. Okay. You had mentioned that there were multiple audits available and that some of the audits—and maybe I misunderstood———

Mr. MCDONALD. Yes. So the first part of it is, there is a redundancy, and numerous amounts of audits that are driven mainly by kind of the buying community, because there isn't an FDA standard approach.

So it is two extremes. You have no standard as far as the government, something that is not very clearly measurable; and then you have a proliferation of third-party audits that are driven by the buying community.

Mr. CONAWAY. I guess that is the group I am focusing on. Why wouldn't that group, along with the growers and the folks that have to comply with those audits, why wouldn't you work through a process so that everybody gets it as close to as workable as you can? And I trust that system far more than I trust FDA coming up with those audit standards.

Mr. MCDONALD. Exactly. And the Leafy Greens Marketing Agreement is that scenario.

Mr. CONAWAY. Okay.

Mr. MCDONALD. It still takes time to get everyone convinced of it.

Mr. CONAWAY. Even though there is the economic reason why it is clearly better. Okay.

Mr. MCDONALD. Absolutely. Yes.

Mr. CONAWAY. Thank you, Mr. Chairman. I yield back. And I appreciate—yield back to the gentleman from Kansas my minute and a half.

Mr. MORAN. Mr. Chairman, I yield back the balance of my time.

Mr. HOLDEN. The chair thanks the gentleman and recognizes the gentleman from North Carolina, Mr. McIntyre.

Mr. MCINTYRE. Thank you, Mr. Chairman.

And I want to say to Larry Wooten thank you for your leadership, your commitment to agriculture, and your service to our nation's farmers and ranchers through your work with the Farm Bureau.

Some of you may not realize, but Larry Wooten grew up on a small farm in Pender County in the Congressional district in southeastern North Carolina that I have the opportunity and privilege to represent.

And thank you personally and professionally for the commitment I know you have and the service you give. I wanted to ask you a question.

On page six of your testimony, you discuss your concerns about the bill that the Energy and Commerce Committee has put forward as it relates to FDA authority to come onto a farm and search production records. Specifically, the bill would remove language in the Bioterrorism Act that requires FDA to have a, "reasonable belief" that a product is harmful to public health before they can inspect a farmer's production records.

As you know, I have had serious concerns about the FDA coming on the farm. That has been a battle cry that many of us have had in North Carolina in our concerns, as well as nationwide, about the FDA coming onto the farm.

Would you please elaborate on what your concerns are about the FDA coming on the farm, and this specific provision that would remove that requirement?

Mr. WOOTEN. Well, obviously those of us in North Carolina, we are working, particularly tobacco producers, are working with FDA on FDA coming on the farm dealing with tobacco, as well you know, Congressman McIntyre.

We just think that this bill says explicitly that FDA can come on the farm. There is explicit record-keeping. We have just got real concerns about a Federal bureaucracy that can come to any farm in North Carolina or another state without a reasonable reason for being there.

Mr. MCINTYRE. Let me ask you this. I know our time is limited.

Last summer, the FDA falsely advised consumers against consuming raw tomatoes—all of us in this room will probably remember that—when tomatoes were never part of the food safety incident in question.

Could you elaborate on this situation and the hardship it caused producers? And would you support some type of indemnity initiative for producers who have been negatively impacted by mistaken determinations by the FDA?

Mr. WOOTEN. No question about it, that was a terrible thing. It caused terrible financial hardship on many producers not only in our state, but around the country. And myself, as well as American Farm Bureau, we have in policy to support indemnification back to producers where agencies of government—whether it be FDA, CDC or whatever other agency of government—makes erroneous accusations that hurt farmers, that there needs to be an indemnification program there.

Mr. MCINTYRE. Thank you.

Mr. Maravell, in order to comply with the new food safety rules, producers such as you would have to keep significant records on production and handling practices that must be available to FDA inspectors on demand. We know that failure to produce accurate records may result in serious monetary fines, even if those record-keeping errors do not directly endanger food safety at all.

As a producer, are you concerned about your ability to comply with these potential regulations and civil penalties?

Mr. MARAVELL. Yes, I am. Let me just state that as an organic producer, we already have a close relationship with the USDA program. And I don't want to overstate this, but after one of my inspections, because we are inspected annually, one of my employees said, "You don't really need a farm to be certified, all you if need is a file cabinet." Because we have—and I have multiple file cabinets; we have tremendous documentation.

If documentation on my production practices were to have an inadvertent mistake, I am not subject to a fine unless it produces an adverse effect and I violated the law somehow—I mean, if I put something in the wrong file, put the wrong number on something, if there is no harm.

So let me just say that, yes, I am very concerned about this. And I am also concerned about not understanding what aspects—because I run a diversified operation, I don't know what aspects of my program are going to be subject to the new provisions in this bill. And so I am a little concerned that FDA comes in and requires information on demand, and I may not have it in the format that they want it, because I have the information, but I have it fed into a different program. And my program has a very good safety record.

And I don't know—as the Chairman was referring to—I have grain storage facilities, I have feed grinding facilities. Does that automatically put me under new types of record-keeping? I already provide all that information to my certifier. My certifier is already accredited by USDA under the organic program.

So, yes, I am very concerned. I spend a lot of time putting all of this information together.

I would like to make one point about that, however. This is a voluntary program. I don't have to be an organic farmer. I choose to be an organic farmer, and so I am willing to make that extra effort to be in an organic program. And it is a program that is a public-private partnership. It is a program where we have private certifiers, as well as my certifier happens to be public, the Maryland Department of Agriculture, working together with the Federal Government. And our record-keeping responsibilities are appropriate to the size, scale, and scope of operation and the type of production

methods that we use. So I feel comfortable with the record-keeping that I am currently engaged in.

If I have to do this all over again, I feel very uncomfortable, because I feel as if I already have the information, I just don't have it the way they want it, or I can't get it fast enough or something like that.

Mr. MCINTYRE. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN [presiding.] I thank the gentleman.

The gentleman from Texas, Mr. Neugebauer.

Mr. NEUGEBAUER. Thank you.

One of the things, as I looked at the proposed legislation and listened to the testimony that we had today, it occurs to me that even in this bill everything is looking back. In other words, it is based on, if an event happens, we can go and identify where that source was, and that then, hopefully, we mitigate something after it has happened.

The question I have is, if we implement this legislation as it is, how significant of an increase in food safety are we actually going to have in relation to the cost? And when I talk about cost, I am not trying to put a value on anybody's life. I mean, anytime we lose anybody for any reason it is a tragedy.

But what I wonder is, sometimes in government we try to throw a bunch of government at a problem, and what we find in the end is, we just threw a bunch of government at the problem and we really didn't basically improve what we were actually trying to accomplish.

Everyone in the food business or in the agriculture business has a huge vested interest in getting this right. And as I heard—and I appreciate Mr. Goodlatte asking that question—how many of you supported this bill. But, the most important question I have today is, is this bill going to make a significant difference, or do we—are we still not where we need to be? Do we need to take more time if we are going to have a comprehensive food safety program in this country—have more hearings and make sure that we are actually addressing the problems where they are? Because in any system there are sometimes gaps.

And so the best policy to me is filling the gaps, not just throwing another blanket over the problem.

So just in the remaining time, just kind of to get a feedback, does this bill do it or do we need more study and more work to make sure we are filling the gaps?

Mr. Wooten?

Ms. TUCKER-FOREMAN. Is that to me, sir? I didn't know if you were addressing that to me.

Mr. NEUGEBAUER. To the panel. Anybody who wants to jump in.

Mr. BOYLE. I will take a shot at a response, not so much specifically about the bill, but about your overarching concern and question: Do the government standards really result in a demonstrable improvement in public health? And in terms of two of the strictest standards with which my members deal, *E. coli* and *Listeria*, there has been some demonstrable improvement in foodborne illness data associated with those two pathogenic bacteria.

We also have invested a lot of money on reducing the incidence of *Salmonella* in our beef, pork and chicken products and turkey products. There have been significant reductions over the last 10 years, Congressman, between 60 and 70 percent in each one of those product categories. Yet, the incidence of illness associated with *Salmonella* has increased about 14 percent over the last 8 years.

So we have reduced the presence in our products, but yet we haven't had a positive impact, a positive public health impact. And that is a legitimate area of inquiry for the Congress and for the regulators.

You impose costs, but you have to be able to demonstrate benefits, too. And that is a concern that we have in the industry.

It is also an area where we could make better regulatory and legislative decisions if we had more specific food attribution data from the CDC. They can estimate how many *Salmonella* illnesses occur a year, but they can't tell you which food products are associated with those numbers of illnesses. Therefore, you can't target your resources to the products that are causing the incidence of those illnesses.

Mr. MARAVELL. Congressman, as a farmer, everybody knows the saying, "If it ain't broke, don't fix it." I guess my feeling and my reaction in reading this bill is that if there are science-based and identified high-risk areas, we should investigate how to go after those and solve those.

My concern is that, in 30 years, I have never—as an organic producer, I have never had a food safety issue arise. Food safety is always on my mind. And as a small operator, I am responsible for the growing, the harvesting, the slaughter, the packaging, the processing, and the marketing. If I detect anything in that which I feel is faulty from a food safety perspective, I can make the decision like that to change it. I don't need to go through a corporate committee or an outside consulting study. You know, I can effect it and do it right away.

And I probably shouldn't say this, but I am probably more concerned about food safety than most of my customers are. I have to constantly—I have personal contact with my customers, and I must say that you need to always remind your customers of proper food handling characteristics. And we do things that go beyond what we would be required to do, because if there ever were a food safety issue, the customer isn't going to be wondering what they did, they are going to be wondering what I did. And so that is why we have to be extra vigilant.

But getting back to your question, if there is legitimate scientifically-based areas, or problem identified in certain production practices, then we should definitely investigate those areas and go after those areas.

In my case, I am not aware of any in the types of products that I produce; and so I feel that this is a broad-brush approach, where we should be focusing mainly on those areas where we can get the biggest bang for the increased expenditure of funds and increasing the authority of the FDA.

Mr. REINHARD. I would just like to reiterate that the National Turkey Federation, as Mr. Boyle said and others have said, really

does believe in the principles of preventive-based food safety systems. And certainly when you are looking at where you are going to put resources, how you are going to go about dealing with those issues that occur, preventive is where everyone wants us to be. And to drive consumer confidence, it is most important that the preventive-based methods be what we focus on.

Anything after product is produced is after the fact. And it didn't really achieve what is the desire of everyone in this room.

Mr. WOOTEN. At American Farm Bureau, we have looked at all these bills dealing with food safety; and our preference to this one would be the Putnam-Costa bill, H.R. 1332, because it engages the industry in helping figure out more of these solutions.

The CHAIRMAN. I thank the gentleman.

The gentleman from Iowa, the Subcommittee Chairman, Mr. Boswell.

Mr. BOSWELL. Thank you, Mr. Chairman, and thank you for having this hearing today. And thank the panel. You have given great testimony; and it is important to us.

To save time, I would like to associate my remarks, Mr. Chairman, to what you have said and Mr. Goodlatte. I certainly feel the same. I would like to point that out, before I ask—I will have one question.

But last Monday I appeared before the Rules Committee to deal with some of these issues. Antibiotics was the issue of the day; and I want to say now, so it is in this record, that there weren't others invited that had the opportunity to represent farmers and ranchers and us.

And so I would like to ask, Mr. Chairman, to have the testimony I gave there, in the interests of time, be entered into our record here today.

The CHAIRMAN. Without objection, so ordered.

Mr. BOSWELL. Thank you very much. I appreciate that.

[The information refered to is located on p. 133.]

Mr. BOSWELL. And I just want to say that the discussion we have just had—and I think Mr. Maravell made a good comment—applies to all farmers and ranchers. We do not want to have unsafe food. It is just as simple as that.

We are stewards of that. We take it seriously. And I think every one of you would agree with that, and everybody that is familiar with what goes on out on the farm or the ranch knows that is a true statement. We do not want to send bad product down the road. If we see something going on, we do something about it.

And we don't want to waste money either. So, as Mr. Cardoza said, who is a Member of the Committee—I am glad he was there that day—that we are kind of tight-fisted when it comes to spending money we don't need to spend. And on the antibiotic issue, for example, we wouldn't do that if we didn't think it was safe.

And we have science. We got into the discussion about the Denmark situation—you will see that when you read the record—and the science there and the science here. Let's just talk about the science as we talk about other areas.

Maybe we ought to talk about energy or global climate change. Who do you want to represent? I happen to think there is global warming going on, and there is science to prove it. Then you go

over here, and there are scientists brought forward that say, "No, I don't think that is the case."

Well, we have to have a lot of confidence in having an excellent Secretary of Agriculture—and I've known him personally for years and years—and a Department that is ready to deal with this. And we have that. And we must do all we can, working together, to be sure that these kinds of issues are handled by the people that have the hands-on, the know-how, the staff, the experience, the presentation made here this morning; and it is something that is very, very important to us.

I do have one question. I will direct this, if I could, to Ms. Tucker-Foreman. FSIS is mandated by law to have equivalent standards with foreign countries for imports for beef, pork, and chicken. Fact?

Ms. TUCKER-FOREMAN. Absolutely.

Mr. BOSWELL. Why shouldn't the same standard apply to seafood?

Ms. TUCKER-FOREMAN. I couldn't agree with you more. We think that the USDA system, which requires equivalency before a country can send their products to the United States, is an appropriate protection for American consumers.

We supported your efforts last year to move catfish inspection to FSIS simply because FDA didn't have the resources and wasn't applying any resources to enforcing it; and we got continuous inspection for catfish.

Now the problem, sir, is that USDA began, before we had huge amounts of international trade, and instituted this system of prior certification. FDA had no such system. You now have food coming in here from 100 countries. I think—I am trying to remember, and I just can't, the number of foreign plants that export to the U.S. And you can't go back at this point and say that they have to stop exporting to the U.S. until they can go back and be certified.

So we think there has to be some system that starts from the point where we are that is not totally disruptive of trade, but does a hell of a lot better job of protecting Americans from unsafe imported food than we are having right now. Eighty-four percent of our seafood is imported, and there have been serious questions raised about the contamination with pesticides and other chemicals.

And we join you in any support you can give for that.

Mr. BOSWELL. Thank you.

Because of the clock, I just want to make—if I could, Mr. Chairman—one more comment.

I doubt—maybe there is, but I doubt there is anybody in the room that has spent more time in Vietnam than I have—a couple years to start with, and I was all over that country because I was flying helicopters.

In my second tour, I was in the delta. And it is not to brag, I could probably take you to any major city in Vietnam without a map or navigation aid. I have seen the country.

I went back in December, as you know, you just mentioned, and Mr. Goodlatte was along, and we went down just to have a look. And what has caused me to want to make a comment about this is what was in the *CongressDaily* today.

And people took exception. We don't want to start a trade war, of course not, but we want safe food. We want safe food. And we made comments—I made comments, their processing looked pretty good, providing I don't know about the quality of the water going through that processor, but it looked pretty good.

But the spawning and their growing places for those fish we are talking about is putrid. I don't know what else to say. So let's not have a trade war. Let's not worry about that. Let's invite them to come and see how we do it. And maybe they would like to invite our people to come over and see in detail how they do it. That wouldn't be a bad idea. And maybe that would be a good place to start.

But this statement from the other side of the rotunda about this, I think maybe they ought to go have a look and see what they think.

But I see no controls, no regulation of what is going into those waters where those fish are spawned and raised. I think it is something that we ought to be responsible to do. You know, let's do it in a delicate way if we can, but I don't think we should be ignoring it.

And I wanted that to be part of our record today.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman and thank him for his leadership and tenacity on these issues.

The gentleman from Texas, Mr. Conaway.

Mr. CONAWAY. Mr. Chairman, the gentleman from Kansas has already yielded me time.

The CHAIRMAN. He yielded it to you?

Mr. CONAWAY. He did. He was out of order.

The CHAIRMAN. I am finding more problems with my new system.

Mr. CONAWAY. Exactly.

The CHAIRMAN. Mr. Fortenberry.

Mr. CONAWAY. I will yield to Mr. Fortenberry.

Mr. FORTENBERRY. So I get 10 minutes?

The CHAIRMAN. No.

We have a series of seven votes coming up. I will announce at this point, we will continue as soon as those votes are over with. And I might as well say at this point as well, too, that we purposely put—we reversed the order, which is, I guess, something you are not supposed to do, to put the Administration witnesses after this panel so that the Members could have the input from these folks and would set us up better to ask questions of the Administration.

So that is kind of why we did what we did.

So Mr. Fortenberry?

Mr. FORTENBERRY. All right. Thank you, Mr. Chairman.

Mr. Boyle, thank you for your insightful comments about how any new framework for addressing the essential issue as to how we improve food safety has to look at how that framework actually produces that benefit. I thought that was particularly insightful.

But I would like to turn my attention to you, Mr. Maravell. You have a degree and background in urban studies and you are now a farmer?

Mr. MARAVELL. That is correct. Yes, I am a boy from New York that went astray.

Mr. FORTENBERRY. Well, I congratulate you. Clearly, your choice in life is an indication of what I think is a new movement in society, and the way in which you are conducting your operation as well.

And I thought you were very insightful, in addition to the other comments, with this particular framework of your language. You said these approaches—talking about farmers markets, buying local, as well as community-supported agriculture—represent innovations and alternatives to the mainstream food chain. At the core, they have already implemented transparency and connection between the producer and the final consumer. As long as they provide safe food, these approaches should be given incentives, not barriers.

I think, again, one of the growing opportunities in agriculture is related to this broader philosophical movement of a desire for a reconnection with the land between the urban and the rural, between the family and the farm. And to the degree that that actually is an assist in improving food safety, it should be looked at through another paradigm, perhaps.

We oftentimes follow into a logical, sequential decision-making process here, where if you have a problem with food safety, you tighten up the existing structure rather than reexamine the paradigm. I think you are doing that, along with a number of other people in their desire to clearly understand where their food is coming from and to have a role not just in consuming it, but being a part of its growth and processing.

So, with that said, I am getting a number of people who have expressed concerns that this particular bill is going to adversely impact—and you have laid out some specific ways, such as the fee being necessarily unfair, the added burden of record-keeping—but also the lack of clarity of jurisdiction, who is defining what. I think those are important points to make. And, it is important that we ensure, as this particular bill goes forward, that we are not detracting from this new growth area of farming for entrepreneurs and innovators who are bringing new types of food production—which are really old food production methodologies—back into the mainstream of consumer products.

So is that a fair summary of what you suggested? The fee, the record-keeping, added burden of record-keeping, as well as the jurisdictional questions that remain as to what you are going to actually have to do with the variety of platforms of food that you grow?

People are writing, and they are concerned that they are growing their own food, is this going to impact them? "I am an organic producer, how is this going to impact me? Is this going to basically shut down—because of increased barriers, again—this new entrepreneurial option that is growing because of consumer demand out there?"

Mr. MARAVELL. Let me comment on that a little bit.

People often ask me, where are the new farmers going to come from, because the average age of the farmer is getting older in America. And I tell them they are going to come from the cities. And I am an example of that, but also I see that happening all the

time, people transitioning from the cities into agriculture on the urban fringe.

Last weekend I had a lot of customers show up, and what we try to do is, we try to talk to each customer about what we do, how we do it, and understand what their concerns are. We get a tremendous reception, because the customers very rarely have an opportunity to talk to the owner or the producer of the food that they eat. And they have a lot of questions. They can't figure all of this stuff out. And indeed, some of them are saying, Well, have you seen on the Internet—and there is a lot of misinformation going on on the Internet—that Congress is going to make it so you can't produce organic food anymore and things like this?

There are some legitimate concerns about being able to communicate effectively with the consumer to say that, yes, we are going to encourage multiple models for delivering food to the American public. And that diversity will ultimately build the strength of our food system and make our food system more secure.

And as long as the efforts of this bill can continue along those lines, recognizing the diversity of our agriculture and the diversity of models for delivering our food to our people, and not provide barriers so that people will say—I don't want to go far afield here, but people thinking about entering into the profession of agriculture who are currently perhaps, like I was, a city boy, way back when—don't feel that the barriers are insurmountable.

I am now considering adding additional enterprises to my operation to make it more diverse. The first thing I come up against are regulatory barriers. I don't have knowledge barriers, I don't have production-based barriers. I have a customer base that would support my going into new enterprises.

They are already buying my products. They buy other types of products I produce. And the first thing I run into—and it is not just food safety; I am going to run into planning and zoning, I am going to run into farmland preservation. I mean, I have to consult with so many different places just because I would want to start a small dairy herd, for example, or I would want to put some of my grains into a baked product.

Mr. FORTENBERRY. I am about to run out of time, so I am going to cut you off. Thank you for your insights. Thank you for your work.

I think, again, as we look at how to strengthen opportunities and widen the horizons, for not only new producers that are coming in, but alternative delivery systems—you are on the leading edge of that—that forms another chapter of our very important overall agricultural production system.

So that is one end of it, ensuring that—and we certainly want to clamp down rumors that people aren't going to be able to grow organically, but at the same time ensure that this bill is not putting up artificial barriers to what is already achieving, at least to the degree that we can know it, safe delivery of a food system. And along with the other comments that were made, particularly by Mr. Boyle, if we implement something new, make sure that the implementation actually corresponds with the benefits.

So thank you all.

Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman.

And we are going to recess for these votes. My guess is we will be back about 12:30. So we will recess the Committee until the end of the series of votes.

[Recess.]

Mr. COSTA [presiding.] The House Agriculture Committee will now return to order after our recess.

I hope those of you have had an opportunity to get some lunch. We had a series of seven votes; and, absent any procedural votes, we should be able to finish this panel and then move to the second panel.

I have a list of Members here who I will follow the order based upon when they arrive, and some Members may not be able to return because of other committee hearings or other scheduled meetings. But the Chairman asked me to begin the hearing again, and we will do that. I know my Republican colleagues will join us soon, those that can make it.

But let me make a couple observations here. Chairman Peterson and I have been working, along with Members of this Committee, on food safety issues for, in a number of cases, many, many years. Comprehensive food safety policy is job number one as it relates to farmers, ranchers, and dairymen and the panoply of agriculture in America.

As I am fond of saying, common sense tells you that farmers are, first and foremost, consumers. They eat the food they grow, as do their families and their neighbors. Second, they have an economic interest in the event that there is an issue on food safety regarding pathogens that impact the food line in which illness or more horrific deaths may result.

So when that happens, clearly, it is something that we all ought to guard against to ensure that we produce the safest food in the world. And, obviously, anytime there are illnesses as a result of food contamination, as we witnessed in the situation with the peanut butter earlier, the market is devastated. It is impacted.

Let me talk about the issues that are of most concern, that Chairman Peterson and I and others have been talking about with members of this panel. Certainly the Energy and Commerce Committee with Chairmen Waxman and Dingell are offering to continue to work with us, and we thank them for their efforts to reach out, because there are overlapping issues that both Committees have in concern.

The Food Safety Enhancement Act that has been introduced, I believe, makes several important steps in the right direction. But I do think I speak for many other Members of this Committee on a bipartisan level that there are concerns. There are concerns about the legislation that has come from the Energy and Commerce Committee.

It is a fact that the United States Department of Agriculture has more knowledge and experience on on-farm practices than does the Food and Drug Administration. I don't believe it is contrary to the mission of the FDA—the Department that is in contradiction with efforts they focus on food production and processing and packing, critical steps on the food chain, that they are contrary to ensuring an important role in maintaining the safety of that food.

I know my constituents, in what is one of the most robust agricultural regions in the country, producing over half the nation's fruits and vegetables, want to ensure that safety is job number one. They are playing an active role in continuing to raise the bar to ensure that that food safety happens in terms of production, distribution patterns, traceability, all the critical issues that are important in ensuring and improving food safety in America.

We noticed last year, last summer, to take as an example, the tomato industry as proof that the Food and Drug Administration can make mistakes. Far-reaching provisions like the emergency recall that is in this current legislation, without due process, I find troubling.

I think the bill also contains provisions that deal with geographic quarantines, which is an authority that already the United States Department of Agriculture has for animals, which in some instances is duplicative for products that don't—are impacted when the Food and Drug Administration gives recall authority or administrative detention.

There are not provisions in the current legislation that require or shore up accountability for the FDA should they make another error, as occurred in the tomato example last July. So while there are a number of important provisions, we need to work together and Chairman Dingell and Chairman Peterson have spoken about reaching out to one another in that effort.

Fees are another critical question. How do you provide fees? There is an appropriate role to ensure that we do our part, whether it be specialty crops or others, but we know that the Food and Drug Administration's budget is short and, because of the budget issues, fees that can be adjusted yearly without any sort of accountability I find troubling, especially for small farms.

There are other issues, including trade, finished product testing, and others which I think need to be addressed in this legislation.

Finally, I think we can all agree that, at the end of the day, we want to try to improve food safety in America. We want to deal with qualitative analysis that ensures that American food and fiber is the best it can be when we look at the world markets that we compete in. We want to ensure that the partnership that exists between American farmers and ranchers and dairymen, the partnership that exists between them and consumers is improved. Because, at the end of the day, of course, the consumers are the people that we produce the food and fiber for.

The qualitative analysis is critical here as we weigh the issues of risk assessment and risk management, and we will be working with Chairman Dingell and Members of the Energy and Commerce Committee to try to iron out these differences that I wanted to highlight here this afternoon.

With that said, I want to begin on the list here as I see the Members who are next in line based upon the time that they came in here.

Mr. Boswell, you have asked to yield your 5 minutes to Mr. Kissell?

Mr. BOSWELL. Yes.

Mr. COSTA. Mr. Kissell.

Mr. KISSELL. Thank you, Mr. Chairman.

Seniority tends to work a little quicker when there are maybe a few chairs empty.

Mr. COSTA. Take advantage of it.

Mr. KISSELL. I appreciate the panel staying here through our votes.

Our special guests today, Robin and Jeff and Mr. Almer and our guests from Chicago, whose name I did not get written down, thank you all for being here today; and we especially think of you as we go through this process, because this is the ultimate example of what can happen and what we are here today for.

Once again, my thanks to the panel. I especially want to thank Mr. Wooten for being here today. Being from North Carolina myself, I want to associate myself with what Mr. McIntyre said earlier about the great job that you do for us in North Carolina. Mr. Wooten, we think in North Carolina that we have a food safety program that is as good as anybody's in the nation and is recognized nationally and internationally. I am wondering just what thoughts might you have about what we do right in North Carolina, that you would want to share with the panel and the Committee, that we ought to take into consideration as we look at this legislation.

Mr. WOOTEN. Well, thank you, Congressman Kissell; and we must be doing some things right.

I saw yesterday that the head of the Food and Drug Division of North Carolina, Mr. Reardon, offered his resignation and is coming to Washington to work with FDA. So, apparently, that news was announced yesterday.

But, you have to realize for it to be a good working relationship it has got to be a partnership that one—as I said earlier in my testimony, we think FDA may have some oversight, but it needs to be in conjunction and cooperation with those state agencies. And I know that is already in the bill, those state agencies that have jurisdiction, that are close to the ground.

Where we have had problems in the states, whether it be North Carolina or other states, the local folks are on the ground first. And I think, where appropriate, to be effective you have to engage the private sector working with state agencies and Federal agencies to get to the bottom of the problem as quickly as you can for the benefit of the consumers out there and the producers. For farmers, this is devastating. When these type of things happen, it is devastating to those producers, financially and otherwise. So it is important that we get on it quickly.

Mr. KISSELL. And, Mr. Wooten, also, in North Carolina we have the opportunity for the occasional hurricane or tropical storm, that it creates a situation where the different agencies have to work together. And what do you think we can learn from that in terms of being able to respond to an emergency in terms of a problem with our food system?

Mr. WOOTEN. Well, I think you have to have almost an emergency response team similar to, as you said, what happens when you have natural disasters. Any problem with the food supply in the country is certainly a disaster. It certainly calls for a national concern. And, we are going to have to have that emergency response mentality to get on it, involving all agencies.

Mr. KISSELL. One last question. And, once again—I appreciate all the panel, and I know all my questions have gone to Mr. Wooten, but, once again, I am very proud of what has taken place in North Carolina. But last year when we had problems in North Carolina, along with so many other people, the tomatoes and peppers, I believe, what was the impact on our farmers and what do you think needs to be a way that, when farmers have a situation that crops are pulled, what compensation should they get?

Mr. WOOTEN. Well, as I said, we believe, and I said in the testimony, we believe that an indemnification program—when mistakes are made by agencies of government, whether it is FDA, CDC, whatever agency of government, that farmers need to be indemnified for the losses when those mistakes are made.

Mr. KISSELL. Once again, thank you, panel. Thank you, Mr. Chairman. I yield back my time.

Mr. COSTA. I thank the gentleman.

I have a number of questions.

First, to the panel, and you need not opine if you don't have some quick examples to provide us. But I think it is important, as I said in my opening comments, to understand where there are duplicative functions that exist in food safety legislation and that are being proposed in the legislation. Because, given the importance to improve food safety, I don't think anyone should—I would think that no one would believe that we want to have duplicative efforts as it relates to food safety.

Anyone care to comment?

Ms. TUCKER-FOREMAN. Mr. Costa, under existing law, FDA is the only agency that has responsibility for the safety of commodities raised on the farm. USDA has a number of agencies that are involved with those commodities, but they are service agencies. I am sure you are going to hear that from the Agricultural Marketing Service. Their purpose is not safety. It is what the title of the agency says, "Marketing."

Sometimes they come together, and it is very important for AMS and FDA to be cooperative. And if I could give you an example that is old, but I think it is still good. When I was at USDA, they had a problem of sulfur residues in hogs, and it was being picked up by the meat inspectors, and people were being penalized for it. Farmers couldn't bring their hogs to the slaughterhouse for a period of time after that happened.

And farmers were saying, but we followed the rules. We withdrew when we were supposed, to and we worked with—in this case APHIS, FDA, and FSIS got together; and FSIS has no on-farm authority. FDA knew if they went on the farm, it would be viewed as they were looking for a violation of the law. So we got together with APHIS and got them to go and try to find out why this was happening.

Mr. COSTA. But, Ms. Tucker-Foreman, you would say that either today in existing law with the Federal law, or in conjunction or cooperation with state law as in California as in the proposed legislation, there are no duplicative efforts that either exist or could be created as a result of this legislation?

Ms. TUCKER-FOREMAN. Agricultural Marketing Service———

Mr. COSTA. I am not talking about the Marketing Service. You made that statement. That is clear.

We have food safety as it relates to herbicides, pesticides. We have food safety as required by monitoring with USDA inspectors and meat plants. That has nothing to do with———

Ms. TUCKER-FOREMAN. I thought I was specific to crop commodities. The FSIS has no on-farm authority. FSIS's authority begins at the slaughterhouse door. It has no on-farm capacity at all.

Mr. COSTA. But I am taking the interpretation of my question, being to go beyond on-farm.

Ms. TUCKER-FOREMAN. I am sorry. I thought you were specifically asking about on-farm authorities, Mr. Costa. I may have misunderstood your question.

Mr. COSTA. I was talking about in terms of the full gamut of our efforts to provide food safety.

Ms. TUCKER-FOREMAN. I think there is not a lot of overlap now. There is very little with FDA and FSIS, and they have worked cooperatively for years together. So I don't know that this law creates a problem there. I can't find it in this proposed law.

Mr. MARAVELL. Congressman Costa, this is Nick Maravell. I am an organic producer, and I look at the registration and information reporting requirements in this bill, and I provide all of that information both to state agencies and to my certifier, which is the Maryland Department of Agriculture, which is certified by the U.S. Department of Agriculture or accredited by the U.S. Department of Agriculture.

So the location of my facility—because I do on-farm processing, the location of my production areas, the exact types of crops that I produce, the exact types of animals that I produce, all my emergency contact information, a complete—I maintain a complete list of all of my customers with their addresses and telephone numbers in case there is a problem in terms of having to do a recall.

All of this information I keep, some of which I have to submit to my state agencies or to my organic certification, my certifier. So I am keeping maybe not in the exact format that this bill might require in terms of electronic, although some of mine is in electronic form, but it may not meet the compatibility with the Federal system. So I maintain all of this information and a lot more information because of my organic certification.

I pay a fee also for my organic certification as well, and this information that I submit is submitted annually. I am inspected annually.

Mr. COSTA. Bottom line?

Mr. MARAVELL. The bottom line is that I would have to find out what the new formats were from FDA and to provide yet an additional report and additional fees for information that I am already submitting. That is my opinion. And that is with regard to the registration area. I am not sure if you have specific other areas that you are also referring to, Congressman.

Mr. COSTA. Ms. Tucker-Foreman, I want to move on, but go ahead.

Ms. TUCKER-FOREMAN. I will pass and let you go. Thank you.

Mr. COSTA. Dr. Ives and Mr. Reinhard, in your testimony you talked about the concern of livestock being defined as food and that

the bills that have been proposed were meant to exempt livestock as food. Can you explain why that is needed and what the pending legislation—what areas that you have concerns on in terms of why it is needed and why the pending legislation doesn't go far enough, as it relates to those issues you outlined in your testimony?

Dr. IVES. I will speak for NCBA. With regard to the definition of *food*, we feel very firmly that livestock are not food until the point they get to the packing plant, and that by not having that further defined that would give the FDA potential ability to come on the farm and potentially place regulations on-farm that right now would be duplicative of what is going on right now with USDA.

Mr. REINHARD. Related to livestock specifically for Federal inspection under the meat or poultry act, it does read that they are exempted by the existing bill that came out of Energy and Commerce. The concern is how that is interpreted and how that language should go. Because at some point in time determination has to be made when that product is turned into a food to fall under the Federal Meat Inspection Act or the Poultry Products Inspection Act. So Congress being able to strengthen that and to deal with the other part that my colleagues have testified on the fruits and vegetables and that side of the business where the bill does specifically talk about on-farm could be improved.

Mr. COSTA. Thank you.

Mr. Wooten, I mentioned earlier about the problems last year associated with the efforts when the FDA, I think, falsely advised consumers against consuming raw tomatoes when they were never actually a part of the food safety in question. I am wondering if you could talk about the hardships that has caused producers, and if one should consider some sort of an indemnification effort when there are false claims such as that that have obviously been a mistake that was made.

Mr. WOOTEN. Yes, sir. As I said earlier, there were millions of dollars lost by producers in this effort. We have some farmers—I know one farmer who is still paying back a loan today that he incurred because he couldn't sell his tomatoes. So it just devastated many producers not only in the State of North Carolina but around the country.

As I said earlier, we at American Farm Bureau and our organizations all across the country very much believe that an indemnification program is needed as we consider this legislation, in terms of mistakes that are made by government agencies that wrongly cause financial hardship on producers.

Mr. COSTA. Mr. Boswell, for questions or comments.

Mr. BOSWELL. Thank you, Mr. Chairman.

Just a couple of things to wrap up for me to Ms. Tucker-Foreman.

Again, all of you, thank you. I am sorry we had that long interruption there, but we don't really control that.

Do you think that the FDA has the data necessary to rate products based on risk?

Ms. TUCKER-FOREMAN. I just want to be sure I understood. Do I think FDA today has the data———

Mr. BOSWELL. The data necessary to do this.

Ms. TUCKER-FOREMAN. Not completely, no. And the legislation directs them to do studies to determine what pathogens are the greatest risk and to also assess food products.

Mr. BOSWELL. Thank you.

And just to move on then, Dr Ives———

Mr. MCDONALD. Mr. Chairman, may I answer on that as well?

Mr. COSTA. You may.

Mr. MCDONALD. I agree completely with what was just said. And specifically for us, as we have seen in the last few years, it seems that the category for establishing risks—categorizing it is based on outbreaks.

And I would just like to give an example of a customer call that I had recently regarding onions up in Canada related to an outbreak in a small chain up there. And this customer called and said, oh, I see that onions were implicated; so now that is a risk item, correct? And I said, well, not necessarily. If we go by the kind of method that FDA has used, then yes. But we are just going to keep adding to a list. The list will just keep growing with any subsequent outbreak, and that is not necessarily what risk is about as far as categorizing it.

What we really want to do and what I answered to my customer, I said, what we want to look at is that not onions are the risk but maybe certain practices associated with that product. I think, at this point, FDA does not have that information or enough of it.

Thank you.

Mr. BOSWELL. Thank you.

Dr. Ives, a question, if FDA considers livestock as food, what impact would H.R. 2749 have on cattle and ranching operations, in your opinion?

Dr. IVES. Well, it is difficult to say, because it depends on what regulations would come down from their ability to then regulate what we do. Currently, we have both APHIS as well as the state agencies that regulate the movement of cattle across the United States. It is not so much of an issue within state but of course the international—we do get a lot of Mexican-origin steers as well as Canadian cattle, and we are just concerned that there is going to be an abundance of regulation that could come down from their ability to regulate.

Mr. BOSWELL. Thank you, Mr. Chairman. I yield back.

Mr. COSTA. Before I dismiss this panel and begin with the second panel, I want to focus in on something that in the years that I have served in the California State Legislature, and now in Congress, that I always think is the crucible, the bottom line, in terms of ensuring that we have the highest food efficacy and safety standards that science and technology will allow us to have. In that discussion, obviously, the science and the technology today is different than it was 30 years ago or 50 years ago, and it all comes down to, in my view, the issue between risk assessment and risk management.

And, Ms. Tucker-Foreman, with your experience and background, let me ask you first a question. When we are measuring risk assessment *versus* risk management, when we are trying to do a qualitative analysis in terms of what government can do, whether it be at a Federal or state level, in terms of the dollars available,

the best bang for the buck to minimize risk for the best safety standards we can achieve, I think there is a threshold question here. Do you think it is possible to achieve zero risk?

Ms. TUCKER-FOREMAN. Absolutely not.

Mr. COSTA. Do you think that there is a perception oftentimes out there that somehow, just as we would wake up in the morning and get into our car and go to work or travel wherever, that there is some risk associated with that exercise?

Ms. TUCKER-FOREMAN. I should—I do. I should qualify my statement. I think there are some foods where, in fact, there should be a zero risk. I think all of us understand that———

Mr. COSTA. What foods may they be?

Ms. TUCKER-FOREMAN. Foods that have been cooked to a temperature that kills the pathogens in them and not been exposed to situations where they could get into the food after that.

Mr. COSTA. I think that is a good example. I am glad you raised that.

Where does the responsibility then lie if, in fact, the consumer is made aware that the food has to be cooked to a certain level to eliminate those pathogens?

You know, I tend to like my beef medium rare, pink and juicy. Maybe that is borderline as it relates to the pathogens. But just as a person would get into a car, if they operate that car in a way that they are driving it too fast, or they are driving it recklessly or they are driving it under the influence, great harm can result in what would be the ill-advised practices of operating that vehicle just as cooking the food that you just described, would it not?

Ms. TUCKER-FOREMAN. Let me respond first by saying I heard the phrase several times this morning "we have the safest food in the world," and I think that we take pride in this country in having a safe food supply.

With regard to meat and poultry products, I think there is a very high standard there, because every item of meat and poultry comes to you with an endorsement that says USDA inspected and approved. It is the only product I know that says to you your government has checked this for safety. They don't check every car for safety before it goes out. And so, there is a very high standard with regard to meat and poultry products because they carry that seal, and I think USDA———

Mr. COSTA. But whose responsibility is it—getting back to the point, though, if the consumer is made aware that they need to cook that food at a certain temperature for a certain length of time and they don't follow those—I mean, is that any different than a person that gets in a car and drives 120 miles an hour?

Ms. TUCKER-FOREMAN. It is because the law says that USDA shall not affix the seal of inspection to an unsafe product and that product———

Mr. COSTA. But it depends how the product is operated. If a person drives a vehicle at 120 miles an hour in an urban setting, and the vehicles are inspected, and there are laws that say you shouldn't drive faster than 35 or 60 or whatever———

Ms. TUCKER-FOREMAN. I hope there is a policeman there to catch them, which is why we have inspectors.

Mr. COSTA. Right. I agree. But who is responsible? The person operating the car, the person cooking the food, or the person that produced the food, or the person that manufactured the car?

Ms. TUCKER-FOREMAN. I think, under the meat inspection law, the food is not supposed to be contaminated with *E. coli O157:H7*, even if it is a raw product.

Now, for most pathogens, *Salmonella*, for example, USDA doesn't set a standard in a raw product. For *E. coli*, there is.

But this is not going to be a very fruitful conversation. Let me suggest that my organization for a long time has been active in something called Partnership for Food Safety Education. We think it is important that all consumers practice self-defense, and we urge people to cook their meat not until it is no longer pink but until their ground beef is 160 degrees. So just as a matter of self-protection, you need to cook your food and handle it carefully.

Mr. COSTA. You are probably correct. We may have to agree to disagree on this point.

Ms. TUCKER-FOREMAN. I think so.

Mr. COSTA. But I thank you for your response.

I want to thank all of the members for their response. You have been patient. I hope you did get a lunch during our vote break. If you didn't, you can get one now, unless you would like to sit around and hear the second panel.

So we will take your testimony. Members may have further questions that they would like to ask of this panel. We will ask the Members to submit the questions as expeditiously as possible, and there are 10 days in which panel members will have to respond to questions posed by Members of the Committee, and of course that will be part of the record. So thank you for your patience and your testimony.

Let us begin with the next panel. All right, if we can remove those folks and please find your seats so we can begin with the second panel.

We have Mr. Jerold Mande, Deputy Under Secretary for Food and Safety with the United States Department of Agriculture.

In addition to that, we have Ms. Cindy Smith, acting Under Secretary for Marketing and Regulatory Programs with the United States Department of Agriculture. It is my understanding that Ms. Smith will be available for questions and that she will not present testimony.

And then we will have Mr. Taylor, Senior Advisor to the Commissioner for the U.S. Food and Drug Administration, who will opine on behalf of the FDA.

So we will have two of our panel members out of the three who will make their 5 minute presentations at this time.

Mr. Mande, can we please begin with you.

STATEMENT OF JEROLD R. MANDE, DEPUTY UNDER SECRETARY FOR FOOD SAFETY; AND CINDY SMITH, ACTING UNDER SECRETARY FOR MARKETING AND REGULATORY PROGRAMS AND ADMINISTRATOR, APHIS, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Mr. MANDE. Mr. Costa, Mr. Goodlatte, Members of the Committee, thank you for inviting me to appear before you today as you

review current issues in food safety. Food safety is an important topic, and we welcome your interest.

My name is Jerold Mande, and I am the new Deputy Under Secretary for Food Safety at USDA. With me is Cindy Smith, USDA's acting Under Secretary for Marketing and Regulatory Programs, who will be available to answer any questions you might have on USDA's current activities and authorities on the farm.

Since this is my first time before your Committee, I want to briefly introduce myself. My career has been devoted to public service and public health. Before coming to USDA, I worked in positions affecting public health and food safety policy at Yale University School of Medicine, the White House, the U.S. Department of Labor, Food and Drug Administration, and the U.S. Congress.

This really is an important time for food safety. I am proud to be joining the team at USDA and to be responsible for the Food Safety and Inspection Service, which is the public health-focused inspection agency in the Department.

President Barack Obama, Agriculture Secretary Tom Vilsack, and Health and Human Services Secretary Kathleen Sebelius have made food safety reform a top priority; and they are to be commended for taking on this difficult and challenging issue. Members of this Committee have also demonstrated their dedication to improving the food safety system. I think that we all agree that we need the tools in place to achieve a virtual, single food safety system through cooperation and collaboration, and we cannot let this unique window of opportunity pass us by.

Just last week, the President's Food Safety Working Group released its Key Findings, which identified three core principles: first is prioritizing prevention; second, strengthening surveillance and enforcement; and third, improving response and recovery. The Key Findings highlight steps that USDA and FDA will take in the near future to improve food safety by preventing *Salmonella, E. coli O157:H7*, and building a national traceback and response system.

Let me tell you what we will be doing at USDA. The most important conclusion reached by the Working Group is the critical importance of prevention.

FSIS is moving aggressively to implement sensible measures designed to prevent outbreaks of foodborne illness. FSIS will develop or update performance standards to reduce the prevalence of *Salmonella* and *Campylobacter* in turkeys and young chickens. Performance standards demonstrate the plant's process control by measuring the presence of the pathogen in product. By revising current performance standards and setting new ones, FSIS will ensure food safety improvements in the products it regulates.

By the end of July, we will also take steps to further combat *E. coli O157:H7* in beef. For example, FSIS will provide our inspection program personnel with streamlined, consolidated instructions to inspect, sample, and act to reduce *E. coli O157:H7* in beef. At the same time, we will begin sampling of a new beef component, one not previously sampled. That component called "bench trim" is comprised of pieces left over from steaks and other cuts that are then used to make ground beef.

These actions to combat *E. coli O157:H7* build on a series of previous steps FSIS has taken to ensure our meat is safe. We have

started with the most common beef cuts that are used to make ground beef and added additional cuts step by step when the evidence supported it. We will continue to do that.

We have carefully reviewed the current food safety bills before Congress. In particular, we have studied H.R. 2749, the Food Safety Enhancement Act, which I recognize is of great interest to this Committee. We have concluded that this bill will not change FSIS's and FDA's current food safety jurisdictions. I know that has been a key concern of yours, so let me state that again: H.R. 2749 would not, in our opinion, alter the current jurisdictions of FDA or FSIS.

The President's Working Group also examined the laws that are the foundation of our system. We need 21st century laws to run a 21st century food safety system. With this in mind, USDA will be seeking to modernize its food safety statutes to address emerging threats to the food supply, new scientific understanding of those threats, and new technologies to combat those threats.

We seek the support and help of this Committee to find ways to modernize our current laws. We are developing concepts stemming from the legislative principles of the Working Group on priorities that we think should be addressed to modernize the statutes for the 21st century. I look forward to meeting with each of you in the near future to discuss our ideas.

My USDA colleagues and I are committed to on all-out effort to stop foodborne pathogens from reaching grocery store shelves and the dinner tables of American families. An effective food safety system is critical for all Americans, from farmers to processors to consumers.

Mr. Costa, Mr. Goodlatte, and Members of this Committee, I want to thank you for allowing me the opportunity to be here to discuss current food safety system enhancements; and I look forward to your questions.

[The prepared statement of Mr. Mande follows:]

PREPARED STATEMENT OF JEROLD R. MANDE, DEPUTY UNDER SECRETARY FOR FOOD SAFETY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, D.C.

Chairman Peterson, Ranking Member Lucas, and Members of the Committee, thank you for inviting me to appear before you today at this hearing to review the current issues in food safety.

First of all, I would like to introduce myself to the Committee. My name is Jerold Mande, and I am the new Deputy Under Secretary for Food Safety at USDA as of last week. Before coming to USDA, I was the Associate Director for Public Policy at the Yale Cancer Center, where I developed a national model to increase support for cancer prevention and control, including diet, exercise, and obesity. Prior to Yale, I served on the White House staff as a health policy adviser specializing in key food safety, tobacco control, and cancer initiatives. Among the food safety initiatives were the expansion of FoodNet and PulseNet. I was also Deputy Assistant Secretary for Occupational Health at the U.S. Department of Labor, and I was Senior Advisor and Executive Assistant to the Commissioner of the Food and Drug Administration (FDA), where I led the design of the Nutrition Facts food label. I began my career right here in Congress where I was first hired to work on food safety legislation. Having the opportunity to serve as Deputy Under Secretary for Food Safety returns me to the topic that originally attracted me to public service and I continue to remain passionate about food safety issues. I look forward to working with the Committee in the coming months and years.

Food safety is a priority for this Administration and the USDA's Food Safety and Inspection Service (FSIS). I commend President Barack Obama and Secretary Tom Vilsack for taking on this difficult issue and making review of the current state of our food safety system a top priority. I also appreciate this Committee's work to support FSIS and to explore ways to improve the nation's food safety system.

I would like to begin my testimony today with a description of the mission and a brief overview of FSIS and then I will move on to discuss the President's Food Safety Working Group and the important recommendations it has proposed to improve food safety.

Mission and Overview of FSIS

FSIS is the public health-focused inspection agency within the U.S. Department of Agriculture. It is responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, secure, wholesome, and accurately labeled and packaged, whether those products are domestic or imported. We administer and enforce the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, portions of the Agricultural Marketing Act, the Humane Methods of Slaughter Act, and the regulations that implement these laws.

FSIS Workforce

Our statutes require us to be present for all slaughter operations and to inspect each carcass, and we inspect each processing establishment at least once per shift. Inspection program personnel perform approximately nine million food safety and 1.5 million food defense verification procedures annually at these plants. In Fiscal Year (FY) 2008, FSIS personnel inspected about 50 billion pounds of livestock carcasses, about 59 billion pounds of poultry carcasses, and about 4.3 billion pounds of processed egg products. Additionally, FSIS personnel inspected 3.3 billion pounds of imported meat and poultry products at our borders.

In addition to in-plant personnel in federally-inspected establishments, FSIS employs a number of other field personnel, such as laboratory technicians and investigators. Program investigators conduct surveillance, investigations, and other activities at food warehouses, distribution centers, retail stores, and other businesses operating in commerce that store, handle, distribute, transport, and sell meat, poultry, and processed egg products to the consuming public. These in-commerce businesses do not operate under grants of inspection and are not inspected on a daily basis by FSIS. However, the agency verifies that FSIS-regulated products moving in consumer distribution channels continue to be safe and wholesome.

All products that FSIS inspection program personnel find to be not adulterated receive the USDA mark of inspection. This is one of our most powerful tools in protecting the public health. Denying the mark of inspection means that the product cannot legally be shipped in commerce and sold to the consuming public.

Data-Driven Science-Based Policies

Since 2000, FSIS has required that all meat and poultry plants operate under the Hazard Analysis and Critical Control Point (HACCP) system. Under HACCP, plants are responsible for identifying the hazards presented by the products they produce and the processes they implement, and for determining how to prevent, eliminate, or control the occurrence of those hazards. Our responsibility is to verify that plants are following their own food safety or HACCP plans. The HACCP system is designed to both prevent problems from occurring and facilitate the rapid identification and correction of problems before they occur.

In late 2001, FSIS began to employ food safety assessments (FSAs), further strengthening the public health protection provided by FSIS' program. These FSAs, carried out by highly trained scientific personnel, thoroughly assess the design of the plant's food safety plan, looking closely at whether the establishment has fully assessed the relevant hazards, and they verify that the establishment has put in place controls or preventive measures that are effective. These intensive reviews, now done on a routine basis, are valuable not only for what they accomplish but also because they provide data that the agency analyzes and uses to determine whether changes or refinements in agency policy are necessary. FSIS has committed to conducting routine FSAs in every plant every 4 years, and more frequently as needed.

Our policies at FSIS are rooted in science and based on data. Through science-based initiatives and efforts to continue to strengthen our infrastructure, FSIS works to prevent adulterated food from reaching the consumer. In 2008, FSIS personnel tested about 21,300 ready-to-eat product and environmental samples using risk-based criteria for *Listeria monocytogenes* and approximately 49,000 raw product samples for *E. coli O157:H7* in ground beef and *Salmonella* in raw meat and poultry.

Recalls

Recalls are the last weapon that FSIS uses to combat foodborne illness and protect public health. The purpose of a recall is to remove meat or poultry from com-

merce as quickly as possible when FSIS has reason to believe it is adulterated or misbranded. The agency issues information about a recall as quickly as possible to the public, stakeholders and public health partners through press releases which are also posted on FSIS' website at *www.fsis.usda.gov*. FSIS also posts lists of retail stores that received product if the product presents a significant (Class I) public health risk.

Imports

Finally, FSIS ensures the safety of imported meat, poultry, and processed egg products through a three-part approach. First, FSIS establishes the initial equivalence of the meat, poultry, or processed egg inspection system of a country that wishes to export to the United States. Equivalence is the foundation for FSIS' system of import safety. Second, we verify continuing equivalence of the foreign system through annual audits. Finally, FSIS import inspectors perform re-inspection of all shipments of meat, poultry, and processed egg products at the border, including statistically-based random sampling that is intended to verify the effectiveness of the foreign inspection system.

The country-to-country approach to food safety that FSIS applies is an efficient and effective means to ensure the safety of the products that FSIS regulates and illustrates that our trading partners' governments have appropriately invested in and exercised control of their food safety infrastructure. The equivalence principle recognizes that an exporting country can employ different sanitary measures than the U.S. to address food safety hazards if the country can objectively demonstrate that its safety measures achieve the same level of public health protection as the measures used by the United States for its meat, poultry, and processed egg products.

Food Safety Working Group

The Obama Administration has already begun to act on food safety. President Obama announced the formation of the Food Safety Working Group in March and called on Agriculture Secretary Vilsack and Health and Human Services Secretary Kathleen Sebelius to co-chair the Working Group. While FSIS and FDA have a major role in the Working Group, input from other agencies and stakeholders is critically important. At a Listening Session hosted by the White House on May 13, representatives from industry, consumer advocacy groups, state governmental agencies, and even members of your own staffs participated in breakout sessions to discuss important food safety priorities. The members of the Working Group value all the comments heard that day and are dedicated to bringing all stakeholders into the picture. The public can post their comments on the interactive website, *www.foodsafetyworkinggroup.gov*. Summaries of the Listening Day breakout sessions are also available on the same website.

Just last week, the Key Findings of the Working Group, which incorporated some of the comments from the Listening Day, was released and identified three core principles: (1) prioritizing prevention; (2) strengthening surveillance and enforcement; and (3) improving response and recovery. The Key Findings highlights steps that FSIS, FDA, and other Federal agencies will take in the near future to improve food safety by preventing *Salmonella* contamination, reducing the threat of *E. coli O157:H7*, and building a national traceback and response system.

Focus on Prevention

The most important conclusion reached by the Working Group is the critical importance of prevention. Too often in the past, the food safety system has focused on reacting to problems rather than preventing them from occurring. The Working Group recommends a shift to prioritizing prevention and moving aggressively to implement sensible measures designed to prevent outbreaks of foodborne illness.

FSIS fully supports the Working Group's recommendation to focus on preventing foodborne illnesses from occurring. In fact, FSIS has already begun moving in the direction of prevention by increasing its focus on risk. As stated previously, the agency has already implemented HACCP for meat and poultry products. In addition, FSIS has used performance standards for some foodborne pathogens to reduce the occurrence of those pathogens in meat and poultry products. The agency is conducting baseline studies that will provide the data necessary to establish new and up-dated performance standards for the foods that FSIS regulates.

FSIS will continue to develop and implement other preventative measures. The Key Findings highlighted two recommendations that will work to prevent the prevalence of two common foodborne pathogens in meat and poultry products. FSIS is moving forward to implement these recommendations. First, FSIS will develop a performance standard for use in reducing the prevalence of *Salmonella* in turkeys and will revise the current *Salmonella* performance standard for young chickens. In

addition, FSIS will develop performance standards for *Campylobacter* for both turkeys and young chickens. Performance standards demonstrate the plant's process control by measuring the presence of the pathogen in product. By revising current performance standards and setting new ones, FSIS will ensure food safety improvements in the products it regulates. The agency will also enhance its *Salmonella* verification program with the goal of having 90 percent of poultry establishments meeting the new standards by the end of 2010. FSIS will also provide our inspection program personnel with streamlined, consolidated instructions to inspect, sample, and act to reduce *E. coli O157:H7* in beef. At the same time, we will begin sampling of a beef component not previously sampled. That component, called "bench trim," are the pieces left over from steaks and other cuts that are then used to make ground beef. These actions build on a series of previous steps FSIS has taken to ensure our meat is safe. We have started with the most common beef cuts that are used to make ground beef, and added additional cuts step-by-step when the evidence supports it. We will continue to do that.

Strengthening Surveillance and Enforcement and Improving Response and Recovery

FSIS is just as committed to the other two core principles identified by the Working Group. The agency will be implementing regulatory and administrative actions over the next 2 years to strengthen its surveillance, inspection, and enforcement activities and to improve outbreak response and recovery such as enhancing the national surveillance networks for foodborne diseases like FoodNet and PulseNet and improving coordination and communication with food safety and public health partners in an outbreak.

To strengthen its surveillance through inspection, FSIS has been working on a number of actions related to data integration and analysis. The most significant initiative is the development of a Public Health Information System (PHIS), which will integrate the agency's data systems to allow FSIS to quickly and accurately identify trends, including vulnerabilities in establishments' food safety systems, and thus allow us to more efficiently and effectively protect public health. It will be a truly remarkable new tool that will revolutionize how our inspection program personnel work by dramatically increasing the value of their observations in the field.

The Key Findings identified the following other recommendations for FSIS. First, within 3 months, FSIS will work with other Federal agencies to create a new incident command system to address outbreaks of foodborne illness. This approach will link all relevant agencies, as well as state and local governments, more effectively, facilitating communication and decision-making in an emergency. Second, FSIS, FDA, and the Centers for Disease Control & Prevention will work with state and local agencies to update their emergency operations procedures to be consistent with the new "Guidelines for Foodborne Disease Outbreak Response" to be issued by the Council to Improve Foodborne Outbreak Response this month. Implementation of these guidelines will lead to quicker response, better communication, and better coordination by all Federal, state, and local agencies. Third, FSIS will improve collaboration with states by increasing the capacity of its successful public health epidemiology liaison program to state public health departments and expanding outreach within 6 to twelve months. Finally, the website *www.foodsafety.gov* will be enhanced to better communicate information to the public and include an improved individual alert system allowing consumers to receive food safety information, such as notification of recalls. Agencies will also use social media to expand public communications. The first stage of this process will be completed in 90 days.

Modernizing Food Safety Laws

The Working Group was charged with examining the whole picture of the U.S. food safety system and emphasizes the need to upgrade our food safety laws for the 21st century. The current system is hamstrung by outdated laws, some of which were enacted over 50 years ago. While the meat and poultry acts have been amended many times, they do not allow us to address the significant risks facing our food supply as effectively and efficiently as possible. These laws should be modernized to allow for improved flexibility and coordination and to enable USDA to move quickly to address the emerging threats to the food supply.

We seek the support and commitment of this Committee to find ways to modernize the current laws. We are developing concepts, stemming from the legislative principles of the Working Group, on priorities we think should be addressed to modernize our statutes for the 21st century. I look forward to meeting with you in the near future to discuss our ideas. There are currently bills before Congress to address FDA's authorities, such as H.R. 2749, the Food Safety Enhancement Act of 2009, but we must also modernize FSIS' statutory authorities to create a national food safety system. There are many valuable provisions in H.R. 2749 and we would

like to see similar legislation for FSIS. There has been unprecedented cooperation and collaboration between USDA and HHS on the Food Safety Working Group.

In the future, once Congress passes a bill and it is enacted into law, the cooperation and collaboration will continue as FSIS will work closely with Congress and FDA to implement the new legislation. We think that this modernization will be facilitated if we gather ideas from the public and our workforce through listening sessions and other means. For example, this hearing, as well as the one held by the Subcommittee on Livestock, Dairy, and Poultry in April, is very useful to gauge the input from Congress.

Not only will the modernization of FSIS' authorizing statutes improve public health outcomes, but, in conjunction with modernization of the Federal Food, Drug, and Cosmetic Act, it will be an opportunity to better coordinate food safety laws and regulations across the Federal Government.

Next Steps

Mr. Chairman and Members of the Committee, I am proud to be joining the team at USDA and to have the opportunity to oversee the Food Safety and Inspection Service. It is an exciting time for food safety in this country. President Barack Obama, Secretary Tom Vilsack, and Secretary Kathleen Sebelius have clearly expressed a willingness to tackle food safety, and they are to be commended again for taking on this difficult and challenging issue. Members of Congress have also demonstrated their dedication to improving the food safety system. We cannot let this window of opportunity pass us by.

High profile outbreaks in everything from FSIS-inspected ground beef to FDA-inspected peanut products and cookie dough cause American consumers to lose confidence in the safety of their food supply. For its part, FSIS is ready to continue this dialogue and will remain committed to improving its preventative public health infrastructure in an all out effort to stop foodborne pathogens from reaching grocery store shelves and the dinner tables of American families.

Chairman Peterson, Ranking Member Lucas, and Members of the Committee, thank you again for allowing me the opportunity to be here today to discuss our current food safety system and future enhancements. I look forward to your questions.

Mr. COSTA. Thank you, and we look forward to asking the questions.

Next is Mr. Taylor, Senior Advisor to the Commissioner of the U.S. Department of Food and Drug Administration.

Mr. Taylor.

STATEMENT OF MICHAEL R. TAYLOR, J.D., SENIOR ADVISOR TO THE COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MD

Mr. TAYLOR. Good afternoon, Mr. Costa, Mr. Goodlatte. I am Mike Taylor, Senior Advisor to the Commissioner at the Food and Drug Administration; and I want to thank you for the chance to be here and particularly to join my colleagues at USDA.

Just last week, I started work as Senior Advisor to the Commissioner. It really is an exciting time to be back at the Food and Drug Administration, where I happened to work twice before in my career. I look forward especially this time to working closely with USDA and all of our food safety partners, especially Congress, as we move forward to modernize the nation's food safety system.

As you know, I also had the honor from 1994 to 1996 to serve as Administrator of the USDA's Food Safety and Inspection Service and to appear before this Committee in that capacity, so it is a pleasure to be back before you as well.

Mr. Chairman, I greatly value my experience at USDA, both because of the opportunity that I had then to work with the dedicated people at FSIS on important improvements in the inspection pro-

gram, but also because of what I learned about how the major elements of the nation's food safety system work together. There is, in fact, a long history of collaboration between FDA and various components of USDA to manage and prevent food safety problems, and both agencies, in fact, have a long history of working with the agricultural sector.

I am especially delighted to be coming back into government at a time when the President, as Mr. Mande indicated, has not only made food safety a high priority, but has called for even greater collaboration among the food safety agencies. We at FDA embrace that charge enthusiastically, because we know that the vision of a modern, science-based and prevention-oriented food safety system simply demands that we all work together.

As you also know, FDA is the Federal agency that is responsible for most of the food supply except for the meat, poultry, and processed egg products, which are overseen by our partners at USDA. Ensuring the safety of FDA-regulated products is really central. It is a vital part of FDA's public health mission; and, importantly, our work on such topics as animal drug approvals, animal drug residues, and animal feed supports USDA's mission in turn in ensuring the safety of meat, poultry, and processed egg products.

As Mr. Mande indicated, the President's Food Safety Working Group recently issued its Key Findings, which we at FDA of course embrace fully and Mr. Mande has outlined: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The Working Group noted the need to modernize the food safety statutes to provide key tools that both FDA and USDA need to keep food safe. At FDA, the new statutory tools that we need, broadly speaking, include enhanced ability to require science-based preventive controls for food safety at food facilities; enhanced ability to establish and enforce performance standards that ensure the proper implementation of preventive controls; better tools to foster compliance with science-based standards, including enhanced inspection and access to basic food safety records; and, finally, new tools to strengthen FDA's ability to oversee food imports.

H.R. 2749, the bill we are focusing on today, addresses all of these authorities. But I also note, Mr. Costa, the bill that you introduced with many of your colleagues on this Committee, H.R. 1332, the Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009, also addresses many of these points, as does the bill introduced by Chairwoman Rosa DeLauro of the Appropriations Subcommittee that oversees the budgets of our two agencies. These bills are really important to note because they illustrate the broad agreement that exists today on the general direction of food safety reform toward risk-based preventive controls to reduce foodborne illness, which is a public health goal that, as evident from this hearing today, we all share. That is a common objective for all of us.

Now, for FDA, one of the most important elements of the legislation that is before the Congress that has come out of Energy and Commerce is that it provides a mandate for FDA to achieve specified frequencies of inspection. The legislation also provides a funding source to help FDA fulfill its new responsibilities. A greater in-

vestment in inspection is critical to ensuring high rates of compliance with preventive control standards and other food safety performance standards that will help drive improvement in food safety and drive reduced rates of foodborne illness. FDA thus supports the bill's inspection frequencies for domestic facilities.

However, food imports present a significant resource challenge. FDA plans to increase inspection of foreign food facilities, but we are concerned that the bill's foreign inspection mandate may not result in the best use of FDA's resources in light of the approximately 200,000 registered foreign facilities, and the high cost of overseas inspections.

We believe we can achieve cost-effective oversight of imports by working with foreign governments, increasing targeted risk-based foreign inspections by FDA, strengthening importer accountability for the safety of the food they import, and supporting strong third-party inspections. We think it will take a mix of these initiatives to provide the oversight of imports that we need.

Before closing my oral statement, I just want to say that I look forward to the discussion that we started earlier in this hearing, and I hope we will continue now with the scope and the impact of this legislation on the farm. I think that is an important discussion to have, and I hope that we can allay some of the concerns that I have heard expressed about the scope and impact of the bill.

There are three points that I will just touch on briefly and we can hopefully go into a little bit more.

First of all, there is nothing new about FDA's presence on the farm. We have already mentioned FDA's role with animal drugs, animal feed regulated by FDA, feed additives, and produce. FDA has a long history of being present on farms with respect to produce and shell egg safety. Most recently, FDA issued a new rule to address shell egg safety.

The second point is that there is a history of collaboration with USDA with respect to on-farm matters in cooperation with the agriculture sector in ways that have yielded real benefit, both for food safety, for public health, and for the agricultural sector. And we could talk about the collaboration between FDA, APHIS, and FSIS on BSE control and prevention, which has been a real success story that has been very collaborative; the whole issue of animal drug and tissue residues, which again FDA set certain standards. FSIS inspects. We investigate when there are problems. There is a very cooperative relationship that has ensured high compliance with the standards to limit animal drug residues in meat and poultry products.

I could go on. Dairy regulation—I mentioned eggs—there are a number of examples of this sort of cooperation; most recently, produce. With good agricultural practice and guidance, we will be coming out with some more of those soon.

The final point that I just want to flag and I know you will want to probe is that the bill that, as it has emerged through the process so far, has actually done a very good job of being very judicious about the way the bill would reach the farm.

First of all, farms continue to be exempted from the registration requirement and the requirements that come with that including the fee concern I heard expressed earlier. Farms are exempt from

registration and from the fee. That applies only to facilities as defined in the Act. Farmers are exempted from the comprehensive preventive control requirement that applies to all food facilities. That does not apply to farms.

Those authorities that FDA would be given to address food safety problems that do arise on the farms, such as potentially with produce, are authorities that require FDA to meet a certain risk threshold to do rule making, to devise anything but one-size-fits-all controls that really address the particular hazard. I think that is very much in keeping with the science-based approach that FDA believes is important for food safety.

There are other ways in which the authorities that FDA has to pursue traceability, to potentially require record-keeping, these all require not only that FDA meet some test of its being risk-based, really serving a food safety purpose, but will require FDA to consult with USDA, which we would do anyway, and would require us to engage the community through rule-making.

So, we have a bill here that has gone a long way towards addressing some of the concerns here, and I look forward to further discussion of that. Thank you.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF MICHAEL R. TAYLOR, J.D., SENIOR ADVISOR TO THE COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MD

Introduction

Good morning, Chairman Peterson and Members of the Committee. I am Mike Taylor, Senior Advisor to the Commissioner, at the Food and Drug Administration (FDA or the agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to review current issues in food safety, especially pending food safety legislation. I am pleased to be here with my colleagues at the U.S. Department of Agriculture (USDA).

Last week I was appointed as a Senior Advisor to the Commissioner of Food and Drugs. I am happy to be back at FDA to continue my work in the food safety arena. When I served as FDA's Deputy Commissioner for Policy from 1991 to 1994, I was involved in the issuance of regulations to address seafood safety and to implement nutrition labeling requirements. From 1994 to 1996, I served at USDA as the Administrator of the Food Safety and Inspection Service and as Acting Under Secretary for Food Safety. While at USDA, I led the development of new safety requirements for meat and poultry. Since 2000, my food safety work has been in the academic and research arenas. It is an exciting time to be back at FDA, and I look forward to working closely with USDA and all of our food safety partners, including Congress, as we move forward to modernize the nation's food safety system.

By way of background, FDA is the Federal agency that is responsible for most of the food supply except for meat, poultry, and processed egg products, which are overseen by our partners at USDA. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission, and FDA's work on animal drug approvals, animal drug residues, animal feed, and other issues also supports USDA's vital food safety responsibilities with respect to meat, poultry, and processed egg products.

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

President Obama has made a personal commitment to improving food safety. On July 7, 2009, the Food Safety Working Group, which he established, issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group recommends a new public-health focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

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

- the ability to require sanitation and preventive controls at food facilities, based on a scientific hazard analysis;
- the ability to access basic food safety records at facilities;
- the ability to use resources flexibly to target food at the highest risk and achieve the maximum gain for public health;
- the ability to establish performance standards to measure the implementation of proper food safety procedures; and
- the ability to require mandatory recalls.

A food safety bill recently passed by the Committee on Energy and Commerce in the House of Representatives, H.R. 2749, the "Food Safety Enhancement Act of 2009," addresses all of the above authorities and includes many of the other key recommendations of the Working Group. This legislation's primary sponsors include Chairman Henry Waxman of the Committee on Energy and Commerce, Chairman Emeritus John Dingell, Chairman Frank Pallone of the Health Subcommittee, and Chairman Bart Stupak of the Subcommittee on Oversight and Investigations.

Another comprehensive food safety bill is H.R. 1332, the "Safe Food Enforcement, Assessment, Standards, and Targeting Act of 2009" or "SAFE FEAST Act." Its sponsors include many Members of this Committee, including Representative Jim Costa, Chairman Collin Peterson, and Subcommittee Chairmen Dennis Cardoza, Leonard Boswell, Joe Baca, and David Scott, as well as other Members. H.R. 1332 also includes many of the authorities identified as important by the Working Group, such as preventive controls and mandatory recall authority.

The Chairwoman of the House Appropriations Committee's Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, Representative Rosa DeLauro, also has introduced legislation, H.R. 875, the "Food Safety Modernization Act of 2009," which provides comprehensive reform to the food safety statutes.

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

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

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

Food Safety Legislation

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

- First, does the legislation support a new system focused on prevention?
- Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities?
- Third, does the legislation provide or anticipate resources for the agency to match its responsibilities?

As H.R. 2749 was recently passed by the Committee on Energy and Commerce, I will focus on that bill for a discussion of these questions. I will address each of these three questions in turn and highlight a few of the many important new authorities in this bill.

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

The legislation would indeed transform our nation's approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

FDA is eager to further the development of this modern system. Working with USDA, industry, consumers, states, localities, and other key partners, we will establish basic standards for preventive controls. We will then join with states and localities to create an integrated national system of inspection, verification, and enforcement.

Key relevant provisions in the legislation include section 102, which requires facilities to conduct hazard analyses and implement preventive controls. It also requires companies to have a comprehensive food safety plan. Section 104 requires adherence to science-based safety standards issued by the Secretary for fresh produce and certain other raw agricultural commodities to prevent contamination. Section 112 improves FDA's ability to share key information on food safety between levels of government. These, and other provisions, are critical to modernizing our nation's food safety system.

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

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

The legislation recognizes the importance of modernizing FDA's efforts to protect the safety of the food supply. Under sections 102, 103, and 104, the failure to comply with preventive controls, the food safety plan requirement, performance standards, or safety standards for produce would result in the food being deemed adulterated. An adulterated food is subject to seizure, condemnation, and forfeiture, and also may be refused admission when offered for import into the United States. Section 132 makes the agency's administrative detention authority more useful by expanding the circumstances under which the agency can detain a food, thereby preventing its movement or distribution while the agency takes appropriate regulatory action. Section 134 increases the criminal penalties for certain "knowing" violations, including distributing violative food, and section 135 provides the agency with civil penalties when a person violates the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Together, these authorities underscore the responsibilities of firms to only market safe food and give the agency essential tools to enforce these requirements to protect American consumers.

The bill also recognizes the importance of providing FDA with improved access to information. Section 101 requires facilities to register annually, deems products of non-registered facilities misbranded and consequently prohibits their sale, and allows FDA to modify the food categories that firms provide during registration. These measures will help ensure that the agency has accurate information about who is making food for American consumers.

Section 204 will provide FDA with important information about commercial importers and require that they comply with good importer practices as a condition of maintaining the registration. This section also prohibits importing a product without being properly registered, and deems a product misbranded if it is imported by an unregistered broker or importer.

The requirements in this section of the bill represent significant enhancements to FDA's authorities with respect to imported products. At present, importers and brokers are not required to register with FDA. These changes will reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety, and by allowing FDA to take action against importers who do not implement appropriate measures to ensure the safety of the products they import—similar to FDA's ability to target domestic producers and facilities that have not taken these measures.

Section 106 provides FDA with explicit authority to access food records during routine inspections, thereby addressing one of the most significant gaps in FDA's existing authority. The authority provided in this provision is essential to enable FDA to identify problems and require corrections before people become ill. It also enables the agency to verify during routine inspections that firms are maintaining required records.

Although FDA has routine records access for certain other FDA-regulated products, and USDA has routine records access for USDA-regulated products, FDA does not have explicit authority for routine access to records for the vast majority of foods under its jurisdiction. This provision provides FDA with access to critical information to identify problems before an emergency occurs. Under current limited authority, FDA generally only has access to required records during an emergency situa-

tion involving serious threats to health or life. Records access and record-keeping by all persons in the distribution chain are the key mechanisms of providing regulators with information on plant operations, product safety, and product distribution. Such information is necessary to verify compliance and identify problems.

The requirement in section 107 to implement a product tracing system for food will also provide FDA with enhanced information that will help the agency trace foods more quickly during an outbreak. The current requirement to keep records for the immediate previous source and immediate subsequent recipient (one up/one back) requires the agency to go to each point in the distribution chain during an outbreak to trace the source and distribution of the contaminated product, which is not a sufficiently expedient process when trying to prevent more people from becoming ill. The ability to trace the path of any food, including tomatoes, other fresh produce, and peanut butter, back through every point in the supply chain to the source, or forward through the supply chain to the retailer or food service establishment is crucial for limiting foodborne illness during an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses.

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

One of the most important elements of the legislation is that it provides FDA, for the first time, a mandate to achieve specified frequencies of inspection. The legislation also provides a funding source to help FDA fulfill its new responsibilities. A greater investment in inspection is critical to ensuring high rates of compliance with the preventive control standards and other food safety performance standards that will help drive improvement in food safety and reduced rates of foodborne illness.

Section 105 proposes a rigorous inspection schedule for food facilities, ranging from at least every 6 to 12 months for high-risk processing facilities, every 18 months to 3 years for low-risk processing facilities and food labelers and packers, to at least every 5 years for warehouses. These requirements start 18 months after enactment. To meet these requirements, section 105 allows the agency to use inspections conducted by inspectors from recognized state, local, and other Federal agencies, and foreign government officials.

FDA supports the bill's inspection goals for domestic food facilities. We also welcome the challenge and opportunity provided by the bill to develop and apply the most modern approaches to inspection, including wider use of microbial testing, to verify that companies are meeting their prevention responsibilities and to achieve our public health goals.

We also appreciate the flexibility the bill provides to adjust inspection frequencies based on solid information about where we can achieve the greatest public health benefit through wise use of our finite resources. This flexibility would allow for more frequent inspection of foods, facilities, and processes that we find to be high risk and possibly less frequent inspection of facilities that we can have confidence, based on evidence, pose low risk.

Food imports present a significant resource challenge. It is important that food imports meet the same requirements as domestic products, and we are pleased that the bill provides FDA with new tools to help achieve this, including the requirement that importers observe good importer practices and authorization to require certification of compliance for imported food under certain circumstances. FDA plans to increase inspection of foreign food facilities, but we are concerned that the bill's foreign inspection mandate may not result in the best use of FDA's resources, in light of the approximately 200,000 registered foreign facilities and the high cost of overseas inspections. We think we can achieve cost-effective oversight of imports by working with foreign governments, using the bill's new tools for import oversight, supporting strong third-party inspections, and increasing targeted, risk-based foreign inspections.

The bill authorizes three fees that are also requested in the President's FY 2010 budget. For example, section 101 provides for a registration fee. This fee is of critical importance to enable the agency to increase its inspection coverage of the approximately 378,000 registered facilities and to enhance its other food safety activities. Section 108 provides for a reinspection fee for a food facility that commits a violation that requires additional inspections by FDA. This will help cover the costs of reinspecting FDA-regulated facilities that fail to meet Current Good Manufacturing Practices (CGMPs) or other FDA requirements. Section 203 authorizes the Secretary to charge and collect a fee for the issuance of export certificates for food and animal feed which would facilitate trade. This fee will help cover the cost of this program, which is necessary for firms to do business with countries that require such certificates.

We are committed to working with Congress to ensure that FDA has sufficient resources, including fees, to carry out its inspection mandate.

Conclusion

This is a historic moment for food safety in the United States—a moment for FDA and its sister agencies in the Federal Government to rise to the challenge of the 21st century. Success means fewer hospitalizations and deaths, fewer economically devastating recalls, and greater health for the American people. As Secretary Sebelius recently noted at a Food Safety Working Group listening session, "with the leadership and commitment by our President and so many Members of Congress, and this renewed partnership across HHS, USDA, and our sister Federal agencies, I know that this is the time when we will finally make real progress and strengthen our nation's food safety system."

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

Thank you again for the opportunity to discuss FDA's perspective on pending food safety legislation. I would be happy to answer any questions.

Mr. COSTA. All right. I think you hit at the heart of a number of our questions, but let me first go back to Mr. Mande.

In your oral testimony, I thought you mentioned that the goal was to move toward a single food safety agency.

Mr. MANDE. No, I said sort of a single food safety system, a seamless system.

Mr. COSTA. A seamless system but not a single agency; is that correct?

Mr. MANDE. What I said was a single system so that producers and the public can look at one food safety approach.

Mr. COSTA. So it is not the Administration's intent, then, with this collaborative effort that you have spoken of, that you have participated in to produce this report, to, in fact, produce a plan that would create a single food agency.

Mr. MANDE. That recommendation is not in the President's Working Group report.

Mr. COSTA. All right.

Mr. Taylor, you hit the nail on the head as it relates to many of the concerns related to the certain proposed legislation. Are you saying or am I to take from your last comments that the FDA does not believe that it is necessary to have the authority to inspect farms, from our grain farms in the Midwest to our vegetable farms, where a great deal of specialty crops are raised, to our livestock?

Mr. TAYLOR. No, sir, that is not what I am saying, Mr. Costa. In fact, FDA has long had the authority under the current Federal Food, Drug, and Cosmetic Act to inspect farms, inspect anywhere—anyplace where food is produced or held. It is authority that traditionally has not been exercised very much, but it is authority that is important. Because when there is a problem that arises and—for example, when we have problems with a produce situation, it is essential that FDA be able to get back to the farm, the source of production, so that we can know what the source is, contain the problem for the benefit of the public health.

Mr. COSTA. So is it the intention of the agency, then, to promulgate rules and regulations for on-farm food safety practices and then to begin conducting inspections to see if those on-farm safety practices are being followed?

Mr. TAYLOR. The bill will give FDA the authority to establish on-farm safety practices with respect to produce, and they require the

agency to, on a risk basis where we believe it would make a meaningful difference in improving the safety of the product, to establish regulations with respect to particular commodities or classes of commodities.

And then the question is, how do we ensure compliance with those standards? And this is where I think we would envision working closely with state agencies, devising a way to ensure there is adequate oversight to verify compliance.

Mr. COSTA. So it is the intention then for the agency to promulgate rules and regulations that will provide for on-farm inspections, and then I would assume with the fees the Food and Drug Administration would intend to send those inspectors to those farms to determine whether or not those rules are being followed?

Mr. TAYLOR. Well, again, the first step is setting standards; and there are a number of ways that we would go about seeking to ensure compliance.

One role, one function of the standards would be to say to the commercial sector, the purchasers, that these are the standards that products are required to meet; and we would expect, as is often the case with these standards, the private sector would do a lot of the enforcement, if you will———

Mr. COSTA. So have you taken the time to envision how many new inspectors the Food and Drug Administration would need to provide these on-farm inspections?

Mr. TAYLOR. Again, the scope of the on-farm inspection activities can't be mapped out at this stage because we haven't decided what commodities will be subject to the new standard.

Mr. COSTA. Do you think in determining risk assessment and risk management that that is the best way to address these issues of safety?

Mr. TAYLOR. Yes. That in effect is what the bill calls upon us to do, is to identify where the risks are and to establish appropriate controls and standards to minimize those on the basis of science, on the basis of where we can demonstrate this for the benefit of food safety.

Mr. COSTA. In addition to the legislation that we have been discussing, there has been talk about FDA's authority to have quarantine in geographical regions, the ability to provide that quarantine for various products. Some products do move, as animals do. Shouldn't the goal be to move away from, it seems to me, a negative or a reinforcement or a punishment to a geographic region in the use of this quarantine?

Mr. TAYLOR. Well, again, what we want to be doing is preventing problems and not having to deal with situations that might arise where some sort of a reaction to a problem is needed. As I read the quarantine provision, though, that is a provision that is aimed at a very unusual situation where there is an imminent risk of very significant harm to the public health.

Mr. COSTA. But don't you think if you have a significant traceback program that people have confidence in that a quarantine is not necessary?

Mr. TAYLOR. Quarantine simply addresses what you do if you do traceback to a situation where the only way that you can protect

the ag sector and the public is to contain the food that you believe is at most risk.

Mr. COSTA. But if you can traceback—we had an example last year where Members of the Committee, not this Committee, I believe the Committee that has jurisdiction of the bill, went on farm; and they looked at tomatoes grown in various stores that were being sold and traced it back to five different farms within a period of a half an hour to a 5 hour period. Why would you want to put a quarantine over a region when you have the ability to trace the individual farms in which that product came from?

Mr. TAYLOR. That is a very important point. One of the values of traceback would be to target where the problem is. Quarantine is going to be a very unusual remedy. I mean, in the ordinary case if you traceback and you know the scope of the problem and you can take care of the problem there is no need for quarantine. That would be a very unusual remedy where there was no other alternative way to contain a problem.

Mr. COSTA. My time has expired; and I think the gentleman from Kansas is next, Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you very much.

The on-farm performance standards that are being considered in this legislation, a couple of questions. What is the conclusion or the basis that FDA would be the better regulator than USDA in regard to those performance standards? And are those performance standards going to be compatible with what we can expect from foreign producers of agriculture products who import into the United States?

Under current law, meat and poultry, we have some assurance that those meat and poultry products that are coming in are produced under similar standards. It seems to me that we are once again creating a significant competitive disadvantage, increasing costs for production of agriculture in the United States in a sector of our economy that continues to compete with foreign producers.

Mr. TAYLOR. Let me address that second question first.

Any standards we set domestically for domestic producers would have to be met by foreign producers. That is an absolute basic principle. We can't have a separate standard for domestic producers.

Mr. MORAN. And our ability to ensure that those standards are being met would be what?

Mr. TAYLOR. Well, if this law were passed, it would be this combination of new authorities and tools that we would have to oversee and ensure compliance with those standards. So it would include working with foreign governments to step up what they do. It would include for the first time FDA clearly having legal authority to inspect foreign facilities and to prevent food coming in if companies overseas have prevented us from inspecting.

We need to look at strengthening, very fundamentally, the importer's duty to manage that supply chain. That is another important part of the puzzle. And third-party certifications done in a rigorous accredited sort of way are all elements of doing this.

When you have 200,000 overseas facilities, it is very clear that there is not one sort of simple way to provide the level of assurance that we need. And I agree with you completely. We need that. We

have to look at putting together a set of elements to produce that result.

Mr. MORAN. Would the U.S. be able to enforce those performance standards in foreign countries?

Mr. TAYLOR. We would do the enforceability at the point of entry. I mean, one of the elements of this bill is to require the importer to maintain good importer practices, which includes documentation of the controls that are in place overseas and the fact that those products have met our standards, so we have direct authority over the importer.

Plus, the bill would give FDA extraterritorial jurisdiction over violations of the Act so that again we can begin to address those problems upstream. I think that one of the strengths of the bill is that it addresses FDA's need for strengthened legal tools to oversee imports.

Mr. MORAN. Are there scientific standards that are accepted globally in regard to food safety?

Mr. TAYLOR. For some commodities and some hazards, yes, and for some, no. I think in the case of produce this issue of how you set specific, quantitative standards to try to give benchmarks for controlling pathogens, that is a work in progress. We have more work to do with the scientific community, with USDA, with the agricultural community.

We have Good Agricultural Practices, sort of broad guidances and standards; and the industry itself has started to develop specific quantitative metrics for what would be the microbial quality of the water used in irrigation. And we need to move in that direction to use these science-based criteria so we can have objective benchmarks for safety. But that is a work in progress that this bill would really compel FDA to pursue; and, hopefully, we would invest in the science that makes that possible.

Mr. MORAN. We have been trying for a long time to utilize scientific-based standards in regard to, for example, meat export, our battles with Japan and Korea and others to accept meat products from the United States. It seems to me it has been very difficult to reach a conclusion, and particularly when there is a competitive advantage or disadvantage based upon that scientific standard.

Mr. TAYLOR. Right. These are difficult issues, and there are always going to be disputes, and there is a long way to go to harmonize standards internationally. But that is a worthy goal.

Mr. MORAN. Then my question about USDA *versus* FDA. The FDA, it seems to me, doesn't have the tools, the personnel, the county FSA offices that USDA has. Is there a reason that FDA makes more sense than USDA?

Mr. TAYLOR. Well, Congress in its wisdom gave FDA its jurisdiction decades ago that FDA has been exercising and working with the agricultural community, working with USDA on developing guidances. I think there is actually a lot of expertise at FDA on this subject. But FDA would not work in isolation. I think no one could work in isolation on this topic. We have to work with others.

Mr. MORAN. Let me ask a different question on a different topic of today's hearing. The prevention and pro-growth antibiotics, it seems to me—in fact, as I understand it, the President announced his support for the ban in recent days. What has happened scientif-

ically? What study has arrived that says this is the new standard? Are we basing this belief on some—it seems to me that almost in a very short period of time we have changed our theory about the use of antibiotics; and my question is, what is the scientific basis for that change?

Mr. TAYLOR. Well, actually, the scientific consensus on this issue, that we have a public health concern with nontherapeutic, nontreatment uses of antibiotics, that consensus has emerged over the last several years. The World Health Organization, our Institutes of Medicine, the National Academy of Sciences here have made this finding before. So in terms of scientific ground breaking, we really didn't break new scientific ground.

FDA expressed its public health judgment really in line with the judgment of scientific bodies, consensus bodies, that this nontherapeutic, growth-promotion, feed-efficiency use presents a public health concern and is not a judicious use of antibiotics from a public health standpoint. So there is really not new scientific ground being broken, particularly.

Mr. MORAN. Was there consultation with, for example, Ms. Smith at USDA before reaching this conclusion?

Mr. TAYLOR. Well, I have to take a little bit of a pass on exactly the details of what happened before I started a week ago last Monday, but this is—FDA has been part of an interagency task force on antibiotics. CDC is involved. I know there has been involvement of USDA in that process, and we can brief you happily on all the details of that.

But, no, the FDA definitely doesn't work in isolation on this issue. The Center for Veterinary Medicine is very engaged with the whole animal production industry and with colleagues at USDA.

Mr. MORAN. Mr. Chairman, thank you for the time. I have not seen Mr. Boswell's, the gentleman from Iowa, testimony before the House Rules Committee, but I feel very comfortable in at least commending him for his leadership on this topic of antibiotics, and I appreciate his involvement in this discussion.

I yield back. My time has expired.

The CHAIRMAN [presiding.] I thank the gentleman.

I think you folks, I guess, heard the testimony of the previous panel where the livestock, poultry people, and the grain people are concerned that the language that is in the current bill that was marked up by the Energy and Commerce Committee is not sufficient to take care of their concerns. How do you interpret the situation, all three of you? Their concerns, do you think they are valid enough?

Mr. TAYLOR. I did hear a number of concerns expressed about—for example, from the standpoint of the gentleman who runs the organic farm business, that he had the impression that he would be required to register and pay a fee. Well, that is just not the case.

I think there are a number of concerns about the reach of this that really go way beyond what the bill would actually do. Because, again as I indicated earlier, I think the bill has been very judicious about putting boundaries around the scope of this authority and exempting farms very broadly from the core requirements of registration and preventive controls. So I would like to think that we can dialogue to allay those concerns and answer those questions.

And, it is still a work in progress, of course; but, we have come a long way to produce a pretty well-bounded bill.

The CHAIRMAN. Do you two have any comments?

Mr. MANDE. I would add that, as I said in my testimony, we have looked at the bill, and we don't think it changes the jurisdiction between FDA and the Department of Agriculture. I think the one thought I'd add is I did hear some from the panel maybe a higher comfort level with some of the work that USDA has done over the years. And, while this legislation doesn't change that, I think what we are witnessing, and have seen a trend toward this, is growing cooperation between our two agencies.

So I suspect that, as we have done in the past and will do more of, there will be the expertise and the experience that we have we will be sharing with FDA; and hopefully that will assure that they benefit from the experiences we have had in the past in carrying out new authority should Congress provide those to them.

Mr. TAYLOR. Mr. Chairman, I can't help but note that your USDA witness once worked at FDA and your FDA witness once worked at USDA. So I think we have a good line of communication.

The CHAIRMAN. Well, that could be, but we haven't convinced everybody.

One of the concerns I guess the language in there where it says you guys are to consult with each. What it is, it says you "may" consult. Why couldn't that say you "shall" consult?

Mr. TAYLOR. You know, the President says we shall consult, so we shall consult. I———

The CHAIRMAN. Would it be a problem if we made that change?

Mr. TAYLOR. I—we are going to consult. So, if it is the wisdom of the Congress how you want to admonish us to do what we intend to do, we have to consult. We cannot implement these provisions without consulting.

The CHAIRMAN. The FDA, on a livestock farm or a grain farm, you have no intention of changing what you are doing and going out there———

Mr. TAYLOR. No. I think that is the point. For the vast majority of grain farmers, ranchers, they are not going to see this bill making—changing their practices. We are required under this bill to target what we do on the farm to those circumstances where we can identify risks that can be reduced through some appropriate intervention.

The CHAIRMAN. One of the concerns is that there was apparently some court someplace, some judge that declared that live cattle was food. Now, I don't know how you eat a live cow, but that has created some concern. Do you know anything about that?

Mr. TAYLOR. I am aware from my old food law days that there is such a court case. So, I mean, FDA doesn't—it regulates what those cattle eat, the animal feed. It regulates the drugs that are administered to them. And it is important that those regimes stay in place. They provide protections for farmers as well as consumers. But, again———

The CHAIRMAN. What problem would it cause if we clarified this to make it clear that this does not apply to livestock and grain farms?

Mr. TAYLOR. I think the important thing is in terms of the preventive control mandate and those new authorities. That is one question. One thing you don't want to do is take away existing authorities that FDA has had for years and has used successfully to deal with issues. Don't get in the way of FDA's ability, for example, I would suggest, to deal with BSE in the way it has done that, working with APHIS and FSIS.

So I think real care needs to be exercised to not inadvertently trim away necessary authorities to deal with matters that, again, are important both to consumers and to the agricultural sector.

The CHAIRMAN. All right. I thank the panel.

The gentleman from Iowa, Mr. Boswell.

Mr. BOSWELL. Thank you.

Mr. Moran, I didn't follow all your questions, because I let this thing interrupt me. I apologize for that. So I may have to ask you to help me out here a little bit.

Back to summarize that conversation, I guess I would direct this question to Ms. Smith. Did the FDA, in fact, consult with USDA before changing their policy?

Ms. SMITH. Before changing the policy on the———

Mr. BOSWELL. On the use of antibiotics for feed efficiency and growth promotion.

Ms. SMITH. I am not personally familiar with what the level of collaboration was. I know we have very recently been working with FDA on this issue.

Mr. BOSWELL. You are not sure they did or did not?

Ms. SMITH. I am not sure at what point in the process we were collaborating. I would be happy to go back and check with those that were more directly involved.

Mr. BOSWELL. Is it normal operating procedure for decisions of this magnitude to be cleared through OMB's interagency process?

Ms. SMITH. Yes, it is.

Mr. BOSWELL. I would like to know if that happened or not.

Ms. SMITH. Okay.

Mr. BOSWELL. Do you know?

Mr. TAYLOR. The testimony that was delivered Monday was cleared through OMB.

Mr. BOSWELL. It was cleared.

Mr. TAYLOR. Yes.

Mr. BOSWELL. Well, I think some fence mending is going to have to take place around here. Because that total process was very offensive. It was like you deliberately tried to blindside some of us on this Committee, and we really don't appreciate that. But we have to go forward. We have to work together, and we need to do that. So I would suggest that we may have to have some continuing discussion about this. We may need to call the Secretary and visit with him. I don't know. But I was stunned.

When I went over there Monday and found that out cold turkey, if you will, it didn't seem like that is the way you ought to be doing business here. So if that is not the way you should be doing business, it creates doubt in your sincerity or whether you are disingenuous or not, or just what in the heck is going on.

This has a lot of potential impact on farmers and ranchers, and you know that. And I think with all the experience you tell us you

have had—and I am glad for that—that you also know that those of us who do farming and ranching we, of all people, want the food to be safe. You heard some of that said this morning from the first panel. And I don't mean just the organic farmer but from all the farmers. And I have to wonder if you really get that. I am concerned about it.

So I think we just have to take a hard look at this, Mr. Chairman, and see what we need to do. But I didn't hear any recommendation. Maybe I missed it, but I think your question was from "may" to "shall" and we probably ought to do that. I think that would be a wise thing for industry and for the country and for the whole process.

So, with that, I am going to yield back. But I think you better come visit with us.

Mr. TAYLOR. If I may———

Mr. BOSWELL. No, I think I am done. Thank you.

The CHAIRMAN. I will give you a chance to say what you want to say, and then we are going to wrap this up.

Mr. TAYLOR. First of all, the statement Monday about FDA's position on the public health issue here is one thing, that the question of what the solution is to what is a difficult problem for everybody including—certainly, we understand the agricultural sector—I mean, what is the right solution and how does the community come together to address what is a long-standing concern of the scientific and public health community? How do we address that?

And, that is the question that I hope we can have dialogue on, and also I am sure that the folks involved in the decision and the statement that was made would be delighted to come and brief, and would welcome the chance to come and brief and have that communication.

The CHAIRMAN. All right. Mr. Boswell.

Mr. BOSWELL. There may be another question. Ms. Smith, could you discuss APHIS's current quarantine authority and how it is used?

Ms. SMITH. Sure, I would be happy to.

The Animal and Plant Health Inspection Service has authority under two different areas, under the Plant Protection Act and under the Animal Protection Act. We have the authority to quarantine, which means we can prohibit or restrict the importation—exportation or interstate movement, and in the case of animals, depopulate those as well for plant and animal pest and disease purposes. We take the action under the authorities to maintain U.S. agricultural health and to protect exports, export opportunities for U.S. producers, as well as to work to protect human health in concert with other Federal agencies as well.

In the case of livestock, we will quarantine animals to stop the spread of disease or depopulate the animals if other options such as testing quarantine will not mitigate the disease spread, or there is an imminent threat to public or animal health risk.

In the case of plants, APHIS will quarantine an area to prevent the movement of plants and plant products such as firewood to prevent the further spread of a plant pest. We generally work in cooperation with states, because they typically will leverage an intrastate authority.

The CHAIRMAN. All right. I thank the gentleman.

If there are no further questions, under the rules, 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 to the panel.

This hearing of the House Committee on Agriculture is adjourned.

[Whereupon, at 2:38 p.m., the Committee was adjourned.]

[Material submitted for inclusion in the record follows:]

SUPPLMENTAL MATERIAL SUBMITTED BY HON. LEONARD L. BOSWELL, A REPRESENTATIVE IN CONGRESS FROM IOWA

Testimony for the Record of Hon. Leonard L. Boswell, Before the House Committee on Rules, H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act of 2009

H–313, the Capitol, July 13, 2009, 2:30 p.m.

Chairwoman Slaughter, Ranking Member Drier and Members of the Rules Committee, I would like to thank you for allowing me the opportunity to testify here today. I have spent most of my life involved in animal agriculture and have seen first-hand the responsible use of antibiotics.

I understand the issues that affect the livestock, dairy and poultry industries having spent most of my youth working in livestock production and today I still have a hand in managing a cow/calf operation on my farm in Lamoni, Iowa. Once I retired from 20 years in the Army I moved back to Iowa to begin farming. I sat down with my local veterinarian to discuss the use of antibiotics to treat sick animals and prevent future illness. From my experience with producers and veterinarians, the thoughtful use of antibiotics is not the exception, it's the rule.

During the 110th Congress, it was my privilege to serve as Chairman of the Agriculture Subcommittee on Livestock, Dairy and Poultry. On September 25th of last year, we held a hearing to review the advances in animal health within the livestock industry. We were specifically looking at how antibiotics are used on America's livestock farms. Our witnesses included veterinarians from USDA's Animal Health and Plant Inspection Service and FDA's Center for Veterinary Medicine (CVM), producers, veterinary practitioners and academics from across the country. We believe that we heard from a good cross-section of the users of the animal health products, the doctors responsible for the use of antibiotics and the experts studying the resistance trends from use of antibiotics in animals.

As the Subcommittee Members listened to the witnesses, it became very clear that America's livestock, dairy and poultry producers have a responsibility to safeguard animal health and public health. A responsibility they take very seriously. They are committed to using antibiotics responsibly and have developed responsible-use guidelines for each of their respective industries. They didn't develop these guidelines because Congress told them to do so; they developed the guidelines because it was the right thing to do for their animals and their consumers.

I think that the perspectives the witnesses shared at our hearing last year are important to the discussion here today about H.R. 1549, the Preservation of Antibiotics for Medical Treatment Act of 2009. I would like to take a few moments to take what we learned from that hearing in terms of what H.R. 1549 would do to the livestock industry.

H.R. 1549 would remove seven classes of antibiotics from the market unless sponsors can demonstrate that they are safe and effective. Our witnesses clearly outlined the rigorous approval process that animal antibiotics must go through to gain approval already. All antibiotics used to keep animals healthy have passed the in-depth FDA process, and have been shown to be safe and effective and have undergone review for their potential to cause increased antibiotic resistance. H.R. 1549 would require antibiotic sponsors to prove again what has already been proven during their initial FDA approval. This FDA process is a stringent, science-based regulatory review takes years and millions of dollars. Requiring another step undermines the FDA's process of reviewing the human health impacts of individual animal drugs based on science and risk assessment.

Our witnesses also shared with us that not many antibiotics are currently available for use in livestock. H.R. 1549 overlooks the legitimate veterinary need to preserve these antibiotic classes for use in food animals to ensure that healthy animals enter the food chain. There are few new antibiotics anticipated for approval by FDA, so if H.R. 1549 is enacted and products are removed from the market place, America's livestock producers will be left with few, if any, medicines to prevent and control animal disease. H.R. 1549 will result in more sick animals and it is my fear that it will leave us with a potentially less safe food supply.

In the mid-1990's the European Union made a decision to phase out the use of antibiotics as growth promoters. Denmark, which had a pork industry roughly equivalent to the size of the pork herd in Iowa (which is the largest pork producing state in the country), instituted a full voluntary ban in 1998 which became mandatory in 2000. Many proponents of restricting the use of certain animal antibiotics as a model often point to this ban instituted in Denmark, citing a drop in total tons of antibiotics used in pork production in that country. When you ban the use of a product, it is self-evident that usage rates would drop. Citing this obvious con-

sequence as a rationale for restrictions in other countries borders on the illogical. Interestingly, what the proponents never seem to discuss are the other effects of that ban. I would like to call your attention to the testimony received in my Subcommittee where these effects were discussed in detail. Some of our witnesses had even visited Denmark and seen first-hand the downturn in swine health in that country.

After the ban became fully implemented in 1999, Danish pork producers saw an immediate increase in post-weaning diarrhea and an increase in piglet mortality, which has had long lasting effects on the Danish pig industry. The increase in piglet deaths and the overall impact on animal well-being might be acceptable if it resulted in improvements to public health, but such improvements have not materialized. And while overall use of antibiotics in Denmark declined, there has been a marked increase in the therapeutic use of antibiotics—those used to treat and control diseases. Today, the use of therapeutic antibiotics in Danish pigs now surpasses what was used to prevent disease and promote growth prior to the ban in 1999 and continues to rise each year. I think the Danish pork industry can now attest to the validity of the age-old cliché: "an ounce of prevention is worth a pound of cure!"

As for costs, a 2009 Iowa State University study estimated that the effect of a ban in the United States similar to Denmark's would raise the cost of production by $6 per pig in the first year after such a prohibition; 10 years after the ban, the cumulative cost to the U.S. pork industry would exceed $1 billion.

A recent study by Dr. Scott Hurd, associate professor at Iowa State University's College of Veterinary Medicine and former U.S. Department of Agriculture Deputy Under Secretary for Food Safety, demonstrated that when pigs have been sick during their life, those pigs will have a greater presence of food-safety pathogens on their carcasses. This is a serious implication that must be considered when looking at the costs and benefits of antibiotic use in livestock.

In all discussions on antibiotic use in food animal production, we need to be clear what the issue really is. H.R. 1549 is confusing the problem of antibiotic resistance in general with the faulty proposition that blames human resistance issues on antibiotic use in animals. Most informed scientists and public health professions acknowledge that the problem of antibiotic resistance in humans is overwhelmingly an issue related to human drug use.

A 2006 report from the Institute of Food Technologists, an international scientific society, said "eliminating antibiotic drugs from food animal production may have little positive effect on resistant bacteria that threaten human health." In fact, eliminating animal antibiotics may be detrimental to public health.

As our witnesses outlined for my Subcommittee, antibiotic-resistant bacteria develop from many factors, including human use of antibiotics and routine household use of disinfectants such as antibacterial soap. According to a paper published in 2001 in the *Journal of the American Veterinary Medical Association,* people and their pets on a per-pound basis use ten times the amount of antibiotics that are used in food animal production. More than 95 percent of the antibiotics used for animals are devoted to treating them for disease conditions, not as growth promoters as many claim.

Protecting human health and providing safe food are paramount concerns of America's livestock producers. That is why we test for antibiotics residue as part of our food safety programs. The FDA establishes withdrawal times or withholding periods which are times after drug treatment when milk and eggs are not to be used for food, and during which animals are not to be slaughtered.

If I may speak specifically to H.R. 1549, ⅔ of the bill has been enacted into law and should be allowed to work before removing products from market. Provisions requiring more USDA research into the causes of and solutions to antibiotic resistance were passed as part of the farm bill in 2008. The Animal Drug User Fee Amendments of 2008 require FDA to collect antibiotic sales data from companies and make a summary of that data public. The provisions were designed to provide better information to researchers conducting risk assessments and should be allowed to yield information before products are removed from the market. Congress has already taken action, and we should see the results from our action before we start removing antibiotics from the market.

Risk assessments are an important tool in approving antibiotics and ensuring that they are not harming public health. Voluntary risk assessments have been done by sponsors, and FDA is now requiring specific risk assessments for new and existing antibiotic products. Dr. Randy Singer, a veterinarian and epidemiologist working at the University of Minnesota, testified last September about a risk assessment in which he participated. His team assessed the risk of the agricultural use of the macrolide family of antibiotics poses to human health. The research hypothesis was that since macrolide-antibiotics are also used in human medicine, the use of

macrolide antibiotics in animal agriculture could compromise the efficacy of these antibiotics in human medicine and potentially increase the number of macrolide-resistant bacterial infections in people. The team developed a risk assessment model following the format of FDA's guidance document #152. Dr. Singer and his team of researchers found that all macrolide antibiotic uses in animal agriculture in the U.S. posed a very low risk to human health. The highest risk was associated with macrolide-resistant *Campylobacter* infections acquired from poultry, but this risk was still estimated to be less than 1 in l0 million and would thus meet the standard of "reasonable certainty of no harm" employed by FDA–CVM.

Dr. Singer also shared with us that animal illness likely plays a critical role in reducing the chances of contamination during processing. He participated with a team that developed a mathematical model relating animal illness to human illness. In this model, there was a large increase in human illness associated with small increases in animal illness. This suggested to the group that agricultural management strategies that fail to employ the judicious use of antibiotics may have significant negative impacts on human health. While I accept that there are those who will always believe that antibiotics administered in feed at low doses over several weeks raise hypothetical concerns about their potential to increase rates of resistance, in my opinion the evidence is undeniable that these applications improve animal health. Antibiotic uses in animals therefore have human health benefits. This goes back to our livestock producers' moral obligation to care for their animals and protect public health.

If policy decisions are going to be made regarding antibiotic use, we need to use the proper tool for making those decisions; risk assessments are the most appropriate tool, as Dr. Singer described to my Subcommittee. Decisions made without considering the results of scientific risk assessments will result in unintended consequences, including increased animal death and disease and increased risks to public health as we saw in the Denmark example.

As your witnesses today discuss a topic that is important to the livestock producers in not just my district and home state but yours as well, I sincerely hope that you consider what my Subcommittee learned last Congress. H.R. 1549 will have detrimental effects, not only on our farmers who feed the world safe and wholesome meat and meat products, but also on public health.

Again I would like to thank you for allowing me the opportunity to testify before you today. I hope as a farmer and user of antibiotics I have offered you some insight into the livestock industry's perspective. In the United States we are very blessed to have the safest, most plentiful, and most affordable food supply in the world. As policy makers we must take a hard look at how our decisions affect human health and our ability to feed ourselves and the world.

I'd be happy to answer any questions. Thank you.

SUBMITTED STATEMENT OF NATIONAL COUNCIL OF FARMER COOPERATIVES

Chairman Peterson, Ranking Member Lucas and Members of the Committee, on behalf of the more than two million farmers and ranchers who belong to one or more farmer cooperatives, the National Council of Farmer Cooperatives (NCFC) thanks you for your continued leadership on issues affecting U.S. agriculture. NCFC appreciates this opportunity to submit its views regarding food safety, in particular H.R. 2749, the Food Safety Enhancement Act of 2009, and respectfully requests this statement be made part of the official hearing record.

Since 1929, NCFC has been the voice of America's farmer cooperatives. Our members are regional and national farmer cooperatives, which are in turn composed of nearly 3,000 local farmer cooperatives across the country. NCFC members also include 26 state and regional councils of cooperatives.

We believe farmer cooperatives offer the best opportunity for America to realize the farmer-focused ideal of American agricultural policy. Farmer cooperatives allow individual farmers the ability to own and lead organizations that are essential for continued competitiveness in both the domestic and international markets.

America's farmer-owned cooperatives provide a comprehensive array of services for their members. These diverse organizations handle, process and market virtually every type of agricultural commodity produced. They also provide farmers with access to infrastructure necessary to manufacture, distribute and sell a variety of farm inputs. Additionally, they provide credit and related financial services, including export financing. Earnings from these activities are returned to their farmer members on a patronage basis, helping to improve their income from the marketplace.

America's farmer cooperatives have a large stake in producing, handling, and processing our nation's food supply, and take pride in providing the most safe, abun-

dant, and affordable food in the world. NCFC supports science-based, risk-based enhancements to our nation's food safety system, but some of the policies put forward in H.R. 2749 are overly burdensome, duplicative, and may not actually result in a safer food supply. We appreciate the many changes that have already been incorporated into the bill, and the work that the Members of the Energy and Commerce Committee have done to make it more feasible for agriculture—but we continue to have the following concerns with the bill.

NCFC is opposed to the inclusion of a facility registration fee in the Food Safety Enhancement Act. The bill currently requires all facilities to register with the Food and Drug Administration (FDA) annually and pay an annual registration fee of $500 per domestic or foreign facility, not to exceed $175,000 per company per year. For farmer cooperatives, any facility registration fee is a direct tax on cooperative members; we are opposed to such a tax.

This registration fee is particularly onerous and burdensome for small- and medium-sized producers and cooperatives. One illustrative example comes from the National Grape Cooperative Association, Inc., which grows grapes and processes Welch's grape juice and other grape products. Along with the Concord grapes that made their cooperative into a well-known national brand, many of National Grape's members also grow smaller acreages of a white grape variety, the Niagara grape, which is used to make white grape juice products. One of the challenges of harvesting and processing any white grape variety is color retention—avoiding the darkening and browning of the juice that starts with oxidation as soon as the grapes are harvested. In order to control this oxidation and retain the desirable light color of the Niagara juice, the industry has always had to depend upon the addition of small quantities of potassium metabisulfite (PM) to the grapes in the field during harvesting. PM is one of the most widely used food preservatives, has been used for many years, and is classified as GRAS—Generally Recognized as Safe—by the FDA.

As part the Bioterrorism Act of 2002, "food facilities" were required to register with the FDA. In reviewing the wording of this new registration requirement, National Grape found that the FDA defined food facilities in their regulations as any "domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption." This left the cooperative wondering whether some of their members' farms might be considered "food processing" facilities.

National Grape requested a ruling from the FDA at that time on whether their members' application of PM to their grapes in the field during harvest meant that their farms could be considered to be food "processing" facilities under the new regulations. The FDA warned that the farms ***could*** be considered food facilities under a strict interpretation of the regulations and recommended that everyone involved should register as such.

While this registration was not onerous—there were no big expenses to the cooperative or its members—the bill passed out of the Energy and Commerce Committee includes a $500 annual registration fee for all facilities. The 600 grower members of National Grape are now facing a $500 per farm annual registration fee that has the potential to add $300,000 annually to their cost of doing business at a time when the costs associated with labor, fuel, and other inputs are also increasing.

This is one example of the ill effects of what a registration fee could mean for cooperatives. There are many other cooperatives, small and large, which would be severely impacted by a registration fee. We appreciate that the registration fee has been reduced as the bill has progressed through the drafting process. But any registration fee is unacceptable—particularly for cooperatives, where that fee is a direct hit on cooperative members—and we urge Congress to remove any registration or user fees from the bill.

Another concern with the bill is the new authority granted to FDA to access confidential food safety records. The bill dramatically expands FDA's access to facility records and expressly encompasses farms in the records access requirement. The bill deletes the current limitation in the Bioterrorism Act that FDA first must have a "reasonable belief" that a product is adulterated and presents a threat of serious adverse health consequences or death to humans or animals—inspectors would not need to have any indication that a food/feed safety issue may exist as a precondition to accessing or photocopying records. FDA should only have access to records that directly bear upon product safety, and the bill must provide protections against unauthorized disclosure by FDA of proprietary or confidential business information to which the agency gains access when reviewing the contents of written food/feed safety plans and other records.

We also are concerned with the mandatory recall and quarantine authority granted in H.R. 2749. The bill gives FDA mandatory recall authority as well as new authority to quarantine products within a geographic area. The bill should provide an

opportunity for affected facilities to voluntarily recall products before FDA issues a mandatory recall. And because FDA is given recall authority, product quarantine is redundant and unnecessary, and could harm producers who are caught up in a geographic quarantine but are not part of the problem. Also concerning is that the bill lacks any kind of indemnification for producers who may be wrongly harmed in a regional quarantine.

Additionally, the Food Safety Enhancement Act of 2009 requires FDA to develop and implement regulations setting standards for safe growing, harvesting and holding of raw agricultural commodities if they are required to minimize the risk of "serious adverse health consequences or death to humans or animals." The bill also cites "manure, water quality and employee hygiene, sanitation and animal control and temperature controls" that FDA determines to be "reasonably necessary." NCFC strongly urges that any standards set by FDA must be commodity-specific and risk-based. Also, FDA is not the expert agency to set standards for issues like manure and water quality—the setting of those standards should be deferred to the U.S. Department of Agriculture. NCFC is also concerned that the bill muddies the jurisdiction between USDA and FDA in the regulation of meat, and hopes Congress will strengthen the livestock exemption in the bill by clarifying that livestock is not "food" and thereby is exempt from these new FDA authorities.

One final area of concern is product traceability. The bill currently requires FDA to establish a product-tracing system that far exceeds the current one-up-one-back system required by the Bioterrorism Act. Many commodities are already traceable and many others are in various stages of developing a commodity-specific traceback system. Any federally-mandated traceback program must take into account the feasibility and costs associated with implementing such a program. In addition, any new Federal program must also take into account the work that is currently under way and systems that are already in place.

Again, America's farmer cooperatives have a large stake in producing, handling, and processing our nation's food supply, and take pride in providing the most safe, abundant, and affordable food in the world. We appreciate the Committees' attention to this critically important issue and urge the Committee to continue to push for agriculture's interest as this debate moves forward. NCFC looks forward to working with the Committee on food safety legislation that makes science-based, risk-based enhancements to our nation's food safety system.

SUBMITTED QUESTIONS

Submitted Questions by Hon. Eric J.J. Massa, a Representative in Congress from New York *

Question 1. H.R. 2749 gives the Secretary wide discretion to set packing standards. What is the likelihood that these "standards" would include mandatory disinfectant wash water. Such a standard, requiring a highly chlorinated wash water for instance, would put many of my farming constituents who are engaged in direct sales out of business. These farmers would be put out of business not only because of the cost of such a standard, but a mandatory disinfectant wash would adversely affect the "freshness" of their product:, not to mention the environment and those people engaged in washing the produce.

Answer.

Question 2. Specifically, how do the food safety standards in HR 2749 take into account the specific variations and unique needs of different commodities, geographic locations and production methods, *etc.?* Agriculture is not a one size fits all industry.

Answer.

* There was no response from the witnesses by the time this hearing went to press.