U.S. FOOD AND DRUG ADMINISTRATION

Public Hearing: Strategic Partnerships to Enhance the Safety of Imported Foods: Capacity Building, Risk-Based Decision Making, Recognition of Commodity Food Control Programs, and Systems Recognition

Conducted by Camille Brewer, M.S., R.D.

Tuesday, February 14, 2017

9:00 a.m.

U.S. Food and Drug Administration (FDA)

Center for Food Safety and Applied Nutrition

FDA, Wiley Auditorium, 5001 Campus Drive

College Park, MD 20740

(240)402-6411

Reported by: Natalia Thomas, RPR/CSR

Capital Reporting Company

A P P E A R A N C E S

Camille Brewer, M.S., R.D
Director, International Affairs Staff
Center for Food Safety and Applied Nutrition (CFSAN)
Office of Foods and Veterinary Medicine (OFVM), FDA

Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs, FDA

Mary Lou Valdez, MSM
Associate Commissioner and Director
Office of International Programs, FDA

Julie Moss, Ph.D.
Acting Third Party Program Director, CFSAN, FDA

Lystra Antoine, M.B.A., J.D.
CEO, Global Food Safety Partnership, The World Bank

Brian G. Bedard, DVM
Executive Director, Grocery Manufacturers Association
(GMA).Science and Education Foundation

Robert E. Brackett, Ph.D.
Vice President and Director, Institute for Food Safety
and Health, Illinois Institute of Technology

Kelley Cormier, Ph.D.

Division Chief, Inclusive Market Development
Office of Market and Partnership Innovations
Bureau for Food Security
U.S. Agency for International Development
Melvin Spreij, Counsellor and Secretary
Standards and Trade Development Facility
World Trade Organization (WTO)
Susan Berndt, M.B.A.
Acting Deputy Director, International Affairs Staff
CFSAN, FDA
Joann Givens, Human and Animal Food Program Director
Office of Regulatory Affairs, FDA
Mickey Parish, Ph.D.
Senior Science Advisor, Office of the Center Director,
CFSAN, FDA
Bettye Walters, DVM, International Policy Analyst
Office of the Center Director, Center for Veterinary
Medicine (CVM), FDA
Karil Kochenderfer, North American Representative,
Global Food Safety Initiative
Hank Karayan, Global FSMA Program Director, SGS
Shannon Cooksey, GMA

Jason Cochran, Branch Chief
Office of Capacity Building and Development
Foreign Agricultural Service, USDA
Weng Xinyu, First Secretary, People's Republic of China
Jennifer Miner, Canadian Food Inspection Agency
Janie Dubois, Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
Susan T. Mayne, Ph.D., F.A.C.E.
Director, CFSAN, FDA
Ritu Nalubola, Ph.D.
Senior Policy Advisor, Office of Policy
Office of the Commissioner, FDA
Mark Burgham, Senior Director
Program Policy Integration, Canadian Food Inspection Agency (CFIA)
Herman Diricks, Chief Executive Officer
Federal Agency for the Safety of the Food Chain, Belgium
Steve Wearne, Director of Policy
Food Standards Agency, London, United Kingdom
Mark Abdoo, Assistant Commissioner for Global Regulatory Policy, Office of Global Regulatory

Operations and Policy, FDA
Jenny Scott, Senior Advisor
Office of Food Safety (OFS), CFSAN, FDA
Steven Solomon, DVM, Director, CVM, FDA
Sharon L. Mayl, J.D.
Senior Policy Advisor, OFVM
Brian Pendleton, J.D., Senior Policy Advisor, Office of the Commissioner, FDA
Raina Spence, Director, of Producer Solutions, GlobalG.A.P.
Ron Tanner, Specialty Food Association
Bill Folkerts, Vice President
Strategy and Program Operations, U.S. Pharmacopeia

C O N T E N T S

P R O C E E D I N G S

MS. BREWER: Good morning. Could we please take our seats?

I'd like to welcome everyone. My name is Camille Brewer. I'm the director for International Affairs here at the Center for Food Safety and Applied Nutrition and the Office of Foods and Veterinary Medicine.

This meeting -- this hearing is a public hearing, and it's the opportunity for FDA to hear from key stakeholders on a number of compelling issues for us. It's a little bit of changing the tables in that we are the ones who get to answer the -- to ask the questions. And the experts here today will address the issues that have been outlined in the Federal Register.

So we really appreciate all of you taking time from your busy schedules to be here with us today.

Let me just spend another moment talking about the purpose of the public hearing. It's one of many administrative tools that FDA can use to obtain information from external experts and stakeholders. Typically, we use this tool when we're in the very

early stages of considering policy options.

Again, it's the opportunity for FDA to ask questions and obtain information in a way that's transparent to all stakeholders.

We've established a docket in the Federal Register that outlines our interest. And any stakeholder can provide information, comments, data, studies, anything that's relevant to the questions raised by FDA.

In addition, we have a panel of FDA experts who will be posing the questions. If they raise a question that's not in the Federal Register, you can still respond to that question via the docket.

This hearing will be transcribed. And that will give FDA the opportunity to go back and reflect on the debate over the next two days.

So for today and for tomorrow, we've planned four panels that address four different areas of partnerships, including capacity building, private standards, commodity-specific recognition programs, and systems recognition.

With respect to the format of the hearing,

each panel with -- will start with a very short FDA presentation that will set the stage simply by describing our activities in the topic area under discussion.

The audience here in the room and on the web via WebEx have the opportunity to ask clarifying questions of the FDA presenters.

Next, we'll have a series of presentations by stakeholders, followed by questions from the roster of FDA experts.

Finally, we will receive testimony from those who have registered to provide testimony. FDA may also ask questions of those stakeholders who are providing short testimony. Again, I can't overemphasize that this is the opportunity for FDA to deepen our own understanding as we develop and improve our programs.

With that, it's my honor to introduce the FDA speakers who are up front with us today. First, we will have the keynote address by Dr. Stephen Ostroff, Acting Commissioner for the U.S. Food and Drug Administration.

Following his presentation, we will move

immediately into Segment 1, Partnerships to Improve Food Safety Capabilities with a focus on capacity building. And we will hear from Mary Lou Valdez, Associate Commissioner and Director of the Office of International Programs, and then to Dr. Julie Moss, Acting Third Party Program Director.

So please join me in welcoming Dr. Ostroff.

(Applause.)

DR. OSTROFF: Well, thank you very much, Camille. And let me welcome all of you to today's public hearing. It's really great to see such a terrific turnout for this particular meeting. And I know that there are also many that are participating through webinar.

So I welcome you today both in my usual capacity as FDA's deputy commissioner for foods and veterinary medicine, but also as FDA's acting commissioner. And I also want to thank everybody for being here on the sweetest day of the year. Camille chose Valentine's Day for this, and I guess spending the day talking about imported food is our Valentine's Day gift to you.

(Laughter.)

DR. OSTROFF: So because this is a public hearing, I'm required in my role as the acting commissioner to designate presiding officers. So let me just say for the record that I have designated Ms. Camille Brewer and Dr. Don Prater, who's sitting over here, as the presiding officers for their -- this hearing. And I understand that they have graciously accepted that designation.

So many of you obviously know Camille as the director of the International Affairs staff at CFSAN as well as in the Office of Foods and Veterinary Medicine.

Don has been our acting assistant commissioner for food safety integration in OFVM since last December. And although his title may be somewhat obscure, he actually plays a very important role in strategic resource planning to ensure that imported foods meet the same food safety standards required of domestic producers. And that is the focus of this meeting, as today we are here to talk about partnerships to ensure the safety of imported food and to help achieve that particular goal.

So this is clearly a topic of great interest to anybody involved in food production and in our food safety system. And it's also of interest to anybody that consumes food here in the United States. That last category, of course, includes all of us because, ultimately, what we do is for and with the American consumer.

So as we meet today, about 15 percent of the U.S. food supply is imported. And if you look at the trends, that proportion and that percentage is actually increasing. But the proportion of the food supply that is imported really varies considerably by commodity category, and it includes about 50 percent of fresh fruit and 20 percent of fresh vegetables, 80 percent of seafood, and an even higher proportion of the spices that are used in this country.

And not only is the volume increasing, but so too is the variety and the diversity of sources. Today, we import food in the United States from more than 200 countries, and there are about 125,000 registered firms that export food to the United States. Those are clearly very big numbers. And there are both

benefits as well as challenges that are associated with the volume of food importation into the United States.

American consumers very clearly benefit because they increasingly desire and demand a diverse and abundant food supply that reflects the diversity of our population. And they want that diversity and that availability throughout the year, which for many commodity categories can only happen through food importation. And they also want that diversity to be affordable.

But there are also challenges. One is the capacity of our regulatory agencies to oversee the growing volume and the source diversity of imported food and how best to deploy the resources available to us to oversee that.

Another is that many of those 200 countries that export food to the United States have vastly different food safety systems, different standards, and different regulatory capacities than we have in the United States.

Finally, there are different potential microbial and chemical food safety risks associated

with foods that come into the United States, although there are not necessarily increased risks when compared to domestically produced foods.

So as we approach the question of partnerships and how to use them to oversee food imports, we have to keep these benefits and these challenges in mind.

As you all know, we're really at a crucial transition period when it comes to the Food Safety Modernization Act, or FSMA, as we pivot from the development of the regulations to their implementation. Partnerships were critical to developing FSMA regulations, and partnerships are more important than ever as we begin to operate under FSMA.

Therefore, we are holding this meeting in the context of what our overall responsibilities are for food safety in a landscape that is undergoing changes in many dimensions.

However, even with change afoot, FSMA has embodied and will continue to embody certain core principles. One of them is the importance of prevention and trying to move the food safety system from a reactive posture to a preventive posture.

Another is that the food industry is ultimately responsible and accountable for preventing food safety problems in the first place and that FSMA will only be successful if we can ensure high rates of compliance with the various requirements.

Another is that we will assure that food that's imported from abroad meets the same food safety standards as food that's produced domestically and, finally, the importance of partnerships both inside and outside of the United States.

While the FSMA regulations themselves are not the subject of this hearing, the context of FSMA, I think, is really critical. And so we are soliciting input broadly on two of those core FSMA pillars. One of them is assuring that the food that comes from outside the United States meets the same food safety standards as foods that are produced domestically. And the other is using partnerships to be able to leverage our resources.

So assuring that the food that comes from abroad is as safe as food produced domestically while maintaining a level playing field is really very

important. Our legal framework provides us with a variety of regulatory oversight tools and mechanisms whereby we may leverage the work of our regulatory counterparts and industries.

One of them is the new requirements under the Foreign Supplier Verification Program, or FSVP, for importers to verify that their foreign suppliers are meeting U.S. safety standards. Another are the new programs related to the accreditation of third party auditors. There's the Voluntary Qualified Importer Program and additional measures that can be used at points of entry.

Integrating our existing and our new authorities while leveraging other credible work is, in our minds, the best pathway as we move forward to accomplish our public health goals. The information we hope to receive in today's hearing will be useful as we identify a risk-based allocation of our regulatory resources across the supply chain.

So partnerships are really quite critical to the progress that we make in the Office of Foods and Veterinary Medicine and our foods and veterinary

medicine programs in general, whether we talk about food safety, food labeling, or animal health.

And with the growing diversity of the food supply, partnerships are really critical to our program to ensure their safety. For many years, FDA has partnered with exporting countries to support capacity building, and this makes good sense because investing in food safety in exporting countries at the beginning before the food even reaches our shores makes good sense.

Another way that we have been partnering with exporting countries is through our systems recognition programs. Two countries, New Zealand and Canada, have been recognized by FDA as having comparable food safety systems, and others are in progress. These agreements allow us to leverage each other's science-based regulatory systems. And in addition, these partnerships allow us and help us to more efficiently target our inspectional resources.

We recognize that there is a wide continuum in the level of development of national food control systems of our trading partners. Capacity building and

comparability assessments represent two very different places in that continuum and reflect our understanding of the robustness of other countries' domestic food safety control systems.

I also should acknowledge the important role that our state and local partners play once food comes into the United States. Once the imported foods cross our borders and enter commerce, state and federal agencies work together to verify the strength of our new import controls.

We recognize that when it comes to approaches for ensuring safety through partnerships, one size does not fit all. FDA has a number of partnership tools that we can use to enhance food safety, and they must be deployed keeping this continuum in mind.

This public hearing will assist us to advance our thinking on how best to use and refine existing tools and, if needed, to develop new tools.

So today, we will have the opportunity to obtain input from stakeholders and global experts on food safety capacity building to advance the concept of same level of public health protection and how to

consider private entities in our oversight of our imports.

In addition, we will receive input from stakeholders that we hope will help us to enhance risk-based decision-making in the context of private standards, commodity-specific export programs, and the implementation of the existing systems recognition programs.

So once again, let me just finish by thanking you for your participation in this important hearing, which I am sure at the end of the day will provide very useful information as we continue to strengthen our import partnerships and programs.

So let me thank you once again, and I'm delighted that you're all here. Thanks.

(Applause.)

MS. VALDEZ: All right. Good morning, everyone. It's really an incredible privilege to be here today with all of you. And a special thanks to my CFSAN colleagues for extending the invitation. They know I don't get out much, so it's always a pleasure to be with a roomful of experts, which is who you are.

Let me begin by saying that it was clear in 2007 and 2008 that if we were going to keep our food supply safe and our intelligence and knowledge robust, we were going to have to work much further upstream with regulatory counterparts to be able to understand the dynamics in which food is produced and food is regulated.

So it was in late 2008 and in 2009 that FDA established its foreign posts abroad. We currently have seven posts in seven countries. We are in China in Beijing. We're in New Delhi in India.

We're in Brussels. We have a person seconded, or positioned, within the European Medicines Agency in London. And then we are in Mexico City. We're in Santiago, Chile, and we're in San Jose, Costa Rica.

I would also say we have a -- the rest of the globe, so to speak, is managed out of our White Oak Headquarters Office of Regional and Country Affairs, which is -- we have folks on staff here today in case people have questions.

But I would say that the purpose of these foreign posts is really that commitment to work better

upstream so that we understand the regulatory landscape better. We are able to share information much more routinely and in a timely way. And it is important to us that we are there serving as that face and voice for the Agency abroad.

I was very gratified this past year, having visited both with our Chinese colleagues and our Indian colleagues, both of them remarking how not just pleased and proud they are to have FDA in country, but also recognizing that it is of real benefit, mutual benefit, so that we can really work together very routinely and in ways that are -- that protect both our food supplies, but theirs as well.

So moving on to -- we certainly can't do it alone, so moving on to outreach and linkages. And I will say the foreign posts have been really part and parcel with our CFSAN colleagues in the rollout of the FSMA rules since it started. And so we have been really pleased to be part of that.

But these are by no means exhaustive, but only to be illustrative for you. So I'll start with the U.S.-Mexico produce safety partnership. We do have a

post in Mexico City, as I said. It is not just that we get an enormous amount of produce from Mexico, but an enormous amount of produce comes through Mexico.

And so a few years back, we have developed a series of working groups with our Mexican colleagues so that we can be sure that we are working in ways that will really stop -- or help to mitigate the risks before they really happen.

We are working both with SENASICA and -- so that we can be sure that the partnership -- it's not just for the sake of partnership alone, but really that we are working in sustainable ways in a focused manner so that we can ensure the safety of the product coming through and from Mexico.

The China-EU-United States trilateral is somewhat of a new model for us. We obviously have a long history of working with our European colleagues as well as our Chinese colleagues. But it was in November 2015 that we decided to work together in a trilateral manner.

The interesting thing about this effort is that it will really be led and driven by our technical

experts. So we will be having a series of both scientific and technical workshops that are really going to help set the agenda for the trilateral. It will not -- it will focus on those things that matter most to us as a group of three, and what we're hoping to do is really deepen our understanding about the ways we regulate product and the ways we mitigate risk.

I'm happy to say that the trilateral will be meeting here at the end of March. And there may be a number of agenda items, although the agenda is not yet finalized -- but obviously, the role of risk assessment, promoting the safety of foods through e-commerce, and obviously the regulatory requirements that pertain to the certification of imported food products.

And then I'll move to the memorandum of understanding with the Indian Export Inspection Council. This was signed in 2015 by two of our deputy commissioners at the time. But it is an agreement that helps us, in particular, through our foreign posts and the Agency more broadly to really focus our efforts. Obviously, the need is going to always be far greater

than what we're able to do.

And so this agreement helps us with EIC to focus our efforts to ensure that we are better understanding the complexity of India's food safety supply system, the role of the regulator in the safety and quality of the product as well as the incredible mosaic that is India in terms of its industry.

I think it's known to most of you India, for us, is the seventh-largest supplier of food to the U.S. And many of these goods, whether it's seafood -- but just think about spices. So it's an incredible challenge for us to better understand how India regulates and how we can collaborate better for mutual benefit.

Our commissioner spoke a lot about partnerships. And I think partnerships are really an incredible opportunity for the Food and Drug Administration as we work abroad.

The one that's not here that's probably most known to everyone is the Codex Alimentarius Commission. And I'm sure someone will be speaking to that today later on.

But I've no -- I've highlighted three of these partnerships. I won't go in deep because we have experts for the panel following. But the World Bank -- the Office of International Programs is -- has been working with the World Bank, who will be developing a study on making the case for investments in food safety systems.

It's a little bit of out of the box for FDA, but we're hoping that this -- it's a similar kind of economic analysis that the World Bank is well known for. And this report will come out probably in the spring of 2018 in the time for its annual financing conference with financing ministers in Washington, D.C.

The World Health Organization is a longstanding partner of FDA. And in October 2015, both through CFSAN technical experts for years and then OIP helped to kind of finalize this, but WHO released a report on the WHO -- global burden of foodborne diseases. And it was really the first of its kind.

We all talk about the burden of the disease anecdotally, but it was clear that we really haven't pulled together enough of the data to begin some of

this conversation.

And then just on that report alone, the report estimates 31 foodborne hazards causing 32 diseases, the most frequent of these being diarrheal disease. And we all know the millions of people that are impacted each year globally from foodborne illness.

And then the whole genome sequencing in foodborne pathogens are -- which is known as the Genome Trakr here in FDA, is really an excite -- this is an exciting time, and CFSAN is to be commended.

But whole genome sequencing really does have the potential to change the way we detect, characterize, and monitor microbiological food safety hazards and help to improve the suffering from foodborne diseases. The technology is really relatively inexpensive, and it does have far-reaching public health benefits.

The whole genome sequencing has an important global element to it. And that is a collaboration of FDA with WHO and PAHO and nine public health labs that are located in Austria, Canada, Argentina, Australia, Denmark, Germany, Italy, Ireland, and the UK.

We -- right as we speak, we have one of our CFSAN experts at WHO who will be spending a little bit of time so that what we can really do together is have a sustainable strategy in which we can introduce and help to roll out and really increase the knowledge and understanding about whole genome sequencing.

So I'll end just by saying that this is an incredible time for food safety systems, and we really appreciate the leadership of our Center for Food Safety and Applied Nutrition. FDA continues to create and maintain what is a momentum of interdependence among regulators. No one regulator can do it alone. We've all known that for years, and it's kind of come to the fore.

We also need to focus on transparency and accountability throughout the supply chain. The multilateral efforts are really important to us -- again, partnerships, synergies. And I was just speaking with a speaker earlier about the need for changing the paradigm for food safety. So there's a lot of work to be done but a lot of opportunity in which we can do that work.

We all recognize that regulatory systems in both low- and middle-income countries really do need to be strengthened. The resources for global health efforts is really, indeed, competitive. Food safety doesn't always rise to the forefront. And so again, there's a real opportunity, I think, that we can all work together to make sure that we help to increase the investments in food safety systems so that we can all build this global safety net for who are our consumers around the world.

So I thank you.

(Applause.)

DR. MOSS: Hi, everyone. My name is Julie Moss, and I'm going to talk with you also about capacity building. And I'd like to talk with you a little bit today about the -- why we do capacity building and how we do it and build off of Lou's remarks.

So I'm going to talk about two things today, that being the basics of why we do capacity building and how we do capacity building. With the why, FSMA in Section 305 called out capacity building for the first

time to us in statute. And it specifically directed the FDA to do it, and I'm going to read this verbatim.

"Directed the FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries from which foods are exported to the United States."

And in that section, it identified six very specific elements that the FDA was asked to address, from agreements and arrangements, from international standards, to laboratory methods, to the security and sharing data, to training of foreign stakeholders that want to export food to the United States.

And so I'm just going to focus on Element 4 that states, "To train foreign governments and food producers on U.S. requirements for safe food."

This is the document that we issued in 2013, which is our International Food Safety Capacity-Building Plan. And in this plan, we have over 30 action items for us to address specific to food safety capacity building. And I just want to focus on a few of those action items, specifically in Objective 4.2

that talks about training efforts.

Some of the key actions that we will be doing will be coordinating with other U.S. agencies. We will be rekindling existing relationships with other agencies, such as with the USDA's Foreign Agricultural Service, and we will be seeking out new relationships with other agencies, such as with the U.S. Agency for International Development.

We will also continue to develop training materials through our partnerships. And we see this working with the University of Maryland in our agreement with the Joint Institute for Food Safety and Applied Nutrition, and we see this very clearly with the alliances that we've set up with training on the FSMA requirements.

We will also prioritize training and capacity building efforts. Not only will we recognize the interests that we have in the United States, but we also are very interested in knowing what the receiving country's interests are and what they are interested in moving forward within their own food safety systems. And as Lou mentioned, we're also here to support and we

want to support our own foreign offices around the globe that are there to help with technical assistance as well.

Another reason why we do capacity building is the World Trade Organization and the SPS agreement, and we're going to hear a little bit more about this later today. The U.S. is a signatory to this agreement, and we take it very seriously. As part of that obligation, members specifically are to provide training to facilitate the provisions of technical assistance to other members, especially developing countries. And we take that provision very seriously.

So for the next three slides, I want to share with you about how FDA engages in food safety capacity building. For food safety capacity building generally, FDA has established and maintains partnerships with many international organizations, U.S. agencies, other countries, academia, and industry. These partnerships enable the Agency to leverage the greater bodies of work being undertaken by these entities with their focus on SPS generally and on food safety capacity building. And these were highlighted often in Lou's

talk prior to mine.

I have listed many of our partners on this slide and acknowledged that many of them are represented here on our panel today. I'll let them explain the specifics of what they do, and I'm looking forward to hearing their responses to our questions. What I do want to underscore is the value that we place on our partnerships and the recognition that we cannot do capacity building without them.

So how is FDA engaging with regards to FSMA training? FDA has conducted several FSMA outreach sessions, primarily in 2016. Through meetings and webinars, cadres of FDA experts made a series of visits to various partner countries and regions around the world to meet with government, industry, and academic stakeholders to discuss the FSMA rules, what's in them, what's not in them, and to discuss its impact.

FDA also looked at FSMA preparedness training, and we worked on a program called the Food and Agriculture Sustainability Training, or FAST. We partnered with the USDA's Foreign Agriculture Service, the United States Agency for International Development,

Texas Tech University, and the Inter-American Institute for Cooperation on Agriculture to provide some of this FSMA readiness training in Latin America and the Caribbean region.

And because of the success of that program, we were able to maintain the partnership with USDA's Foreign Agriculture Service and the U.S. Agency for International Development to broaden that FSMA training beyond just the Caribbean and Latin American region, but to focus it globally. And that program is called the Food Safety Network.

And perhaps the most important for both domestic and foreign industry is FDA's work through the alliances. That is the Food Safety Preventive Controls Alliance, the Produce Safety Alliance, and the Sprout Safety Alliance. These were formed to support safe food production by developing core curriculum, training, and outreach programs to assist industry to become and maintain, prepared to adhere to the FSMA requirements.

And the last point I'll say with regards to what we've done to help with FSMA outreach and training

is we have set up a technical assistance network so that any stakeholder around the globe who has a question can be able to submit a question electronically to the web or via mail. And subject matter experts within the Agency will respond to all of those queries.

And we have also linked up with the alliances so that we provide the most accurate responses to the stakeholders that need this information to implement the FSMA rules.

Thank you.

(Applause.)

MS. BREWER: I'd like to thank all of our speakers.

And we saw some list of partners, but the list is hardly exhaustive. I'm looking at the audience, and I'm seeing colleagues and partners of longstanding.

So if you're not officially on the program, take heart. The docket is open. We welcome your comments. We welcome any data that you have.

So again, thank you to our speakers. And I'd like to open it up to the audience in the room for any

questions of the FDA panelists.

As -- if you come to the microphones, which are here on both sides of the room, please identify yourself and your affiliation.

Are there any questions?

So I guess that means you were perfectly clear.

(Laughter.)

MS. BREWER: So thank you for that. Let me turn to --

UNIDENTIFIED MALE SPEAKER: (inaudible - off mic).

MS. BREWER: Yeah. Let me turn to the WebEx. Are there any questions via the web?

Okay. So what I'd like to do, I'll just give you one more minute. If there are any -- this is the acting commissioner of FDA.

(Laughter.)

MS. BREWER: I don't want you to lose the opportunity.

I see someone coming forward. Again, your name and affiliation, sir.

MR. HASSENPLUG: Hello. Hi, Camille. Thank you.

My name is John Hassenplug. I'm a senior policy analyst with OFVM. And I was shy at the beginning, but I don't want to lose the opportunity to pass.

So keeping in the theme with your comments this morning, my question was really about bilateral agreements with other foreign countries. And I'd heard in the workgroup that I'm working on, if we ask other countries to share some of their regulatory information with us, does that also open us to the expectation that we need to provide something reciprocal back to them? And maybe that kind of transparency might keep these kinds of bilateral agreements from moving forward immediately.

So I just wanted comments on that or if you see there's opportunities to solicit information and then work towards sharing in the future.

MS. VALDEZ: Thank you, John. Oh.

So just a quick answer to that. I think all of -- if you don't know, all of FDA's agreements,

current agreements, are found on our website. We do have a number of confidentiality commitments that enable us to share nonpublic or deliberative information now.

I think that with any of these types of agreements there will always be expectations. So we enter into these very judiciously and have a very robust conversation internally to the Agency before we sign on the dotted line, so to speak.

But I think one of the things we've seen in our foreign posts is just by the act of being there and having relationships with key institutions and stakeholders, there's a whole host of things that can be shared that is just happening, you know, public, nonpublic. And I think we see it as mutual benefits.

So we have not had impediments, so to speak. But we do have in place as the Agency these confidentiality commitments that allow us to share information of that nature.

MS. BREWER: Please come down. Thank you.

MS. LEVY: Okay. Hello, everyone. I have, actually, not a question. But I just want everybody to

know that when you were talking about Asia international, about their ability to find ways to heal a lot of people who are struggling with these diseases -- and I just want to let everyone know that I am a recipient of diabetes, high cholesterol, blood pressure, and overweight.

As you know, the last eight years, I've been trying to find research for myself. And I just want to tell you that the way to curb the American diet, from my perspective, is to look at the carbohydrates that we've been eating all these many years, 200 years ago, and the diets that happen, again, 200 years ago.

But I had for a whole year stayed on a low-carbohydrate diet, and this -- it kept me at my height weight for a whole year. And I just want to just have somebody to look into it.

So all those who struggling now still with diabetes, that a certain diabetes -- a certain carbohydrate will reflect your glycemic index. And it would give the blood glucose a response. It's either going to go up, or it's either going to go down. Or it's going to be stable.

That's what I wanted to tell everybody. I have pictures, too.

MS. BREWER: Thank you. Could you give us your name, please?

MS. LEVY: My name is Julie Levy, and I'm with Transformation Neighborhood Initiative for Prince Georges County.

MS. BREWER: Thank you for that.

Other questions, comments?

So I had a question this morning. And the question was what will happen after this meeting. What you will see is a transcript on our website and a meeting summary. What you won't see is the deliberation based on the comments, on the testimony that we've received.

We have a number of very active working groups -- Joann Givens, Rebecca Buckner, Jennifer Thomas -- lead our Phase II FSMA Implementation Team. We have an imports team led by Sharon Mayl and Todd Cato. We have a systems recognition team led by Caroline Smith DeWaal. So we will take the testimony, we will take the comments, and we will deliberate.

Where that ends, we're not sure. That may be reflected in some of our implementation plans. It may be reflected in white papers. It may be reflected in guidance.

Our commitment here is to continual improvement, and that is the real point of this hearing today.

So with that, I'm going to look to the booth. Any comments, questions from WebEx?

Okay. Hearing none, we're going to take a short break. Please be back at 10:00 o'clock, and we will move directly into Session 1.

Just a reminder, there's no food allowed in this auditorium. So if you have food, please be very careful with it.

(Laughter.)

MS. BREWER: Another announcement is that we have an information room, 1B002. And there's information to share from various stakeholders.

So thank you. Enjoy the break. We'll start promptly at 10:00 o'clock. Thank you.

(Break.)

MS. BREWER: So let's get started. Welcome back from break, and we will resume with Session 1.

And during this session, we'll hear from a number of global experts. And they're going to be providing their insights and experiences on capacity building and how they've used partnerships to improve food safety capabilities.

FDA has a number of areas of interests, including how food safety performance is monitored and evaluated; how donor organizations minimize duplication and support leverage partnerships; how providers of training programs assure that affordable, accessible, and culturally specific information is available to various regions of the world; how development agencies interface with food industry supply chain management programs; and finally, how government and industry can leverage each other's efforts.

A reminder, the biographies of the speakers and the panelists are in your information packet. For those of you on WebEx, the information is listed on our website. And here's the link [points to slide on the screen], and you'll see the link information

repeatedly.

So our speakers are as follows. I will list them in order in which they'll present.

We have Lystra Antoine, who is the CEO of Global Food Safety Partnership of the World Bank; Brian Bedard, who is the executive director of the Grocery Manufacturers Association, Science and Education Foundation; Robert Brackett, Vice President and Director, Institute for Food Safety and Health of the Illinois Institute of Technology; Kelley Cormier, who is the division chief for Inclusive Market Development for the U.S. Agency for International Development; and Melvin Spreij, Counsellor and Secretary, Standards and Trade Development Facility, World Trade Organization.

Again, each speaker will speak in turn.

And Ms. Antoine, over to you.

(Automated message.)

MS. ANTOINE: Okay. Thank you. I've been given a green light to proceed. So thank you for waiting through that commercial break.

(Laughter.)

MS. ANTOINE: And good morning, everyone. It

gives me great pleasure to accept and that I have accepted this invitation to participate in this hearing by the FDA. I'm extremely honored to participate on this panel with other esteemed colleagues, several of whom I work with very closely.

This morning's presentations have all been about partnerships for enhancing food safety capacity. And it's in that vein that I want to speak with you about a partnership that has been developed to improve food safety capacity worldwide.

And that partnership -- okay. I think I'm having some technical difficulties here. I am pressing this button, but the slides are not advancing. Oh, there we go. So do I -- okay. Let me go back.

Okay. So this is a public-private partnership for food safety capacity building, and it's called the Global Food Safety Partnership. I am thrilled that this morning, along with FDA sitting on this panel, there are members of GMA, of USAID, of STDF that we work very, very closely with in this partnership.

So for the next couple minutes, I want to tell you a little bit more about who we are. I also want to

let you know a little bit about how we'll work with partners to actually improve a sustainable and a renewable base for food safety. I'll tell you a little bit about how we develop priorities for capacity building in country and then some of the tools and approaches that we use.

So a little bit on the, you know, who, what, where, why, how. So the GFSP, as I mentioned before, is a public-private partnership dedicated to food safety capacity building worldwide. Why were we organized? We were organized to promote food safety systems based on prevention, underpinned by science, to improve the effectiveness of food safety capacity building investments.

In terms of how, we convened players to assess the food safety landscape, prioritize, and take actions that are scalable and sustainable. And we share lessons and leverage resources from varied sources.

We are hosted at the World Bank Group, and we have an opportunity there to leverage the independence of the World Bank, its expertise, funding, and its convening power. This partnership started in December

2012, and now it has a revised strategic framework.

So who are the key players on the decision-making body of the GFSP, which is called the governing council? We have, very similar to our mandate, public and private sector entities on our governing council. In terms of bilateral organizations, we have Canada, Netherlands, and the United States. Important to know that the U.S. is represented both by FDA and USAID.

In terms of private corporations industry, we have Mars Corporation, Waters Corporation, and Food Industry Asia. And for the international or the multilateral institutions, we have on the governing council FAO, UNIDO, and the World Bank Group. And the World Bank Group chairs the governing council.

So a little bit about our strategic framework. And this slide, I'll just mention three things. In line with our desire to ensure that we focus on capacity building, the three key pillars of our strategic framework focus first on assessments. So Pillar 1 looks at how we analyze, how do we capture, and report on priorities, tools, and effectiveness of food safety capacity building.

So in this first pillar, we're very keen. Before we do anything, when we engage, we need to engage from a position of knowledge. And that knowledge comes from assessments.

And our Pillar 2, how do we do that? We actually convene and we collaborate so that, as you've heard from other speakers this morning, we are trying as much as possible not to duplicate efforts that already exist on the ground and, more so, to build on and leverage on those resources that are already in country. And we collaborate to ensure that there is transparency in terms of approaches, in terms of what's being done so that we can really move the needle and have more impact.

And our strategic Pillar 3 is really along the lines of implementation. After we have assessed and after we've collaborated and convened -- and the collaboration and convening takes place even at the assessment level as well, where we often collaborate to assess.

But on 3, we're focusing here on implementation. What is it that we can do to enable

effective execution of food safety capacity building initiatives?

So the support base for food safety -- you know, one of the questions that we were asked is how will we work with partners to develop that sustainable, renewable support base? And for us, this is such an important agenda, as your own presence here would suggest. We all know that food safety is an important agenda that we sometimes take for granted.

But this morning, I want to show you where we're rooting our supporting base, how we're grounding the importance of this agenda. And we're grounding that in an agenda that's already been accepted worldwide by countries, multilateral organizations, the private sector, non-government organizations, individuals themselves. And it is the sustainable -- the UN sustainable -- development goals.

I won't take a long time this morning to walk through this with you. But on this, of these 17 goals, there's some that are clearly applicable to food safety. And you know, when you look at zero hunger, when you look at good health and wellbeing, you know

that these things cannot be accomplished if you don't have safe food.

But I want to challenge you this morning that at least 12 of these 17 UN sustainable development goals are co-dependent on food safety. They are -- you know, let's just take one, for example. And it may be life below water.

But you listened this morning to, I think, Julie and even to Commissioner Ostroff say that 15 percent of our food supply comes in. Well, some of that, as you heard this morning, comes in the form of shell meat and fish and other supplies. And that, of course, is life below the water.

And several of these, even as you look at reducing inequalities, clean water, and sanitation, this is critical for food safety to be had in many countries around the world, including the developing countries.

So I challenge you this morning to take a look at these sustainable development goals and see if you, too, would agree that at least 12 and even more of these sustainable development goals are co-dependent on

food safety.

And so in terms of building that sustainable base, we are certain that if we anchor our voice with the voices of those who have already accepted that these UN sustainable development goals are critical for us to really move the needle in development over time before and by 2030, you will agree that food safety needs also to rise much higher in the development discourse.

So what's the rationale as you look at it? We know, of course, that in the public sphere -- and we have been asked do you support infrastructure that focuses only on domestic food safety, or do you support exports -- food safety for exports. And we would say both because food safety not only protects and promotes the health of consumers, it facilitates market development and employment. It facilitates trade.

And these things are both domestic and external. And even for the private sector, the business case for better food safety is very clear. It improves smallholder access to major retailers.

So when you're looking at supply chains, it is

important that food safety is addressed. It reduces production losses. It lowers recalls.

I was just in Ethiopia a week and a half ago where they are concerned about food safety. And why? Because they are trading now in honey and other things. But they're trading honey. One shipment was rejected for food safety issues. And that's when, you know, authorities stand up and say we really need to address this.

And to their credit, they're taking this very seriously and are working on the food safety systems within Ethiopia and have asked for our help as well to address these things.

Let's look at even protecting your brand in terms of reducing risks. For the private sector, branding is extraordinarily important. And food safety, as you know, with any one scare -- and you can ask any of the companies that would probably come to the tip of your tongues about a food safety scare that has impacted their product or, perhaps, caused by their product. Loss of brand image just eradicates consumer trust in a very short space of time. And in terms of

reducing risk, ensuring that there is food safety capacity makes for more efficient and sustainable suppliers.

Now, in terms of our approach and impact, the GFSP has been looking very closely at how do we work at the country level in what we call country compacts. And these country compacts are rooted in our strategic framework that, as I mentioned before, allows us to assess, to convene and collaborate, and to leverage the expertise, the resources, the knowledge of our collaborators and partners. And then how do we work to implement on the ground in country?

It is important that as we set our own agenda based on our core competence, we look very carefully at the priorities set in country for food safety. Our country's prioritizing food safety capacity building. That's important for us because when countries do, it means there is ownership at the country level for this agenda. It means that it is more likely that there is a willingness, an openness to participate with an agency such as ours that brings public and private expertise and resources to bear on food safety in a

country.

And so the way we collaborate and the way we prioritize is to do it jointly in country, particularly in the form of these country compacts.

In addition, there are very key regional issues, for example, that we know, or larger issues, that cut across several countries that we can also work on. For those, we also look to ground that in the expertise and work of other partners. The World Bank where we sit is a good example of that.

FAO, FDA, all of our collaborators -- we try to say what are key issues that are facing, you know, a particular region or block of countries that we can work on. Aflatoxins in Africa is one such.

So if you look at this slide, when we consider the GFSP-coordinated approach for greater impact, we look at assessments first. And the -- I've listed only three countries here.

In China, we've been working with the Chinese authorities through CFDA, China Food and Drug Administration, largely, and other entities within China. We've worked there closely with GMA. We've

worked there with UNIDO, with the World Bank, and we've done an assessment of food safety capacity building.

We did a needs assessment. And from that needs assessment, we conducted supplier food safety training. We also supported laboratory capacity building. And the approach in that laboratory capacity building that we have actually rolled out beyond China to India as well and to other countries is a three-pronged approach, or three phases.

The first phase is that we train trainers. And in that first phase, one of our key partners for that is the International Food Safety Training Laboratory that is a key partner here for FDA as well. And that center is at Maryland University (sic)] [the University of Maryland] across the street.

They train trainers first. After training these trainers -- and that training -- first training can take place either in country or -- it really depends on the laboratory facility that's available. They sometimes come here to Maryland at the IFSTL. And -- or they -- it can be done in another country.

After that, we scale up that training in

country with the trainers who were trained, scale up the training for many more lab scientists in country. It allows them to build on the expertise that they've gotten and then allows for ground truthing in their own environments.

And the third phase of that is that after the training is done, about a year after, we go back in to verify that those who have been trained indeed remember and have built capacity so that they can test samples and come up with the right results.

Interestingly, in China when we did that, when we did the validation at the end of a year, the -- we go that 99 percent -- 95 percent of those who did the training got the correct result. And those scientists who did not do the training, the -- they -- the percentage that got the right result was at 45 percent. So that validates the importance of and the effectiveness of the methodology that we've developed for lab capacity building.

We've also done the same in terms of laboratory needs assessment. We're doing that now for India. We've been asked by the food standards and

safety authority in India to support food safety systems in India. And there, we're looking at a holistic program that not only involves training, capacity building in that sense, but also looking at their -- at the agency, in general, to support them with an international advisory body and, in addition to that, conducting some assessments of their overall training -- lab training capacity needs as well.

And then in Africa, we now -- we have embarked on a study that will -- that would look at the entire landscape within Africa to say who's actually supporting food safety in Africa, at what level, what are the institutions, what are they investing, which are the countries that are very keen to put food safety capacity building as a priority for their development.

And after we do that landscape analysis, we will then dive much more deeply into countries that are ready, countries that would like us to come in to do much more of a deeper assessment at the country level that will then be followed by investments at the country level.

Our last slide here, in terms of what sets us

apart, how will we know that we've accomplished what we're doing, you know, this partnership convenes public and -- the public and private sector to work together and to share lessons learned. We will know -- and that is versus, you know, sort of working, you know, in silos.

We will also test new approaches and leverage partner resources. We will also coordinate synergistic interventions. And of course, here, we're going to look to see how we can address the entire supply chain.

And here -- I don't know if you looked at our very first slide in this presentation. But that first slide showed pictures that went from farm to fork. And you would agree that food safety capacity building has to be addressed from farm to fork and everything in between because it is such an important agenda item for us.

We are delighted to be here today as a partnership that really embodies many global organizations and bilateral and, you know, other entities as stakeholders. We're delighted to participate in events such as this.

We're also working very closely at the country level, but we're looking forward to continuing the collaboration that we started with USAID, with FDA, with many others on the panel here so that we, indeed, can move the needle on food safety capacity building in country.

Thank you.

(Applause.)

DR. BEDARD: There we go. How many people in the room here are actually from industry from the private sector companies? Great. Thank you.

I lived in Indonesia for about six years a few years ago. And we raised three children there, so we were obviously very concerned about food safety and what was going into their mouths and what they were drinking. And I made a point of -- particularly, we were concerned about the water and what we were drinking on a daily basis.

And I, as you can appreciate, doing a lot of government meetings on a day-to-day basis and traveling in the field, we were -- you know, we were quite thirsty in Indonesia. So we were always worried about

what we were drinking, and we were a little suspicious of the water, especially in the plastic bottles.

So I made it a habit of only drinking bottled tea -- very nice. I mean, if anyone's been to Indonesia, you can appreciate bottled tea -- safe, glass bottle, cap on top.

And then one day, I was not far from home. We were collecting some ice in an icehouse. Actually, we were buying great big blocks of ice to make an ice-skating rink for my kids for their birthday.

(Laughter.)

DR. BEDARD: So you can imagine what that took. It worked.

But anyway, I was in the icehouse. And as I was going, I noticed in a room there was some activity. And I turned and looked in the room, and there were three ladies sitting around great big plastic garbage buckets with a big plastic hand bucket and bottles of tea -- empty bottles. They were taking the tea out of the bucket and filling up the bottles as they went along. And they actually had a capping machine to put the caps on them.

And I said what's going on here. And they said, oh, it's home industry -- in the cases and off they went to the market. So this is what I was drinking.

And this is -- really is a metaphor for what we're dealing with here. If you look at what Steve Ostroff was talking about and what -- the food coming into the U.S., if we agree that there are 250,000 suppliers from 150 countries that are supplying food into the U.S. and a lot of those supply chains, at the source of those supply chains, look like what I saw in Indonesia years ago -- and many of them still do -- how do we deal with that?

And I think that's what we're here to talk about today, is maybe looking a little bit different paradigm about how we take what is actually an excellent document for those of you that haven't read this report. Well, I actually have used it as a guide, and we refer to it in our work working with the private sector.

So how do you take this food safety capacity building, and how do you really drive it down to the

grass roots so you can have some kind of impact?

Those of you that are not familiar with GMA, the association represents many of the leading multinational companies that are working internationally. And I, as the executive director, represent the GMA Science and Education Foundation, to which many of those companies contribute on a regular basis.

As I go through the talk, I'd like you to think a little bit about how maybe -- I'm going to share some examples about how we use the private sector and our programs to drive this public good and these regulatory food safety capacity-building programs that have been talked about and will be talked about more today.

A shout-out for Shannon Cooksey. Is she here? Thank you very much. Just to let you know that I didn't do this deck by myself. Shannon, thank you very much.

So what's the GMA Science and Education Foundation? So we're a foundation that focuses on a number of areas -- research, education, and training --

both in the U.S. and internationally. I've highlighted three programs here because those three programs we've begun to roll out over the last few years internationally. And they provided a platform to actually scale up some of the training on a more sustainable basis.

One of the reasons we can do this is we facilitate a network of almost 35 institutions around the world now that are known as the Better Process Control School network. You can go on our website and see where they are. We're hoping to have 40 by the end of this year. And those schools and institutions, some of them are companies, in some cases, are dotted around the world, including the EU, Latin America, Asia, China, Japan, and elsewhere.

So I'd like you to just think about these three programs, the HACCP training a trainer programs. We're the designated -- GMA is a designated trainer of trainers for the International HACCP Alliance, and we like to wave that flag around.

We coordinate the Better Process Control Schools and network. And then we've become more

involved with the FDA and the FSPCA and FSMA training programs both in terms of lead instructor programs. We just completed one in Japan, and we're doing one in Italy next month. And we'll be doing more over the next year or so in other countries as well, working very closely with the FDA. And that, obviously, leads to the PCQI training programs.

Why do we do this? Well, obviously, we're interested in this objective here. But how it impacts the private sector -- what I'd like to do is just highlight a couple of things here. I mean, fundamentally, as Lystra alluded to, there's a fundamental need to look at food safety as it fits in the whole paradigm of food integrity in terms of quality, safety, food fraud, and food defense. And that's very important to the private sector, as you can imagine, very important for us to invest in. And I'll give you some idea of what that means in a minute.

The other umbrella that we play under is the food safety culture umbrella both in terms of the regulators and what it means to have good food safety culture within your own regulatory organization. I

know the FDA is looking at that. But then what does it mean to have food safety culture within your own organization and company but then all along your supply chain -- your ingredients supply chain and especially if you have international ingredient supply chains that you're working with.

The second thing that we try to focus on is we want to make these programs sustainable. When going to a given country, we want to get in there, establish a sustainable program that we walk away from and it still carries on. And I'll show you some examples about how this is working.

And we're not the only ones to use this approach. But this -- driving this food safety capacity building internationally -- only works if we get the local institutions and the local governments to establish sustainable institutions just like we have here in the U.S. -- I mean, JIFSAN, our organization.

How many universities and others and their food safety programs are dependent upon a sustainable business model? That means they have revenue and they're making money so they can carry on and deliver

these programs without additional public support and public money.

The other thing we try to do and other sort of fundamental principle and objective is to leverage the funding that's out there. There's lots of funding. The World Bank is spending millions of dollars internationally on food safety capacity building. USAID is also doing those kinds of things.

Other organizations -- how do we try to work along with those organizations so we're not being redundant and we're not duplicating efforts? And that's something that we're very, very hard on.

This is the landscape in which we operate. Take a small-medium enterprise, a small company with maybe 25, 30, 50 employees in China or India or in the Caribbean where we do a lot of work. They want to sell into the United States.

How do they do that? It's really daunting for them, and that's part of the problem, is we think, well, let's go do a two-and-a-half-day course. We're done.

It takes a small-medium enterprise 12 to 18

months to make the changes that need to be made to meet these requirements, whether they're national requirements, FSMA requirements to export to the U.S. Or now, we have the private sector specifications as well in terms of GFSI and other schemes that are out there and other programs that are supply chain-focused.

So I just wanted to give you an impression of the scope of the problem for these companies we're expecting to produce safe food.

And I'd like to thank Lystra for not stealing my thunder on this slide. This slide was actually developed as part of a collaborative effort with the Global Food Safety Partnership.

And what this slide does -- do we have a pointer here? Yeah, I think we do. Is this the pointer? Yeah.

So this slide -- what you -- the way you look at this slide is everybody starts with the basic fundamentals of food safety, primarily Codex, OIE, or others, that this -- the regulatory standards, the public and international standards.

And then these drive -- up above here, these

are the national food safety regulatory systems. It doesn't matter what country you go into. These fundamental principles are important, and the regulators need to have good food law and a good regulatory system in place if it's going to work at a country level.

The other side of this, this is the private sector side. This is the space that we tend to operate in. But you can see there has to be very close alignment, collaboration, and cooperation with the government sectors, and I'm going to show you how that works.

If we're all moving towards safe -- whoops -- safer food not only for their own country, but for export to the U.S., who are we going to train? That's another problem in terms of scope and how you get to these trainers. Who has to be trained out there?

From farm to fork, yeah, that's an easy thing to say when you get right down to it. And in China, you have 400,000 small and medium enterprises for processing food. India's the same. Indonesia has 250,000. How do you deal with them? How do you do

that, realizing again that those are all private sector companies, although perhaps in China one might argue that?

So this is the scope of the training that we have to get involved in. I will say that the space that we tend to play in obviously is in the processing sector. But we also get engaged with regulators and inspectors and also with consumers in terms of education -- school education programs.

Again, to reinforce what others have been saying, we can't do this alone. We have lots of collaborators out there. We usually partner with institutions either internationally or locally, partner with organizations in the United States.

And this means we get into a project together. We just did a project, a really successful project -- shout-out to JIFSAN that worked with us on that project -- that now is growing and building.

And again, we can only do this with partners and others. So it's not us standing alone. We're not big enough to do that. But when you work with other organizations, you can have some real impact. And

obviously, we're working with the U.S. FDA, USDA, and other representatives as we go overseas.

Some of the expected results -- I just wanted to highlight a couple of these things, and just two of them I really want to highlight. One is the important thing for us is we need to establish a sustainable institution and a program in a given country that has a revenue model that it can continue to exist after we leave. We have to be able to walk away from it, and that's the focus for us. And it should be for all of us, I think, if we're really serious about rolling out and scaling up food safety capacity building.

The other thing is results. The private sector is not interested in a program that we say we delivered that and we train 50 or 150 or 250 people. How has it actually changed the food safety practices in the company and my supply chain so they can meet third party audits, they can meet the FSMA requirements, they can meet EU requirements?

Those are the kind of metrics we have to be measuring against. And we have to be very serious about this if we're expecting the private sector to put

any money on the table. And in fact, they are doing that.

And I'm going to give you an example. I'll give you two examples. One is China. And the approach we use here is very much when we go into a given country, we engage with the government not by ourselves. We work with FDA, USDA, the other organizations that have those government gradations.

We work with the industry associations there. In China, for example, GMA signed an MOU with the China National Food Industry Association. We have five institutional partners there now in China, and we've delivered some programs starting HACCP.

But now, working with FSPCA that did some lead instructor training there, we're doing PCQI training. We're building up the Better Process Control Schools, of which we've delivered four now in China, that we're establishing as sustainable institutions, working with organizations that actually have a vested interest in making this survive and providing services to the industry.

We also include in our training program,

obviously, academics and regulators. We had a direct contract with the China FDA to do training for them.

Here's something to think about. So we have all of these trainings that some are very specific and technical. And FDA came to us and says, well, how does this all fit together? We don't understand.

So we created a program for them -- we call it FSMA 101 -- that was very well received. And we're going to start to scale that up.

So it's very important for us, sort of as representing the private sector, to have a very good engagement with regulators not only in the U.S., but where we work internationally.

And again, I've listed some companies up there. And a shout out here, and I apologize, Cargill should be on that list of companies. They've been very supportive of the work we're doing not only in China, but elsewhere.

And again, these are companies and organizations that we work with in order to have some real impact. And they drive us to make sure we have impact for our programs.

I put this up there just not for you to memorize.

(Laughter.)

DR. BEDARD: This is a framework for regulators that's being used by FDA. It was developed by the International Food Protection and Training Institute in Michigan. It was developed for FDA. It's being used in Canada also to train their inspectors and regulators. The Chinese are looking at it. The Indonesians are looking at it as a framework.

So we don't have to reinvent the wheel. And I believe that the U.S. has something really powerful here to offer the rest of the world in these developing countries in terms of training inspectors and regulators.

And I should say we're doing this -- supporting this. We're using private sector funding. And our GMA member companies are supporting us to push this out and help regulators to get trained in this space. So there's a real opportunity to look at a different paradigm, a shift, I wouldn't say -- but a shift in the public-private partnership.

Somebody from one of the international organizations said to me: a public-private partnership -- that's where the private sector gives the public sector money and then gets out of the way. Yeah, I mean, it's -- it sounds funny, but it's the way it works. And it can't work like that if we're really going to have impact.

So when I think -- and some of the examples I'm going to give -- I've got one minute? One more example.

So this SPS Caribbean project, you can Google it -- SPS Caribbean. There's a website for it now. We've just completed that project -- very successful, funded by IICA, the Inter-American Institute for Cooperation and Agriculture, and the EU, working with 15 countries in the Caribbean training HACCP trainers using the International HACCP Alliance program.

Fifteen trainers trained -- thank you very much. But they now have an institution they've established in the Caribbean. We're working with institutions there. And as of two weeks ago, they're coming back and saying to us, well, we need your help

to do FSMA training and [Preventive Controls Qualified Individual] PCQI training. We need your help to do Better Process Control Schools. And we're now scheduling those programs. They're paying for it. The companies in those countries are paying for it.

So there is an opportunity here to piggyback on a lot of the work that's going out there with the private sector and really create a dynamic and exciting new relationship in this public-private partnership.

Thank you very much.

(Applause.)

DR. BRACKETT: Well, good morning.

First, I'd like to thank FDA for inviting me to provide comments at this very important event. I've been asked to present the academic perspective on international capacity building in food safety, but focusing specifically on the role of the various alliances in helping FDA further their mission in this regard.

Universities and institutions of higher learning have traditionally been indirectly involved in capacity building through their traditional educational

efforts. And by this, I mean classroom training or degree programs or graduate research.

And indeed, foreign students often came and still do come to the U.S. to learn the latest about food safety. These students have then gone back to their countries to share what they have been taught. In some cases, they are academics.

In other cases, they've taken senior leadership roles in industry and in their governments. So we have had an impact in that way.

More recently, universities have viewed international outreach as part of their mission in a way they hadn't done in decades past. Virtually every university that has a strong or significant program in food science or food safety has engaged in some type of training efforts abroad, particularly in developing countries.

The efforts -- these efforts have, in large part, been funded by government agencies, such as U.S. Agency for International Development, USDA's Foreign Agricultural Service, and of course FDA. However, private companies and charitable foundations have also

been active in funding and, in some cases, doing the international training efforts in food safety.

So with the passage of the Food Safety Modernization Act, it became readily apparent that more training would be needed to help the regulated industry to comply with the various new rules. And this was especially true in the case of small and midsize companies.

This need for enhanced training offered new opportunities as well for universities to collaborate more closely with the Food and Drug Administration as well as the regulated industry. This demand for collaboration led to the establishment of the various training alliances, specifically the Food Safety Preventive Controls Alliance and the Sprout Safety Alliance, which is based at the Illinois Institute of Technology in Chicago, now being called Illinois Tech, as well as the Produce Safety Alliance, which is based at Cornell University.

All of these alliances work in a similar manner in that they rely upon the expertise and the involvement of the industry, FDA, state partners, and,

of course, other university educators.

This morning, I'll focus primarily on the Food Safety Preventive Controls Alliance to sort of showcase how these alliances assist the industry to comply with the various FSMA rules.

The Food Safety Preventive Controls Alliance, or FSPCA, as we call them, was established at Illinois Tech in 2011 shortly after the passage of FSMA. The alliance was modeled after an earlier successful alliance, the Seafood HACCP Alliance.

The primary mission of the FSPCA was to develop a standardized curriculum that could be used to train the industry on how to comply with the new rules. A secondary but important outcome as well would be to establish a mechanism to deliver the training to both domestic as well as foreign facilities.

Initially, this involved assembling a group of food safety experts known as Train the Trainers, or ToTs, as we call them, whose primary function would be to train lead instructors who would then be -- serve as force multipliers to actually go out and train the industry.

The FSPCA training efforts can be really divided into three basic elements, and that being industry training, government training, and technical support. Of these, industry training is the primary priority. Not only is this training designed to provide attendees with the requisite knowledge to understand and develop a food safety plan for their facility, but successful completion of the training is one way that the attendee can attain the designation of Preventive Controls Qualified Individual, or PCQI, that you just heard Brian talk about.

The preventive controls for human and animal foods rules require such an individual at each -- or for each registered facility. The Produce Safety Alliance provides similar training for those entities that are subject to the produce safety rule.

Although FSPCA training is primarily intended for the industry, it's also being used to train government personnel, including state regulators, FDA investigators, allied U.S. government agencies such as USDA's Agriculture Marketing Service, and foreign governments. The intent here is to provide the

government inspectors and investigators with the very same information that is being provided to the industry.

As mentioned previously, the primary target audience for FSPCA were small and midsize companies. Such entities often lack the technical expertise that is present in large national or multinational companies.

Consequently, the third element of the training effort was to provide basic technical support to these small companies. This is done through a technical assistance network, or TAN, that mirrors the FDA TAN that you saw Julie present a little bit earlier that was established to address regulatory or policy questions but not technical questions.

The FSPCA TAN is staffed by volunteer food safety experts who are qualified to answer basic science and technical questions that may arise as a food company is developing or implementing their food safety plans.

The lead instructors are key to the success of the alliance efforts in that they do the actual

teaching and training. But they also serve as the face of the alliance to the public.

Consequently, the choice of who would or would not make a good instructor is taken very seriously. Lead instructor candidates are chosen based on their educational background, experience working with the food industry, as well as training experience. Those candidates that have the appropriate backgrounds then take lead instructor training that provides them with the background to do that.

Other considerations are also important and impact the training of lead instructors. For example, the regions in which the training is offered is based on a number of factors such as the number of registered facilities in that area or region, the trade volume in that region, or whether or not the country or region is important to other U.S. Government partner agencies such as USDA's Foreign Agricultural Service or U.S. Agency for International Development.

The information provided to lead instructors during the training goes beyond just food safety and FSMA, particularly for international audiences.

Candidates are taught the basics of adult education and the role of different learning and teaching styles as well as cultural sensitivities and inclusivity.

The curriculum itself is currently available in English and Spanish, but there are plans to also make it available in French, Portuguese, Hindi, Mandarin, and Japanese, and perhaps some other languages as well in the future.

An important component of inclusivity is affordability. The Alliance strives to keep the cost of training as low as possible so that the -- it can be affordable for as many people as possible.

One means to do this, that we've recently launched is our so-called blended course, which allows individuals to take most of the course content online at their own pace and then requires only one day in person for an instructor-led portion.

This is not only a less costly means of delivering the training, but lessens the time that the learner needs to actually be away from their job, which is very important to them. Likewise, it will enable international audiences greater accessibility to this

type of training.

Finally, another very important consideration for training is quality control. In addition to choosing qualified lead instructors, it's also important to follow up to make sure that the training sessions are, themselves, are being delivered properly and meeting expectations.

To this end, the Alliance will be monitoring and evaluating lead instructors to be sure that the training is meeting expectations. Some of the factors to be considered are the mechanisms to provide the instructors with timely feedback, auditing of training sessions, and procedures to deal with lead instructors whose performance may not be meeting expectations, or perhaps, if they are misrepresenting the Alliance in some way.

Of course, the reason we want to monitor and evaluate the training is that we want the training to be successful. There are a variety of metrics that one can use to measure success. One of the easiest metrics is simply accounting for the number of individuals who have successfully completed the training.

In addition, we use and keep track of evaluations from the, like, learners provided by the attendees during the training sessions. These evaluations are important in helping us assess if attendees are deriving the required value from the training and if they believe that the training helps them to better comply with the rules.

However, the real measure of success of the training would be evidenced by improved regulatory compliance by the industry. For that, we will rely on feedback from FDA as to if they are seeing improvements in the field in compliance as compared to what they have seen in the past and, perhaps, where training needs to modify to suit even better.

The Alliance officially started conducting training in December of 2015. And initial efforts were twofold -- that is, providing training to the industry as intended while at the same time building up a cadre of lead instructors to further increase our capacity to conduct more industry training.

Since that time, we've expanded training to international stakeholders as well. And so at this

point, you'd have to say, well, what have we accomplished in that time.

Well, this slide shows the number of certificates, which really equates to the number of people trained, issued since we started the training. As you can see, we have issued over 31,000 or 2,100 certificates for human foods and animal foods, respectively.

Most of those certificates were issued to domestic trainees. But what this slide does not show you is, sort of, the rate a training had occurred throughout this time, which is illustrated in the next slide.

In this slide, one can see that the proportion of international certificates was initially very minimal. However, it has increased dramatically in the last few months, and we expect this trend to continue as the preventive controls rules continue to be implemented.

Another measure of outcome is the training -- for the training is the number of actual training sessions that have been conducted, which is shown in

this slide on the top. This slide also shows where international courses have been conducted, which has been driven mostly by demand from those countries. As you can see, Canada and Mexico have been the primary recipients of the training, followed by other important U.S. training partners in Europe, Asia, and Latin America.

Well, I've emphasized the importance of training lead instructors so that we can actually increase the capacity to train interest -- yeah, industry. This slide shows that we have been successful in actually attracting individuals who wish to become lead instructors.

As of last week, we have conducted over 43 lead instructor training sessions, increasing our training cadre to almost 1,300 individuals with about another 900 approved candidates still in the queue to be trained yet.

Finally, I'd like to share with you the Alliance plans for future international activities. Our international subcommittee has put together an aggressive action plan to continue to increase the

number of international lead instructors; provide them with an interactive web-based community to support their efforts and develop an international technical assistance network, or the ITAN, which is similar to the TAN, but we want this to be in local languages; and, through our international lead instructors, provide training to stakeholders, both industry and government, across the globe.

So in conclusion, I again want to thank FDA for allowing me to show you what the alliances are doing. And hopefully, you will be able to better understand what the alliances are and how they have contributed to capacity building. So thank you very much.

(Applause.)

DR. CORMIER: Hello. You know, I've noted so many familiar faces in the -- in front of me and in the front of the room. And I think this is evidence of some already very strong collaboration.

I'm happy to be here with you today to talk about USAID's perspective on this topic of partnership in food safety capacity building. I wanted to add to

the discussion, in particular, by describing what USAID is doing in partnership with other U.S. Government agencies and the private sector to combat food insecurity. And I'll do that by highlighting how food safety capacity building is playing an increasingly important role in that -- in those efforts.

So I'm going to share a little bit about how USAID enters this space, what our framework for engaging in food safety capacity building is. I want to highlight some examples of how we work on -- with food industry supply chain management, in particular with the private sector, but also with U.S. Government agencies such as FDA and USDA and tell you a little bit about how we measure our success.

As the lead agency for Feed the Future, which is America's initiative to combat global hunger and poverty, USAID works with 10 other U.S. Government agencies to equip people with the knowledge and tools that they need to create sustainable livelihoods.

Some of the impressive results that we've seen include reductions in poverty and stunting. And it's these contributions to global food security that have

garnered broad bipartisan support, culminating in the enactment of the Global Food Security Act last year.

As called for in the Act, USAID worked with these 10 other agencies and departments to develop a new U.S. Government strategy for global food security, which we call the GFSS for short. And it's this strategy that really charts the course of our work for achieving the sustainable development goals that Lystra mentioned in her presentation.

And it also highlights how food safety has become a crosscutting issue across the strategy. And this is something that I'm really happy about, and it represents a lot of opportunity for collaboration.

We recognize that food safety is a factor in combating food insecurity, and it has to be addressed starting at the foreign level, bringing technical -- technologies to scale, and continuing all the way to the table.

So because we know that food safety can be threatened at each step in the agricultural value chain from production to consumption, we must find ways to incorporate food safety capacity building in the

agricultural development work that we do. Increased food safety capacity can result in food products that meet international standards as well as demand for safe home consumption.

We address food safety capacity building for three main reasons -- mainly, because it advances trade, it improves public health, and it enhances food security and nutrition. These are high-level objectives that are prominent in the Global Food Security Strategy.

We've found that developing countries -- and we've seen this -- they're increasingly becoming key actors in global supply chains. Brian's presentation spoke to many companies that are looking for strong supply chains. It underscores the importance of addressing through the Feed the Future initiative food safety capacity building needs.

We can -- we do this in a number of ways -- through supply management efforts, risk analysis, regulatory systems, strengthening, laboratory competency strengthening, incident management. And I'm going to give a couple of examples of how we do this in

a couple of minutes.

But first, I wanted to note that the strategy that we're taking is facilitative. We support country-led agricultural development strategies, and we do this in partnership with diverse stakeholders. And as the panelists have already pointed out, we are increasingly aligned in strategic ways that leverage limited technical and programmatic resources.

I wanted to highlight the private sector engagement part of our approach to implementing the Global Food Security Strategy. It's a critical part of our approach, and it's central to our work with the food industry.

We -- because our resources are limited, we can't partner with everyone, but we are always open to great ideas that enhance both development impact but also company bottom lines. We work with partners in food industry because companies are looking for reliable supply chains.

And we know that when we can link the farmers and the small- and medium-sized businesses that we work with in developing countries that we can find win-win

opportunities for all stakeholders. We do view our private sector partners as thought leaders who bring crucial feedback, a fresh perspective, and innovative insights to the development table.

One example that I want to highlight is Partners in Food Solutions, and some of you might be familiar with this industry-based group. It's a nonprofit that uses employee volunteers from companies such as General Mills, Cargill, Hershey's, DSM, and Buehler.

These employee volunteers have supported the capacity building in food processing companies throughout eastern and southern Africa. And in so doing, they've increase the availability of nutritious foods -- nutritious and therapeutic foods in the region.

Another example is the Global Food Safety Partnership, but I won't give -- share too many details on that because Lystra has highlighted what the work of this partnership does. And USAID is a strong supporter of the partnership and sees it as a really important network of stakeholders and a critical part of our

ability to align strategically.

So now I want to talk about how we've partnered in particular with U.S. Government agencies. USAID has been collaborating with U.S. Government agencies for a long time. And to highlight -- two examples with USDA and FDA highlight our work with food safety capacity building.

Now, I mentioned that we operate to support country-led agricultural development strategies. The first example highlights a project that emerged when Latin American countries saw the potential new regulatory requirements of the U.S. Food Safety Modernization Act as a priority for technical assistance.

USAID's Latin American-Caribbean Bureau worked with our missions in the region, with USDA FAS, and with FDA to design the food safety and agricultural sustainability training, or the FAST program. And I -- Julie Moss mentioned that in her remarks.

This is a program that's exciting to talk about since it's been around for a while. And we know that the impact of food safety capacity building takes

a while sometimes to be realized. But this project was created when we formed an interagency agreement with USDA and developed education and training materials under FDA's guidance.

So you've heard a little bit about this. And the presentation by Bob Brackett also highlighted the work of the alliances. And these -- that work is -- the FAST program does help to advance some of this work.

Through -- from the time period of April to July of 2015, USDA and partners implemented several workshops that built awareness in the region about FSMA, its impacts, and practical ways to prepare for implementation of new food safety processes. There was an enormous demand for this information. And coming together, USAID, USDA, and FDA were able to meet this demand and work with stakeholders in the region.

Another critical partner is IICA. And USAID, [USDA] FAS worked with IICA to define gaps in the food safety processes that exist and measure the strength of the existing food safety systems and processes. Some of the models that were used and developed in

partnership with IICA are ones that we believe can be replicated and scaled up in other geographies.

I'll wrap up my example of the FAST program by just noting that the next phase of this project sees increasing work with the FDA-funded alliances. The FAST program will facilitate, in particular, opportunities to participate in the Food Safety Preventive Controls Alliance and the Produce Safety Alliance. So this -- so there's a lot of work still to be done under that project, and there's a lot of demand still to be met.

A second example of collaboration among these three agencies is the Food Safety Network, also mentioned in earlier presentations. It's relatively new. It's something that we created with another interagency agreement in September of last year. And it's designed to take some of the best lessons and practices of the FAST project, and it positions USAID and USDA in collaboration with FDA to meet increasing demand for food safety capacity building around the globe.

So we're looking at countries in Africa; we're

looking at countries in Asia; in particular, countries that feature within the Feed the Future initiative, our focus and target countries, countries that have the most need.

But also, we're looking for -- we're looking to focus our efforts on food safety capacity building needs where there's also private sector engagement and interest so that we can identify ways to leverage those resources and really achieve those sustained impacts that we know are so important.

So how do we measure success? The Feed the Future initiative has enjoyed a pretty robust monitoring and evaluation system with a set of indicators that we've been working with partners to track over the years. And the Global Food Security Act strengthens that and, in fact, gives us an opportunity to refresh it and to take another look at how we can assess systems change better.

We do track output indicators such as how many people were trained. But we're increasingly trying to become more sophisticated about how we assess outcomes and impacts.

Capacity building and systems strengthening is an entry point for a lot of our development efforts. We don't always do a great job of assessing the success of those efforts, but it's a long-term endeavor. It's also the best way to measure success in the long term.

One example from Guatemala -- when we see fewer exports of snap peas from Guatemala rejected due to pesticide residue and we see an active private sector and associations working with government regulatory authorities to train, build knowledge, and install and instill institutional capacity on both sides, we're getting closer to success. In many countries in which we work, local capacity is a huge concern and, in many cases, a debilitating factor.

So I think what this example shows is that a measure of success is almost the strength of the relationships across the diversity of actors in any one system. So you know, I welcome thoughts on that. But that's something that we're going to be paying closer attention to.

We've worked in other countries, too. But I know my time is short. And so I want to just close by

saying that, given the complex and pervasive nature of food safety problems in developing countries, some of which have been highlighted here, we can't hope to gain ground without close collaboration. This is a message that I think every one of us here has shared today.

Food safety capacities depends on the strength of public and private organizations working and investing together, building new markets and supply chains and sustainably taking new initiatives to scale. So I welcome the opportunities to work with everybody further.

Thank you.

(Applause.)

MR. SPREIJ: Should I do that? Okay. Great.

UNIDENTIFIED MALE SPEAKER: (inaudible - off mic).

MR. SPREIJ: Yep. So good morning, ladies and gentlemen. Let me start at the outset by thanking FDA for the kind invitation to share information with you about the Standards and Trade Development Facility, as you can see, a partnership to build sanitary and phytosanitary capacity building. So this is a bit

broader than just food safety, and this also encompasses animal health and plant health and trade.

This partnership was established by five organizations -- originally at the OIE; the FAO, as you can see; the World Bank; the World Health Organization; and the WTO, the WTO which houses and manages the secretariat of the STDF. As requested by FDA, I will also share with you, towards the end of the presentation, and some of the experiences and some of the lessons that we have learned throughout implementation of the STDF program over the years.

So very quickly, the role of the STDF, or the goal here, is to increase the capacity of developing countries to implement international SPS standards. So here we are talking about Codex, about OIE, and about IPPC for plant health and to enhance their ability to gain and maintain market access.

And of course, we do this with a vision. We do this in order to contribute, as was already mentioned by speakers before, to sustainable economic growth, to poverty reduction, to job creation, to food security. So we are contributing to these sustainable

development goals.

If we look at the STDF partnership, then essentially, we have two parallel work streams. On the one hand, the STDF has evolved over the years into a leading coordination mechanism and knowledge hub in SPS capacity building. And what we do here is we link up organizations that are involved in SPS capacity building to -- how to collectively identify good practices to strengthen coherence and to avoid duplication and also to enhance the result of what we collectively are trying to do.

On the other hand, the STDF is also a funding mechanism. And here we provide funds -- seek funding to start with for developing countries to turn good ideas into sound and sustainable projects. Up to $50,000 U.S. are provided for this kind of work, which can also include needs assessments and needs prioritizations.

There is also funding available in the STDF for projects. These are projects that are collaborative, that are innovative, and that, again, support compliance with international standards and SPS

requirements and market access.

And of course, these two parallel work streams do not work in isolation. They continuously strengthen and reinforce each other.

Since the establishment of the STDF, we have generated over $60 million U.S. in direct contributions from donors, for which we are grateful. This includes contributions from FDA and also USDA.

But within the projects, we've been able to leverage much, much more resources than those 60 million, for instance, from, again, bilateral donors from the private sector and also from governments.

So who's involved? What does the network sort of, of the STDF look like? Well, of course, we have the five founding partners of the STDF -- the FAO, the OIE, the World Bank, the WHO, and the WTO. And this includes also Codex and IPPC secretariats.

We have a large amount of donors that are providing funds to the STDF, but donors who are also implementers and providers of SPS capacity building themselves.

Within the projects that we have -- and I will

give a few examples later on -- we work with a wide variety of public sector institutions, ministries of agriculture, ministries of trade, ministries of health. We work with the private sector. We work with regional organizations for regional projects. We work with NGOs. We work with universities and so on.

Within the network of the STDF, there are other organizations that engage with us. And these are also organizations that participate in the STDF working group meetings -- organizations like CABI; like the Global Food Safety Initiative, GFSI; IICA; the International Trade Center is very important due to its work with the private sector; and small and medium enterprises; (inaudible); UNIDO. There's a wide variety there.

And of course, finally, we do this for -- beneficially so developing country experts have a voice and play a role in the STDF.

Looking at this coordination and knowledge platform, the role of the STDF secretariat in the WTO is very much one of, I would say, advocacy and information exchange. And central here is the working

group meeting where the key stakeholders meet twice a year under margins of the SPS committee meetings of the WTO in Geneva.

We issue briefing notes. We issue project result stories. We issue electronic news items on topical issues.

We've developed a number of film products -- film products that, again, showcase stories -- why is it important to invest in food safety, animal, and plant health in the first place. And all that information is collected in an STDF website.

We are a leading voice in global, in regional, in national seminars, programs, trainings. We participate very actively in the national trainings that WTO provides on the SPS agreement. And within the STDF, the partnership, we have been working on identifying and disseminating good practice on a number of crosscutting topics. And these topics and that cut across the three areas of food safety, animal, and plant health and also trade.

Quickly, some examples here, prioritizing SPS investments for market access is a framework that we

have developed in the STDF. The background here is that there are still a lot of capacity needs in developing countries.

But we do know that there are still also resource constraints. We know that decision-making in developing countries often lacks transparency. And also the dialogue between the public and private sector can be improved.

We've done a lot of work on trade facilitation in an SPS context. As some of you may know, a new trade facilitation agreement in the WTO will enter into force very soon. We're only two ratifications away from that agreement entering into force.

But we've looked more at sort of trade facilitation in an SPS context. And the background here is that the costs of trade in food and agriculture products are still very, very high, especially if we compare that, for instance, to the trade in manufactured goods. And we also know that SPS measures, SPS constraints, are one reason for that.

So this calls for streamlining regulations, for improving transparency, and also to base your

inspections on risk. And not everything has to be inspected. And also, it calls for better collaboration among the SPS agencies themselves within countries and also better collaboration with customs.

This work in STDF is currently focusing in a bit more on electronic certification in the SPS area and how to integrate that within the national single windows systems that are being established currently in the trade facilitation area and with Customs.

The discussions in the STDF working group are also focusing on good regulatory practice. How do we actually develop good SPS measures? And what's the role of the private sector in that?

Public-private partnerships to build SPS capacity -- how can the public and the private sector collaborate and to build food safety, animal, and plant health capacity for market access? This has been work that has been ongoing in the STDF for many years now. We started working on this back in 2010.

We issued a flagship publication with numerous examples of public-private partnerships for SPS coordination, for value chain development, for

infrastructure, for diagnostic capacity, for trade facilitation, even up to the level of what we called back then co-regulatory approaches and which is probably more aligned with sort of the topic that will be discussed on the second panel. But if you're interested in this study, please go to the STDF website and have a look.

We've also looked more critically at the projects that we found in the STDF, and a briefing will be issued next week officially. I put a few hard copies, a few available upstairs in case you're interested.

And we've looked in this briefing note. How do we work with the private sector to -- within our STDF projects? And so the private sector sometimes is an implementer of capacity building projects. But more often, the private sector provides financing, provides expertise, provides knowledge. And the private sector is also an important link and -- to some of the small and medium enterprises and small-scale farmers.

Just a few more -- a few examples to give you a flavor of what we do, there are many, many more

examples available on the STDF website. These are projects that mobilize resources that are innovative, that are catalytic, that are -- we try these projects to be scalable. We've funded 76 projects up to now, and over 60 percent of those projects are benefitting the least developed countries, the poorest countries in the world.

In Thailand and Vietnam, we've worked with local producers, with retailers, and also with local universities in a project that was implemented by Michigan State University to boost the safe -- boosts safe food and vegetable experts -- exports. Training manuals have been developed very much based on the GFSI Global Markets Program. We're currently looking into developing a case story on this with GFSI.

In Sri Lanka, we've worked with the Spice Council setting up a training academy for the exports of cinnamon, a project implemented by UNIDO.

We're also working globally to support selected countries in Africa and Latin America and Southeast Asia to meet pesticide standards for exports for so-called minor use crops, again, a partnership

approach. Especially, I would say, USDA has been very instrumental in setting up this project.

But the FAO is involved, the Joint Meeting on Pesticide Residues (sic), Rutgers University, CropLife, also a number of large chemicals companies such as Dow and Syngenta.

So some of the key lessons learned -- and I still have a little bit of time left. Of course, this is not all of it. It's, again, just a sample.

I think it's very important that we continue to increase the awareness of the importance of making investments in the SPS area -- as Ms. Valdez already mentioned that the World Bank is doing good work in that area. WHO is doing work in that area.

But this is very important. Why is this important? For economic growth, for public health. And we need to do more economic analysis also at the country level.

SPS is often perceived, especially by the higher-level decision-makers, something that is just very complicated. But you know, if you give these politicians, if you give them numbers, then they might

wake up and they might make those investments.

Mobilizing resources, public-private collaboration, and for catalytic and scalable project and consider value chain approaches where possible -- this is critical.

And we should also continue to avoid fragmented and supply-driven interventions. Despite all the good intentions, many of the interventions are still not based on demand, are very much supply-driven. So it's important to pay attention to ownership and to absorb the capacity in developing countries as well.

Integrating SPS capacity building into other areas of development cooperation is important and was just mentioned also by previous speakers. Of course, we have stand-alone food safety projects, animal health projects, plant health projects in countries. And that's good.

But more often, there are opportunities within much broader programs on agriculture development, on private sector development and, more recently, also on trade facilitation to really also help to scale up food safety in this case.

We need to work on regional SPS solutions. Again, the resources are limited. And perhaps this is more applicable to the animal health area and the plant health area where you have pests and diseases do not respect borders. So you need to work together.

But even in the food safety area -- for instance, in the area of laboratory capacity or doing joint trainings -- we can identify regional solutions and develop regional projects.

Improve institutional management -- the SPS agreement in the WTO has been in existence now for over 20 years. And I think that we have come a long way. And if, you know, I go out to developing countries and I speak to the stuff on the ground, for instance, in the SPS agency, technically, this stuff is often very good. There is still a lot of gaps, of course, to be filled. But I think, you know, we've come a long way.

For the future, probably what is going to be more important is to pay also attention to institutional management in SPS agencies and also in the private sector and also to measure for result and look at budget allocations for this type of work within

national government budgets.

And finally, reducing trade costs, as I have said before, is very critical in terms of, I would say, increasing the competitiveness of developing countries in order to being able to trade and especially to enhance a regional trade agenda. But this is also very important for other reasons -- for instance, to reduce issues around food loss and food waste.

So thank you for your attention. We have a website. On this website, you can find all the information about the STDF, the publications, the briefing notes, the result stories, the training tools. All the information about the projects is there.

We also have a possibility to search in a virtual library where you find documentation about SPS capacity building.

So thank you for your attention.

(Applause.)

MS. BREWER: I'd like to thank all of our speakers. I see the FDA questioners have been listening with rapt attention. So I'll turn it right over to Susan Berndt, who will lead us into the next

part of our program.

Susan?

MS. BERNDT: Thank you, Camille.

I'd like to introduce our expert panelists from FDA. From your left to right is Lou Valdez, Associate Commissioner for International Programs, Office of International Programs; Joann Givens, Human and Animal Food Program Director, Office of Regulatory Affairs; Mickey Parish, Senior Science Advisor, Office of the Center Director, Center for Food Safety and Applied Nutrition; Julie Moss, Acting Third Party Program Director, Center for Food Safety and Applied Nutrition; and Bettye Walters, International Policy Analyst, Office of the Center -- Director, Center for Veterinary Medicine.

And we'll start off with Dr. Walters.

DR. WALTERS: And this question is going to be for Dr. Bedard.

I think I should move this.

A developing economy, almost by definition, means increasing supplies of good-quality foods, especially proteins, as populations begin to demand

more animal source foods -- meat, milk, and eggs.

By way of example, would you please highlight where animal feed safety would fit as part of GMA's food safety capacity development?

DR. BEDARD: Thank you very much.

So you're asking how does the animal feed safety fit into the overall food safety --

DR. WALTERS: Correct.

DR. BEDARD: -- program?

DR. WALTERS: Thank you.

DR. BEDARD: Okay. So we -- I wish my colleague, Shannon Cooksey, was sitting up here because she deals in that space more than I do.

From our programming perspective -- and Shannon, it might be useful, actually, for you, if you don't mind taking a microphone, you can help because that would be very helpful.

From our perspective, we're not dealing in the feed space a lot. Obviously, for animal products, that's not a high priority for GMA. A lot of our members -- some members do produce that. But there are other associations that are more focused in that meat

space, per se.

But internationally, we're dealing, particularly, in China and Indonesia as well, in the dairy sector. I think that's one I can speak to where we see, looking at safety in dairy products, it goes right down to the farm level, obviously, whether it's antibiotics or contamination of the feed and so on and so forth. So where we're dealing with dairy companies, that does fit into the supply chain part of compliance with food safety and food safety audits.

Shannon, do you -- did you want to comment?

MS. COOKSEY: Yeah, we really don't play a lot in that space. We do provide technical support to the other trade associations that provide the food and feed -- animal food-type training.

So -- oh, sorry. Is that better?

Okay. So we really don't do a lot of the animal food training or the feed training. But we do work -- it's hard because I can't stand. So we work with the other trade associations, and we do provide technical support to the other trade associations that do deliver those training programs.

DR. BEDARD: I can give you a little example. In China, again, we're working with -- I can't tell you which company. It's one of the largest dairy producers there that's very focused on infant formula. And we're working with them because they want to comply with the requirements for infant formula, which are very specific these days, as you may be aware of.

So we're working with them, and we're right down on the farm working with their formula around diets and what they're feeding the cow, where the source of food is, what they're using in the way of any supplements to the feed as well. So again, that's where the training fits in. But we usually farm that out to partners who are really working in that space.

DR. WALTERS: Thank you.

DR. BEDARD: Okay.

MS. BERNDT: Okay. Our next question.

(Side conversation.)

MS. BERNDT: Dr. Moss?

Oh, sorry.

MR. SPREIJ: No, maybe just to add that, in Codex, there is -- there are guidelines on feed safety.

And in the STDF, we work a lot with International Feed Industry Federation and with IFIF, as we call them. In FAO, we have developed a training manual on how to implement these Codex guidelines many years ago.

That project has first been implemented regionally in Latin America. There's now a lot of interest to replicate that in Asia. And we're also working with a big association of feed producers, FeedLatina in Latin America, to help improve feed regulations. That's another STDF project which is ongoing.

MS. BERNDT: Thank you.

Dr. Moss?

DR. MOSS: Thank you for the wonderful presentations. My question is for Kelley Cormier with USAID.

Kelley, when we were drafting the capacity building plan, USAID was one of our key new partners that we wanted to develop, and we have done quite a good lot of work thus far. You mentioned some work that USAID is doing with the food industry. And I'm -- you know, what popped in my head is how could FDA be

part of those conversations or partner with you.

So my question is, from USAID's perspective, what does the -- a leveraged partnership with FDA look like to USAID?

DR. CORMIER: Thank you, Julie.

So I -- in my earlier remarks, I did describe how we have worked together. And I think that in -- if I can elaborate more, it's continuing to put best practices of collaboration together to continue to share information. And what I'm particularly excited about is the opportunities for greater collaboration at the country level.

Lou, you mentioned that, you know, there are staff in so many places around the world. And I think something that USAID hasn't taken full advantage of is working together with our U.S. Government counterparts in the field, as we say. So I see great opportunities for that.

And then as the FAST program continues to advance, as the Food Safety Network continues -- really gets up and running and starts to meet the needs of countries in other geographies, I -- we have to

continue to be collaborating and identifying points of contact in countries in which we're working.

MS. BERNDT: Okay. Next question.

Dr. Parish?

DR. PARISH: So as Julie said, thank you all very much for your presentations -- very educational.

I'll -- I'd like to start, Melvin, with you with a question. On one of your slides in key lessons learned, you talked about avoiding fragmented supply-driven interventions. Could you provide an example of what that means in terms of fragmented and what lessons have you learned and how to avoid those?

MR. SPREIJ: Well, obviously, the answer to that is that there should be better coordination and there should be better coordination at different levels. But eventually, the coordination, where it's needed most, is, I would say, at the national level. It's really the country that you set the agenda and should identify its priorities.

And too often still, we see, you know, interventions also from donors that are, you know, very well intended but that are not necessarily aligned with

some of those country priorities.

MS. BERNDT: Ms. Givens?

MS. GIVENS: Good morning, and thank you very much for the presentations -- quite insightful.

This question is targeted to Dr. Brackett. First of all, I'd like to congratulate you on the sheer numbers of starting the FSPCA courses in December 2015 and reaching the milestones -- I'm sure you exceeded the milestones that you probably have set forth and goals.

But the question I wanted to raise to you is how engaged have the competent authorities been with the -- with regard to training as lead instructors. Is there a push? How many of them are part of the numbers that you highlighted in terms of lead instructors? Because I do believe that they have -- they certainly have value and can contribute to us expanding internationally with all the alliance trainings that we have put forth.

So could you address that question?

DR. BRACKETT: Well, thank you, Joann. You're right. In many cases, especially where we've done

international training, the competent authorities, or members of them, have actually been part of the Preventive Controls Qualified Individual cadre. And then they've gone on, also, to do lead instructor training.

In some countries -- for instance, in China -- the government entities are actually doing some of the training for Preventive Controls Qualified Individuals within their own industry as well. So I think one of the benefits of that is this is also expanding to their own food safety plans as well as products that are going to be destined for the U.S.

MS. BERNDT: Ms. Valdez?

MS. VALDEZ: Thank you. Again, terrific presentations, really -- lots of learning to be had.

A number of you mentioned this -- and I think it's something we also struggle with -- is whether it's doing a lot of training or what we would call capacity building or curriculum development or the standing up of better processing in schools.

We struggle with the actual outcome and impact. It's kind of like the so-what factor. And it

would be really interesting to hear from, you know, whomever has a great idea off the top of your head. How do you really think through that measuring of outcome and impact?

DR. BRACKETT: Well, the one thing -- and we've talked a lot about that in terms of metric and impact. I mean, the ultimate impact is if we would see illness statistics go down. I mean, that is really the goal. And that's the whole reason why you would want regulatory compliance.

That's a very difficult thing to measure these days because, as we are getting better at detecting those illness cases and outbreaks, we're likewise getting better at finding them. So it ends up being a moving target.

So what you have to do is sort of a surrogate metric such as, as I mentioned before, where we could work closely with investigators to find out if, in fact, they see improvement in the industry.

MS. ANTOINE: Lou, very good question. I think one of the things that we try to look at as well is sort of understand what is the problem that we're

trying to solve. I think if you're looking at what impact you have, you have to be very clear on what is the problem.

And so whether it is that in a country there are not enough laboratory scientists who are capable of doing tests or whether it is hard infrastructure, whether there aren't enough laboratories themselves available to the private sector and even to the public sector or whether the problem is that there aren't enough or there isn't clarity on the regulatory institution that is responsible for food safety capacity, as we've seen in many countries.

Once we determine what that problem is, then how you determine whether you're able to move the needle either way is to see, for example, at the beginning, you know, or whatever point it is that you intervene, what then two years or three years down the road is a measurable difference that you can see and account for.

Again, with that, no one institution, neither one of us sitting here, can take the credit for moving the needle in a country by ourselves. And that's why

collaboration is so critical.

But on our own, we can measure the impact of some of the things we do. And I provided an example to you that we do together with JIFSAN. When we do our training for lab capacity building, we go back in one year hence, to say the problem we were trying to solve here is that we wanted to ensure that these scientists were trained and had the ability to test accurately.

One year hence, what have they learned? And are they truly able to do that? And if we take a control group that didn't, what's the result?

And so I think it's really critical to understand what is the problem that you're trying to address, first of all. And then, subsequently, see what have you done, you know, determining up front what that measurable indicator is going to be and what have you done and, of course, recognizing that several players are involved in moving that needle.

DR. BEDARD: Yeah, I think you have to look at these metrics in two ways, okay? So I hear Bob, and I think others are talking about the public health outcomes -- so foodborne illness, those kinds of

things. And I think you need to look at it that way, and there are measurements that you can do it. There are ways you can measure that if that's the outcome you want to measure.

The other set of metrics that you want to look at from the private sector, if you want the private sector engaged, they're very demanding about results. They're very demanding on us. If you're going to -- if they're going to pay for us to do some training, what's the result? What am I going to get out of this?

So -- and we work closely with JIFSAN. Actually, Clare -- and there was a group under the GFSP that looked at metrics, the Monitoring & Evaluation Working Group. And there was a set of metrics that were developed both from the public sector good, if I'm not mistaken, and from the private sector good. So those are things that you might want to look at as capturing specific outcomes.

You know, a company looking at this, for example, well, why are they going to invest in food safety? Well, it's going to increase the safety of their supply chains. The -- are they going to measure

-- how many of their suppliers pass a third party audit or pass a FSMA audit?

Those are the kind of things that we need to start to -- we're measuring them now because we have to show to our investors and funders what we're delivering, what's the value proposition. And I think those are the kind of hard questions you have to ask.

MR. SPREIJ: So in the STDF, we essentially approach monitoring and evaluation at different levels. I mean, the first level is the STDF partnership as a whole, which is evaluated every five years. The last evaluation was done in 2014. The next one will start in 2018 where we critically look at where does STDF, you know, have an impact sort of beyond its own sort of immediate activities.

Within the projects, we also, of course, measure results, and we try to measure impact. So all the projects, you know, have their log frames, as many of us know them, activities leading up to (inaudible), leading to sort of longer-term impacts.

And we try to measure that, of course, through indicators and indicators of our projects. And this is

often in looking at indicators like rejection of imports, enhanced trade, and so on.

There is, of course, the question, "How do some of these export-oriented and food safety projects have an impact on the domestic food safety situation? And that's often a statement that's made in some of these projects. Oh, and this project will also have a spillover effect on the domestic food safety situation. But that is actually something that we do not measure really well.

So we're starting on a project very soon together with Michigan State University, with FAO, the World Bank, also IFPRI). And we would be very interested, also, to have collaboration from FDA in that project. It's to see if we can come up with some evidence there and, perhaps, some indicators on how to make that case for having that -- having those spillover effects and how to improve in that area.

DR. CORMIER: If I could just add to the responses, so thanks to Brian for mentioning the Global Food Safety Partnership Monitoring & Evaluation Working Group, which was something that Clare Narrod and I and

so many others spent a lot of time thinking about.

One of -- I just wanted to note one of the conclusions that we drew from that experience is that when you bring a diverse set of stakeholders into one room to talk about these things, you learn quickly that you're not talking with the same language. And so I -- just for the record, that still is a barrier that we need to overcome, is making -- I mean, aligning agendas, aligning resources, and aligning terminology is going to be really important.

From the Feed the Future recent experience with a global performance evaluation, we learned that our very sophisticated monitoring and evaluation system, it's quite a burden, and it can be really expensive.

And so as I think with colleagues about how we can do better at measuring our outcomes and impacts in food safety capacity building, we also have to balance that with the time/cost burden, too. So it's still a dilemma, but definitely one worth pursuing.

MS. BERNDT: And is this on?

So that is all the time we have for questions

right now. I'd like to thank our speakers and our FDA experts.

(Applause.)

MS. BERNDT: Another very important part of the public hearing process is to hear from people who have pre-registered to provide testimony.

If I can have someone advance the slide.

So I'll call you one by one, if you can come to the microphone. And after you've provided your testimony, we'll give an opportunity to the FDA panelists to ask any questions they may have.

So Karil Kochenderfer, please, if you're here. Yeah.

MS. KOCHENDERFER: Good morning. My name is Karil Kochenderfer, and I'm the North American representative of the Global Food Safety Initiative.

Is that better? Can you hear me now?

My name is Karil Kochenderfer, and I'm the North American representative of the Global Food Safety Initiative, most of you know of as GFSI. And I'm pleased to hear this morning how much materials are being used in so many of your programs at STDF, USAID,

Food Alliance, and GMA Foundation as well.

GFSI is a nonprofit organization based in Paris that brings together food safety experts from around the world to identify the best food safety management practices across the agri-food supply chain and then to encourage the auditing and certification of those practices at food facilities around the world to ensure safe food for consumers everywhere.

Like FSMA, GFSI is based on the principles of transparency, science, risk management, and the international food safety standards of ISO and the Codex Alimentarius.

It is not surprising, therefore, that food safety professionals familiar with GFSI who are busy working to comply with the new law see similarities between the two. In fact, we often say that GFSI is a marketplace FSMA operating quietly between customers and suppliers in the marketplace.

To many, GFSI is a recognized symbol of global mark of distinction. And some of our most well-known and widely respected companies annually certify their operations to GFSI-recognized schemes or require their

suppliers to be certified.

For those of you that shop and eat locally, you will recognize the names of Wal-Mart, Costco, Amazon, Redmond's, Giant, McDonald's, Cheesecake Factory, Domino's Pizza, Lone Star Steakhouse, Bimbo, Nestle, (inaudible) and others. And for those of you shopping abroad, it is Aeon in Japan, Carrefour in France, Woolworths in Australia, METRO in Germany, Tesco in the UK, and Loblaws in Canada.

And should you find yourself attending the 2020 Olympics, you can be assured that your food will be safe, as the Tokyo Olympic Committee has required food vendors to be certified under GFSI, too.

And yet while I've mentioned the names of many, many large multinational companies, it is really the small local business and producers that benefit the most from GFSI, acquiring the necessary food safety tools that they often lack to produce safe food that meets the same high standards of GFSI through our Global Markets Program.

It is a two-year program open to any producer, any processor, simply by downloading the materials.

And they are often supported by their mentors and suppliers and their customers.

For those -- for example, I know many of you enjoyed your guacamole during the Super Bowl festivities. I'd like to take a moment and acknowledge the investment of GFSI's Global Markets Programs by avocado producers in Mexico as well as Wal-Mart. Together, they trained their workers to ensure Mexican avocados were safely produced, picked, packaged, and transported to the U.S. in time for the big game. So I hope you enjoyed your guacamole.

And needless to say, GFSI has been closely following the development of FSMA. We met most recently with the folks in White Oak to assess the alignment between GFSI, the PC human food rule, and FSMA, and the GFSI required -- benchmarking requirements.

The meeting was very upbeat, very productive. Thank you so many of you that are in the room that participated. We enjoyed the discussion.

We've had similar discussions with the government of Canada, and we assessed the alignment

between the new Safe Food for Canadians Act. And we were pleased by the outcome of both the meeting as well as the issuance of a November 2015 policy recognizing the role of private standards and helping to comply with their new law.

With that said, we welcome the opportunity to engage with other governments as well. And at the end of this month, we will be sitting down with upwards of 30 governments, and we welcome the participation of many in this room to talk about how GFSI can help comply with state regulations and to improve food quality and food safety.

Some of the countries that will be attending include Canada, the Netherlands, Mexico, Australia, the United Kingdom, Qatar (ph), China, and others. And we look forward to anybody coming to that meeting from this room here today as well as attending the larger conference in Houston at the end of the month.

That said, I'd like to say thank you for the opportunity to speak, and I look forward to seeing you all in Houston.

Thank you.

(Applause.)

MS. BERNDT: If you could just stay there for a second.

Do we have any questions from the FDA panel? No? Okay. Thank you very much.

Our next testimony will be heard from Hank Karayan.

Are you here? If you can say your name and your organization. And we're trying to keep these to two minutes, please.

MR. KARAYAN: Sure. Good morning. My name is Hank Karayan, SGS. I'm the global FSMA program director of SGS looking after program for -- in all areas, whether it's inspections, testing, certification, and audits.

I would like for so all to thank the FDA for the opportunity to provide our comments today.

And as a global audit training, testing, and certification body operating in over 100 countries, we take upon ourselves a solemn responsibility of being at the forefront of the ongoing battle, we're ensuring food safety every day.

From the early days of FSMA's adoption, we have had direct interaction with the food industry both inside and outside the United States. We therefore hope that our testimony will serve as an objective analysis and that our recommendations will contribute to the fulfillment of the FSMA program objectives.

In our interactions across the globe, we regularly found -- find ourselves playing the role of coaches when educating the industry, partners when dealing with governments, and guardians of food safety as an audit inspection and testing body.

Overall, we deal with three levels of capacity building -- industry capacity, stakeholder capacity, and auditor capacity. We would therefore like to make recommendations regarding each.

First, with regards to the industry, we need to build capacity to address FSMA as shaped by the geography and the relevant countries' involvement in the U.S. food supply chain. We will therefore suggest that the FDA adopts a phased approach, first targeting countries which are main U.S. trade partners by propagating FDA’s message actively to all players in

that market in both private and public sectors.

In our experience, once the message gets across to those key countries, the adoption rate will increase and then have a knock-on (ph) effect in other countries as well.

Second, as to stakeholders, that is, including government agencies, associations, and compliance service providers such as ourselves, we would recommend having these involved in the capacity building process and making them FDA messengers, if you like, across -- or outside the U.S. This meeting will hopefully be the trigger for an ongoing global FSMA stakeholder forum that meets regularly to discuss industry topics related to FSMA.

Third and last, I would like to touch upon auditor capacity. We've taken on the challenge of educating ourselves and addressing FSMA compliance from day one. However, experience with other schemes has shown us that audit quality depends largely on auditor competency. But not only that, it also relies on the thoroughness of the audit exercise itself.

Therefore, we consider it critical that the

FSMA Third-Party Accredited Certification (sic) Rule be further strengthened with criteria for auditor competency and guidelines for assigning audit durations.

I would like to thank you again. Thanks.

MS. BERNDT: Thank you.

(Applause.)

MS. BERNDT: Do we have any questions from FDA? No? Thank you very much.

Our next speaker, Melissa San Miguel.

MS. COOKSEY: Sorry. I am not Melissa San Miguel, but she was unable to make it today and asked me to give some brief remarks. So --

MS. BERNDT: Your name, please?

MS. COOKSEY: Shannon Cooksey with GMA. Hold on one second. It was just -- okay. Sorry for the delays. So GMA has submitted detailed comments to the Federal Register Docket regarding our participation with FDA, other governments, and other stakeholders in the Asia-Pacific --

MS. BERNDT: Excuse me. Can you take the mic?

MS. COOKSEY: Okay. Let's try this again.

Shannon Cooksey with GMA. I'm giving these remarks on behalf of my colleague, Melissa San Miguel.

So GMA has submitted detailed comments to the Federal Register Docket regarding our participation with FDA, other governments, and other stakeholders in the Asia-Pacific Economic Cooperation, otherwise known as APEC; Food Safety Cooperation Forum, FSCF; Partnership Training Institute Network, PTIN. So put that acronym soup all together, and you have a lot of letters.

The PTIN is a public-private partnership that aims to support development and implementation of science-based food safety standards in APEC economies and has made meaningful contributions to the policies and practices of participants.

GMA welcomes the ongoing opportunity to work with the U.S. Government, other APEC economies, and other stakeholders in the PTIN and encourages the United States to continue advancing the PTIN's priority focus areas.

The PTIN's model of shared values and leadership has demonstrated positive impact and will

continue to increase the capacity of economies throughout the APEC region to produce and trade safe food for consumers everywhere.

So again, more detailed comments were submitted to the docket, and I just didn't want to read the whole thing.

So thank you very much.

(Applause.)

MS. BERNDT: Thank you.

Any questions from FDA? No?

Our next speaker is Jason Cochran.

Check to be sure the mic is on.

MR. COCHRAN: Okay. Is this on then?

MS. BERNDT: Yes.

MR. COCHRAN: Okay. I got through green light, so we're good to go.

Good afternoon. Is it afternoon yet? Almost.

My name is Jason Cochran, and I'm a branch chief in Office of Capacity Building and Development of the Foreign Agricultural Service within the U.S. Department of Agriculture. Let me start by thanking U.S. FDA for hosting us and giving me the opportunity

to introduce our programs.

The mission of our capacity building office is to advance global trade, development, and food security through agriculture training and technical assistance to emerging economies worldwide. Ninety-five percent of the world's consumers reside outside our borders. Our office helps break down trade barriers to reach those customers.

We build regulatory and institutional capacity, train agriculture specialists, and ultimately engage in emerging markets to become healthy trading partners.

For example, our capacity building activities in Central America cover food safety, plant health, and market information systems. Under this program, USDA has been providing training to growers in Guatemala and Honduras since 2012 in order to reduce pesticide use and cost.

Targeted interventions include good agriculture practices training to teach farmers the proper use of pesticides, enabling them to produce products that are safe for domestic and international

consumption; increasing national pesticide residue laboratories' diagnostic capabilities; introducing integrated pest management to provide alternatives to pesticide spraying; and technical assistance to educate government officials regarding safe, low-risk pesticides.

The program is focused heavily on U.S.-bound products such as French beans and snow peas. Due in large part to USDA assistance, the number of detentions of Guatemalan horticulture products at U.S. ports of entry due to exotic pests and excessive pesticide residues dropped from 1,890 containers in 2014 to fewer than 100 in 2016.

Also in Central America, we at USDA have worked together with USAID and FDA, as mentioned before by our colleagues, to help producers prepare for implementation for the Food Safety Modernization Act so that they can meet the new requirements and so that trade can continue uninterrupted.

In Africa, we have three resident SPS advisors who are our eyes and ears on the ground leading the design and implementation of animal health, plant

health, and food safety activities managed by USDA together with the USAID's Bureau for Food Security and as well as the Africa Bureau. The SPS advisors support larger-scale U.S. trade growth and food security initiatives.

This is just a sample of the type of work we do. Our success lies in our unique ability to harness expertise of the entire USDA, leverage that with our overseas presence in embassies across the world, and our close collaboration with interagency partners such as FDA, USAID, EPA, USTR, and others.

Thank you again for this opportunity to share some of our good work.

MS. BERNDT: Thank you.

(Applause.)

MS. BERNDT: Questions from FDA? No?

Our next speaker is Weng Xinyu.

No, not yet. Just turn -- okay. Help is on its way.

MR. XINYU: It's okay now. It's okay now. It's okay. It's okay.

MS. BERNDT: Thank you.

MR. XINYU: Yeah. Good morning, everybody. I'm Weng Xinyu, first the secretary of its embassy of the People's Republic of China to the U.S. I was transferred to the Chinese embassy by China Food and Drug Administration in August of 2015. And I have been the focal point of the CFDA in the U.S. I'm pleased to be here today to discuss the importance of partnership to improve food safety.

In light of the food safety law and its provisions of the State Council of the People's Republic of China, CFDA is responsible for (inaudible) laws and regulations for (inaudible) or for food safety, making policies, plans, and administrative measures, carry out inspections on food manufacturing and distribution activities.

CFDA is also responsible for managing the routine tasks of the Food Safety Commission of the State Council, coordinating food safety (inaudible) among all relevant government agencies, and improving the coordinating mechanism to ensure food safety.

CFDA attaches great importance to food safety cooperation with the U.S. FDA. Based on the

established cooperation mechanism between our two agencies, we have had a productive communication and cooperation of food safety supervision.

CFDA hopes to further cooperation with the U.S. FDA, especially against the backdrop of China's (inaudible) five-year plan on food safety and its implementation of FDA Food Safety Modernization Act.

We wish to enhance our cooperation of food safety capacity building to better protect the food safety and the public health of our two countries. Thank you.

MS. BERNDT: Thank you.

(Applause.)

MS. BERNDT: Questions? No?

Okay. We have two more speakers.

Michael Hawkins or Jennifer Miner?

MS. MINER: Good morning.

MS. BERNDT: You need to push that.

MS. MINER: Is this working now? Okay.

MS. BERNDT: You're good. Good.

MS. MINER: Okay. Hi. My name is Jennifer Miner. I work with the Canadian Food Inspection

Agency, and I am the technical specialist that is posted here at the Embassy of Canada.

Just to discuss a bit about what the CFIA is doing, Canadians trust the food that we -- that the food we eat is safe. To maintain this trust, the food safety system must keep pace with the global operating environment to most effectively protect the health of Canadians.

Today's food environment is increasingly complex with rapid increases in global food trade. Canadians themselves continue to seek out a greater variety of foods, often from different countries. And many foods in Canada are manufactured with foreign ingredients.

Increasingly, interconnected global supply chains are creating new risks for hazards to enter the Canadian food supply. Canadians expect that the food they buy is safe, irrespective of the country of origin. The CFIA has recognized that it must continue to strengthen its risk management approach to food safety.

For food imports, we are working with partners

to reduce risk through preventive activities at the source. Early identification of potential risks at source will be effective in preventing potentially unsafe food from reaching Canadians.

But we as regulators do not do this in a vacuum. Equally important is the role of private industry and how they manage their supply chain, ensuring that they know where the products or ingredients are sourced and that food safety practices were respected.

To achieve this, the CFIA is looking to a three-tiered offshore approach to, one, gain an enhanced awareness of a foreign country's national food control system, address a perceived or known food safety risk to Canada's food supply through verification activities in source countries, and offer technical assistance to emerging economies trading with Canada to build capacity and food safety oversight and enhanced compliance.

Canada is currently undertaking targeted assistance in capacity building with several trading partners in order to proactively address repetitive

noncompliance issues in the country of origin by seeking to understand and then address the issue before the product enters the Canada market.

By engaging in collaborative information workshops with these countries, Canada can learn about other countries' food safety systems and help build capacity in targeted areas.

Implementation of these offshore activities will not only help manage risks prior to food reaching Canada, but will also build on the CFIA's current relationship with its foreign counterparts and trading partners and establish new collaborative relationships with foreign jurisdictions in emerging markets entering the global food supply chain.

Building awareness through education and training, enhancing knowledge and regulatory competency contributes to strengthening regulatory capacity. Capacity building also includes working with private and public partners to collectively develop and implement approaches to address food safety issues.

As mentioned earlier, the CFIA has been active -- an active regulatory partner in the Global Food

Safety Partnership and its strategic direction since its inception in 2012.

Domestically, we are also undertaking modernization in capacity building in order to strengthen our approach to food safety. We have recently updated outdated laws, giving us the opportunity for new regulatory tools for food safety as well as plant and animal health. We're transforming the way by which we conduct our business to ensure that we remain effective, relevant, and focused on delivering results for Canadians.

The new Safe Food Canada -- The Learning Partnership, is dedicated to promoting food protection excellence in Canada through learning partnerships. It is modeled on the principles of the Global Food Safety Partnership with broad representation from industry, academia, and governments.

Online tools and resources are being developed to highlight regulatory requirements under the proposed Safe Food for Canadians Regulations. And we will be providing timely, clear explanations of the regulations through fact sheets, infographics, and videos in both

Canada and internationally to help industry better understand what they need to do to comply.

In conclusion, in the regulatory sphere, Canada continues to be innovative in how it responds to the ever-changing needs of Canadians and our global partners. Food safety capacity building efforts are a key component in ensuring we maintain a strong and effective food safety system, and we will continue our efforts to strengthen global food safety through continued focus on capacity building, international intelligence sharing, and international standard development.

Thank you.

MS. BERNDT: Thank you.

(Applause.)

MS. BERNDT: Questions? No? Okay.

Janie Dubois.

MS. DUBOIS: Okay. Hi. My name is Janie Dubois, and I represent JIFSAN. And thank you for all the good we've heard about our activities. JIFSAN is now a 20-year-old partnership with -- between the Food and Drug Administration and the University of Maryland.

It started quite small with a focus on risk assessment and gaps and has grown since to include a lot of other topics. And I'll name Good Agricultural Practices, HACCP, SPS, TBT, inspector training, and laboratory methods training.

I'd like to take this opportunity to highlight, so take a very complicated and long story and highlight three advantages, really, that we see in this kind of partnership. This engagement over the long term has the benefit of allowing us to leverage and, first, to leverage the FDA expertise to develop training materials in collaboration with the FDA, the university, a number of other academics, but also with the industry.

And this allows us to develop this knowledge around the world. And the busy bees that go and deliver all that training have a much broader pool of information to work from. And the training wouldn't have the same impact if it was not developed in conjunction with the regulators because the messaging is very important.

We are able to deliver this training also a

lot more broadly because we're able to leverage the relationship and work with other organizations, as you have heard -- with GMA, with the Global Food Safety Partnership, with the USDA FAS. And we are able as part of this program to also implement the measurement and evaluation tools to be able to assess how this is impacting.

Second advantage is really the multiplicative effect. So being able to develop these train-the-trainer programs, we're able to serve to ensure a greater impact and improve the practices following the philosophy of prevention that we use here.

And it's really something that we have to work hard at explaining that we -- the philosophy is not driven by telling people what to do, but, rather, telling people what we need -- what we want to achieve together. And everybody picks the part where they can have an impact.

So the philosophy of prevention verification of risk-based standards and also of economically achievable controls is something that we need to have regulator industry and then the academic ability to

teach these principles in order to get people to understand them.

I wanted to mention the long-term impact in certain regions where we have established collaborative centers. We have such a center in Bangladesh on the production of shrimp, aquaculture; in India for spices; and we're working to have one in Mexico on produce.

The third advantage and final one is that such a partnership enables the leveraging of the financial resources not only from the FDA because we do get support from the FDA, but through research, training grants, industry support, and also fee-for-service activities. We're able to about double the value of the FDA investment. And this is all targeted towards the FDA priorities established while we were developing these materials.

So even though a country, a region, a particular industry may not currently be a priority that would necessarily get investment from any of the groups that have capacity building monies, they are able to get access to these through partnership with our organization and other organizations that can

leverage the fact that this material exists to offer it at a cost that they can afford.

So the synergy of these partnerships really contributes to safer food in the U.S. market to, we hope, reduce risk to the consumer, but also to provide American businesses to -- with easier access to safe goods from foreign countries.

Together, we build confidence in the prevention system-based regulatory system, the model of the FDA and the USDA, which supports the development of new markets for our own agricultural commodities as well.

Thank you.

MS. BERNDT: Thank you.

(Applause.)

MS. BERNDT: Questions? No?

If there are no questions, then that concludes the testimony for this session.

I'll turn it over to Camille.

MS. BREWER: Well, thank you all.

It's lunchtime, but we can't go.

(Laughter.)

MS. BREWER: I'm going to exercise my prerogative as presiding officer. I do have a burning question, so we need to reopen with apologies.

So my question is for Ms. Antoine, Dr. Bedard, and Mr. Spreij. Each of you mentioned food safety needs assessment. Can you talk a little bit more about that process -- what tools you use, are those tools broadly available, who are your partners, and assessment development?

So please, Ms. Antoine.

MS. ANTOINE: So thank you so much for that question, Camille.

In terms of what we've done, in terms of the food assessment tool that we've developed that we worked with in China, the assessment was really done as a series of questionnaires -- of questions and interviews to key stakeholders in the food safety sector.

So the assessment was done looking at trying to understand what are the gaps in food safety, what really accounted for the issues around food safety that were experienced in China.

Was it that there was deliberate, you know -- sort of deliberate bad behavior? Or was it a question of capacity? And if that capacity was met, then you would have less instances of food safety and foodborne illnesses and other food safety issues in China.

So the way this was done was largely through interviews. And through those interviews, the results of that food safety assessment in terms of what are the issues that accounted for the issues that were happening in China, what was the result?

The result showed that the issues that were being faced was -- were not because of difficulty or deliberate bad behavior. But it was really a question of supplier training, other capacity that needed to be built within China. And once those were built, then the behaviors and the results would be very different.

So for that, that needs assessment that was conducted was really one done on the basis of interviews. And that we have replicated elsewhere, but I'll let others add to that as well.

DR. BEDARD: Yeah, the assessment approach that we use is more specific in terms of dealing with

companies. So most of the companies we deal with know what their needs are. They either have to meet -- be compliant with FSMA or be compliant with one of the GFSI specifications or be compliant with some other supply chain specification from their customers and their buyers.

So our approach is very much we have systems and checklists to go in that are based on either HACCP or GFSI or FSMA requirements, that we go in with a company, we work with them or a group of companies to go through a gap analysis within that company and then work out a game plan, a food safety plan, a food safety development plan, to get them up to compliance. And as I said earlier, it could take up to a year to 18 months.

So that's our assessment approach. We have the tools to do that, and we can share them with you if you'd like, depending on what their market requirements are.

On the regulatory side, because we do regulatory training as well, there we're responding to needs as well. So we respond to a particular

government that says, well, you know, what we really need is we need to scale up this particular training program. And here's a gap we've identified. And we respond to that on a case-by-case basis.

And again, in some cases, we work with the World Bank and GFSP where they've identified some key problems. And then we'll go in and focus on those specific areas. We don't get involved in those -- the national assessments that the FAO and GFSP are involved in.

Thank you.

MR. SPREIJ: Thank you, Camille.

In the STDF, essentially, we rely on three capacity evaluation tools that are the core that provide the basis for intervention. So in the plant health area, that's the IPPC, which has its phytosanitary capacity evaluation tool. The OIE has its Performance of Veterinary Services tool, the PVS. And FAO and WHO are together jointly developing a new food safety assessment tool.

Now, that is the basis, of course. But in many cases in many countries, much more assessments are

going done. What you can observe is that if a donor wants to make an investment in a country, the first thing that the donor usually does is doing a needs assessment.

So you can imagine that for developing countries, there's quite a lot of needs assessments that are out there and that there's also quite a lot of what we observe reinventing the wheel exercises going on. That's also why we established this virtual library in the STDF to put all those assessments together and to limit those reinventing the wheel exercises.

Eventually, you know, donors or countries will have to set their priorities. And the resources, as I mentioned, are very limited in countries. But also in donors, the resources are shrinking.

Decisions are often not very transparent. Sometimes it's the person in an office that has the best political connections that get his or her pet project funded.

And there's also limited dialogue still between public and private sector. That's why we

developed this decision-making tool in the STDF to help countries to really set their priorities.

DR. BEDARD: Can I make an additional comment.

MS. BREWER: Yes, please.

DR. BEDARD: Yeah, I just make an additional comment on a request that I heard Lou Valdez saying you're looking at doing some investment analysis and investment climate (ph) analysis. And I'd just like to make a comment from the perspective of the private sector.

You know, I used to work at the World Bank, by the way, and we did some of this analytical work. We do know that compliance with food safety requirements, whether it's the EU, FSMA, and elsewhere is extremely expensive for small and medium enterprises.

Work done in Turkey, Eastern Europe, and now the Caribbean shows that basic compliance with one of these food safety systems can cost a company up to 500,000 -- the average is around half a million to $750,000 U.S. So I would hope when you're doing that kind of analytical work, you bring that to bear so you appreciate that.

The other thing that happens in this environment is attrition rate. The attrition rate we know, for example, in Romania, in Bulgaria, in Poland, and elsewhere and even in Ireland was between 50 and 75 percent of small and medium companies went out of business because they just can't afford to comply with food safety requirements.

And Italy (ph) has also done some work in this space, so I would encourage you to look at that when you're doing your assessments.

Thank you.

MS. BREWER: I want to thank you once again and apologies for keeping you longer. But it is time to eat now. We do have sandwiches available at the Wiley Cafe, which is right outside the door. Make sure you keep your badge on. That way you can get back into the building.

There's an information room right outside the door. I believe it's 1A002. And you can sit there and enjoy the materials from our various organizations.

So thank you once again for your patience, for your interest.

I want to give our speakers and our FDA panelists a round of applause. Thank you all very much.

(Applause.)

MS. BREWER: So let's meet back here promptly at 1:15. If the panelists and speakers could stay at the front of the room. And any other speakers on the program today or tomorrow and any other FDA questioners, whether you're on today or tomorrow, if you could come to the front of the room.

Thank you. Enjoy your lunch.

(Lunch.)

MS. BREWER: -- like to get started. Could I have the mic please? So welcome back from lunch. I hope you all had a good meal.

We are about to begin Session 2 of our hearing. And the title of Session 2 is Partnerships to Incorporate Information from Competent Authorities and Private Entities, Including Accredited Third Parties Private Standards.

And the idea -- the questions we have before us really have to do with how to operationalize the

concept of same level of public health protection that's mentioned in several of the FSMA rules and what types of partnerships facilitate the application of this concept.

Another question for us is whether and how we should consider private standards and risk-based decision-making, including how other competent authorities use such information such as information from third party certifications, or other assurances from private entities.

But first, let's turn to the FDA setting the stage presentations. And I would like to introduce you to Dr. Susan Mayne who is the director here at CFSAN. Then we'll move immediately into two presentations -- one from Dr. Julie Moss, whom you know from this morning, our acting third party director here at CFSAN; and from Dr. Ritu Nalubola, who is a senior policy advisor in our office of policy.

So Dr. Mayne, welcome.

DR. MAYNE: All right. Thank you. Good afternoon. I hope you all had some good lunch together.

It's my pleasure to welcome everyone here to the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

CFSAN here, we are composed of about 1,000 staff who are dedicated to executing our mission to protect and promote the public's health by ensuring the nation's food supply is safe, sanitary, wholesome, and honestly labeled and that cosmetic products are safe and properly labeled as well.

Partnerships are essential to effectively execute our mission, and we are especially pleased to be hosting this public hearing on partnerships to ensure the safety of imported foods.

FDA is responsible for the safety of approximately 80 percent of the U.S. food supply, the food that's consumed in the United States. We regulate the entire domestic and imported food supply with the exception of meat and meat products, poultry and poultry products, frozen, dried, and liquid eggs, and catfish.

We regulate over $417 billion in domestically produced foods and $49 billion in imported foods. This

involves over 225,000 food facilities of which 92,000 are domestic and 134,000 are foreign.

Most of our activities are post-market. For example, foreign facilities do not need to be inspected by FDA before exporting foods to the United States, nor is a certificate needed for FDA-regulated foods imported to the U.S.

Food safety is a major public health and economic concern in the United States. It is estimated that here in the United States we experience about 3,000 annual deaths, 128,000 hospitalizations, and suffer 48 million illnesses due to foodborne disease. This costs the U.S. tens of billions of dollars in related costs.

FSMA provides a basis for a modernized food safety system. FSMA takes a preventive approach to food safety, and FDA is committed to helping industry obtain compliance via providing guidance and technical assistance on the new standards as well as by using a variety of tools, including enhancing the safety of imports.

Many parts of FDA have come together to

organize this particular hearing with the participation of a broad array of stakeholders. This hearing is a testimony to our commitment to partnerships for food safety. This hearing is an opportunity to gather information from experts and key stakeholders as we refine existing partnerships and develop new relationships to help ensure the safety of imported foods.

Our next two speakers will be exploring issues embedded in FSMA, particularly as they relate to private entities. Key to this discussion is how we assure safety while working with private entities and other competent authorities and whether and how we should incorporate information from private entities into our risk-based activities, such as our inspectional planning.

For those of you who are participating in person, we invite you to enjoy the exhibits right outside the auditorium which provide some historical perspective on our history at CFSAN. There's many really interesting photographs lining that hallway, and I encourage you to take a few minutes to look at those.

But once again, on behalf of CFSAN, welcome, and best wishes for a productive afternoon.

Thank you.

(Applause.)

DR. MAYNE: And the first speaker will be Julie Moss, our acting third party director here at CFSAN.

DR. MOSS: Great. Thank you, Dr. Mayne.

It's nice to see you all again. And I'm here as a -- wearing a different hat for this presentation. As was just mentioned, I'm in a temporary position as the acting third party director here at CFSAN.

So what I want to share with you are the places within FSMA where third party audits are identified and will or may play a role for us. And I'm going to talk about, very briefly, three specific areas.

Of course, we have the FDA's accredited third party program. I'm just going to touch on some highlights of the program today for you.

Secondly, I'll talk about the supplier verification activities and the foreign supplier

verification program and the preventative controls rules.

And then lastly, I'll touch on the potential for leveraging audits in our compliance strategies.

So moving on to FDA's Accredited Third Party Program. The Third Party Accreditation Rule issued in 2015 and establishes a voluntary program for the accreditation of third party auditors to, one, conduct food safety audits and issue certifications of foreign facilities and the foods they produce. I want to emphasize again that this is a voluntary program.

Through this program, FDA will recognize accreditation bodies who will then accredit certification bodies to conduct audits. And I want to highlight two recent companion documents that the Agency issued in December of 2016.

The first one is a guidance to industry, which contains FDA recommendations on third party certification body qualifications or the model accreditation standards guidance.

The second document is a final rule which provides for reimbursement or user fee program to

assess fees and require reimbursement for the work the Agency performs to establish and administer the Third Party Certification Program. And you can find these on our website along with a whole host of information with regards to the third party program and some excellent fact sheets in various languages.

FDA's third party program has two very limited purposes under FSMA, and I want to briefly share those with you today. First, importers will use facility certifications from foreign suppliers in helping to establish their eligibility to participate in the Voluntary Qualified Importer Program, or VQIP.

VQIP is a voluntary program that provides for the expedited entry of foods imported by participating importers.

Second, FSMA did provide FDA with a new tool that allows us to require certification as a condition of entry when certain statutory criteria are met.

Moving on. Under the Foreign Supplier Verification Program and the preventative controls regulations, the importer or processor must perform verification activities that demonstrate that their

suppliers are producing food using U.S. safety standards.

Both of these rules include audits as one option when conducting supplier verification activities. Under these rules, a receiving facility for preventative controls, or an importer for FSVP, must verify that suppliers are appropriately controlling hazards.

I do want to make note of one caveat here, that if the hazard being controlled is a SAHCODHA hazard -- and SAHCODHA stands for a serious adverse health consequence or death to humans or animalsdd -- when a SAHCODHA hazard is present and the default verification activity is an annual onset -- onsite audit of the supplier, unless the receiving facility or the importer determines that another activity or another frequency is appropriate.

When an onsite audit is used as a verification activity, there are two requirements. One, first, the audit must be conducted by a qualified auditor. This is based on the auditor having a certain amount of experience, training, and education.

And I want to make a clarification here. That -- I want to clarify that onsite audits under these rules do not have to be conducted by auditors accredited under FDA's Third Party Program. An importer or processor may choose a certification body that has been accredited under FDA's Third Party Program or not.

The second requirement is that audits need to consider FDA's food safety standards, such as the Preventative Controls Rule, the Produce Safety Rule, low-acid canned foods, seafood HACCP, et cetera. I do want to mention that FDA is in dialogue with several groups to look at alignment between their standards and the relevant FSMA rules. For the preventative controls in FSVP, we are currently in dialogue with GFSI. And I want to highlight that this is a process for us.

The first step is to look at the alignment of standards to determine if audits, certain schemes, can serve as a verification activity under FSVP or produce.

The second step in this process is then to understand the auditor competency requirements and the oversite of the program. So I just want to highlight

that we're in the very initial stages of this dialogue.

FDA also intends to explore whether we can use reliable information from third parties to inform our risk-based decision-making, especially with respect to inspections. While audits are not required in the produce rule, FDA specifically mentioned leveraging third party audits as part of its compliance strategy in the rule.

FDA envisions a broad, collaborative effort for implementing this rule. The Agency intends to do this, in part, by building on current private audit activity and by working with the produce industry and other government and private partners to strengthen the rigor and reliability of private audits.

And I'll reiterate again that FDA is in dialogue with several groups to look at alignment between their standards and the relevant FSMA rules. And for produce, we're currently in discussions with USDA's Agricultural Marketing Service's Harmonized Gap Program and a Leafy Green Marketing Agreement Program.

Again, alignment is just the first step for us in determining if audits to certain schemes can serve

as reliable information to -- for us. The second step is then having an understanding of auditor competency requirements and the oversite of the program.

We look forward to continuing these and other dialogues and learning from our key partners today.

Thank you.

DR. NALUBOLA: Good afternoon, everyone. And thanks, Julie.

So I will give you very briefly some background on a very specific targeted area that we asked for -- or we highlighted in the Federal Register notice that announced this public meeting. We are very early in our thinking on this concept of same level of public health protection.

I'll give you a little bit of background on where exactly this provision appears in our regulations and then some questions and considerations that we believe are relevant to actually implementing this specific provision.

And then I should preface also that I -- as -- although I will pose a number of questions and considerations that we are still thinking about, I

don't have necessarily any specific answers. And really, the interest here is to highlight some of these areas as items for broader public input from our stakeholders.

So with that, same level of public health protections. So where this appears in the key FSMA provisions is in two specific regulations. One is the foreign supply verification regulation, and I provided some citations there. And essentially, what this provision allows is that under this provision a -- an importer is able to import foods consistent with the foreign supply verification regulation even if the foreign supplier uses a process or procedure that varies in some way from the specific FDA requirement.

And the FDA requirements that this applies to is the -- are the standards for produce safety that FDA established in Part 112, as well as the preventive controls requirements that are in the PC for human food and PC for animal food regulations. I will note that this does not apply to the cGMP requirements that are in the PC for human food and animal food regulations.

And the second place where this applies --

where this appears in our regulations is in the produce safety regulation. And here, again, we have provisions under -- again, I provided the citations there -- where farms are able to use measures that are different from those that FDA has established as standards for produce safety under various conditions, among which, that measure, must provide the same level of public health protection that's underlining the corresponding FDA requirement.

So these -- this is intended to provide some flexibility for farms and importers and facilities to be able to use processes and procedures that are different from what FDA has established. But under the condition that those -- the use of those measures provides the adequate level of public health protection that FDA has determined is necessary by establishing our requirements.

So we also looked at whether and where this concept or similar concepts appear in other national and international texts. And two here -- in the national arena, we have the USDA FSIS guidelines for equivalence evaluation. There, this exact same phrase

appears in their texts, and that's "the same level of public health protection." It provides guidance for a process for evaluating the equivalence of foreign meat, poultry, and egg products that are covered under food regulatory systems of other countries.

And in the EPA context in the U.S. Safe Drinking Water Act, this is actually a legal provision where this other phrase that is similar to same level, equivalent level of public health protection is in that statute. And again, there it refers to alternative water that can be supplied by states or other localities, provided that water provides the equivalent level of public health protection compared to the applicable national drinking water standards. And the national drinking water regulation then specifies certain contaminants and maximum levels of contaminants that become relevant for making these judgments.

In the international context, in the SPS agreement -- the WTO's agreement uses the phrase "appropriate level of sanitary or phytosanitary production." And under this agreement, each member nation of the WTO, including the United States, is

obligated to accept as equivalent a food regulatory system of another country if it provides the same level of public health protection or health protection as is provided to consumers by its own system.

And here the SPS agreement goes also on to define that specific phrase, and it's defined as "the level of protection deemed appropriate by the member establishing a sanitary or phytosanitary measure to protect human, animal, or plant life or health within its territory."

And then the exact same phrase then is carried on into the Codex guidelines that are established by CCFICS, the Committee on Food Import/Export Inspection Certification Systems (sic). And they provide some guidelines on equivalence and food import/export inspection and certification issues.

And I listed three of those Codex guidelines where the specific phrase is -- appears in the guidelines, and then there's some additional information and details that our guidelines are provided.

Specifically, the first one that I listed,

CAC/GL 53-2003, that refers to the guidelines on judgment of equivalence, and it really has some detailed information as to the specific process of undertaking an equivalent determination, including the scope of determination, what, you know, the experience, knowledge, or confidence of experts conducting those determinations as well as guidance on the actual judgment. How do you evaluate the level of public health protection, and how do you determine equivalence?

So these documents in the national/international context do provide some reference for FDA as we think through how to implement the same level of public health protection in our own context. And so with that background, here are some questions and considerations that we have been thinking about in terms of how to actually operationalize this. What does it look like in practice?

One of the first questions -- what is same level of public health protection? Is it something that FDA should define, or, in fact, can it be defined? Because as I mentioned, it applies to a wide range of

FDA requirements that are established in four different regulations. And is it possible to come out with a meaningful definition that also is applicable across the board?

Another question is what is -- or how is same level of public health protection evaluated, and how is that determination made? The actual process -- there are process considerations, of course, as I mentioned. In the Codex guidelines, they talk about experience, confidence, and knowledge base of experts who actually conduct these types of evaluations and make these determinations.

And then there are the technical and scientific considerations, right? So some of the things that can be considered under that prong are what type of data are sufficient to support a determination of same level of public health protection.

What's -- what is the rigor and robustness of the analysis that would be required? What types of methodology or data must be obtained? And as well, should there be any additional accompanying assessments of risks or hazards to the extent that FDA itself has

conducted those types of assessments in establishing our own requirements?

So these are all types of questions that need to be considered, potentially, in how we implement this concept. As well, who -- with respect to scientific data and evidence, who develops the data or who gathers the scientific evidence? There's some information in the preamble discussion of the produce safety rule when we responded to some of these comments. And so the question is how do we operationalize this and take lessons that -- and information that we already considered with respect to specific regulations?

And then another question is how is same level of public health protection demonstrated? Clearly, there are within our regulations, the produce safety as well as the preventive controls regulations, there are -- and as well as the FSVP regulation -- we have certain requirements for documentation and who establishes those records and who maintains those?

So with respect to same level of public health protection, what are -- what should be required or what should be recommended with respect to documentation and

maintenance of that information?

And then another question that potentially we could ask is, once a determination of same level of public health protection is made, should that be revisited? And under -- if so, under what circumstances and how often?

For example, if there is new scientific information that becomes available that suggests that the use of that process or procedure perhaps doesn't provide the level of controls that we initially envisioned, should that in and of itself trigger the need for revisiting the same level of public health protection determination?

And then there are other questions in addition to that. For example, who makes these determinations? So under the various provisions that I just mentioned, clearly, there are circumstances where FDA itself could make this evaluation. For example, under the produce safety rule, we have provisions for foreign governments to be able to submit variances or requests, petitions to FDA to use measures that are different from the ones that FDA has established. And so there's a

circumstance where FDA would be making such evaluations and determinations.

There are others for -- where -- for example, a farm could make its own determination under, again, other provisions in the produce safety rule. So clearly, there are various entities that potentially could be making these evaluations and making these determinations. And so that is another consideration.

And then all of the questions that I just listed, do those, in fact, the answers to those questions depend on the type of requirement? We have, as I said, across the board in the produce safety regulation as well as the preventive controls requirements, different types of requirements, some that are quantitative, very prescriptive and specific quantitative parameters -- for example, microbial die-off rates or maximum time intervals for use of certain types of water.

So -- and then we have other types of requirements that are more qualitative. And so -- and then we have others -- again, I listed here -- performance-based where a farm, for example, in the

produce safety rule is able to use any method provided that method achieves a certain level of microbial standard, except for use of soil amendment. So that's a performance-based measure.

And so the question here is whether all of these considerations for how to operationalize this concept of same level, does that, in fact -- in part, is that, in fact, determined by the type of requirement, and what is the underlying basis for FDA's requirement? So -- and then of course maybe there are other considerations that we haven't really listed here or mentioned here.

So as I mentioned, these are all questions and considerations. We are still early in our thinking about how to specifically implement this provision and so look forward to your input on this.

Thank you.

(Applause.)

MS. BREWER: I would like to thank the FDA presenters, and now I would like to open the floor to our audience. Are there any questions for the FDA panelists? If so, could you please come to one of the

microphones? Please identify your name and your affiliation.

Yes. Please.

MS. DE KLAUMAN: Yes. My name is Anna de Klauman, and I'm the agricultural counselor with the Embassy of Denmark. Thank you so much for hosting this great event.

When I work with Danish exporters, it's my experience that they actually live up to FSMA, but we have to help them translate into FSMA language. And I think that one of the ways that we can help them translate their rules and procedures into FSMA language is guidelines and also what Julia Moss mentioned with regard to the third party auditors.

So I was a little bit disappointed when you said that you were in the very initial stages of your dialogue with private entities because I think that a way that we can really help the exporting companies is by giving them the tools to enter into a dialogue with importers. And one tool is those private schemes that they already use. But they are a little bit uncertain whether to move forward or whether to wait because they

don't really know how that could help them in living up to the FSMA regulation.

And the last thing I wanted to ask -- I have to ask -- I know it's annoying -- but can you give us any perspectives on publication for FSVP guidelines? Because it could be very useful this spring entering into May 3rd -- May 1st.

Thank you.

MS. BREWER: Thank you for that, Anna. I'm looking at Sharon Mayl, who looks like she wants to respond.

MS. MAYL: No one's going to like the response, but you know, we're working on the guidance. As you know, there are -- we've had administration change. There's a number of executive orders that have come out that we have to consider when we're issuing rules and guidances that we need to take into consideration. So we are attempting to get it out there as fast as we can within the parameters and rules that we have.

AUDIENCE MEMBER: (inaudible - off mic).

MS. MAYL: There has been no announcement to

postpone the deadline. No.

MS. BREWER: Over to you, sir. Name and affiliation, please.

MR. JORDAN: Thank you. My name is Bill Jordan, and I'm here representing the Equitable Food Initiative. I have a question for Dr. Nalubola and also Dr. Moss.

I think the first one is easy, which is same doesn't necessarily mean same, I assume. I think you could mean more protective. Is that correct?

DR. MOSS: That was a trick question.

(Laughter.)

DR. NALUBOLA: I was just going to say that. I mean, I agree with you on the first part. Same doesn't necessarily mean the exact same. The second part, I think that's actually a comment that -- or if that's your perspective, that's something you should add -- you could add to your -- as a comment to the docket.

I'm not sure that FDA itself has decided that same level means more protective. I think the intent is that same level of public health protection, at

least looking at some of the international texts and the underlying principles, it's more about providing an adequate level of protection that we had envisioned under the FDA established requirement.

MR. JORDAN: Okay. And for Dr. Moss, is FDA preparing training for its inspectors for the produce safety rule, for FSVP? Are you preparing guidance or instructions, compliance manuals for your inspectors? And if so, will any of that material be made public?

It seems to me it's useful for private bodies, third party bodies, to adhere as closely as we could to the same approaches that would be used by FDA inspectors.

DR. MOSS: I'll just say one thing and then I'll -- I'll say one thing, and then I'll pass to Sharon. So the first part of your question had to do with training. Are we training ourselves internally? And I'll say absolutely.

Just -- it's new for us just like it is new for stakeholders as well. So we're having to train ourselves internally just like we're getting the information out to stakeholders about the rules and how

industry can comply and so forth. We're doing the exact same thing internally.

And Sharon knows some more details about how that's happening.

MS. MAYL: Well, I'm not going to provide a huge amount of more details, but I think that, you know, we take that concept of training internally very seriously. We have developed courses -- regulator courses for all of the new rules and have put not only our field staff through these courses, but also supervisors and food safety staff at Headquarters all rotate through these courses.

The idea at the end of the day is to have a consistent approach to compliance with these. Decisions are not going to be made in a vacuum. They're going to be made in consultation and, in fact, real life consultation where an inspector can pick up the phone and talk to a food safety expert at Headquarters and make sure that all of our inspections are being done in a consistent manner with compliance actions also going through a rigor to make sure they are all done consistently if that is where we're going.

With respect to -- I will say one more thing about training with industry and with our regulators is that we are also sending us prerequisites to our regulator courses. Many of our investigators are going through the alliance courses side by side with industry.

So -- and we decided to do it that way so that we could get that interaction between our regulators and industry. People could understand each other, where they're coming from, and also to get a consistency of approach. So we're having our regulators go through the alliance courses as a prerequisite -- so again, to ensure the interaction between industry and regulators as well as consistency.

MS. BREWER: Thank you for that. I would like to ask Ms. Givens. Would you like to add anything to that response?

MS. SCOTT: Joann wanted to pass on to you that the states are also being trained, too. We do use states as partners in doing some of our inspections, and we're making sure that they have the same training and they are also calibrated the same as our

inspectors.

MS. BREWER: Welcome, sir. Name and affiliation, please.

MR. JONKER: (inaudible - off mic).

We'll start over. Jamie Jonker with the National Milk Producers Federation.

I think this is for Dr. Moss. The dairy industry operates under a federal/state food safety program that's overseen by CFSAN through the Pasteurized Milk Ordinance. Within that program, there is a third party program for foreign suppliers to meet the requirements of that food safety program. And I was wondering if you had any comments on how that fits in or aligns with the third party requirements through the FSMA process for a foreign supplier verification program?

DR. MOSS: The short answer is, no, I don't have any insights to share with you. But I can certainly bring it back with the team and get you some responses.

Just looking at Camille to see is it any part of the panel sessions tomorrow?

MS. BREWER: No.

DR. MOSS: Okay.

MS. BREWER: I would turn to Jenny Scott. Did you want to add something there?

(Laughter.)

MS. SCOTT: No. I think many people are familiar with the Pasteurized Milk Ordinance and that anybody that's producing Grade A dairy products must operate under that, whether it is domestic milk or foreign milk that is coming in to the United States.

Also, we know that the Pasteurized Milk Ordinance is being revised to make sure that it is completely consistent with our requirements in the preventive controls for human foods rule. And if there are adjustments needed with respect to import, we would see that those are made as well.

MS. BREWER: Thank you. Any last questions?

MS. SOUTHEE: Good afternoon. My name is Jacqueline Southee. I'm the U.S. liaison for FSSC 22000.

FSSC 22000 is one of the GFSI benchmarked international standards. And we certify over 14,000

companies all over the world. And I get hundreds of phone calls each week asking how are we going to continue importing into the U.S.?

So first of all, I want to thank you for all your efforts for aligning FSMA with the existing GFSI standards. I hope that you know that we're also -- all the standards are also working very hard to align our own schemes to the standards that you have set. So I think it's going to be a -- an ongoing process that we're all going to sort of want to work in harmony.

But I have two questions. One of them is have you got -- you have any efforts to align with the ISO standards, the international standards which are operative all over the world? And many companies sort of already use it as a national standard. And that is a way of sort of leveraging sort of efforts that have already been started in international food safety.

And the other question I have -- is there any provision for importers that already have a business importing into the U.S. that suddenly find that they're not meeting the standards of foreign supply verification? And what do they do? Do they come to

the FDA, or will they have to go to the private sector to sort of work towards those standards? Because there are existing companies that aren't going to meet the standards, and we'll need to do a lot of investment to do that.

DR. MOSS: So I can address the first question. I would suggest that you take a look at the recent guidance that we issued in December, the model accreditation standards guidance, and that's where you're going to get a lot of the answers to your questions with regards to the ISO standards. It contains FDA's recommendations on third party certification, body qualifications. And ISO is mentioned in that document as well. Go ahead.

MS. BREWER: Sharon?

MS. MAYL: Yeah. Let me just also add to what Julie said, which is that in meeting the qualifications for -- or the criteria for the third party rule, an accreditation body or a certification body can use its compliance with ISO to demonstrate compliance with the rule. Then they need to add some, but they don't need to create new documentation.

So if they have documentation meeting ISO standards, they can use that. And then if they need to supplement them, for instance -- for perhaps with our conflict of interest provisions that need additional supplementation, they can add to that. So the idea is to be able to allow accreditation bodies and certification bodies to use existing documentation.

MS. SOUTHEE: I'm not talking about the ISO standards for accreditation. I'm using -- I'm talking about ISO standards with new safety management like ISO 22000.

MS. SCOTT: I think, similarly, to the extent that they have documentation for provisions in the ISO standards that meet the requirements of our regulations, they can use that documentation. There's no need to recreate anything.

We actually specify in the preventive controls rule that it's acceptable to use existing records. And again, as Sharon said, they may need to be supplemented if they're provisions for things that we require that are not covered by a specific ISO standard.

MS. SOUTHEE: Thank you.

MS. BREWER: Thank you for that. I would like to turn to WebEx. Are there any questions from the web audience?

MS. MCCORMICK: Yes. We have a question that came in from Serap Ozcan. He's the director -- he or she, I apologize -- is the director of quality and food safety at Savencia Alouette Cheese U.S.A.

The question is -- starts with a scenario. Let's say a foreign supplier has a third party audit fulfilling the FDA requirements. Would the summary of the audit report be sufficient for importer's verification activities? Or does the importer need to review and assess the full audit report, which would be an assessment of programs, procedures, and the records?

MS. BREWER: Mr. Pendleton, please.

MR. PENDLETON: Yeah. The -- both the FSVP regulation as well as the preventive controls supply chain program provision don't require that the -- either the importer or the receiving facility under PC have the entire audit report. There are specifications in the regulation about what needs to be -- information about the audit needs to be retained -- basically, how

the audit was conducted, what the audit looked at, the conclusions, if there were any, corrective actions need to be taken. That has to be documented.

But there's a -- oh, so it must -- it has to be done by a qualified auditor, yes. But the bottom line, though, is that the entire audit does not have to be retained by the -- either the importer or the receiving facility.

MS. BREWER: So thank you for the question and for the response. And with that, I would like to thank the FDA panelists. We're going to take a five-minute, stay-in-place stretch break as we change panels. So once again, please join me in thanking the FDA presenters.

(Applause.)

(Pause.)

MS. BREWER: So if we could take our seats, we'll get started. Can you all hear me okay? Is the mic on? Okay.

All right. This is Session 2. And during this session, we will hear from representatives from food safety organizations from other nations. They'll

provide us with information on how they leverage results from private entities and private standards for regulatory purposes. Also, we'll hear perspectives from the World Trade Organization on private standards.

I'll identify the speakers, and they will each speak in turn. We have Mark Burgham, who's the senior director for Program Policy Integration -- Don, that title is similar to yours -- from the Canadian Food Inspection Agency; Herman Diricks, CEO, the Federal Agency for the Safety of the Food Chain from Belgium; Steve Wearne, the director for Food Safety and Policy, Food Standards Agency from the UK. And we met Melvin Spreij this morning, Counselor and Secretary, Standards in Trade Development Facility for the WTO.

So please welcome our guests.

Mr. Burgham, over to you.

MR. BURGHAM: Thank you very much and good afternoon. I'm very pleased to be here and speak to you about what we're doing within Canada with respect to how we're leveraging private certification schemes and how we are taking advantage of that.

A word first, I should say, about the Canadian

Food Inspection Agency. We are the regulatory body responsible for overseeing the safety of Canada's food supply and protecting both plant health -- plant protection-- and animal health in Canada.

Within the -- specifically within the food context, we develop and deliver oversite and regulatory responses to prevent and manage food safety risks both domestically and also for imported food products. And we contribute to consumer protection and marketplace fairness as well as contributing to international market access for domestically prepared food products.

I'm going to skip over the third slide here because I think the knowledge and maturity of folks in this room with respect to private certification is fairly well advanced and just get into a little more detail about what we're doing within Canada to recognize third party private certification schemes and how they can play a role in helping us -- in helping -- or the role that they play in helping industry achieve regulatory objectives.

For us, it's very important to ensure that they are going to be effective, credible, and aligned

with public policy objectives. And so that's why last January, a year ago, we had published our private certification policy, initially for food safety. We are keeping the door open that we will extend it beyond the areas of food safety, but initially it is focused on food safety.

What the policy is intended to do is to allow us to take advantage, really leverage the private investments that are made in food safety to achieve certification status into consideration when we're determining our oversight activities regardless of where the scheme is developed. That -- this initiative supports our transformation initiative, which is really going to cross all parts of our agency. It's providing an additional data input for our establishment-based risk assessment model.

So this is something that's been developed by our science branch, which, frankly, is an algorithm that looks at a whole range of risk factors that go into how we characterize a risk associated with a particular establishment.

So ultimately, that will allow us to improve

our risk-based planning for more targeted compliance verification. And that, in fact, enables us to be more focused with our resources and to present those to areas where the greater -- the risk is greatest.

So the policy itself -- in the design, we were really wanting to be careful that we designed the policy that it had really a light touch, that it was not going to be prejudicial to any particular schemes. It was a policy that was designed to influence our risk prioritization and how it -- the -- both the frequency, the level of the focus as well as the duration of, ultimately, inspections that were undertaken at private establishments. We wanted to make sure that it would influence how we characterize the risks associated with those establishments.

Key to note here is there's no regulatory requirement with respect to implementing this policy. There's no intent to replace our regulatory oversight, so we still have as many inspectors in the field. And it's really about targeting them more effectively -- and no intent to outsource our inspection at work -- at the agency.

It does not obligate industry to use private certification schemes. We wanted to be very light -- as I say, a light touch on this, but it does recognize that, more and more, those business-to-business relationships are using private certification to give some assurance within the food supply chain.

So importantly, though, for us, the policy does not constitute any type of approval or recognition or endorsement of private certification. So again, it doesn't obligate, nor, once we assess the scheme, does it give any recognition to that particular scheme.

So the policy requirements -- we're developing a systematic robust assessment process where we'll look at schemes against our regulatory requirements. And just recently, if any of you paid attention to the Canada Gazette in Canada, on January 20th we published the Safe Food for Canadians Regulations.

So it's -- the draft regulations are out for a 90-day consultation period, which do -- it's a very big remake of our regulatory environment for food safety in Canada. In that, we are looking at how the -- we'll develop a process by which we look at doing a really

equivalency arrangement against the private certification standards against our regulatory standards under the FSCR.

We'll also be developing a process to assess and maintain confidence in the auditor competency associated with that. So it's not only about looking at the scheme standards itself, but they're about the whole accreditation/certification approach around the scheme.

So three aspects, really, in terms of how we're going to look at them. First, as I say, at the scheme level, we assess against the standards against our regulatory standards. We will select different schemes to get assessed through this process.

And in fact, we'll have two types of scheme intakes. One is a voluntary submission of schemes where scheme owners can basically put up their hands to say we would like you to assess us. We know from that -- from some discussions there is interest definitely in some scheme owners to do that. And of course, there we have full cooperation in terms of having answers to our questions, to having the documentation that we

need, and so on.

The other type of scheme intake is we will look at the market penetration within Canada of the scheme itself. And we will obviously prioritize schemes that have greater market representation in Canada.

When we do assessments at the scheme level, the schemes may be deemed to be partially, fully, or, in fact, exceed our regulatory standards. Or they may not. In that case, we will be providing the results of the assessment to the scheme owner. It allows for, first of all, the due diligence to be undertaken if they take exception with some of the findings. It allows us to go back, look at that again. As well, it allows for the scheme owner to make adjustments. If they feel that in some area they did not meet the regulatory standard, it allows them to make course correction.

Second is with respect to the whole accreditation system in the certifying body or bodies. And there again, we're looking at the -- accredited to the ISO standards with respect to accreditation. And

we'll be looking at that. Depending on where the scheme is derived, it will depend on how quickly we can proceed with the assessment of that particular aspect of schemes.

And then lastly is, of course, at the establishment level. And so once we have done the scheme assessment, then it really is that we're looking at what regulated parties, what establishments are certified in good standing to that scheme. Obviously, that's a point in time, and we need to be in regular contact with the scheme owner to ensure that that particular establishment maintains its certification standing.

So with respect to the confidence in the certification, just to expand a little bit, really, there are three broad areas that we are undertaking here. First of all, if the scheme was derived -- and we have in Canada a program called The Food Safety Recognition Program, where, in fact, there are -- that -- where the CFIA works with various national associations to develop private certification schemes. In those particular cases, we have a very good

knowledge of not only the standards, but also the accreditation system around that scheme. And so that is a very quick, effective assessment.

Secondly are private certification schemes that -- well, for example, all GFSI benchmark schemes, we know based on some previous research and discussions where they are with respect to the accreditation system. So again, it's a fairly fast pass.

And then we will assess other private certification schemes and look in more detail at the accreditation system around those schemes.

So what have we learned? First of all, the expansion of private certification schemes, it is a reflection of businesses seeking to manage their risk environment, and it really does offer regulators an opportunity to leverage those private investments in food safety to help meet public sector -- public policy aims.

Secondly, we do need to have a systematic robust assessment process, and that's really critical to benchmark against the regulatory standards. And we will be publishing our assessment process when it is

complete so that it is transparent.

With respect to the compliance history of establishments, it really is in one particular area in Canada, which is what we call our non-federally registered sector, where we don't have a lot of history of this particular sector. This is going to be an area where it's going to be particularly effective for us to help frame the risk characterization of those types of establishments.

With the FSCR coming into force, we will have licensing requirements for much of this previously unknown sector. But again, we won't have the history necessarily with them. And so here is a particular area where private certification can really give us additional information to help us characterize the risks.

In terms of information needs, to date, scheme owners that we have talked to are very enthusiastic to have their schemes assessed. We have a need for regulators to develop, first of all, as I said, a transparent, credible review process. That's still being completed.

We are needing to obtain clarification on third party standards, but also with respect to accreditation systems. As I said, we need to continue to make sure that we are updating the certification status of establishments in good standing and then share the results of our assessments with scheme owners.

In terms of ongoing data sharing with the schemes, we do need to, obviously, know where there are any changes made to the schemes -- to the -- for example, to the private standards. Whether they -- we need to update the list of certification -- of certified establishments, I should say, as well as certification bodies associated with the scheme. A change -- any change to the accreditation status of a scheme -- of a certification body is important to -- for us to know.

And then finally, where there's any non-conformity associated with an audit with a private certification scheme, if it represents a significant or imminent risk to food safety, then we will need to know about it.

In terms of other views, I won't go through these all just with the time. But generally speaking, we have had very good response to this. There were some concerns around whether we were outsourcing our inspection oversight, but we managed to deal with that.

Lastly, in terms of the considerations for -- to be considered as part of a National Food Control System, we think that a third party standard should incorporate the core mandatory requirements, obviously, of the country. The competent authority should also consider the auditor competencies, the approaches to auditing, the audit quality and consistency, the ability to share audit information with the competent authority.

In our case, we don't have the legal requirement for sharing that, but we will be in discussions about what can be shared. And we also need to be mindful of the trade implications. And that was something, again, we took a light touch to our policy development with respect to that.

It's also why, together with the UK, we had been developing a joint paper for consideration at the

next CCFICS meeting in May. So this is with Codex. And there is a work proposal that we're proposing for Codex to actually develop some guidelines with respect to how to incorporate the whole trend of private certification schemes into a country's national food control systems.

So with that, I will, close. Thank you.

(Applause.)

MR. DIRICKS: Okay. First of all, I would like to thank the FDA for the opportunity to explain to you the way in which we have integrated private assurance schemes in the Belgium Food Safety Policy. I must say that what I have heard this morning and the beginning of the afternoon, does mean that you are posing yourself the same questions as we do in Europe and that a lot of parallels in between -- sorry -- a lot of parallels between what you are doing, what you are reflecting on, and what we are reflecting on.

Now, as you might know, Belgium is part of the European Union, and I cannot explain our approach without briefly explaining how the European regulatory context has an influence on how Belgium and other

member states implement regulation.

So first of all, the European Regulatory Context. At EFSA in Europe, we have what we call the hygiene package. It's a comprehensive set of legislation which is governing all of the aspects of food/feed's safety. And the regulation is -- was written down in 2002. And as in FSMA, it lays down that the food business operator is a primer responsible for the food safety.

European regulation can be divided into two main pillars -- the first of all, the one who is directed to the competent authorities and the other ones who are to be implemented by the food business operators.

Why is it important? Because we have a regulation 882/2004 which lays down the principles which are used by the member states to implement enforcements of food safety legislation. And what does that regulation say, in essence? Your inspections have to be risk-based with an appropriate frequency; you have to take into account past records of the food business operators; and you have to take into account

own checks, or what we call in Belgium, self-checking.

As you see, the basics that are laid down in 2002, a number of more descriptive regulations were laid down in 2004 and later on. And in Belgium, from 2003 on, we have put into effect legislation in which assurance schemes play an important role.

So the responsibilities summarized here in this slide, you see that at any level we have the basic legislation. As a member state, we implement that legislation and we enforce it. And the food business operators have to implement legislation and have to address self-checking, or own-checking.

So from the European level to the Belgium level, I'm Chief Executive Officer of the Federal Agency for the Safety of the Food Chain. We have different responsibilities, and we are competent authority for the legislation of all food business operators.

We have the responsibility of implementing a multilateral national control plan. We are inspecting food business operators. We are inspecting products and production processes. We are responsible for

export certification.

And as Belgium is a country which produces about 150 percent, so 50 percent more than self-sufficient, my consumers are not only the Belgium consumers, but also the consumers of all the countries to which Belgium food products are exported.

And as you have mentioned in your own legislation, we have also a task in prevention, awareness, and information. We are, like you, a government agency under the authority of a minister. But the management has chosen -- the management of the Food Safety Agency has chosen to be ISO-certified. In general, we have a certification 9001. All our inspections serve as -- are accredited 17025, and -- 17020, sorry -- and our laboratories, 17025.

How do we go on with the official controls in the food chain? Well, we are a relatively new organization. We have been founded in 2000s. We have been, in effect, executing controls from 2002 on. And we are controlling and inspecting the whole of the food chain, which means not only the food business operators, but also the feed business operators.

We are competent for animal health, plant health, which means that all of the different inspection organisms in Belgium have been fused into one organization, which is doing the oversights.

I said our official controls are based on an annual program for inspections and sampling. We are determining who is inspecting which food business operator when. All food business operators are inspected with a pre-determined frequency, and -- and here we come to the point of the assurance schemes -- that frequency is determined taking into account the different activities of the food business operator and his status. In fact, we take into account to determine the frequency of our inspections if they have implemented a private assurance scheme -- and I'll explain to you why I have private between brackets -- and the results of past inspections.

How do we determine frequencies? First of all, we are looking at the fruit of activity of the food business operator. It can be a supplier to agriculture. It can be in primary production for produce. It can be processing foodstuffs and the

distribution of foodstuffs, which means that in function of its activity, we have the predetermined frequency.

Now, in our approach, we have three frequencies of inspection -- the base frequency, a lower frequency, and a higher frequency. And how they may determine for food business operation the frequency of inspection -- for example, once a year, four times a year, once in three years -- what we take into account is risk profile.

And I'm not going to go into the details, but you see for yourself on the left, the first important criterion is, does he have a validated self-checking system? I will explain that later. And the second part is the risk profile is also determined by the inspection results, and one or more measures taken by the competent authority.

While I'm speaking of validation of self-checking system, you could easily say certification of an assurance scheme because the self-checking system are all the measures taken by the food business operator to produce safe foods and feeds, including the

implementation of HACCP.

By validation, we mean the certification of this self-checking system by an approved and ISO accredited certification or inspection body, based on a self-checking guide in an assurance scheme. And the self-checking guide is a national standard developed by the representative, food business organizations, and approved by the Belgium food safety authority.

Next to HACCP, we also implement the measures for traceability in the self-checking system. So if you are talking about assurance scheme and certification of assurance scheme, you could say that we mean by that validation of self-checking systems.

How do we implement this? Well, in the lower part here, you see our organization, yeah? And our organization has a supervision of the accredited certification bodies. The accredited certification bodies, in their turn, do external audits. They can do testing or inspection with the food business operator who has an independent certified self-checking system, which in our case is based on guides.

Accredited certification bodies are also

obliged to inform the Belgium Food Safety Agency if they have information of a direct danger for the food safety.

Now, what we don't do is completely delegate inspections. We will inspect those food business operator but with a much lesser inspection frequency than the other ones.

In a number of cases, there was no guide, and this is really an exception. And then the agency can itself order the food business operator. And in the end, all of the food business operators who don't disclose -- who don't have a certified self-checking system will have a normal inspection rate. As said, we are dependent on the activities of the accredited certification bodies.

Our supervision has three main pillars. First of all, if certifications bodies are auditing, we follow them in witness audits. A second aspect is that we are controlling what they have audited. And thirdly, we compare during our regular inspections the results of our inspections with the audit results from the certification body.

So during a number of audits, we will observe the audit activities so we have a good view on the capacity of the auditors. Secondly, in a small number of cases, we will do an inspection shortly after an audit of a controlled body to be sure that we can compare the immediate results of the audits with our inspections. And thirdly, in the more long term, we always compare inspection results with the results of the audits.

If I am comparing self-checking guides and private assurance schemes, you will see that there are, in general, a lot of similarities -- okay -- a lot of similarities. On the one hand, our self-checking systems are national. A lot of the assurance schemes are international. We approve, as a competent authority, the standards and private assurance schemes it -- are the guides and other standards.

Our assurance schemes are managed by the food business operator federations, which means that they don't only write down the guides, but they also give training, et cetera, to help food business operators implement these guides. They are vertical in details,

whilst private assurance schemes are horizontal.

Our goal is confirmative with legislation, and they get a financial bonus, important. Since we don't have to do as much inspections, they pay less taxes than those who don't have a certified self-checking system. And for private assurance schemes, their goal is a little bit different. They have market assess as primary goal.

So the role of those private assurance schemes -- first of all, private assurance schemes can be declared equivalent to guides. Some of them have already done it, which means that there is no difference between having a self-checking system audited into a private assurance scheme or a guide.

Secondly, if there are more than 66 percent equivalence of the self -- private assurance scheme with the guides -- for example, in our cases we have done it for BRC and IFS -- well, those can be used to cover activities which are not approved by national -- by the national guides. And those activities represent less than 20 percent.

And in the last element in private assurance

schemes, what we have seen during the time because from 2003 we have about 13 years of experience, a lot of the food business operators choose combined audits. The auditors come once, and they do the audit for, hence (ph), the private assurance scheme and guides.

Does this help? Yes. Here you'll see the comparison between the inspection results of food business operators who have and who haven't implemented a validated self-checking system. In green, those are the inspections without any problem. The yellow, if it's quite right -- yes -- those are the warnings, and the red ones are the citations.

As you see, there is a clear difference between the two systems, but it also shows that inspections can be completely put out of the way. You should continue to inspect.

What are the lessons learned? First of all, for us as a competent authority, we believe that private assurance schemes have an overall added value. Food safety results are better. There is less burden for the companies because a lot of those companies have to have already an audit in their private assurance

scheme. So if they can combine, they get the same results.

We do introduce sampling plans in some of the schemes. And this means that we can take into account the results of those private sampling plants -- plans, sorry.

And in exports, we use validate self-checking systems in trying to integrate specific requirements from third countries into the functioning of the food business operator.

So we have a double-check before we do a certification of products. We have our own inspections, and we know that the requirements from those third countries are integrated in the quality system of the food business operator.

What do we have to do to improve the system? First of all, we have to be careful not to be prohibitive for small and medium enterprises, certainly in the relation at audit and implementation costs. And we have to increase complementarity between our system of guides and the private assurance schemes. And we are now looking how to -- we can accept the private

assurance schemes. I have mentioned already BRC, IFS, and ISO 22000.

And we would, in fact, invert our reasoning. We would say that what is in the private assurance scheme, what is missing to be completely coherent and consistent with our legislation, and we would only ask for supplementary audits of only the points that are not -- that are in our legislation but not in the private assurance scheme.

And it's also interesting to know, which I didn't put on the slides, that we have the same reflection at the European level, and we are now with the different food safety agencies of the European union in a working group how to see -- how we can, let's say, have a uniformed approach to private assurance schemes.

Thank you very much.

(Applause.)

MR. SPREIJ: So hello again. I'm changing hats. Apart from managing the Standards and Trade Development Facility in the WTO, I'm also part of the SPS unit in the agriculture division in the WTO. And

that's the unit that administers the SPS agreement and also the SPS committee.

So let me thank FDA once again for allowing me to share some WTO perspectives on another discussion on private standards.

So I mean, I'll probably go through some of these slides quickly because, you know, you may know some of this. But just as a background, under the SPS agreement, as we know, SPS-related standards are developed by Codex, by IPPC, and by OIE. And these standards are adopted by governments.

So the question is then, of course, what happens when standards are developed by private sector actors, so supermarkets and retail chains? First, a little bit perhaps about the why and the how. And we have had a lot of discussion, you know, in the SPS committee about private standards.

Private standards are there because of food safety concerns, as we know, because of private companies' liability for food safety risks, there are issues around corporate social responsibility and reputation risks, and there are also, as we know,

increasing consumer expectations. Their consumers are better informed nowadays, also more health conscious, and also better organized. And a few years ago, (inaudible) made an estimation that they are currently about 400 private schemes out there.

So some of the examples -- and we have seen already some of that passing by with the previous speakers -- are individual firm schemes, so for instance, Tesco or Carrefour. We have collective national schemes, such as British Retail Consortium. And we also have collective international schemes. GlobalG.A.P. is a good example.

So this slide just shows you sort of very quick sort of synopsis of what we have in terms of private standards and the wide variety of private standards that we have out there.

If we look at government food safety requirements and we look at SPS principles as we see them in the SPS agreement, then SPS measures and, in this case, food safety measures, they should be based on correct standards or on a risk assessment. They should have a consistent level of health protection.

They should also be, at the least rate, restrictive measure of trades. This is also very important.

These food safety measures should be notified in advance to the WTO with a comment period allowing other WTO members to comment. And eventually, these food safety measures should be published with also, again, a reasonable interval before they actually enter into force.

WTO members should recognize, as was already mentioned also in the introductory presentations, the equivalence right, of other SPS measures. There should be no unjustified costs in testing and certification and approval. And food safety measures are subject to WTO formal dispute settlement procedures. And it's important in this discussion on food safety to separate that from food quality requirements, which would be a TBT issue.

So looking at some of the positive aspects, sort of based on all the discussions that we have had also about in the SPS committee, there are definitely a lot of positive aspects about private standards.

They, you can say, facilitate compliance with

national/international standards. They promote best practices. They can improve brand reputation. They facilitate access to markets.

It's also possible to address merging risks rapidly. And they can pave the way for the eventual adoption of an international -- or even an international standards.

That said, you know, we have also heard, at least in discussions in the SPS committee, a number of negative aspects about private standards. Or some people prefer to not to call private standards but, rather, certification schemes.

Negative aspects could, for instance, be that the private standards are more restrictive than the official regulations. There can be deviations in the private standards, for instance, in the area of maximum residue limits for pesticides. And as we have seen in one of the previous slides, there's this multiplicity of private standard schemes. I once visited a company in Peru, and the company had to comply to 15 different schemes in order to be able to export to different parts of the world.

There might be issues around equivalence. Of course, the private standard schemes tend to be very prescriptive. There's issues around transparency, perhaps.

Codex standards are essentially agreed among leading scientists around the world. There's a long and careful process. And the developing countries are sometimes complaining, the developing country members in the WTO, that they don't have a say in how these private certification schemes are established.

Control inspection and approval procedures, definitely, as was mentioned to us by the previous speaker, the cost of certification can be prohibitive, especially for small and medium enterprises. And there is the outstanding question, is this subject to WTO mechanisms for consultations and dispute settlements?

So the developing countries, in short, say well, this is just for us, an additional costly market access barrier, especially for our small-scale producers.

So why is this being discussed in the WTO SPS committee? Essentially, I would say three reasons.

One is the market access implications that private standards can have, especially where the private standards are going beyond the official food safety requirements. And we have seen some of that in the area of maximum residue levels, the MRLs.

There are clearly developmental implications here, and those are related to the costs associated with private standards. And there are also the legal aspect -- in particular, the applicability of Article 13 of the SPS agreement.

So what does it -- this article say? Essentially this article in the SPS agreement says that members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories comply with the relevant provisions of this agreement.

And it also says that members shall not take measures which have the effect of directly or indirectly requiring or encouraging such non-governmental entities to act in a manner inconsistent with the provisions of the SPS agreement.

And finally, it says that members shall ensure

that they rely on the services of non-governmental entities for implementing SPS measures only if these entities comply with the provisions of this agreement.

We have had discussions, as I said, in the committee since a long time. The background to this was that in 2005 a small island state in the Caribbean, St. Vincent and the Grenadines, raised a concern in the SPS committee about what was then still EurepGAP, which is now GlobalG.A.P., certification for bananas.

We have had several subsequent discussions in the committee. We have seen information sessions. The STDF even organized information session back then. And we have seen the creation of an ad hoc working group on this topic in 2008.

And in March 2011, the committee adopted 5 out of 12 proposed actions, and I put the document number there. You can search for this document also on the WTO website.

And the discussions are now around how to implement these agreed actions. And since then, unfortunately, I must say, but those discussions have still centered around the very first action, and --

which is the SPS committee should develop a working definition, yes -- so please note a working definition; it's not even an official definition -- of private standards. And members are essentially stuck there.

In the March 2015 meeting of the SPS committee, a report was submitted by China and New Zealand, which are the co-stewards of the private standards e-working group that we now have in the WTO regarding this first action.

The proposed definition of a private standard is that an SPS-related private standard is a written requirement or condition, or a set of written requirements or conditions, related to food safety or animal or plant life or health that may be used in commercial transactions and that is applied by a non-governmental entity that is not exercising governmental authority. There's also a disclaimer, or footnote, in that decision.

That's a proposed definition. The report noted also that the e-working group could not reach a consensus. There are especially concerns in the European Union and also in the United States in

relation to these -- to this terminology of non-governmental entity and requirement in this definition.

The co-stewards, China and New Zealand, then suggested a cooling-off period for all e-working members. And that's essentially where we still are -- a cooling-off period.

On these last slides -- and I hope that they will be distributed to all of you or made available somewhere. But these are the actions that have been adopted by the committee. And as I said, we're stuck in the committee -- members are stuck with Action 1.

You see some of the other actions. The SPS committee should regularly inform Codex, OIE, and IPPC. SPS committee invites the secretary to inform the committee on developments in other WTO fora. Members are encouraged to communicate with entities involved in SPS-related private standards and so on. But the e-working group hasn't gotten to that yet.

On this second slide here, you see the actions where the SPS committee could not reach consensus. For instance, Action 8, the SPS committee should develop guidelines on the implementation of this Article 13 of

the SPS agreement, which I just mentioned.

So this is sort of where we currently stand in the WTO. I hope this information was useful, and I look forward to the discussion.

Thank you.

(Applause.)

MR. WEARNE: Thanks everyone. And as Herman said, I'm very struck by the similarity that there is and that you will see in the presentations from the three national agencies that you're hearing from today. And maybe you can yourselves pick out the things that are common and the things that might be subtly different between the three approaches that we have developed in the three countries.

As Herman outlined, it's a fundamental principle of food in the UK and across the European Union that food business operators themselves are responsible for the production of safe food and animal feed. But the way in which the EU member states then structure themselves to deliver those official controls, the things that regulation 882 of 2004 requires is a matter for member states' national

competence.

So in the UK, the Food Standards Agency, as the central competent authority and local authorities, municipalities, as the competent authorities, are each then responsible for different aspects, defined aspects, of the oversight and verification of official controls and for enforcing them in 600,000 food and feed businesses in the UK from farming production to manufacturing to retail and food service.

In the UK, the use of private entities to inform our regulatory approach has been introduced using the concept of earned recognition -- two words, each of them important. And under this approach, business operators who demonstrably maintain high standards of compliance with food or animal feed law benefit from reduced official controls, due in large part to the increased competency it gives us in our ability to risk-profile them.

Our objective in applying earned recognition is to reduce the burden on compliant business whilst concentrating our oversight and enforcement activity on those businesses that are less compliant and/or higher

risk, a similar rationale as you have heard from both Canada and Belgium.

And this approach is targeted at domestic UK producers, often importers, but we believe the principles that we apply are transferrable between those two different sectors. And underpinning this approach is the understanding that a range of different forms of assurance can have value in building an intelligence-led approach to delivering official controls.

So there were three common approaches to earned recognition in the UK. First, a business can be a member of an assurance scheme, the operation of which has gained primary recognition from us for delivering regulatory compliance through its member businesses. And that's what I'll spend the majority of the remainder for my presentation on.

But two other means -- second, a business on its own can demonstrate good levels of label compliance prior to their previous inspection history, which may itself include and take into account any checks undertaken by third parties on its own behalf, what

Herman is describing as self-checks.

And thirdly, a business can be part of the statutory Primary Authority Scheme, which is a particular national scheme that I can describe later in answer to questions if appropriate.

So talking about our use of recognized assurance schemes, I think it's important to stress, particularly given what Melvin was saying, that what we are doing in recognizing schemes is delivering regulatory compliance to its member businesses, which are referred to -- and you'll see referred to in its slides is FSA approved assurance schemes, that we're using the information to inform rather than replace official controls.

And the most significant examples of this approach in the UK are in dairy and animal feed sectors where we recognized sector-wide assurance schemes in 2011 and 2014, respectively. And the application of earned recognition to the animal feed sector has been by far the most significant for us with all stages in the production and use of feed along the feed chain being covered.

So private organizations wishing to seek FSA approval for their assurance schemes must meet an established and published set of criteria -- you can find them on our website, food.gov.uk -- to demonstrate the robustness and independence of their scheme.

And there were these six criteria -- standard setting, so how the scheme standards are developed and reviewed; compliance and certification, including required accreditation by UKAS, a national accreditation body, or its equivalent; thirdly, an assessment process, so the effectiveness and frequency of assessments of scheme-member businesses; fourthly, assessor authorization and competence, so the induction and continuous learning of auditors and assessors; fifthly, data sharing and communication on membership status and on the details of non-compliance with us as the central competent authority; and finally, standards mapping, so mapping the standards against all relevant aspects of legislation, remembering that what we are recognizing is that the membership of the scheme will deliver regulatory compliance for member businesses.

Some private assurance schemes do go further.

We're not interested in that part. All we're interested in is the extent to which those schemes deliver regulatory compliance.

So to date, we have approved the Red Tractor Assurance Scheme for dairy and a number of schemes for the various stages of animal feed production and use. But all of these schemes operate under the (inaudible) of one of these two umbrella organizations -- Red Tractor Assurance in terms of farm activities or the Agricultural Industries Confederation in respect of all other aspects of animal feed production.

And approval by the FSA is formalized from a memorandum of understanding that we sign with the scheme owner. And those memoranda are published on our website so anyone can see the basis on which we have recognized those schemes as delivering regulatory compliance.

So if we look at the practical operation of approved assurance schemes -- and it's important to say that each of these schemes was already well established in the UK in food or animal feed sectors for many years before we came along and applied the end recognition

principles.

They're mature schemes. And for each of those that we have recognized, membership typically represents a very significant proportion of our industry between 65 and 95 percent of domestic production. And that's particularly the case in dairy and animal feed sectors where we have applied earned recognition where membership is part of the private standard required by each of the main UK food retailers.

So what we believe is that, as a result of that compliance with the scheme standard, it's a significant driver for business in any case. And it means that our approval of those schemes doesn't, of itself, introduce any significant commercial advantage for any particular scheme or disrupt the operation of the market. The market's already mature. Instead, we believe that what we're doing is using the market to gain new streams of assurance we can use in our regulatory decision-making.

So under each of those schemes, businesses receive an assessment from their certification body at

least every 18 months, depending on the type of operation. The degree to which the frequency of official controls is reduced by us is dependent on the inherent risk of the operation -- so higher risk businesses, such as some manufacturers, attracting less of a reduction from those considered to be lower risk.

But importantly, businesses who are members of an FSA-approved assurance scheme must also be assessed by their enforceable authority, the local authority, achieving a satisfactory level of compliance in order to receive earned recognition, the type of double rock mechanism that Herman was describing. If not, the frequency of controls -- official controls won't be reduced.

In deciding to implement earned recognition in the way we have, we have recognized that the process needs, above all, good management and governance. So it includes, for example, quarterly meetings between us and the assurance scheme owners. Linked to these, we have received data on a quarterly basis from the scheme owners, highlighting the type and frequency of any known compliances that they have identified.

We also receive management information on the supervisory audits carried out to ensure the effectiveness and consistency of the assurance scheme assessments themselves. Data on non-conformance -- non-compliance is shared with local authorities to inform their focused intervention.

And the memorandum of understanding we have with each of the scheme owners make it clear -- a clear requirement. In each case, we should be informed immediately should anything be identified through with their assessment that represents a serious risk to public or animal health.

We keep the schemes under review. There's a formal annual review process to ensure fitness for purpose. We also actively consider further opportunities to extend the approached assurance schemes, and/or industry sectors. And we are currently involved in pilots with British Retail Consortium standard and GlobalG.A.P.

I mentioned at the outset that these are our common approaches to earn recognition. We're also one year into a major transformation program to modernize

and reshape the regulation regime for food in the UK.

It's important to stress that the legislative framework isn't changing. We still apply, because we are members of the European Union, precisely the same legislative framework as Herman described -- the pillars of General Food Law, the Hygiene Package, Official Controls.

But the way in which we're applying the delivery of official controls will change. And that program, which we have called Regulating our Future, will change the way in which food businesses are regulated and inspected across the UK.

We're trying to take a whole system approach, seeking to understand what information is available from as wide a range of sources as possible and how that can be used in the future to gain assurance that food is safe in what it says it is and that public health is being protected.

So one assurance, our current thinking is that there should not be a one-size-fits-all approach. Herman talked about the possible disincentives there are for engaging with small and medium-sized

enterprises and some of the classic approaches to the use of assurance schemes.

What we will instead do is set an assurance standard. So the -- what -- the thing that businesses need to be able to demonstrate based on what regulatory compliance looks like, that's what will set the assurance standard.

A cornerstone of that standard will be the competence of the persons providing assurance data in terms of their training, skills, and qualifications. So we will set the assurance standard. We will look to businesses to provide that assurance using the whole range of data streams available to them.

So what we anticipate is that that new model, when we finalize it and apply it, will allow data from multiple assurance providers, including official control delivery bodies and voluntary private assurance schemes, to be taken into account to be brought together by that business to demonstrate to us, the central competent authority, the business' compliance.

Critically, I think in all of this the FSA will remain the overarching competent authority with

oversight of the system.

I see the time is more or less up. So thank you. I'll conclude my presentation there.

(Applause.)

MS. BREWER: Well, thank you all for those excellent presentations.

I would like to take a 15-minute break. And when we come back, I'll turn it over immediately to Sharon Mayl, who is the session chair for Session 2, and we'll start with the FDA inquisitors. So see you back here at -- inquisitors, was that a bad word -- questioners. See you at 3:20. Thank you.

(Break.)

MS. MAYL: Okay. I think we are going to get started here. Thanks for getting back on time.

My name is Sharon Mayl, and I work in the Office of Foods and Veterinarian Medicine as the senior advisor for policy.

I would like to start by introducing our FDA panel of experts for -- or inquisitors for this section. So I'm going to start on the right. I think you have already met Dr. Julie Moss, who's the acting

third party program director. Next -- I have to change my order here -- I -- the next is Mark Abdoo, who is our assistant commissioner for Global Regulatory Policy in the Office of Global Regulatory Operations and Policy; Brian Pendleton, who is a senior policy advisor in the Office of the Commissioner; Jenny Scott, Senior Advisor in the Office of Food Safety at CFSAN; Steve Solomon, who is the director of our Center for Veterinarian Medicine; and lastly, Ritu Nalubola, who is a senior policy advisor in the Office of Policy in the Office of Commissioner.

So I want to start really by thanking our panelists for giving very informative and provocative presentations. I'm sure we are full of questions there at the other table for FDA experts, so I'm going to start with Dr. Nalubola, and she can start with a question.

DR. NALUBOLA: Sure. So I have, I think -- you know, thank you again. As Sharon mentioned, it was very informative.

So I have a couple questions, I think, in relation to what I had talked about earlier this

afternoon about, you know, the same level of public health protection and some of the things that we are thinking about as we implement those provisions.

And so particularly, my question is for Melvin on your SPS discussions. In one of the slides, you talked about the principles for governments for food safety requirements and the SPS principles. Clearly, there's some language there about consistent level of health protection. And then in the SPS agreement, members refer to that phrase generally as acceptable level of risk.

I'm wondering if you have any insights for us, you know, based on how you have seen that -- those specific provisions implemented in different countries?

And then I guess related to that, you also talked about some of the potential negative influences about private standards and especially concerns from developing countries. I'm just wondering if you have some thoughts on, you know, what is acceptable across different member nations?

Thanks.

MR. SPREIJ: That's a lot. I guess the

observations that we have, of course, is that there are still, you know, quite a number of developing countries out there that still need support in sort of implementing the SPS agreement and to do that properly.

As I said, SPS measures should be based on risk. Codex or risk assessment should be, at the least rate, restrictive ones. And there's still quite a work that needs to be done. That's also one reason why in the STDF we would like to start that work on good regulatory practice in the SPS area. How do you actually develop good SPS measures?

I guess in terms of the whole discussion about private standards. I mean, of course this is a very sensitive issue, so I have to be a bit careful here as well. But what I would say is that I usually try to make a distinction between sort of the legal implications of this and sort of the more practical implications.

So from a legal perspective, there is this question around Article 13 on which we don't have clarity. One could perhaps also argue that the mere decision of the government to base its inspection

levels on whether imported goods are certified against a certification scheme. That mere decision, is that an SPS measure in itself? I mean, that is also, I guess, an open question.

But we don't have any agreement on that in the WTO SPS committee among members. Now, never say never, but I don't think we'll get any agreement, you know, soon on that. Maybe the best that we will get is that we all agree to disagree, kind of moving in that direction. Maybe you get more clarity when, too, WTO members start a dispute around some of these issues in the WTO, but we haven't seen a dispute on this either.

So practically, I mean, essentially, what we're talking about here is public regulators acknowledging, you know, private sector regulatory activities as part of their risk-based frameworks for food safety regulation. And I mean, there are definitely, in my view, advantages to debt in terms of I guess compliance performance or businesses maybe more committed to those rules that they own.

There could also be opportunities in terms of flexibility, responsiveness, changing technologies.

And there's definitely an efficiency argument that enables inspectors, essentially, to distinguish between high- and low-risk establishment, and it reduces costs.

But I would say there are also perhaps some risks to be acknowledged, and that is perhaps the potential for capture of the regulatory process by dominant economic interests.

And also, let's not forget that participation in these schemes, in the end, is voluntary. And the decision not to implement the scheme, one could argue, it could not be an argument sort of to punish a food business operator. So there also may be some concerns about legal certainty, proportionality, and equal treatment.

Maybe in the end sort of the test will be sort of when, you know, there is a major food safety incident or measure, food safety failure that occurs. And then we need to see sort of what is the economic and also the political sort of fallout of that.

Thank you.

MS. MAYL: Dr. Solomon?

DR. SOLOMON: So thank you for your

presentations, and thank you for traveling all this way. Let me assure you it's not an inquisition. It's an engagement in the discussion here so we can learn from you.

So there was a lot of similarities as you went through -- and this is directed to the countries for your thoughts. And we heard that there's 400 different schemes, which was an impressive number out there.

And I heard each of you describe that you had multiple mechanisms for how to accept a private scheme. And I got the impression that there was one that was kind of at the top of the list that had the most recognition. And we didn't get into all the other schemes. But it suggested to me -- are there different levels of confidence associated with the multiple ways that a private entity could get into the scheme? And if so, would you think about using the data differently depending on your level of confidence?

And then the second part of the question is there was a mechanism described to how to get into, accept, recognize the third party, but I didn't hear a discussion as what happens if a problem was found with

a third party. Is there a means of no longer accepting them? And what are the challenges associated with no longer accepting them?

MS. MAYL: I think that was directed -- I don't know who -- which -- Steve, do you want to go first? You look raring to go.

MR. WEARNE: Yes, there are. In the system we operate, there are quarterly meetings, annual review. That's a memorandum of understanding, which is a -- not a contract, but a formal agreement. So if the assurance scheme is in breach, effectively, then the memorandum no longer holds, and it has to suffer the consequences for its members.

I think for us, some of the questions that you have posed have led us to the thinking about how in the future we might deal with assurance, which is, for us, less about valuing assurance and more about valuing the data that underpin assurance, so becoming less a body that recognizes or approves assurance scheme and more, I think, in the pure spirit of EU official controls becoming a verification body -- us saying to each and every food business: this is what you need to

demonstrate; we will verify it; you can use whatever data streams, whether they are your own data, private entities, or third parties data, whatever you use. But put it together in such a way as it assures your regulatory compliance, and we will verify it.

I suppose that's what I was getting at when I was saying we are thinking about how we might have an approach to assurance that isn't one-size-fits-all and allows each of the 600,000 food businesses that, together with municipalities we regulate, to decide for itself what the package of assurance is it needs and how it's going to present it to us.

And you then need some underpinning mechanisms. You need a license to trade or some prior licensing probably of businesses before they are allowed to start trading. And then you need to think about how that -- how those requirements for domestic producers are replicated in terms of your import controls. But at least the starting point is turning away from assurance and towards data and seeing ourselves as primarily a verification body rather than anything else.

MS. MAYL: Any other countries want to take a crack at that?

MR. DIRICKS: If I may?

MS. MAYL: Yes, Herman, please.

MR. DIRICKS: Okay. I heard, in fact, two questions. The first one was what do we do with foreign (inaudible).

First of all, I don't think that it should be our ambition to accept them all. First of all, as Steve has said, they and we do have a set of criteria to which those schemes have to respond. Secondly, I do believe that we are going to see how it is with international recognized standards because we are living in a global world trying to do something on a national level. And certainly as a small country as Belgium, it doesn't have any added value.

And so I believe that's -- sorry -- so I believe that we -- I'm not sure that we should leave the assurance schemes and go to simply data collecting. I think perhaps the best thing is to combine the two.

And as for your question about what do you do if something doesn't work out, first of all, we work on

three levels. As a competent authority as civil servants, we can revoke the validation of a self-checking system. Without going through a lengthy process, if we see that it isn't correctly implemented after a certain time, we can revoke it. That's on individual level.

Secondly, as I have shown, we have an oversight on the different control bodies. We authorize them. If necessary, we can revoke the authorization. And thirdly, we can also revoke the recognition of the standards. But I don't think that's the good way. I do believe that, as you have said in your FSMA, you have to work preventive -- first of all, being closely to the certifying bodies in their daily work, being aware what their quality is, et cetera, so that you avoid coming into a situation. I'm not speaking about private companies, but control bodies and the standards. I do believe that, as a competent authority, you should foresee problems and try to intervene before they become real problems.

And I think it's possible. We have in certain cases sent letters to certifying (inaudible) you're

slightly deviating from the standards, so make sure that you get back into the row, or otherwise we will retract your authorization. So it's possible.

And if I may, I would add something. We have talked, or there has been a talk, about the negative aspects. What I have seen are also positive aspects. Let's be clear, I'm a civil servant, and I look at it from that perspective, and we will always have the last words.

But if I have seen what has happened with, for example, the food fraud, yes? What we have seen is that, first of all, when we had the problem with the horse meat, all of the capacity -- analytical capacity was taken by the private sector. So we were sometime in a little bit of trouble.

But secondly, we saw that the assurance schemes quickly evolved and saw to it that there were new requirements integrated in the -- in their standards even before the authority was able to adapt its legislation. And I think -- and I'm looking always at it from a food safety or fighting against food fraud perspective. If it helps, we have to be very careful

that we don't distort trades, but there are a number of (inaudible) that we cannot ignore.

MS. MAYL: Mark.

MR. BURGHAM: Thank you. First of all, I just I guess I -- I mean, I have heard the number of 400 schemes. And I want to, I guess, provide a bit of clarification, at least from our perspective.

Based on the research that we have done, in terms of sort of generally applied schemes in the area of food safety, we're probably looking at more like around 14 that would cover probably 98 percent of the businesses, not 400. So we think that's a manageable number in terms of undertaking assessments.

The assessments that we undertake at the scheme level will be done in a manner that gives us a level of confidence. However, over time -- and because I think your point is a good one in terms of if, in fact, a scheme shows a weakness and how do we -- how we -- how do we discover that.

We will be undertaking over time a data analysis for looking at compliance levels within Canada against the certification status of different regulated

parties. And over time, if that demonstrates a weakness, we can certainly go back to reassess the scheme, as we will be doing on an ongoing basis anyway. But certainly, that would cause a much closer look in areas that we have identified as weaknesses.

MS. MAYL: Jenny, do you have a question?

MS. SCOTT: I have many questions, but let's start with one. And this is going to go for Steve, Mark, and Herman, all of you, because each of you described some assessment of private schemes.

And I'm curious about the transparency of the process and how much of that information gets made public. So I would like each of you to discuss that so we have the comparison from -- for each of you.

Thank you.

MS. MAYL: Mark, why don't we start on that end this time?

MR. BURGHAM: Thank you. So this is one that we have been looking at carefully. Certainly from a transparency perspective, which is getting more attention certainly in the government of Canada, we are -- we will publish our assessment process. So once

it's completed in terms of the design, it will be published, and it will go out for some comment. And we expect to hear some comment from scheme owners and probably the Global Food Safety Initiative as well.

But once we have landed on that process, we feel it will be robust. It will be transparent. It will be available for all.

The actual assessments themselves of the schemes will only be shared with the scheme owners. The idea behind this is because this is not -- for us, it's not an official recognition. It is simply a -- an assessment that we're doing that will influence the risk characterization of any subsequent establishments that are certified. So we will share the results with the scheme owner. And part of that reason, as I said in my presentation, was to allow for a conversation and make sure that we get it right in terms of how we assess that.

But just to add that we will have a variable -- in a sense, a variable ranking in terms of the result of that assessment so that it will weigh the risk characterization, along with those other things such as

inherent product process risks, compliance history, international intelligence, et cetera.

MR. DIRICKS: Thank you. I think there are two parts to the answer. First of all, what we use as assurance schemes guides are developed openly by the food business industry. One of the requirements is that they have an exchange of views with all of the stakeholders involved. So even at the time of the writing of the assurance schemes, there are -- there is given feedback.

Assurance schemes are subjected to our scientific community, which is giving an advice which is publicly available. And I think from that perspective -- in fact, we explain everything to our stakeholders. They have access to the data we use to approve the guides, the assurance schemes, the data we use to see how they are working.

And secondly, when I -- and the second part was when I -- when we discussed about what is the relationship between our assurance schemes as guides and other standards -- for example, ISO 22000 -- we asked university departments to do an independent

assessments of the schemes explaining to us where were the differences, where were the deficiencies compared with what our legislation said. And we published that -- or we explained that to our stakeholders meeting.

MR. WEARNE: I think the transparency of the operation of schemes and of their recognition in the first place is critical. What we have published -- we have published the criteria for the approval of individual schemes. What is published on our website is the memorandum of understanding with each of the two scheme owners we have recognized.

So this is the one, actually, before Assured Food Standards, otherwise known as Red Tractor. One is to 15 pages signed by them, signed by us. A formal agreement includes everything from how they -- how we expect them to train their auditors, to the frequency of meetings, to what electronic access we and local authority regulators have to their databases. And that's published, and we think that is a strong foundation for the schemes as we currently operate them.

MS. MAYL: Brian, do you have a question?

MR. PENDLETON: Yeah, I guess this is for Herman, Mark, and Steve, although I think --

(Laughter.)

MR. PENDLETON: -- Steve touched on this briefly. Are there -- I wonder. Are there different ways that you -- under your regulatory approaches -- that you take into consideration this information from private entities for domestic food raised, grown or produced domestically versus food that's imported? Or is that pretty much you make the same use of such information?

MR. WEARNE: Okay. We'll start with this end then.

Our scheme is for domestic production only. We believe that the same principles could be applied to imports, and we're working with -- Canada, as Mark said on a paper for Codex and as Herman said, all of the EU member states are working together to come up with proposals that would integrate use of assurance schemes.

I think it's appropriate that we should apply precisely the same challenge to anyone in the food

supply chain. Actually, that's another fundamental principle of the EU Food Law, that every link in the food chain has responsibility for what they sell.

So whether you're importing a raw material into the UK or using that in your -- in the manufacturer of a finished product for domestic consumption or even creating a new product for an export market, the same principles and the same control should apply.

MS. MAYL: Herman.

MR. DIRICKS: Thank you. What we have done is trying to see how we could take the -- how should I say it. One moment.

You go, then I can reflect on it.

MS. MAYL: Okay. Mark?

MR. BURGHAM: Certainly. So with our new Safe Food for Canadians Regulations, as I say, that were published in January, purity is actually a really important principle.

In terms of whether the food is derived overseas and is imported, whether it's produced domestically for export, or whether it's inter-

provincially traded, there will be a number of requirements -- first of all, license; secondly, the -- a preventive control plan (inaudible) requirement; and then thirdly, recordkeeping that allows for trace -- traceability -- one step forward, one step back. And that will apply to all of the entities, all regulated parties, as I say, whether they be domestic or importers.

Likewise, our private certification policy applies to all of those licensed parties. So it can be applied whether it's domestic or whether it's an importer, and it will be.

MR. DIRICKS: Okay. Found my words back. Sorry.

What we have done is putting into place one system -- one for the domestically produced, one for the exported products. And as I have briefly explained, if there are specific requirements from a third country, we can always introduce that into the system so we are sure that all of the aspects are covered by the audits by the third party.

And I think that is something we have seen now

that, first of all, people want to avoid to have different schemes. So we see a movement into trying to integrate different things into one scheme.

For example, in the primary production with farmers, we have schemes where they not only have -- had the food safety aspects integrated, but also some requirements on environments, and so which makes it for the food business operator, or the farmer in this case, much more easier. There is one auditor who's taking care of all of the aspects. And so the -- there's no need to have an auditor for the different aspects on different regulatory requirements.

MS. MAYL: Okay. I'm going to turn to Mark Abdoo for a question.

MR. ABDOO: There we go. For Mark, Herman, and Steve as well, looking back at the implementation of your reliance on private assurance schemes, what unforeseen challenges did you encounter as you began implementation? How did you manage those and address them? And what lessons learned do you have from the process?

MR. MAYL: Mark, are you starting? I'm just

saying that so the people on the web know who's speaking first. So …

MR. BURGHAM: Okay. Thank you.

So for us, we are -- we have yet actually to go to implementation. And part of the reason for that, we have been designing the assessment process, but we didn't want to get out in front of the new regulations that we'll be assessing against those regulatory standards.

So we don't have practical experience to share on that front other than we did do a pilot based on our old regulations. And in fact, it was one of the GFSI benchmark schemes that we looked at.

In that pilot, the pilot demonstrated very clearly to us that the concept that we were designing was going to work. We do have, I think, some challenges still to further define our assessment process related to the accreditation oversite that we will need to look at as well.

MS. MAYL: Herman, do you have anything to add?

MR. DIRICKS: Just (inaudible - technical

difficulty) one of our main challenges is the small and medium enterprises to get them into such systems. And we are working now closely with the managers of the scheme to see if we cannot implement specific paths designed to small and medium businesses so that they also can enter into the system.

MS. MAYL: And Steve?

MR. WEARNE: Thank you. I suppose two things for us about lessons and challenges. The first was the need to establish appropriate level of data exchange between the scheme and us to support effective implementation without creating an undue administrative burden on the scheme or its members.

And what we have settled on for both of the schemes we now operate are quarterly reports from the scheme on non-conformances and monthly notifications on new and withdrawn memberships so we know who's in and who's not. And that's shared with our local authorities, so the municipality enforcement partners to -- so they can reflect that in their local work planning.

And the second is about our delivery partners

in the municipalities. I suppose we underestimated the extent to which this was a significant change for them in terms of delivering official control on the ground in the majority of the 600,000 food businesses that we regulate and getting them to change their working practices. So I suppose this needs to be seen as a whole systems change if it's going to be implemented successfully.

MS. MAYL: Julie.

DR. MOSS: So thanks for your presentations. They were very insightful and very helpful in terms of some of the thoughts that I have been thinking about.

When I gave my remarks early in this panel, I alluded to the fact that we're just beginning this conversation. So what I'm keenly interested in is what is that thought process that your agencies went through to get to the point to launch this program that each of your respective agencies have?

So Mark, you just alluded to a pilot that you went through. So some thoughts of how -- what that process was for that pilot would be very helpful.

And Herman and Steve, if -- what were that

pre-process steps that you went to, to get to the, yes, this is where we want to go? It would be helpful.

MR. WEARNE: Okay. It's --

MS. MAYL: Steve.

MR. WEARNE: It's Steve here. I'll start.

I suppose, thinking back just over a decade now, the first time we applied earned recognition was in 2006 to primary producers, otherwise known as farms, because the European Union legislation on food hygiene that Herman referred to had brought those establishments into the -- our working definition of a food establishment for the first time.

So we had to create a new regime for primary producers. And there are tens of thousands of farms, many of them small ones, across the UK. And so it was largely opportunistic (inaudible). So what is there around that can help us in the process of setting inspection frequencies, understanding what the different risks of different farms might be because we had had, as a regulator, no interaction with those businesses in the past?

And that was the start of our work with

assured food standards, the Red Tractor scheme. So it was a bit opportunistic, necessity being the mother of invention for us. But we have expanded it subsequently, I suppose.

And the thing that caused us to have these new thoughts about assurance is the recognition that there is now so much data around, and it's so amenable to analysis, so transportable between systems -- the thought that we just need to make the best use of it we can in terms of delivering a regulatory regime that focuses our limited resources where they are going to make the biggest difference in terms of consumer protection.

MS. MAYL: Herman, do you have anything to add?

MS. DIRICKS: I think in the beginning it was a political decision in the sense that when we started we were a fusion of different inspection services. And I think the bottom line was they wanted to avoid to have an army of inspectors coming from the different entities, and they wanted to have an agency which was, let's call it, lean in the sense that administrative

burden had to be diminished. There should be more collaboration between the public and the private sector.

And then we came with -- up with a system where we tried to implement keeping good inspections in place and trying to find a complementary system which was also what we -- which was already existing in the private sector. And that was, in fact, the main goal -- having a complementarity with -- between the competent authorities and the systems which were already in place in the private sector.

MS. MAYL: And Mark, do you have anything to add?

MR. BURGHAM: Thank you. For us, our process actually started very bottom up where, in fact, we had some analysts that were familiar with this world that saw an opportunity. We started to engage and develop and enhance the conversation within our agency for the opportunities that this could provide to us.

And then, frankly, we sort of got lucky because we found that it fit well within our broader transformation initiative in the agency where we were

developing this -- what I referred to as this establishment-based risk assessment model where it was now easy for others to see how this could fit into a broader risk characterization and that they saw some real opportunities for sort of a win-win here.

So with that, we then launched a think piece to begin to have the conversation beyond simply the agency. We drafted a policy. We wanted to test our ideas behind that policy, and that's where we got into the pilot.

With the pilot, what we did is we -- first of all, we engaged with GFSI, and they were very helpful in helping us to round out the idea behind that. We chose a particular scheme that was very on board to be assessed.

So we worked with the scheme owner, and we did a -- basically a desk audit side-by-side on the standards against our regulatory standards. And then what we did is we wanted to actually see how that translated in the field.

So we did choose a -- in this case it was a fresh fruit and veg establishment. We took some of our

inspection managers out with us, and we went through that looking at the results of our desk audit against what we were seeing in the field. And it was a very positive experience from that. We drew some lessons learned. We managed to then finalize the policy, and now we're back to finalizing the process.

MS. MAYL: Okay. I -- like Camille, I think I'm going to invoke my authority as chair of this panel and bring Melvin back into the conversation.

In your presentation, Melvin, you stressed the need under WTO standards for a -- for transparency in looking at private certification schemes. And we have heard several of your colleagues on this panel talk about the transparency of their efforts.

And I'm wondering if you could add some thoughts as to what would satisfy WTO in terms of transparency, or what your thoughts are on that.

MR. SPREIJ: Well, I guess in terms of transparency, what I meant to say was that it's an issue that is often raised by developing countries in this discussion in the WTO. So they are essentially saying where, you know, within Codex, you know, all

member countries are sitting around the table and decide among leading scientists this is the standard. And true, that sometimes takes a very long time.

There's no opportunity for us to do so with private standard schemes. These are just sort of very one-sided by industry. That is something that we often hear. Probably that's also one of the reasons that, you know, private standards continue to be discussed in the SPS community because there's just not that many venues where developing countries can voice their concerns.

MS. MAYL: Okay. I -- I'm looking at my colleagues over at FDA. Jenny, I know you said you had several questions, so maybe I'll jump to Jenny, and then you guys can just make eye contact with me. I can see who else has questions.

MS. SCOTT: Thank you, Sharon. And I'm going to direct this one to Steve.

You know, we're interested in the criteria for -- that each of you are using, but we're also interested in the process that you use to assess these scheme owners.

So Steve, when you conducted your assessments, I presume you did this desk audit comparing the scheme with your regulations. But do you also look at actual audits that have been conducted under those schemes or observe the audits similar to what Mark was talking about doing with the pilot?

MR. WEARNE: I think we started with, effectively, a desk audit and a series of iterative discussions with the scheme owners in order to build the agreement, the memorandum of understanding. But within that is the process by which, as the scheme operates and we provide recognition of it, we will assure ourselves that it operates as it should.

So I suppose we don't have that prior stage of seeing how things work in the field, but a set of review points which demonstrate, once the agreement is struck, that it does work with the ability for us just to withdraw it if it patently doesn't.

DR. SCOTT: So just as a follow-up, do you have within that agreement some sort of provision that you could go out and look at an audit or get some of the audits if you needed to as part of your

verification activities?

MR. WEARNE: Yes, there is. And what we do require, specifically management information on, as the minimum is on the supervisory audits of the assessments that the scheme makes of its members. And that's like the minimum level of independent audit that we look for.

MS. MAYL: Steve? Oh, Steve Solomon.

MR. SOLOMON: So each of you mentioned in your countries that there's a requirement for immediate notification if there's a public health issue. I would be interested in your experience about how that process is worked. And was there pushback from the industry that is paying for these audits and they either wanted opportunities to be able to fix these issues before that notification occurred? Or if there's been any challenges; have you gotten those notifications? And how well has that process worked?

MS. MAYL: Anyone? I'm looking.

Mark, would you like to take that one?

MR. BURGHAM: Well, I'll start, but I'm afraid my answer is not going to be very satisfactory simply

because we haven't gotten to implementation yet. So we're -- we'll -- I would be interested, actually, in hearing the responses of others.

(Laughter.)

MR. DIRICKS: In fact, there's regulation, new legislation that food business operators have to inform competent authorities if there is a danger for the health in relation with foods. And in fact, since we are implementing European legislation, we have imposed that on the -- all of the organisms involved in food safety as well as the control bodies as the laboratories.

In the beginning it was a hard struggle to get them to do what was imposed on them, but now I think, for the most part, everyone knows that he has to inform the competent authorities. They do it. And perhaps they do it also now much more easily because they know that we, in contrast to in the beginning of the agency, we will not overreact to the messages we get.

It's very important that, for us, we get the message. We can intervene mostly in collaboration with the food business operator who asks, for example, to

organize the recall that we have the review over it.

And in essence, since everyone sees the advantages of obligatory notification on the one hand and quick but appropriate action from the competence on the other hand, that the system works quite well.

MS. MAYL: Steve.

MR. WEARNE: A really interesting question. I suppose around major non-compliances, those where there's a demonstrable potential risk to human health, no kickback because that's already a requirement of European General Food Law, Article 18 I think of Regulation 178 of 2002, where we did have more a discussion but got the assurance schemes to see our point of view, I suppose, in the end.

It was what we do about minor non-compliances because we thought if there was a history of minor non-compliances, that suggests that something isn't right in that company that's a member of the scheme.

So we -- and again, it's in the memorandum of understanding with each of the two schemes that if there were four minor non-compliances within a rolling 18-month period, we want to know because we believe the

corrective action then needs to be taken.

And since we started the schemes -- these two schemes in 2011 and 2014, there have been no instances of major non-compliances, but there have been 13 where people have had the full strike -- of only 73 -- but full strike rule, I suppose.

And then we have intervened as central competent authority, or the local authority has, as the competent authority to acquire corrective action. And when that happens, they lose their -- the benefit of reduced inspection frequency that they had gained through membership of the scheme until they have satisfied us that they have put the corrective actions in place.

That was a harder one.

MS. MAYL: Ritu? Ritu, do you have a question?

MS. NALUBOLA: So I -- this is just some clarification I think I missed. If you already covered this, Herman, I apologize.

But one of your slides that talks about the rule of private assurance schemes, you had this

categorization of if the scheme is 100 percent equivalent to the guides, you know, this -- these are the conditions.

And then if it's greater than two-thirds, then these are -- I'm just wondering how you -- what was the thinking behind that categorization? And also, if you could explain a little bit in terms of what exactly that process looks like for determining that equivalence?

Thanks.

MS. MAYL: Herman.

MR. DIRICKS: Sorry. Perhaps -- I have to go perhaps a little bit in detail. In the beginning -- well, now we have for practically each sector, each activity, a guide or a reference or an assurance scheme. So normally, all of the activities in the food chain are covered.

But in the beginning, there are a number of activities which weren't covered by our guides. So what we tried to do is to see if it could complement because before you have been validated, you have to be validated for all of the activities. So if there was a

remaining part of the activities for which an assurance standard didn't exist for the activity itself, it could be complimented with a number of private assurance schemes. I would call them general private assurance schemes, like BRC, like IFS, which go beyond one distributor.

And that's -- that was the main reason that we introduced that. And for the equivalence, it was a question of the different sector organizations or the organizations which were assembling the food business operators, to lower administrative burden. So what we want -- what we give to them was the possibility to say, well, this is my standard, I can prove that my standard gives the same quality or assurance, and then we accept that as a basis for the validation of the self-checking system.

One of the most interesting examples are -- I don't know if it's your competence, but the feed business. I think in Belgium, all of the feed businesses who are really in the food chain active have a certified self-checking system. They have their own guides developed.

They had an association with the Dutch colleagues. And they asked us, well, instead of making two -- have to do two audits, can you combine it, and do we have to maintain two assurance schemes? Well, we said no. For as long as you can show that your scheme is equivalent to ours, you can manage your own scheme.

MS. MAYL: Looking over at my FDA colleagues, Brian.

MR. PENDLETON: I have another question for Mark, Herman, and Steve. I do have a separate question for Melvin, too.

(Laughter.)

MR. PENDLETON: I was wondering what kind of metrics you are using, or plan to use, to sort of assess the valuation or evaluate the success of these regulatory approaches in terms of -- because obviously, there are going to be some costs that are involved either for the government and the regulator entities, then you hope to see some benefits from it.

I know that, Herman, you had a slide on the inspection results showing the impact of the validated self-checking systems, and they had better inspection

performances than those that did not have that. So that could be one. But I was wondering what type of metrics you're planning to use to evaluate these approaches.

MS. MAYL: Mark.

MR. BURGHAM: So for -- in our system, we first of all -- well, are not diminishing our inspection oversight. So it is going to be used to hopefully better target our inspection to areas of higher risk.

Over time, that should be demonstrable through looking at our data relative to the non-compliances that we see, whether that's a co-corrective action requests or our administrative monitoring penalties, and so on.

It will be a little bit difficult over time though to attribute the trends in that relative to other efforts that we make in terms of compliance, promotion, et cetera, as to whether that's a result of this effort or other efforts.

In addition to that, we will be, as I mentioned, looking at our data relative to the

regulated parties that are certified to particular schemes versus the data that comes from those regulated parties that have no certification status. And we'll be looking at that to both look at the -- what are the benefits of -- and the credibility of the particular schemes -- so that's one aspect -- as well as whether there is, in fact, a differential between those in terms of compliance.

MR. DIRICKS: I don't know if I have to comment on the slides. But it's clear that we have done the exercise for different activities, and we always came out with the same results. What we are now doing is assessing why is there still a very small amount of companies which are not complying.

And the main difference we see is an inspection is unannounced, and whether it's announced and it's not in the system, but in the way that the system is implemented in the daily practices of the companies. So now we are, let's say, redirecting our attention to those questions to be able to even improve the difference between the two.

And secondly, we are working in a closed

system. We don't get personal (inaudible), which means that for every company we can set aside because they have a recognized self-checking system. We can't focus our attention on the less performers.

MR. WEARNE: I would like to say that we have the same quality of qualitative data that Herman has comparing the performance of assurance scheme members with those who aren't. That's another comparison. We have only just got enough data to conduct, but we're looking to demonstrate the same thing.

In terms of a qualitative assessment, I think it's clear what we're aimed to do -- a better use of resources, increasing the transparency and credibility of the whole system, developing new capabilities in terms of using the data from the schemes to identify trends that we would otherwise not be able to pick up from official control data alone.

In terms of an independent assessment, the European Commissions, food and veterinary office, now Directorate F), undertook study visit in January of last year to the UK to look at our operation of the schemes. And their report's being published. And they

highlighted the mechanisms we have put in place to monitor and review the systems as a positive -- as a particularly positive feature of our operation of them.

MS. MAYL: Brian, I thought you said you had another one for Melvin?

MR. PENDLETON: On a very different topic, but yes. Can I -- okay. You were talking about the -- in terms of the discussion of the WTO with respect to your private standards and how there was this -- the hang-up with respect to the terms non-governmental entity and requirement. Can you -- this is a really sort of an arcane legal issue that -- or can you talk about why those are so critical and have been such a barrier?

MR. SPREIJ: Well, essentially, it goes back to Article 13 of the SPS agreement, which says -- and I need to put my glasses -- that, "Members shall ensure that they rely on the services of non-governmental entities," so perhaps private scheme owners, "for implementing SPS measures only if these entities comply with the provisions of the SPS agreements. Meaning perhaps that these private standard schemes should comply with -- should essentially be based on risk,

should be the least rate-restrictive measures, et cetera, et cetera, et cetera.

So if in a working definition of a private standard, as proposed by the electronic workgroup, this term, non-governmental entity, appears that might make some WTO members nervous. That's the reason that I can give. And I really don't know how this will move forward, if it moves forward at all.

I said, you know, maybe there's, you know, agreement that we disagree in the WTO for now, although I am very interested to see the proposal that will be submitted by Canada and the UK to Codex. Maybe that can, you know, get things moving.

And I was also interested to hear about the discussions that Herman has with the scheme owners in relation to how can we include small and medium enterprises in this. And that might also take out sort of that kind of political angle out of the discussion a bit.

MR. PENDLETON: Thank you.

MS. MAYL: I think we have time for one or two more questions since we don't have very many public

testimony.

Steve.

MR. SOLOMON: So you all did a very careful job to say that this -- the process you put in place is supplemental to your governmental oversight.

But just speculating that your government may be way similar to my government that sometimes has budgets that go up or go down, if the program is successful, as you're sort of describing it, are there concerns that eventually with budgetary declines or changes that there's going to be more reliance on the private sector schemes and the governmental oversight that you were so carefully describing stays in place will decline over time?

MS. MAYL: Steve.

MR. WEARNE: Yes. One of the drivers for us, thinking in the way that we have in terms of trying to re-engineer a systems approach to food regulation, was a recognition that public resources in the UK are evermore limited and evermore constrained -- so in order to try to get ahead of that curve, to think how we can use data that doesn't rely on official controls

in order to make judgments about compliance and put the -- to put the onus of demonstrating assurance onto each individual business with the regulator then verifying whether those systems and whether that data -- whether those systems should deliver compliance and whether the data demonstrates that it does.

So we're alive to it, and it's informing our thinking. I think it would be wrong if we just sat here mutely and said, well, the money will eventually disappear and so will our capability to do anything meaningful. We need to -- my proposition would be we need to redesign the regulatory systems. They make best use of the resources available to us at any one time.

And if at any stage we feel they're insufficient to deliver consumer protection even though we have taken the best design approach we can, that's when I'm sure other bodies in each of our countries will raise a flag to their government and say the system is under threat.

We don't see that as our job. We see our job to be designing the best system to do the best job with

the resources we have available. But that sense of declining resource has driven our more radical thinking.

MS. MAYL: Does anyone else want to comment on that question?

Thank you, Mark.

MR. BURGHAM: Certainly. I guess if -- for us, we were very careful in terms of the design of the policy that it was not designed to replace that. If it was to move in that direction, it would require a policy change, which is possible.

Equally, we have another policy in the agency which we call our alternative service delivery policy, which we could go down that road of looking at how we can actually start to make use of third party deliverers for particular aspects. That really would be a complete change in our direction in the way we have approached this. It's not to say it's not impossible.

MS. MAYL: Does anyone else have a question? I think we'll take one more question, and then we'll turn to public stakeholder.

Jenny.

MS. SCOTT: This is for Herman. I'm rather intrigued by your approach. It's slightly different from the others in that you have this food business organizations developing standard that is -- and recognized by the government. So what drove you to choose this approach? Are there advantages to this as opposed to a direct regulatory versus scheme approach?

MR. DIRICKS: In fact, the European legislation foresees that there can be national guides and European guides. And we were investing in the development of those guides because we thought that as a competent authority you should not only do inspections, but also give the tools to the companies to comply with legislation.

And at a certain point in time, we said, well, it's very good that we are investing in this, but how could that create added value? And since we are closely collaborating with BELAC, which is the Belgium certification authority, we were discussing with them what could be approach.

And they said, well, instead of working only

on the guides, on the standards, why shouldn't we develop a system which gets the best of the standards, implements its -- in a system of certification, and we can take under certain conditions that into account in our way of working.

And in fact, it's -- it started with the idea of the guides as laid down in the EU regulation, and we added a layer to help us have better implementation of that food safety legacy -- food safety legislation. And it evolved in a short time because a number of sectors were very keen on it.

Like the food businesses -- sorry, the food business operators -- they were the first victims of one of the food safety incidents. And they said, well, we don't want to have that happen again.

And so we sat around a table with all of the stakeholders and tried to develop this in a more consistent approach where we could use the guides in a certification system.

MS. MAYL: Okay. And I think with that we're going to end the question-and-answer portion of this panel. I want to thank both our guest presenters and

our FDA experts for both an educational and a very lively discussion. I think you have given us a lot of information that is very useful to us and gets us thinking as we approach these same issues.

And at this point in time, I would like to open the floor for -- from testimony from stakeholders who have registered to speak.

Mr. -- Raina Pence (sic), sorry, is the first -- Ms. Raina Pence.

And I -- as you approach the mic, I want to remind you of several things. The first is to turn it on because we have had some issues with that.

The second is to please state your name and affiliation.

And the third is to remind you to try to limit your comments to two to three minutes.

MS. SPENCE: I think it's on.

MS. MAYL: Perfect. Thank you.

MS. SPENCE: All right. Can you hear me? Great.

So I am Raina Spence. I am the director of Producer Solutions for GlobalG.A.P., which is a private

scheme holder. GlobalG.A.P. technical staff, partnering certification bodies, and trained auditors play key roles in addressing producer questions and preparing growers for success in food safety management at the farm level.

With a vast international network of food safety professionals, GlobalG.A.P. is well poised to partner with federal agencies in support of FSMA compliance. GlobalG.A.P. can aid in the implementation process by engaging our network of stakeholders to foster collaborative relationships between inspectors, producers, government officials, and existing scheme owners.

Critical elements of the implementation process include careful calibration of auditors, allowance for standard recognition to reduce audit fatigue for producers, and identifying compliance challenges to ensure both an -- excuse me -- an ease of interpretation and reduced food safety risk to consumers.

The GlobalG.A.P. Integrated Farm Assurance standards for fruit and vegetables has been aligned

with FSMA regulations and can be used by producers to meet both retailer and federal requirements. We have developed a voluntary assessment for producers to complete with an optional review by certification bodies during onsite audits.

Producers developing a food safety plan for the first time routinely struggle with drafting food safety assessments and identifying control points on their farm. In response to this need, GlobalG.A.P. provides detailed guidance narratives with each standard and in-depth capacity-building workshops focused on the creation of effective risk assessments. With experience in coaching producers, private standards are equipped to offer these critical services in partnership with the FDA.

Our program, as with other global food safety initiative recognized schemes, has stringent requirements for inspectors, including education, experience, and a defined mandate for continuous improvements.

Harnessing the proven expertise of private standard holders will improve the efficiency and reach

of the FDA as the agency strives to achieve auditor calibration, science-based food safety programs in the field, and a positive stakeholder engagement in the audit process.

Producers continuously strive to keep pace with changing markets, advancing technologies, and regulatory requirements. GlobalG.A.P. seeks to collaborate with the USDA to aid farmers in compliance with food safety standards and reduce overall audit fatigue. By benchmarking private standards against FDA requirements, valuable time and effort can be saved for both the agency and producers.

Carrying the spirit of collaboration forward to integrate GlobalG.A.P. standard requirements with the control points and requisites identified by the FDA serves to offer producers effective and efficient solutions. GlobalG.A.P. welcomes the opportunity to partner with the FDA in ensuring auditor competency, limiting the audit fatigue experienced by producers, and identifying emerging risks in the supply chain.

Thank you.

MS. MAYL: Thank you, Ms. Pence.

I'm going to turn and see if they have any -- we have any questions from our FDA experts? Okay. Thank you.

Mr. Tanner.

MR. TANNER: Yes, hello. I'm Ron Tanner from the Specialty Food Association. The Specialty Food Association is pleased to present the views of FSA members in the specialty food industry regarding the role that international partnerships can play enhancing the safety of imported foods.

FSA is the trade association for the producers, brokers, distributors, retailers, importers, and others involved with high value and innovative foods that are the cornerstone of $127 billion specialty food industry, which represents about 16 percent of retail food sales. Our membership is international.

Most of the products represented by our 3,600 members are value-added, finished, or processed food products. In this statement, FSA will present the views of very small and small specialty food businesses, including importers and specialty food

retailers.

The industry in association was started 65 years ago by importers of traditional food products from Europe and retained strong links with that part of the world.

Today the demands of U.S. consumers for foods from all corners of the globe have fueled expansion of the industry through retail, food service, and direct-to-consumer channels. As a matter of fact, our research shows the specialty foods are growing four-times faster than mass-market foods.

With that background, the Specialty Food Association emphasizes the following points. Our first point is again to remind the FDA that a one-size-fits-all approach will disadvantage small and very small food companies in the U.S. and other countries.

SFA has suggested that FDA add a small business specialist to its staff. This internal expertise within the agency would make partnerships more useful and meaningful because they would be based on a better understanding of the nature and business practices of small and very small food companies.

This expertise should extend to an understanding of the significant role of the retail sector. Retailers, especially small specialty retailers, are lynch pins of their local economies providing employment, purchasing from local and international suppliers, and participating in and donating to community activities.

For the specialty retailers, a key to their business strategy and success is being the first to offer a new and perhaps imported food or beverage.

The Specialty Food Association again emphasizes the needs for FDA to further partner with state and local authorities. Some of them have more experience than FDA in working with small and very small food companies about safe foods. While their international experience might be limited, their understanding of small business could suggest options and alternatives.

On yesterday's SFA member FSMA Monday conference call, seven participants asked whether FDA has approved any private certification standards. Others asked were there countries other than Canada and

New Zealand -- they didn't know about New Zealand, but they asked about Canada -- need FDA assistance recognition alternative criteria?

Their questions reflect the need of small and especially very small importers and retailers for certainty, simplicity, cost-conscious rules, and guidance or templates, and for an end to the uncertainty quickly.

FDA is requesting for participants in this public hearing, examples of what other countries do. SFA suggests that FDA should quickly make its approach known, especially toward the EU. At least FDA should publish within a few months the principle options that it is considering.

Regarding partnerships, systems recognition agreements are one of the most important series of partnerships for the international success of FDA's new approach to import safety. If this series of agreements is not expanded and soon, the products handled by many SFA importers might be unable to enter the U.S. market at all.

The importers, retailers, and other specialty

food companies that handle the products as well as consumers will be the losers. So SFA urges FDA to develop partnerships more quickly.

In conclusion, on behalf of the Specialty Food Association, thank you for considering our comments. The two thoughts I would like to leave you with are that, throughout the food safety chain and scheme, the special business methods and concerns of small and very small food companies should be considered whenever relinquishing the goal of food safety; and second, that FDA must be a partner also as the process of systems recognition shows.

Thank you.

MS. MAYL: Thank you, Mr. Tanner. Looking at my colleagues, any -- Jenny.

MS. SCOTT: Ron, do you have some idea of the specialty foods members' use of private standards? Is this common? Are they too small? Is it problematic for them?

MR. TANNER: I don't know the exact number, Jenny, but I would guess probably about a quarter of them are using private standards because the ones which

are selling through a Kroger or a Publix or a Target and many of those stores are required to do that.

MS. MAYL: Thank you.

And lastly, Mr. Folkerts.

MR. FOLKERTS: I realize I may be between you and your commute home, so I'll try to be quick. My name is Bill Folkerts, and I'm the vice president of Strategy and Program Operations at U.S. Pharmacopeia.

U.S. Pharmacopeia Convention is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured and distributed and consumed worldwide. We have over 1,000 staff that are located in our headquarters here in Rockville, Maryland, as well as laboratories and offices in India, Brazil, Switzerland, Ghana, and China where we have the Food Safety Center of Excellence.

We appreciate this opportunity to share our views on FDA's efforts in building food safety capacity and to highlight how we can partner with stakeholders in this significant area.

Today we focus on how our standard-setting

activities help ensure the quality and integrity of the global food supply, and we discuss our efforts and food fraud mitigation with the ultimate goal of improving public health.

Specifically, USP has three offerings that complements the agency's efforts to enhance the safety of imported foods -- Food Chemical Codex, the food fraud database, and the food fraud mitigation guidance.

The FCC, Food Chemical Codex, contains over 1,200 standards that help to assure the purity and quality of food ingredients. Each FCC standard is established and evaluated with scientific rigor by USP scientists and approved by a committee of independent experts from industry, academia, and regulatory bodies from around the world. Currently, FCC's specifications are recognized in more than 200 FDA regulations and in countries such as Canada, India, Australia, New Zealand, and Brazil.

USP recently has developed food fraud mitigation tools and services, including training and advising that focus on identifying and mitigating the risk of economically motivated alternation, EMA, as now

required by FDA, GFSI, and others.

Particularly in the context of a preventive controls-based food safety framework, USP's efforts can help FDA and the industry with reducing supply chain risk. USP's food fraud mitigation guidance document provides a framework to help food suppliers perform a vulnerability assessment and develop a customized food fraud mitigation plan.

USP's food fraud database is a continuously updated collection of thousands of ingredients and related records associated with food fraud. Records are compiled from scientific, media, regulatory, and other sources from around the world. It supports compliance with FSMA and GFSA requirements by providing information on the history of food fraud and the identification of potentially hazardous adulterants.

With nearly 200 years of expertise as an independent standard setting organization, USP is well positioned to work with the Agency, the food industry, and other stakeholders to develop and share science-based public standards, data, and other support to help ensure the integrity of the food supply.

We welcome the opportunity to partner with FDA and others as we pursue the key goal of improving global food safety.

Thank you.

MS. MAYL: Thank you. Any questions? Okay.

Well, thank you for giving that testimony. And again, thank you to our panels for a great discussion.

And with that, I'm going to turn it back over to Camille, who actually does stand between you and your evening commute.

(Laughter.)

MS. BREWER: Thanks so much, and thank the panelists. And I do want to clarify that the FDA experts are inquisitive, engaged, and highly motivated to learn all that we can on this topic.

Before we close, I do want to turn it over to the folks on WebEx for any announcements. We had 500 people register for WebEx, and we just want to make sure that we have clear directions for tomorrow. So if I could turn it over to Kelly McCormick, who looks like she's coming downstairs.

MS. MCCORMICK: Nope. So for WebEx, individuals participating via the web, please keep in mind that questions can't be asked directly to the panel members. So if you do have questions pertaining to Sessions 3 and 4 tomorrow, be sure to submit them online by 9:40 a.m. for Session 3 and by 1:40 p.m. for Session 4. That's about it.

Or at any time, please feel free to submit those questions that you do have to the FDA Technical Assistance Network for regulatory interpretation questions as well as to the Food Safety Preventative Controls Alliance for technical questions.

MS. BREWER: Okay. Thank you, Kelly. I would like to thank you all in the room. It's been a long day but certainly a very interesting day.

I would like to thank our experts. We have experts from around the globe participating in this two-day meeting. And I know some of you are still jet lagged, but we very much appreciate your participation.

I want to thank the FDA experts. They prepped hard for this and took it very seriously. We have a lot of work to do. We have a lot of deliberation that

faces us.

I would be remiss if I didn't thank the planning committee that comes from across the agency. We have people from CFSAN, from the Office of International Programs, from ORA, from the Center for Vet Medicine, who all worked together to make these two days happen.

We have a transcriber who's in this little room. Thank you for your efforts.

I had a number of questions about the slides. We will be putting the FDA slides on the web, and we'll do our best to see if we can get the other slides on the website as well.

Tomorrow, Dr. Don Prater will be the presiding officer, and you'll be in good hands with Don tomorrow.

And with that, I want to wish you all a very happy Valentine's Day. Take care, and see you tomorrow.

(Applause.)

(Off the record.)

1

2

CERTIFICATE OF NOTARY PUBLIC

I, Natalia Thomas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Natalia Thomas

Notary Public in and for the

State of Maryland

CERTIFICATE OF TRANSCRIBER

I, Dana Rose VanNoort, do hereby certify that this transcript was prepared from audio to the best of my ability.

I am neither counsel for, related to, nor employed by any of the parties to this action, nor financially or otherwise interested in the outcome of this action.

_____ _____

2/19/2017 Dana Rose VanNoort