INTERNATIONAL CAPACITY BUILDING WITH

RESPECT TO FOOD SAFETY PUBLIC MEETING

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P R O C E E D I N G S

WELCOME - CAMILLE BREWER, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN),FDA

MS. BREWER: My name is Camille Brewer; I'm the Director of International Affairs Staff at the Center for Food Safety and Applied Nutrition, and also Senior Advisor for International Affairs for the Office of Foods. I am not Mike Landa. Mike can't be with us today; he has really bad bronchitis, so he sends his best regards.

I have a bit of an echo. Can you hear me okay?

(No verbal response.)

MS. BREWER: Okay. Well, I want to thank you all for coming. I'm looking forward to a lively discussion today. We're here to talk about Section 305 of the Food Safety Modernization Act, which mandates that FDA develop a capacity building plan.

The plan is intended to develop the technical, scientific, and regulatory capacity building of our trading partners.

So we've assembled a real array of

international experts to discuss these issues with you. Now, we have a set of draft recommendations. I'm really getting an echo. Is this all right? Can we get the AV people to adjust?

So we have a draft set of recommendations which were posted on the web, and they're also in your information packet. We'll be going over those recommendations in some detail later on this afternoon.

I've been charged with reviewing a set of housekeeping items and I'm going to do my duty.

The first thing I want you to be aware of is that this session is being recorded and transcribed. The proceedings will be placed on our website and I know you want to know when that will be, and that will be as soon as possible. Usually we have them done and posted within 30 days, so I'm crossing my fingers there.

The restrooms are right outside and to my left as you exit.

We have a very nice folder for you that contains the speaker bios. We will not be going over the bios in detail through the program, so please refer

to it as we go along.

We also included the Federal Register notice, and that's very important because it has the docket number. We're here today for your comments. We really encourage you to include your written comments to the docket.

Your packet also contains a list of attendees and our draft considerations for the international capacity building plan. So throughout the day, there will be periods for your input. We have speakers throughout the room -- microphones rather, so please come up. Remember to identify yourself, your name and your affiliation.

There is a restaurant here in the hotel on the first level. There's a really nice array of restaurants in the promenade right outside of the hotel on the first level.

If you are press, we do have a press officer here, Curtis Allen.

Curtis, can you stand up so we can see you?

(No response.)

MS. BREWER: Is Curtis here.

Juanita, if you could just bring him and have him give everyone the high five there.

So if you have any questions as the program proceeds, please see Juanita Yates who is there in the beautiful red suit.

We did not receive any requests for sign language interpretation so we do not have that service today.

We also will not be posting the presentations on the website due to what we call 508 readability provisions, but if you want them, please give your card to Juanita and she'll make sure that you get them.

So that's the full list of housekeeping items. Did I forget anything?

(No verbal response.)

MS. BREWER: Okay. So let's proceed. Our first speaker today is Ms. Mary Sophos. She is our lead keynote speaker, and she is the Executive Vice President for Policy and Strategic Planning at GMA. Welcome.

(Applause.)

KEYNOTE SPEECH - MARY SOPHOS, EXECUTIVE

VICE PRESIDENT FOR POLICY AND STRATEGIC PLANNING, GROCERY MANUFACTURERS ASSOCIATION

MS. SOPHOS: Thank you, Camille, I'm delighted to be here today and I appreciate the opportunity to talk about international capacity building. And, in particular, the essential role that partnerships can play in promoting enhanced food safety outcomes globally.

GMA is the voice of more than 300 leading food, beverage and consumer products companies committed to serving the needs of consumers in the U.S. and globally. There is no topic of greater importance to our members than the safety of their products.

The Food Safety Modernization Act, or FSMA, represents the most sweeping reform of American food safety laws in more than 70 years, and a true paradigm shift for FDA and all its stakeholders.

For the first time prevention is now the cornerstone of the U.S. food safety system.

Equally significant, FSMA mandates and

empowers FDA to develop food safety strategies and solutions in a global context rather than focusing only within U.S. borders.

GMA and our member companies take our commitments to food safety and our consumers very seriously. Ultimately, it is the companies who make food and beverages that have responsibility for the safety of their products. That's why we have embraced the goals of FSMA and why we have continued to explore new approaches, new mechanisms and new partnerships to enhance our collective efforts. We welcome the fact that the importance of partnerships in the area of imports has been clearly recognized in FSMA and by FDA.

As we all know, the global marketplace brings both benefits and challenges. As of 2011, one in six FDA regulated food products consumed in the U.S. is sourced from abroad.

Only by extending the FSMA framework of prevention to our work with our trading partners we'll be able to achieve our food safety goals.

FDA is to be commended for the vision and

speed with which it has begun to implement FSMA. No easy task considering the enormous scope and new requirements that the law imposes, none the least of which are those focused on international capacity building, the topic of today's meeting.

I welcome the opportunity to offer our perspective on how FDA might best implement its responsibilities, as well as help private sector initiatives that can contribute to their overall success.

We believe that strong and effective roles for both the public and private sectors, analogous to how we operate in the U.S., is the best way to fully realize the new global food safety regime envisioned in FSMA.

FDA is required to develop a plan to expand the regulatory capacity of foreign governments exporting to the U.S. Among other things, this plan must include recommendations for mutual recognition of inspections, training of foreign governments and industry in U.S. food safety requirements, harmonizing standards and multilateral acceptance of laboratory methods. These are all areas where private sector

knowledge and experience can also play a key role.

In late 2007, GMA's four pillars of prevention proposal anticipated much of FSMA's new food safety framework including new prevention-focused responsibilities for industry and a significant enhancement of FDA's global responsibilities.

We identified what we considered to be essential requirements. These include the need to expand the capacity of foreign governments to prevent and detect threats to food safety, expand FDA training and science outreach overseas, expand FDA access to foreign facilities and data, expand efforts to harmonize globally, and, finally, to leverage resources among governments, academia and the private sector.

GMA's four pillars were formed by our member companies long-standing efforts to strengthen the safety integrity of the food supply. Since 2007, GMA companies have redoubled their efforts to enhance supply chain management processes with a significant focus on training of workers and suppliers, particularly in Asia.

Among other things, GMA companies are

organizing supplier schools to help ingredient suppliers improve food safety, sanitation and quality management. They're developing training programs focused on farm work best practices including proper food handling and storage, and they are increasing both third party and company audits.

Companies are working individually and together to achieve these goals and are committed to developing training programs that are grounded in the same international food safety standards that underpin national regulatory systems.

GMA has supported these goals by focusing on ways to leverage resources through innovative partnerships. We focused initially on capacity building in the Asia-Pacific region. In 2008, we worked alongside governments through the Asia-Pacific Economic Cooperation Forum, known as APEC, to establish the Partnership Training Institute Network, or PTIN for short.

Oversight is provided by APEC's food safety cooperation forum, which is a forum for food safety regulators, co-chaired by China and Australia.

The goal of PTIN is to improve understanding and use of international standards and best practices in food safety management.

We chose to start in the Asia-Pacific region because the 21 APEC member countries constitute 41 percent of the world's population and almost half of the world's food trade. APEC members include top U.S. source countries such as China and Mexico, and emerging source countries such as Vietnam and Thailand.

PTIN enlists the expertise of academia, industry and governments, and builds on existing resources in the region to develop reproducible, sustainable food safety training materials.

PTIN participants believe its unique strength lies in its operating structure that leverages the capabilities of food safety regulators, academia, industry food safety experts and multilateral institutions like the World Bank, all focused on the common mission of improving food safety.

This collaborative approach helps maximize precious resources while harnessing the specialized capabilities of each sector.

Since the formation of the PTIN, industry has provided technical expertise, practical know how and organizational skills to the development and deployment of PTIN training programs.

GMA and food safety experts from its member companies have participated in workshops covering a wide range of topics such as prevention, supplier management, supply chain best practices, risk assessment, incident management, laboratory competency, food safety plan development and HACCP training.

The building blocks of food safety are the same all over the world so it is not surprising that the PTIN agenda dovetails with the key elements of FSMA and affords us with a unique information-sharing and learning platform.

Over the past few years, PTIN has held 32 workshops across the region, and participation has exceeded expectations. Kraft, McCormick, General Mills, Cargill, Bumble Bee, Coca Cola and Waters are among the GMA companies who have provided expertise and support for these workshops.

The November 2010 workshop in Beijing on

supply chain management drew more than 150 representatives from regulatory agencies, academia and industry from 20 APEC economies in a four-day training session. The training modules used in Beijing have become the PTIN's first set of reproducible modules which can now be customized, localized and deployed broadly.

This year PTIN will roll out incident management training modules based on a 2011 workshop in Big Sky organized by Food Standards of Australia, New Zealand. Incident management, as you know, incorporates a number of FSMA provisions including surveillance and a recall.

Laboratory capacity and competency is a key industry priority as well as a key focus of FSMA-related capacity building. In 2012, the PTIN will expand on last year's laboratory capacity workshop held in Thailand, and we are going to have three sub regional train the trainer sessions, including one in Peru this week.

Plans are also underway to build on the two risk analyses workshops held in 2010 in Singapore and

the Philippines.

In addition to its clear potential for advancing the goals of FSMA, the PTIN has been enthusiastically embraced and recognized by APEC's 21 member governments as an innovative success. Governments have credited the PTIN with improving their national food safety systems because of a better understanding of best practices in international standards.

An added and largely unanticipated benefit of the PTIN has been its role in facilitating key government regulatory cooperation goals because it has provided ongoing forums where national regulators can convene. Regulators have made progress in developing transparent information sharing and communication networks, aligning food safety standards with international standards and Codex, and enhancing skills in human resources within national regulatory systems.

Given this track record, there was strong interest in globalizing the PTIN model among leaders of APEC's food safety cooperation forum, U.S. Government, the World Bank and others. The Bank was an early

supporter of APEC PTIN recognizing its importance as a successful partnership model.

In late 2010, GMA and World Bank leadership discussed plans to use PTIN as the basis for a much broader global food safety partnership and exchanged ideas about how to secure sustainable funding.

As we discovered, when there is a consensus on the need and the proposed solutions, things can move very quickly. At the May 2011 APEC ministers' meeting, the World Bank and APEC's Food Safety Cooperation Forum signed a memorandum of understanding that deepened the collaborative efforts in APEC.

This was followed by the announcement at the APEC leaders meeting last fall that $1 million in seed funding had been secured toward the launching of a new global food safety partnership. The partnership along with a new trust fund are designed to bring together stakeholders with a role in food safety, including regulatory and trade agencies, aid agencies, agriculture, food manufacturing and others to promote capacity building to support good food safety practices.

Initial contributions for the fund have come from industry and from the U.S. Agency for International Development. Already, there have been strong statements of support for the partnership at recent APEC ministerials, and growing interest from a variety of countries in participating and providing financial support. You will be hearing more, I'm sure, about this exciting new initiative.

This new global focus on food safety is driving innovative new collaborations every day. We are particularly excited about efforts we've undertaken with Cornel University and Shanghai Jinjiang Tongji University in China to explore the feasibility of developing specific food safety curriculum that will include academic certification and state-of-the-art training.

In conclusion, the food and beverage industry has a long history of innovation, scientific analysis and evolving business processes to bring to the table through public/private partnerships.

The success of APEC PTIN and growing support for the Global Food Safety Partnership is evidence that

the vision of capacity building and international regulatory cooperation contained in FSMA is being reaffirmed daily by governments around the world. These partnerships are helping to build confidence and momentum toward our common goal of strengthening the safety and integrity of the food supply.

So thank you very much.

(Applause.)

MS. BREWER: Thank you so much, Mary.

Next we will hear from Deputy Commissioner Mike R. Taylor, who will be talking about FSMA and international capacity building. Mike?

INTERNATIONAL CAPACITY BUILDING IN THE FOOD SAFETY MODERNIZATION ACT (FSMA) CONTEXT -

MICHAEL TAYLOR, DEPUTY COMMISSIONER FOR FOODS, OFFICE OF FOODS, FDA

MR. TAYLOR: Thank you, Camille, and good morning everybody. I appreciate the chance to be here. This is really quite a gathering of people in the food safety community who have been focusing on the

international dimension of food safety. I see a lot of familiar faces and people who are really committed to this, I know. And so it is great to be here.

I'm just going to take a few minutes to put capacity building in the context of the FSMA vision and the larger frame within which we're working on food safety.

I do want to thank Mary Sophos for being here from GMA. I think that GMA has been an incredible partner and leader within the food safety community in getting us where we are on the fulfilling of a modern vision of what the food safety system should look like, beginning with the work to get the legislation passed and the real commitment GMA has made to work with us as we go through the implementation process both on domestic issues and also international ones.

Also, it just seems timely to really thank a lot of other people who have gotten us where we are. There's a whole stakeholder community, the consumer community, the international community that's worked closely with us, so many people who worked to get this law passed and I know are committed to its

implementation. And we're grateful for that.

There are a lot of people at FDA who are also, as Mary acknowledged and I appreciate it, you know, working extremely hard to get this law implemented and I'm personally extremely grateful to them. A number of them are here today, they are folks who have been focusing on the international dimension, but, again, I just cannot say enough how much I appreciate what everybody has done to get us where we are today. And we've got a lot of work ahead. I think this meeting will underscore that certainly with respect to the international dimension, but I think we're on the right track.

I want to just take a minute to put this international capacity building topic in the bigger context. I mean, we all know that the world has changed. We really do have one global food system. The distinctions between domestic food and foreign or imported food are really breaking down and it's, in part, because of the large volume of imports of staple commodities, but also new ingredients just pervade the food supply. So we really, at FDA, see ourselves as an

agency that's engaging a global food system and charged under FSMA with working with the global community to build a global food safety system, one system for food safety to be successful in a global food system.

And we have these phenomena of global systems not because folks sat down one day and just decided we want a global food system, it's because of these huge driving forces that have created today's food system. It started with consumers demanding and really depending on food from all over the world to meet their nutritional needs. This is economically driven, of course, to a large extent because cost and access to products economically is the driver of the trade phenomenon that has created the global food system. But beyond cost, just diversity that people demanded a diverse food supply. And the only way we get it year-round, obviously, is by looking to other parts of the world to make up that diverse food supply.

And, finally, there are real benefits to this from a public health standpoint. We want people year-round to be eating fresh fruit and vegetables, for

example, to have a diverse diet. And so the global food system and the consumer demand that drives it is a huge reality that nobody made up. It's just there.

A second driving reality, of course, is just how fundamental agriculture and food production are to global society. It's the foundation for economic development and growth in almost every country in the world. And so what we have is a set of communities in very diverse countries around the world eager to meet that consumer demand, eager to produce the products to meet the global demand that has created the global food system. And that's not going away either. That's a driving force in many countries around the world. And with that, with the global trade that has come, the third -- for me, the third driving consideration that has us meeting here today is an expectation of elevated assurances of food safety. There is a heightened consciousness of food safety that, I think, comes in part from the global aspect of the food system.

And, as a result, food safety is a frontline consideration with a very important phenomenon having happened that, I think, surprises a lot of us who might

have looked at this a long time ago, you know, a quarter of a century ago when this was really developing. There was a concern that harmonization, the whole global phenomenon, was going to drive food standards down.

Well, it's had the opposite effect. It's driven harmonization upward. And so that's where we are today, and, I think, that's the brilliance, frankly, of the Food Safety Modernization Act. And if Congress, in its wisdom, is to recognize these trends, recognize these phenomena and to create a law that has a comprehensive vision of how we ensure safety in this global context. And so, I think, frankly, Congress did a heck of a job in developing this law. It was not the prettiest process.

Caroline, I think, has demonstrated a little of the remembering back the process. But, you know, Congress recognized that we can have a food system that meets consumers' expectations for food safety if we have international harmonized prevention-oriented standards and if we have high levels of assurances that those standards are being met. It's sort of that

simple, what's going on here in the Food Safety Modernization Act. And we think that's a powerful vision. We're very much lined up behind fulfilling it.

Congress also recognized, of course, that fulfilling this vision, and, in particular, getting higher assurances that standards are being met does require, as Mary indicated, a really multifaceted approach that builds on clearly defined public and private roles. And, again, there is a transformative mandate to FDA in the import arena that it does recognize private sector responsibility as the foundation, the principle that firms importing food into the United States should be managing their supply chains, taking responsibility for that, shifting FDA's role from reliance solely on looking -- catching and detecting products or problems with products at the port of entry when they come into the country -- but instead putting FDA in the position, empowering FDA to be looking at the systems that the companies have established, to be auditing, to be ensuring that the importers are meeting their responsibility to manage their supply chain and prevent problems.

A big shift, foundational change in FDA's role in the system, but Congress went beyond that. It recognized that private audits, if done credibly, can play an important role in the public assurance system, so it mandated the creation of an accredited third-party certification program. Again, public/private collaboration.

It also saw a heightened role for FDA overseas. It mandated more foreign inspections, and, very importantly and really getting to the subject of this meeting, it mandated our collaboration with foreign governments. Congress really recognized -- that if you touch certain buttons, you get stuff popping on the screen here. You get to give Mary's talk again.

(Laughter.)

MR. TAYLOR: Congress really recognized that we need to work towards -- we can have the optimal system if we work towards harmonized standards, if we look for ways to mutually rely on the oversight that assures that standards is being met. And that mutual reliance aspiration, the ability to perhaps rely on the

assurances that come from foreign governments, to share inspection results with foreign government, to be able to rely on lab results, all of that can contribute to the assurance of food safety that we're looking for in this global food system.

And so Congress mandated that we develop a plan to address these issues, to address these needs and to come up with a strategy and a plan for capacity building that would fulfill this vision.

And that, of course, is what this meeting is all about. It's what the plan we are developing is all about, and this is where, again, we're looking to the community to help us get this right.

As Mary suggested, this idea of capacity building is not new with FSMA, there's a lot that has gone on. You mentioned, Mary, I think, a number of things. I think FDA is proud of what it's done historically, sending experts out to do training on low acid canned foods, GAP's training.

We started establishing foreign offices with a vision toward capacity building before FSMA was enacted, but right now I don't see how we could

possibly implement FSMA without those foreign offices.

The work that JIFSAN has done, the Joint Institute for Food Safety and Applied Nutrition, in GAP's training, you know, and in training to enhance the use of risk of analysis. And of the training that's going on, you know, at the JIFSAN facility in lab skills, and, you know, tremendous collaboration, public/private. The Waters Corporation having putting real resources in. And people coming from all the over the world to be trained in common approaches to laboratory work.

And, of course, Mary mentioned the APEC work, the PTIN initiative, and now the World Bank, the multi-donor trust fund. I mean, these are all activities that reflect the realization that this community has embraced for some time. Congress has now embraced the vision, and what we're really looking to do with this plan is to take this work to a new level, to recognize that in a resource-constrained environment, which we absolutely work in, we've got to build on the foundation of what we've done in order to be strategic in targeting the needs and priorities for capacity

building. We've got to be strategic in building the collaborations that are really essential in designing and delivering capacity building programs, and we've got to really think through this plan to ensure that we can both be effective and know that we're being effective in capacity building.

So how do you evaluate; what are the metrics for the capacity-building work that we do? We're just eager to, again, take the work that's going on before and really build on that to take capacity building to a new level.

We are very conscious at FDA that for all that folks do, you know; we can't make a dent in this challenge by ourselves. It absolutely has to be a community effort, a collaborative effort, and one that is based on partnerships to meet this significant challenge.

I want to close by just relating a couple of experiences I've had that underscore for me just how great the opportunity is to build this capacity, to meet this challenge, and just really how ready, you know, I think the global food system is for

the kind of capacity building initiative that we're talking about.

For the decade or so before I came back to FDA in 2009, I spent a lot of my time working on development issues and particularly focused on agricultural-led economic growth and economic growth to foster poverty reduction in Africa, and focused specifically on those problems that arose in Africa.

And I did some work, particularly in Uganda, on food safety as part of the context for supporting agricultural aid, economic growth and, you know, made a number of trips there, worked with folks in the government, in the private sector working on this problem. And what you see firsthand, you know, is, first of all, the primacy of the food system. It is just evident how foundational that is to the welfare of that country domestically, but also how much weight is being placed on agricultural led economic growth to reduce poverty and hunger in that country. It's central to the economic development of that country.

You also see firsthand by talking to people, the motivation to strengthen the food safety system. I

was doing work that related to a legislative process to develop a new modern food safety law for Uganda, and, you know, had occasion to talk to people in both the public and private sector about that subject. And, you know, there was real serious commitment there and recognition that in order to have a successful food system there needed to be a modern framework that would bring Uganda standards into alignment with international standards.

A corollary to that was the embrace that you saw among people working in the food system there, in global standards, and a recognition that in order for Uganda to achieve its economic goals, it needed to aspire to and, in fact, meet global standards for food safety. And demonstrated, just in the experiences I've had, going and looking at facilities, not only the willingness to do that, but the capacity to do that. You know, I had the occasion to visit a seafood processing plant in Kampala that was taking fish from the Lake Pretoria fishery and processing it, freezing it for export primarily to Europe, but also to the United States.

Well, you know, it was an amazing facility. I mean, it was well-built, it was well-run, it was HACCP-based, and it was, you know, as fine a facility as you can imagine and being run by local folks who were committed to meeting the expectations of a global market. And so, you know, the eagerness, and, I think, the embrace of the capacity building need that we all see, both in private sector and public sector, is real. I am preaching to the choir. I think people in this room all know it, but it just makes me very reinforced that we're doing the right thing here for a lot of purposes, to ensure food safety in this country, but also to foster very necessary development in other countries.

I've also seen the readiness of the community just in my time here at FDA and in the dealings that we have on a regular basis with our major trading partners. And so whether it is Canada, Mexico, Europe or China, you know, the enthusiasm that our counterparts have for the vision that's embodied in FSMA, but the enthusiasm for seeing to it that we are building common ways of doing work, building capacity,

you know, with each country in different circumstances with different challenges, but with a common interest in making all this work.

And so, you know, I feel really inspired by what I see just firsthand in terms of the community's readiness to move forward on this. I know, again, that I'm preaching to the choir, but I think the folks in this room ought to really appreciate that we're at a special moment, that there is a tremendous opportunity to make a big difference for food safety and for the welfare of people all around the world.

This conference for us is really our effort to reach out to you and to get your help in making FDA a worthy partner in that effort.

So I just thank all of you for spending the day here. I thank the folks at FDA who have put the effort into planning this, and I look forward to the discussion. Thank you.

(Applause.)

MS. BREWER: Thanks, Mike.

We're going to spend some time now with some experts who will be sharing their particular

perspectives on international capacity building. We are going to start with Suzanne Heinen, who is the Administrator of the Foreign Agricultural Services at USDA.

We'll move directly to hear from Brian Bedard, who is the Livestock and Food Safety Specialist at the World Bank.

Then we'll hear from UNIDO, which is the United Nations Industrial Development Organization. We have Steve Halloway with us. So we'll start with Sue. Welcome.

PERSPECTIVES ON FOREIGN FOOD SAFETY CAPACITY BUILDING, THE AGRICULTURAL TRADE PERSPECTIVE - SUZANNE HEINEN, ADMINISTRATOR, FOREIGN AGRICULTURAL SERVICE, U.S. DEPARTMENT OF AGRICULTURE

MS. HEINEN: Thank you, Camille, and good morning everyone, and thanks for calling me an expert. I think we just heard from a few experts though already.

I appreciate the invitation from FDA to come

and speak with you and provide USDA's perspective on building capacity and how our experience might influence the work of the Food Safety Modernization Act. I see a lot of friends in the audience, but there's others I don't know, so I'd to take just a minute to tell you a little bit about the Foreign Agricultural Service.

Our mission is to identify trade opportunities, open, expand, and maintain access for U.S. exports where 95 percent of the world's consumers live.

At this point, some 25 percent of what we produce in this country in agriculture is exported. And so FAS works around the globe to build new markets, sustain and expand existing ones, and to improve the competitive position of U.S. agriculture. But we also work to ensure food security for other countries and food safety in these fragile and developing markets that are the markets that we see as the markets of tomorrow.

As you can see, we have a global network of agricultural attaches and counselors serving in nearly

100 offices around the world, and they're really the eyes and ears of agriculture. They help provide real-time information on production trends, technical issues that affect agriculture and the trade and agricultural products and on emerging trends and marketing issues.

We also help to resolve issues that our exporting companies may have before they become barriers to trade.

So we have a long history in trade capacity building through our food assistance programs and through our partnerships with U.S. companies and U.S. agricultural associations.

But, as Mike mentioned, the world has changed and so when I started, I guess, and before, much of our training has really focused on helping our buyers better understand our products and the quality associated with the U.S. brand, and how to use those products to build better food systems in their countries.

But, increasingly, as we work overseas, we've seen as other countries began trading that our focus of trade capacity building has really been on

helping governments understand our food safety systems and build their capacity to participate in the world trading system. And so the core of this training is building capacity to implement a reliable system that ensures food safety both for their consumers, but, importantly, for their trade.

Where trade was once dominated by grains, corn, wheat and other products, I think this next slide shows that we've seen trade increasing along all product lines. Increasingly, we are seeing fruits, vegetables, meat products, dairy products, and all of these products tend to have more regulatory implications along with them.

And we've seen global agricultural trade increase 250 percent over the last 10 years. It was estimated at 890 billion last year with really no change in sight.

By 2021, economists project that global agricultural trade will top $1 trillion.

The United States, of course, is participating in this trend. Last year, U.S. farm and food exports reached a record $137.4 billion, up 26

percent from the previous year because we've done a great job at FAS. But we're also seeing the increase in imports into the United States. We're following a similar trend.

They reached a record 94.5 billion last year and projected to rise to 106 billion in fiscal year 2012, a 14 percent increase.

So this is great news for the sector and for the rural communities and the jobs and the benefits that they reap from this trade. But it also points to the increasing need for cooperation among countries to ensure that food is safe and wholesome when it is traded across borders.

We really believe that to continue to realize the economic benefits of agricultural trade, nations really have to work together to build robust food safety systems based on science and on international standards. And these science-based standards can provide a global benchmark for best practices in production and trade of food and agriculture.

The U.S. has committed to developing standards and guidelines based on science and working

through the Codex Alimentarius, World Organization for Animal Health, and the International Plant Protection Convention.

The health and food safety standards of these organizations serve as key reference points for us, but, more importantly, for countries that really don't have the means and the capacity to do the scientific studies and investigations that are necessary to set the standards and enforce those standards.

And I think this commitment is really reflected in our -- this international obligation is reflected in FDA's comprehensive efforts to ensure transparency as we go through this process of implementing FSMA. And these efforts we see as being very consistent with our obligations on the international trade farms through the WTO.

And, as was mentioned, the Congress mandated capacity building in this law and we really applaud Congress for including this in the law. And I think this meeting today really demonstrates the commitment FDA has to developing a comprehensive plan, one that

our international trading partners will understand, and will give them an opportunity to participate and to feel that the system is fair and provides opportunity for them to continue in the trading environment.

So let me talk just a little bit about some of the work we've done over the past 25 years, I guess, in our capacity building efforts to help developing countries strengthen agri institutions and regulatory systems and encourage them to adopt international standards that will allow trade to flow more freely.

USDA, we think, one our great strengths is the experience we have in regulating commodities and food products and building regulatory systems. And so this is where we really focused with foreign countries to try to impart our capacity-building instruments to other governments.

We've employed various approaches and targeted technical policy and regulatory levels. We've done approaches based on bilateral and multilateral approaches, and doing things such as needs assessments for countries, auditing of facilities, hands-on training in factories and fields, train the trainer

activities to broaden the scope of the populations that are fluent in food safety systems, and technical exchanges where they come and work in the United States or we go over and take people to their countries to help them build a better regulatory system.

At FAS, we employ the expertise of officials from around the U.S. Department of Agriculture, such as including our food safety inspection service, the animal plant health inspection service, grain inspection packers and stockyards, administration, and the agricultural research service, of course, along with our counterparts in the Environmental Protection Agency and Food and Drug Administration who enable us to deliver high-quality capacity building.

We work also with FDA and FSIS to implement the Codex outreach efforts that promote the science-based standards and fair trade practices to improve consumer safety around the world, and to strengthen bilateral relationships with food safety officials, veterinary officials, which really in the end these kinds of associations between our officials helped build the confidence of the systems.

Also, we've been holding regional colloquiums for a long time to help them understand the Codex process, to participate in the Codex process, and to understand how they can implement the Codex standards in their own countries.

We've also worked with APEC, which was mentioned earlier. We've primarily focused with APEC's countries on improving their laboratory capacity so that they can test products as they leave their country and test products coming into their country to ensure that they meet the standards of their trading partner.

Last year, a regional workshop in Bangkok, Thailand focused on increasing this laboratory capacity for governments, academia and institutions, and feedback from that workshop led to the decision to expand additional workshops in Peru, Malaysia and Vietnam.

These will provide hands-on practical laboratory training which is designed to enable participants to pass their knowledge on to others in a train the trainer type of effort.

We are also working through the African

Growth and Opportunity Act, AGOA. This act provides duty-free access to sub-Saharan Africa countries and a framework for technical assistance to countries to take advantage of their trade preferences under the act.

We've worked closely with them to foster a more prosperous and open environment and help these countries improve their policy and regulatory structures. And it is an advantage for them coming to the United States, but, more importantly, these efforts are really giving Africa an opportunity to integrate within Africa and provide more opportunities right there at home.

We currently have advisors in Kenya, Senegal, and South Africa located in partnership with the U.S. Agency for International Development and these advisors are providing day-to-day information and requirements for exporting and competitor information to help them develop their ability to export to some of the global regional markets.

In recognition of the importance of increased trade and the role capacity building plays in

developing countries, the United States has now included a trade capacity component in every one our free trade agreements that's been implemented since 2004. 2004 was the CAFTA agreement between the Central American countries and the Dominican Republic. Other trade agreements that have followed include Columbia, Peru and Panama, and in all of these, we have committed to helping these countries be able to really take advantage of the full possibility of the agreements that they've entered into.

And so under CAFTA, we've led diagnostic training from National Testing Laboratories and at strengthening National Animal Health Laboratory's ability to meet U.S. and international standards, and in the diagnosis of animal diseases really something vital to the agricultural health of the hemisphere and also to the food safety for human consumers.

So I think all of these efforts and many others demonstrate the web of food-safety capacity building that we've been weaving across the U.S. Government and with our private sector partners.

Our experience indicates that there is a

willingness and an eagerness to build better systems for food safety and to meet the standards that the U.S. is putting in place. What they ask is just that they get an understanding of these systems, and that we understand the limited capacity and help them build that up.

I think that our challenge is to impart this knowledge on food safety in a way that is sensitive to their needs, a little bit of time to adjust, but to really mostly just understand what it is we're asking of them.

So I would like to thank FDA for the great job they're doing to encourage all of the stakeholders to develop a comprehensive plan to build capacity, and to understand and comply with FSMA. It's a big task, but I think we're off to a really great start and we stand ready at FAS to use our attaches around the world to help them find the partners that they need to find and implement FSMA in a way that Congress and the American consumer would like to see this done. So thank you very much.

(Applause.)

THE PUBLIC HEALTH FOOD SAFETY IMPERATIVE DONOR PERSPECTIVE - BRIAN BEDARD, LIVESTOCK AND FOOD SAFETY SPECIALIST, AGRICULTURE & RURAL DEVELOPMENT, WORLD BANK

MR. BEDARD: Thank you very much. Before joining the bank, I lived in China for about 12 years, and you can imagine I was raising three children there, very concerned about food safety, as you can imagine, so we went through this elaborate process of working with some other families to set up an organic farm with greenhouses, so we were growing our own vegetables. We only fed our children imported milk, and I happen to be a veterinarian so we were able to obtain meat at source. So we were fairly comfortable that our children were eating safe food until one day I came home early and there were my two middle school sons standing in front of one of the street vendors gobbling down these meat sticks. You've seen that, right? We had gone through all this process.

Obviously, they were reprimanded and they said, "But, daddy, it tastes so good and they're so cheap."

(Laughter.)

MR. BEDARD: And that's the problem we have. Where the rubber meets the road, people want affordable food that's safe and it is very accessible. And that's really what we're -- I'd like to talk to you about today what the bank's trying to do working together with FDA and other partners to try and address these issues at the grassroots level.

The World Bank is essentially a development institution, a development organization with a banking license.

Deputy Commissioner Taylor already described the situation in Ghana. We can multiply that 100 times over or more in many of the developing countries, which are the client countries of the World Bank.

So why is the World Bank interested in food safety? Well, we believe that in terms of the agriculture and rural development agenda of the World Bank food safety is one of the key drivers, the key drivers for public health and nutrition, one of the key drivers for market access for the millions and millions of small holders and households that are reliant upon

agriculture in these rural communities that we're dealing in that affects the national economies of many of our client countries, and the other issues that I'm sure all of you are very familiar with that become a priority for the bank.

But the primary priority for the World Bank is poverty alleviation, that's our main driver, and we believe food safety is an important part of that.

It's interesting, we talk about the tipping point, and I think in the last year to 18 months there's been a convergence of interests, of initiatives and a number of activities globally that have come together in a very timely arrangement. The Bank was approached a year-and-a-half ago to take some leadership role being that we are recognized as being somewhat of a convening agency in terms of bringing diverse and vested interests together.

And the main driver behind this has been this critical food safety capacity building need that we've seen globally. On top of that when you talk to exports around the world, the sense we're getting is a consensus that probably 60 to 70 percent of what's

needed in terms of training in capacity building is already available out there, but there is a need for harmonization, quality control, some refinement, and an urgent need to accelerate delivery of these training materials throughout the developing world especially.

So the Bank was requested by a number of donor agencies and international agencies to come together and assist in this effort. We now are working with them to develop what we call a public/private partnership, including many of the international organizations, the WHO, the FAO, the OIE, UNIDO, International Finance Corporation, and many others, including the private sector. And we believe that the private sector is a very important partner in this.

Safe food is made by the private sector. Governments don't make safe food, but governments have an important role to play. So we think this public/private partnership is a very unique opportunity to consolidate the resources and drive towards the safer food globally, and especially amongst the developing countries.

I'd like to make a point here that this

global food safety capacity building partnership is not a standard setting organization. We really do not want to get involved in standards. It's about training and capacity building, and training towards the standards that our colleagues here from the Foreign Agricultural Service have already outlined in terms of those standards under the Codex Alimentarius, the IPPC and the OIE. So really what we're talking about here is a training and capacity building partnership.

We've also, very luckily, have had the experience of the APEC PTIN program, the Food Safety Cooperation Forum and the PTIN that Mary was describing for you. They've already started the work. It's not as if we're starting from the beginning. There's some very exciting things that have been done in APEC, and as she had mentioned, the World Bank and APEC have signed an MOU to get started. This mobile program now is going to build on that and scale it up and extend it out globally.

Okay. The bank doesn't want to own this. We've been asked to be the driver to try and put it together, and that's our intention. We actually do

have an exit strategy, we hope. After five or six years, we expect to get out. The objective here is to create an entity that will be stand-alone under a unique business model, under a public/private partnership that I will describe to you.

So what we've done initially working together with the APEC colleagues and other international organizations, we've developed a very specific five-year work plan, that will be in the public domain soon, that is very specific in terms of what we're going to do building on the APEC PTIN program, but rolling this up globally, and I'll describe this to you shortly.

Essentially, when we talk about food safety capacity building, and I think in some ways using the words capacity building is an unfortunate term. In the many developing countries that I work in, when they talk about capacity building, in the translation, they're thinking about laboratories and facilities and the hardware and the civil works that go along with that, when really what we're talking about is the soft bits. We're talking about training people, technical assistance and building up those technical resources

that they can actually use the facilities to their best effect.

When we talk about this kind of training or capacity building, we look at it at essentially three levels, and that is we want to look at it at the government level and interventions that our USDA colleagues and FDA are looking at. How do we get involved with governments in terms of looking at their food laws, their veterinary laws, the legislation, enforcements, and how the secondary legislation is drafted and put in place to align with those international standards and what can we do at that level.

The second level is really at the organization level. So that would be within a given government department or organization or within a given enterprise, and how do we address the various constraints and gaps at that level.

And the third level is really how we get people to change their attitudes and behaviors. This is at the individual level, and this is the most difficult part, how do you get my sons to stop eating

that street food? Two of them are still living in China, and I'm sure they're still eating that. They're grown men now, but I'm sure they're still eating that street food.

So how are we going to do this? I'd like to outline for you this five-year work plan that essentially has three components to it. As I mentioned already, the first component is really going to be driven by what's already being done under the APEC PTIN program, and those have already been described a little bit.

They're focusing on a number of technical areas. The programs are already in place. I'll give you one example; there is a program that they just completed in China that was developed from the initial round of discussions on HACCP through APEC, and over the last six to eight months a group out of Michigan State University has developed that into an E-learning module. So what they did is they developed a set of modules over the last month in Chinese. A number of 40- odd Chinese participants from government, private sector and academia and others have participated in

this training program online and then they moved from there into a residential program in Beijing over a 10-day period where they actually did in-plant HACCP programs and plans, interesting enough, using many of the GMA partner companies and their factories and processing plants in China. So that's a very unique partnership. That program is now being scaled up. We hope that, as you heard earlier, Cornell and Shanghia Jinjiang Tongji University will jointly replicate that program. It's being translated into Vietnamese, Chinese, Russian and Turkish to be scaled up and rolled out in these countries in the appropriate institution as an E-learning program, probably using MSU IT platform, but delivered in the local language, and, again, with the residential program. So that's just one of many -- one example of the many kinds of programs that we're working on now to scale up.

The other part I'd like to mention here is this on-farm quality assurance. And it is one of the things we feel very strongly about because, as I said earlier, that's where the rubber meets the road. You can't make safe food out of contaminated raw material.

And we really need to get at the good agricultural practices, how do we deliver that, and how do we do that in country? And that -- I see our colleague here from GlobalGap sitting there. GlobalGap is one option. There are others that are out there that we need to be looking at how we get at the farm level material because that's what -- you know, the food and produce that's coming into the U.S., the biggest risk you have is how it's dealt with at the farm level.

Let me give you another little example from China. And I apologize to my Chinese colleagues in the audience, okay. I use China because I have many experiences there, but this is not unique to China. We were helping Carford to secure produce to meet their premium standard in China. And I was with one of their sourcing agents, and we were out on a farm in Shandong and we were looking at these wonderful eggplants. They were very uniform, high quality, just what Carford wanted. This wonderful plot of eggplants except we noticed in one corner of the plot, the plants weren't so uniform, there were other vegetables around. And we asked the farmer, what's that for? He said, "Oh,

that's for home consumption." So for his own food, he wasn't putting any of the pesticides, wasn't using herbicides, growth hormones. It's for his own consumption. So they are very, very aware of what is safe food and what it takes to grow safe food. But there needs to be a market driver out there, some drivers that ensure they're doing that.

The second component of this work plan over the next five years is you want to scale this up over at least six regions around the world, and we're focusing on the World Bank regions because that seems to be the easiest way for us to do that for now. That may change over time.

In each of these regions we're going to select two or three focus countries who can be champions and we're going to go through the whole process from the national level requirements and GAP's right down to the farm level in two or three countries. And we may seek your feedback from some of the partners here in the audience on how we select those particular countries.

But the core of this program is the open

educational resource platform, and I'll give you a couple of examples of how that's going to work. This is going to be a very sophisticated IT platform where the resource materials, regardless of what is needed, will be available as open source free access materials.

The 60 to 70 percent of the material that's available will be put up there, new material that's needed will be developed as we go along.

I've already mentioned to you the HACCP program - that will be one of the first things to go up there. I think our colleague from GMA mentioned this academic curriculum. We have at least nine institutions around the world and the U.S., in China, Australia, New Zealand and Europe working on a global food safety curriculum framework that will become somewhat guidance for universities that want to follow a standardized curriculum that we will then promote through this platform.

Again, the information systems we're working with are the international organizations. The WHO's INFOSAN program, how does that fit with the information system in APEC? How does that fit with the EU'S

program for rapid alert for safe food and feed? How do they all fit together? So were going to try to align some of these programs working together with the government partners to ensure that there's a rapid alert system out there and traceability system globally or at least regionally if we can get started in that area.

Another example is risk analysis. I've heard several people talk about that. One of my experiences has been in dealing with bilateral negations, often you'll get two countries sitting at the table. They've both done very scientific based risk analysis, but they've come to different conclusions. We're having discussions with the FDA and our colleagues here in the APEC, U.S. Government, as well as Australia, New Zealand and others in the WHO, which has some very good risk analysis frameworks to try and align the risk analysis approach and do that and then institute that through better training and capacity building in many of the countries we will be working.

I'd like to give you -- I don't expect you to read this slide. Please go ahead if you think you can.

This is just an example that was actually developed for the FDA by the International Food Protection Training Institute in Battle Creek, Michigan and it's a very good framework that we can share with you at some point, or they can at least. It's developed for the FDA from sort of entry level down here, certificate programs right through to somebody who is a career manager. And we've actually used this framework. It's been very well received -- It's been translated into Chinese, Turkish. We're working on Russian right now -- as one way to look at how to develop -- for governments around the world, how to ensure that they have qualified regulators and inspectors in the system. So this is one example of how the FDA, for example, can share their experience and expertise and use this kind of program to adapt it to local needs.

How will this Global Food Safety Partnership work? Well, essentially, there's going to be a secretariat at the World Bank with a limited life on it, we hope, that will be used to establish a multi-donor trust fund. There will be an annual partnership open meeting that's very inclusive. It will not be

exclusive, and then there will be a group, set of working groups that will address many of the technical and management issues that will be advising this partnership.

Who's going to pay for it? Well, we already have a million dollars in it that we would like to thank Waters Corporation, Mars and the USAID. The World Bank is putting in $1.2 million into it. And there's a multi-donor trust fund in the order of $42.4 million to do all of these things that are outlined in the work plan.

I'd just like to put this in perspective, however. I'm working -- I do a lot of work in Turkey where we're helping them to prepare for their food safety programs for accession to the EU. Their three-year program for food safety training and capacity building is already at $25 million for one country, for Turkey alone. And that's just a tip of the iceberg. So we're starting with $42 million because we think that's reasonable and we can manage it in five years, but the scope and scale above what we're talking about here today in terms of financial requirement is in the

billions. I think we need to appreciate what the scope of all we're getting involved in here, but we're going to take some little baby steps first, we hope.

The stakeholders, we've tried to divide them for the sake of identifying who they are into three groups. Those are the partner organizations, the international organizations, the governments and the donor organizations that will be working together very closely to drive this thing forward.

Then there's the beneficiaries which would be the government and the recipient countries, it could be companies, it could be the farmers themselves, so there's a whole group of beneficiaries, and then there's that whole group of service providers. It could be universities, institutions, consultants, whoever they are, the FDA staff and the laboratory trainers so on and so forth, that would help to deliver this program.

I mentioned earlier that it's going to be delivered regionally. We're going to focus initially on the World Bank's regional areas that are outlined here. We already have a network of people, what we call

task team leaders or managers in each region who have been nominated and identified to drive this program.

The World Bank already has a set of projects in each of these regions, many projects that have food safety components in them. We also know USAID has projects in these regions. The other international financial institutions and donors have projects in these regions. So what we're going to try to do is use this program to leverage some of these other resources and bring them together in terms of driving towards this Global Food Safety Partnership.

Hopefully what we're going to achieve through this process is an improved food security and contribute towards food security, economic growth and reduce poverty. That's the World Bank's drivers. I know FDA has some drivers and other interests have other drivers as well, and that's fine. We need to try and bring those together and align them. And we think that the World Bank's objectives very much align with FDA and the U.S. Government and other donor organizations.

Again, looking at supporting improved safety

systems, market access for small holders around the world. We're going to deliver this five-year program for training and human resource development, and very much under this private/public partnership we've talked about, which I would assume includes most of the people here in this room today.

Thank you very much.

(Applause.)

MS. BREWER: Thank you. Steve?

THE UNIDO PERSPECTIVE - H. STEPHEN HALLOWAY, SENIOR ADVISOR, UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

MR. HALLOWAY: Thank you, Camille.

Commissioner Taylor, I'd like to thank you for the opportunity to represent UNIDO. My expert colleagues who are headquartered in Vienna, Austria - I used to say Vienna, but then everybody thought I was taking the orange line to the meeting - they are in the field and unable to join us. And so I am going to deliver their brief, so apologies if I read a little bit because I want to make sure I get their points of view across.

Unlike Sue, I know that most of you have never heard of the UN Industrial Development Organization, and I'd like to just take one or two minutes to describe who we are and what we do. We are one of the specialized technical agencies of the UN, the only specialized agency whose mandate is to work with the private sector on industrial development. We have programs in over 100 countries promoting and accelerating sustainable development and in developing countries and economies in transition.

Our projects agency-wide, we're in 100 countries. The map that you saw on the World Bank regions is very much where our programs are.

We are also the only UN agency and maybe even international organization that's headed by gentlemen, Kandeh Yumkella, from Sierra Leone, who has a Ph.D in agricultural markets from Illinois. He studied at Cornel and he taught agricultural marketing at Michigan State. So for us, it's the boss who knows more than we do. He's very, very dedicated to this particular program from his experience at the village level. And so for us it's not just another book of activity, it's very much

part of the DNA of our organization.

The three areas that we operate in, poverty reduction through productive activities, trade capacity building and energy and environment. We're about 40 years old in doing these projects.

Part of our thematic areas in trade capacity building, and which brings us here, are not only SMEs, which we are focused on, modernization of export-oriented agricultural industries, but also standards, metrology, testing and conformity.

There are three or four key points that I'd like to make first, and then I'll go on to follow up on two or three of them. One, UNIDO is on the ground studying quality, food safety capacity in developing countries who export to the U.S. and the EU. Our capacity building programs are coordinated with the FDA and USAID capacity building work.

We use FDA and EU rejection data as an input to the design of our interventions. Our work with the private sector retailers is unique in developing food safety compliance at the supplier level.

Let me take a couple of minutes on how we

work with the rejection analysis with FDA and EU data. Our view, countries must have marketable products to trade. We developed a tool where we can extract data on rejections of countries exporting to the USA and the EU.

Our report - Trade Standards Compliance 2010: Meeting Standards, Winning Markets - focuses on filling the significant gap, the challenges faced by developing countries in complying with key trade-related standards, technical regulations and private standards in international trade.

It estimates the resulting export losses and then relates these compliance challenges and losses to an analysis of developing countries' capacity to establish and prove their compliance, and the cost of strengthening such capacity. And I think you heard the costs are not insignificant.

The study looks at patterns and trends in border rejections, and they clearly point to sectors and products where the real compliance challenges lie for developing countries. They also reveal the reasons for missed traded opportunities when exporting to the

EU or the U.S.

And example -- and I'll give you this, the site if you want to download the report: it's 180 pages, www.unido.org/tradestandardscompliance, all one word. That's the ad for the report.

One example is Indonesia, and we looked at for both the EU and the U.S. fish and fishery product, fruits and vegetables, herbs and spices, nuts and seeds, one side. 2002 to 2008.

And then we looked at the reasons for detention and those reasons, unauthorized food additives, labeling, unregistered process or manufacturing, filthy or unsanitary conditions, micotoxins, microbiological contaminants, product composition, biotoxins, veterinary and drug issues, heavy metals, and we then are able to assess by percent which of these factors created the detention.

In doing that, we then considered precisely what kind of program we need to do in that country, and that's the value of that particular tool. And I think in terms of what have done is a rather unique tool. Our food safety work in the field is an integral part

of our overall programs on building national quality infrastructure. That includes standards, certification and accreditation. And we do this in a variety of ways, as I said before, depending on the country. We have a matrix of interventions based on the tool I just described.

The framework we use -- I should say our pipeline looks very much like the World Bank areas. We have a framework that we rely upon; it's called three C's. I love it when we can come up with something simply like that. Competitiveness, conformity and connectivity. Competitiveness on the supply side, conformity with market requirements and connectivity to the market. How do you get the products from here to there?

Through developing capacity, enhancing capacity to meet those standards, upgrading the conformity assessment capacities, strengthening export promotion activities, promote business partnership and trade agreements, and streamlining Custom's procedures.

And throughout that process, it's a partnership. We can start here, but at every step, you

better have a partner to help not only regulate, but get these products to market and exported.

A couple of examples of projects and some of it kind of has been mentioned before. But Indonesia, for example, we were working with the fishery sector. And here's some of the areas that we looked at. How do you institutionalize the public/private sector dialogue in the fishery sector? And that includes civil societies, by the way. Civil society organizations in the villages. How do you strengthen local business support services to the SMEs in the fishery sector? Developing a master's level education program and productivity in innovation for fisheries, establishing a traceability system for fisheries and other maritime products, accrediting national certification capacities and then trade promotion of Indonesian fishery exports to key markets.

In Pakistan, it was a little broader. We were looking more at global supply chain requirements. We focused on the fishery sector and horticulture, particularly mangos. In the private sector, we are

working on quality hygiene issues, management systems, good practices, compliance with market requirements, pilot certifications, HACCP, ISO 14,001, SA 8000, pilot traceability systems, codes of good practice, better linkages in the global supply chain. That's how in-country we approach various projects.

In implementing, we work with the private sector. You have to. We principally work through the global food safety initiative with whom we have been working since 2009. We developed and implemented a training tool kit for GFSI, basic and intermediate level code. This has been translated into Arabic and Russian. The companies we have partnered with, Metro, the large German retailer, and it was a very specific project. Our first project was in Egypt on traceability to European standards. I have some more information on that. And we've since expanded our work with Metro.

AEON in Japan with retailers in South Africa. Again, building capacity on the GFSI food safety global protocol. Our partners, and, again, this is a partnership. It has been described before, FAO, the World Bank, and, of course, Michigan State University.

I've got to mention that. The boss would not want me to not mention that. And they've been very good partners. There is also Segars from the research institutes that we've been working with.

So this brings us to where we fit in. We believe our work tracks many of the elements set out in the proposed plan, including training foreign governments, and food producers, and suppliers on U.S. requirements. We have developed tools. We can extract data on rejections and pinpoint where the need exists on capacity building. We maintain good working relationships with our member governments, they own us. They listen to us as with the World Bank, we've become an essential part of -- when we walk in the door, there's a level of trust that we really are there to help them export.

We work with the bottom billion. Our job is to help them improve their economic standards, and that means products to export. Of course, we work with the private sector because that's who is buying the products. We work with civil society because interest in country requires that all stakeholders are

represented and points of view are taken into account.

That's our real comparative advantage - is we can work in any country in the world, with any government, with the private sector, and the projects we've developed have proven that, but we're small. And that's where partnerships come in. We can create and do small projects, which is what we do, and then the tools that we've developed have to be taken and scaled up.

We look forward to working with FDA and all stakeholders in developing the international capacity building plan and the extent to which I've been briefed by my experts, I'll be happy to take questions during the Question and Answer period. Thank you very much.

(Applause.)

MS. BREWER: I would like to thank all of our panelists for those stimulating remarks. So now it is your turn. I'd like to open the floor to questions and comments. Everyone sitting up here is fair game, so, please. The microphones are in the middle of the floor, so we welcome your questions and comments.

I would like to say that Curtis is here, our

press officer. Could you stand up so we could see you?

MR. ALLEN: (Complying.)

MS. BREWER: Also, I see Dr. Linda Tollefson in the audience. She's our Associate Deputy Commissioner for Foods at FDA and Roberta Wagner, our Assistant Commissioner for Field Operations.

QUESTIONS AND ANSWERS

MS. BREWER: I see Caroline Smith DeWaal, first question, please?

MS. SMITH DeWAAL: There is always the tension between the public health objective and the trade objective. I thought it was really well-illustrated with your panel with little exception, the concept of public health and food safety were not really represented on the panel. And really -- our consumers, the people who will actually be consuming the food, in a way are the tax for whether at the end of the line the food is safe. So I really would like to challenge each of the panelists to talk about where the consumer fits into the framework. I think Dr. Halloway did mention civil society organizations in the country where that

organization is working. But I would really like every one of your panelists, maybe starting with Dr. Halloway, to talk about where consumers fit into that framework. Thank you.

MR. HALLOWAY: Do you want us to go by one?

MS. BREWER: Yes. And you can use the microphones there on the table.

MR. HALLOWAY: An example I'll give you is the work we do with Metro in Egypt. Metro wanted to expand its supermarkets into the country. They have proprietary brands. Those brands have to be up to standard to put on their shelves for the consumers in that country. They came to us. We worked with the global food safety initiative guidelines and we gave courses right at the farm level, to the processing level.

And I'll give you some statistics to show that this is rigorous in terms of the food not only going into supermarkets in Egypt, but what gets exported, in this case, to the EU for the most part, to the EU standards. In 2010, we gave a basic course. There were 18 suppliers. In the first round, 33

percent passed; 67 percent failed.

In the second assessment, 78 percent passed; 22 percent failed. Now, what does that mean? That means that Metro, when they hired either at the producer level or at the processing level, if you didn't pass, then they didn't use you in terms of getting that food into the supermarket.

In 2011, there were 25 suppliers; 38 percent passed; 62 percent failed.

The second time with more training, 71 percent passed; 29 percent failed.

This is not a slam dunk. We just don't go in and give you a pass. This is not what they used to call the passing C. Standards are high. If you don't pass, then you don't pass and at the farm level or at the processing level. That means a lot. For a supermarket chain like Metro, if you can't sell your products, you are not -- you're just not going to be able to export those products.

The same is true in Russia, the Ukraine, India. Pass rates first time around are 10 percent, maybe 20 percent the second time around.

What that means is that there's a lot of work to be done in the field, but it also means that the consumer, at least through our certification system, is going to be assured that those products meet stands. To specifically answer your question, that's where the rubber hits the road. It is the rigorousness of not only our training, but training the trainers to make sure that that process continues. We're a small outfit. We've got to rely on training the standards and certification officials when we leave a country that they can continue this, the standards. And, of course, that's always a challenge too, but that's more than my two minutes. I'm sorry.

MR. BEDARD: Thank you. If I understand correctly the question is about public health and food safety and how that's being incorporated in this partnership.

MS. SMITH DeWAAL: Can you give us a little groundwork how you are incorporating the views of stakeholders including consumers?

MR. BEDARD: Yes, okay. I think we go to the

bottom line here, depending on whose numbers you use, people quote between 250 or 300 million cases of foodborne illness every year. Two-and-a-half to three million people die of foodborne illness. So, you know, the outcomes and actually the performance indicators for this Global Food Safety Partnership, they will have public health indicators in it, so they will have to show that we are actually reducing these cases of foodborne illness and deaths, particularly in developing countries. I didn't go through all of the details of what we're involved in. There will be some economic analysis that we will look at, not only the trade issues, but the public health impact probably incorporating some evaluation of dailies (ph) or something like that and how that affects public health.

The WHO and ministries of health will be very involved in this whole process at the global level of WHO and you can be assured that they're going to keep us on track as far as public health and food safety issues are concerned. Within a given country, we want to ensure that the ministry of health is involved, as well.

And then in most of the countries, the approach we're proposing to use is in addition to the government interventions and training in the government sector is to very much take a value chain approach from farm right through to the consumers. And included in that set of activities will be public awareness, consumer awareness and communication strategies to show consumers what the issues are around food safety, personal hygiene, all of those issues that go around better practices in the kitchen. So there's a whole string of things that fit into this work plan that we hope -- so the training programs will include consumers in terms of not only cooking practices, but buying safe food, labeling, all of those issues will go into these training programs. Thank you.

MS. SMITH DeWAAL: How do you incorporate the two?

MS. HEINEN: I'm a little afraid of this. I think as a couple people mentioned, really the whole system is driven by the consumer and while we're focused, you know, on the trade aspects of it, the consumer is fundamental to the whole system, and we

very much believe that if we're not producing a safe, wholesome product, we're not doing our job. So for the American consumer, and, I guess, as USDA as a whole, we spend a great deal of time working with consumers, talking with consumers, educating consumers on safe practices, but also with our foreign partners we are focused on making sure that the products that they are bringing to our market are safe products and we work with those governments to help them understand the need for that. And I would say with the companies, as well, who really don't want to get caught in a situation where they're exporting and they lose their market because they haven't met our standards. We do meet extensively with consumer groups and incorporate those thoughts into our plans.

MS. SOPHOS: And I would just add that for GMA companies the investment we make in food safety is all about delivering safe food to the consumer. To the extent we're involved in helping inform around international standards and best practices, these international standards derive from public health agencies that talk about Codex and talk about LIE,

IPCPC, these are -- these emanate from a public health purpose. So we didn't make the standards, we adhere to what we can add and bring value in terms of best practices as well that build on those standards. So, again, it is all about the consumer as far as our companies are concerned.

MR. TAYLOR: Yeah. I guess from a FSMA and a FDA implementation standpoint, I think it's pretty straightforward that consumers are at the heart of it. They're the driving motivation for, you know, a law that is intended at its core to be more effective in preventing foodborne illness. And one of the many dramatic shifts that FSMA brought in terms of FDA's accountability is a shift from a law that simply gave us a few tools to go out and seize adulterated products, but no mandate in particular from a public health standpoint to having an explicit mandate and accountability to reduce foodborne illness. And that's manifest through many provisions of the law. And so we're implementing it in a way that's calculated to do that, and I think, as you know, Caroline, with a lot of engagement, very essential engagement from the consumer

community and the implementation process for those of you who don't know, Caroline does, we meet monthly with the Safe Food Coalition, which is a coalition of consumer groups that are involved in food safety.

I think capacity building is as prime a topic as any for that discussion and that input, and, again, the ultimate test at the end of the day is do we reduce foodborne illness and do we meet the public's expectation for assurances about food safety to give them confidence when they go to the supermarket to buy fresh produce and other products, they do it without undue concern about food safety. So, yeah. Thanks for the question.

` MS. BREWER: Thank you. We have a question. Please introduce yourself?

MS. BUCK: My name is Patricia Buck, and I'm with the Center for Foodborne Illness Research and Prevention. And, first of all, I thought the panel was excellent, very good. One of the things that really struck me was the comment by the World Bank, and I think that was the one that said that we needed to have more accelerated action with regards to food

safety. I very much agree with that statement.

So given this great need to accelerate action, what are the key barriers to implementing FSMA or to building the global network? I believe we need both of these if we're going to meet the challenges of the various foodborne illnesses that could be facing us in the remaining part of the century. So I would like to hear from any of the panelists on that issue.

MR. BEDARD: Thank you very much. What are the main barriers? Well, being that we're a bank --

(Laughter.)

MR. BEDARD: -- that's number one. We need the money in the multi-donor trust fund, to be very frank with you, okay. The second thing is resources. You know, we're trying to move this along and just to find the people that can deliver this. This is our problem. And there are a lot of -- just like what you're trying to do in the U.S., for example, deliver what you need in the U.S. You're under-resourced here. That's my understanding, at least.

I happen to be Canadian, by the way, and I've tried to be informed, living here and trying to eat

safe food. So you're under-resourced here. Can you imagine what it is in developing countries? So now we have to draw on where do we get the resources to do this work? And the approach that we're trying to do to accelerate this, for example, is -- and the two examples are China and Turkey. For example, in Turkey we're trying to get the capacity built up so that Turkey then becomes the jumping-off point for the rest of the region, Central Asia, other parts of Europe, the Middle East in the appropriate languages, and there are people in Turkey that could probably do this, but they need to be trained. The capacity needs to be built there with this HACCP training program or whatever.

The same thing in China. You know, China has its own problems. Where do we find the resources to deliver these programs? And I don't have a good answer for you. We're trying, but I think if we had the money in place. We're beginning to identify who all the service providers are who can deliver these programs.

We're working with UNIDO and the IFC on the private sector side. UNIDO actually has a very good

program and they're moving very quickly in delivering these programs to their private sector partners as is the IFC. So there are a bunch of players out there. What we hope to do on this Global Food Safety Partnership is to identify who the service providers are. Where are the good universities? Where are the good consultants? Where are the good advisors? You know, how many FDA or USDA people can we take down to these -- well, I shouldn't say down, that's not fair. I apologize -- take to many of these other countries to actually do the training and make sure the capacity is built there?

Yeah, we're going to do it as fast as we can, but those are the barriers as I see them. Thank you.

MS. HEINEN: I think that, as I had mentioned, there is no lack of interest on the part of other countries to undertake this and to get more training, but the resources are a problem, and then moving it from the level of the regulators and the big companies down to the entire system in other countries will be a challenge.

MR. BEDARD: One more comment here. The

other thing is commitment and understanding in the developing countries as to what these issues are and how critical they are. And I think that goes back to the public awareness information and advocacy that we need to be doing as part of this to get our client countries fully engaged in changing their food safety practices.

MR. TAYLOR: I would be remiss if I didn't echo the resource problem, but it is far more than FDA's budget. We have budget needs, of course, and we're not shy about it, but I think, you know, Brian's point about this being a billion dollar problem is very real. And to me this is where the importance of this meeting and similar efforts come in to really be strategic about what we're trying to achieve, modalities for achieving it and then having that be widely understood so that we can make this as an inclusive an effort as possible. What you're seeing, and I think by having trade-oriented folks here, I mean the reality is that there are a lot of different motivations for building this capacity. We've had FDA come at it from a public health standpoint.

That's our job, food safety. But the motivation to invest in this comes from different quarters, from a development perspective, from the success of the food system from an industry perspective and so I think we have to be very inclusive about the process of planning efforts and targeting efforts and defining what the needs are so we can bring as many interests in as possible, including developing country governments which have very scarce resources, but also have to -- you know, have to engage. So that's my strategic kind of framing of this so that we can be inclusive and leverage the resources of all the many folks out there who have a stake in this coming at it from different angles. I think that is the only way we'll get to the resource level that Brian's talking about.

MS. BUCK: Mike, this is Pat again. And I was really kind of interested in how FSMA is moving along. And right now we have not met some of the deadlines for the preventive control implementation. And I think as a world leader, everyone is looking towards the United States to see what's

happening. So I was wondering if there were any particular barriers for that?

(Laughter.)

MS. BUCK: Is that an inappropriate question?

MR. TAYLOR: No. It seems like a simple question, but I think -- There's a lot that goes into successful implementation of FSMA. The work we are doing here today is part of it. A lot of systems building work were doing within FDA to develop the programs that relate to imports whether it's credited third party or VQIP or, you know, developing capacity to oversee the imports in a fundamentally different way. Our state capacity building in partnership with our state partnership, leverage those resources. A lot of work going on there. And the rulemaking is a critical part of it. I think everybody is well aware of the status of the rulemaking. There are some key proposals that are under review and pending clearance at the Office of Management and Budget. And that's where it stands.

MS. DAWSON: Do we have time for one more?

MS. BREWER: Yes, we do indeed.

MS. DAWSON: I would like to actually add another line to this process because I think we live in such an exciting time with electronic health records. It cannot be only the United States, but becoming global - so that we can look at that as a rapid response method from a health aspect of it in order to communicate with organizations such as the FDA in each of the counterpart countries. So one of the things that I want to make sure that we consider looking at continuously is the fact that in one country, which is kind of neat, we're kind of the introductory team -- here from the United States -- that kind of curls your toes a little bit. However, that's probably a totally socially accepted food item somewhere else. And so we need to look at the standards so that they include those types of things that we don't necessarily consider food in our culture wherever we are making this decision to include those types of food or whatever it is that's going to go somewhere else. And so each of you in your capacity, and I see some of you that are already reaching those community-based businesses to do those things. I would encourage you

to continue, and as you go through this, include that in your comments and considerations when you're looking at new capacity building.

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

MS. DAWSON: I apologize. My name is Laura Dawson and I'm an educational -- nutritional educational and I'm training traditional medicine. So I teach a nutritional protocol at universities and hospitals.

Thank you.

MS. BREWER: Thank you. Any comments?

MR. BEDARD: There is a little bit of a reality check that we have to be aware of here. I'll give you a couple of examples. In Romania before they joined the EU there were about 12,000 food processing companies. There are now about 1,200.

Poland had the same experience. Okay.

Now, we go to -- take Turkey, take China. Turkey has something on the order, depending on who you're talking to, between 50,000 and 70,000 food processing companies. So when we go to this safety

agenda and we start to promote better food practices - what are the rural development impacts in these developing countries? It's a serious concern for us. So we are all promoting food safety, but as food safety gets adopted, we need to be very, very careful about what the rural development impacts are and are there social safety nets and other options out there for the rural communities.

In terms of what I was hearing - and this goes to this issue around standards - one of the things that we're seeing, one of the ways to mitigate this, and a number of countries have looked at this, how do you create not a separate set of standards, but acknowledge that there are niche markets, niche products, unique products that need to be addressed even in a number of countries in North America, in the EU, they allow for this for local markets. So I think we need to look at that as an issue whether it's, you know, traditional medicines or traditional foods of some kind, we need to acknowledge that, and that needs to be built into the system.

MS. BREWER: Thank you. This side.

MR. UNGER: Good morning, my name is Peter Unger; I'm the chairman of the International Laboratory Accreditation Cooperation. I have heard very little about laboratory competence and we're in the business of establishing laboratory competence, and I think it's important to recognize that HACCP-based systems are only as good as the data that's used at the critical control points, and that we are more than happy to participate in FDA's global plan and ILAC is more than happy to entertain a role in that capacity.

MS. BREWER: Thank you. Mike?

MR. TAYLOR: If I could just say, I mean lab accreditation is a mandate of the Food Safety Modernization Act. It's a front-burner issue at FDA in our implementation, and we see strengthening the network of accredited labs, domestically and globally, as being an important part of a system that provides the higher assurance people expect, so we welcome your engagement and glad you're here. It's a very important part of the capacity building effort for sure. We do a lot of training actually with fellow counterparts in other regulatory agencies on lab methods.

I mean, it's very central. So, again, great you're here. Thanks.

MS. BREWER: Thank you. Mike?

MR. ROBACH: I'm Mike Robach and I head up the Corporate Food Safety Quality and Regulatory for Cargill, and I'm also -- for just disclosure, I'm a member of the Board of Directors of the Global Food Safety Initiative. I appreciate all the presentations this morning. I'm also a Michigan State graduate.

(Laughter.)

MR. ROBACH: So I've got a lot in common here. But I really appreciate the comments you all made this morning. I want to make a couple of points just so that everybody is very clear. A lot of what we're talking about is already in progress through the local food supply chain. A number of us -- I have over 1000 plants in 66 countries so this is something that I live every single day. And I appreciate the enormity of what we're trying to do to bring this all together and harmonize.

The other point I'd like to make about this as well is that even though a number of us that

participate in GFSI are large multi-national companies, we operate locally. And, for example most of the products I produce in India, most of the products I produce in China stay in the country. They don't get exported. So this whole idea of bringing together a harmonized food supply chain based on international standards for the improved food safety and protection of public health is something that we believe in, and we want to work with FDA and other governments around the world to make this a reality. And I appreciate the acknowledgement of the global markets program within GFSI. It's a three-step program; it really provides, I think, an outstanding background and baseline for FDA to look at as we build capacity around the world. And we don't need to reinvent the wheel. There are systems out there.I think the partnership will allow us to kind of bring those things to fruition and work better together and more collaboratively together. And one other point, operating around the world. I just got back from a week in Europe spending time in Switzerland at Nestle discussing a number of these issues and then down at

FAO in Rome with IPPC and Codex.

Some of the really important issues are that we have to make sure that this does not become a U.S. centric dictated edict. We have to take into account the global standards. We have to harmonize and we have to work with systems that are already working around the world.

And I know that there's been a lot of effort around that, and I want to applaud you on that, and my only hope is that we continue to do that in a very collaborative way. Thank you.

MS. BREWER: Thank you, Mike. Any comments from the panel. Brian?

MR. BEDARD: Yes, thanks very much for that comment. I just wanted to reassure everybody that under this global food safety capacity building partnership, the private sector, the GFSI is a very key partner to it, the private sectors companies. And, in fact, this global markets program that's been mentioned, we expect that to be an important part of the platform as a resource for companies in this value chain to access. So just to reaffirm the role of the

private sector in this whole program.

The other issue we talk about is international global standards. What happens often, as you've alluded to, is these get interpreted at the national level. So really what drives most of the national food safety systems is their own domestic laws, rules and regulations which is what they will want the global partnership to drive towards, not to some international standard unless there is some bilateral arrangement. So those are the things and the ways we need to refine that to make sure the Cargills and Wal-Marts and the others of the world are meeting their own local standards in addition to what the export requirements might be. Thanks.

MR. TAYLOR: Just from an FDA standpoint, we embrace the harmonization goal. The Food Safety Modernization Act does it very thoroughly, as well, in terms of reference to Codex standards and the expectation. We take those into account in setting our standards. I think you'll find when we do publish proposed rules on preventive controls in food facilities, for example, that you'll see that

we very much feel we're in alignment with internationally recognized principles for HACCP as established by Codex and as is practiced globally.

There are certain elements in the Food Safety Modernization Act that you also see in our proposals, but they're not really in conflict, we don't think, with international standards. We think that's important to comment on that aspect of our proposals.

The other thing just to illustrate is the flexibility of FSMA and its embrace of harmonization. In the foreign supply verification program where the importer has to verify the product coming in has been produced in accordance with standards that are either the same as ours or achieve the same level of public health protection. So we're all building on the same foundation of modern preventive controls to achieve the same level of public health protection, but you don't have to have exactly an identical system. We're always going to have some diversity around the world and so the law is inherently flexible there, and we intend to implement it the way it was intended.

We've also done some work on comparability assessments looking at foreign government systems and coming up with ways to assess whether those systems provide comparable levels of protection when looked at as a whole, not whether they're in every way identical to ours, but, again, all in the spirit of wanting to recognize diversity in achieving a common level of protection based upon common principles of modern science-based preventive controls. So I think we're set up to do this in a way that has the harmonization element that can then draw in the support and the investment and the commitment, you know, the whole bunch of stakeholders, public and private, to make it work. And so, again, I think it's just -- again, part of the wisdom of this law in the United States that it is seeing what we're doing very much in a global context.

MS. BREWER: Thank you. We'll take two more questions. Faye, would you like to start?

MS. FELDSTEIN: Hi, everybody. Faye Feldstein, Deloitte Consulting. Good morning. It's exciting to hear about all the initiatives, some of the

data and measurement that's already going on, the robustness and break up of the efforts being made here. And I understand that we need to lay the foundations where there aren't any, depending on where they are in maturity with training and other efforts.

My question to the panel is, what's sort of your view three to five years down the road when we hopefully increase the maturity worldwide of food safety programs whether it be private sector or public sector oversight for the continued support of that effort in light of the potential economic challenges facing us?

MS. BREWER: The Bank will speak.

MR. BEDARD: Okay. I'm sort of responsible for managing this work plan in the Bank, and if you're going to put two- to three- year pressures on it, that's not going to happen. The reality check here is, we're looking at a 20- to 25-year program. This is not a three- to five-year work plan. If you look at the five-year work plan, and we are really pushing the envelope here, in five years if we get some significant impact, we'll be very -- we'd like to move at the pace

the private sector is moving, quite frankly. And we struggle with that because of government systems. So I think we need to look at over the next five years. We want to make some early-on successes working very closely with the private sector -- that's why I'm saying, maybe two to three governments in selected countries, and that's 12-15 different countries. We may hit on two or three successes.

So let's be a little bit realistic over five years, not two to three years. So we'll have some early-on successes we can hopefully demonstrate in three years, but I think we need to take a longer view. Thanks.

MS. BREWER: Thank you. Kristian?

MR. MOELLER: Good morning. My name is Kristian Moeller; I'm the president of GlobalGap North America. I appreciate all the discussion, and, in particular, I'd like to bring the focus also on the agricultural side and the source of safe food. Particular structures, national structures, farmers, a lot of small farming, this global food supply comes from the small farms, as well, so there is a big

challenge, I guess, and looking forward also having food security, having enough food. I was wondering when we focus a lot on food safety, what is the component in good agriculture practice sustainability that we maintain our resources and have a realistic approach to the food system?

MR. HALLOWAY: A little bit broader if I might because you touched on something. Since all of you are here, you're not in Rio, but in Rio, and maybe some of your corporate executives are there, the subjects are food safety, water and energy. I'm not sure where food safety is going to come in to that discussion. I've looked at the side events, I don't see it. We then look at competing programs. How many of you here work on global greenhouse gas protocols?

(A show of hands.)

MR. HALLOWAY:One. We are in the countries going to the same folks who are trying to talk about food safety; they're talking about greenhouse gas, lowering your carbon footprint, which has nothing to do with food safety or, for that matter, manufacturing products to standard. And yet you have a huge

community of civil society and others, and companies, who are in the same countries that we're trying to work in with a different message.

And, finally, you have a fund at the World Bank of $900 million that the Gates Foundation was very generous in putting in for agricultural business in Africa, and maybe a buck 239 goes to this subject. And so you have huge resources being directed by donors and private sector donors that also missed this. And so holistic, yeah, but it's a lot broader. You have a lot of colleagues in this area who aren't talking about this subject. We run into it institutionally. I shouldn't say this is going to be; they know it. My experts doing this work do not interact with the energy folks who are working out in the field or the greenhouse gas folks who are doing it. They don't.

And we're in the same building. I think this is a common -- and this is one thing you've got to address as you go out is think about who else is out there giving a different message. It's an important message, greenhouse gas, carbon footprint, but if you're in the private sector and suddenly someone says to you ‘Oh, by the way, you've got to worry

about carbon footprints if you're going to import your products here.'

And then you go back and tell the same farmer, yeah, but you've got to do it to standards so they can trace the product. These folks don't have the money to implement this. These are small inner-producers, and so you're quite right to raise that issue.

But I want to raise the larger issues, which is we're operating with competing policy. I will be real interested to see the final documents for Rio and how food security and where in there do you talk about the issues we're talking about.

MS. SOPHOS: I just wanted to note that I think this is also an area where the private sector can maybe play a connective role because there are a lot of companies who are - like Cargill and others - in countries producing food for those countries as well as for export and are also thinking about sustainable agriculture. They're also thinking about food security. They're also thinking about all the things that relate to their business. So they're taking, for

the most part, a more holistic approach. So they have people worried about all of these things as they produce food. So maybe there's an opportunity to help connect the dots across a broader spectrum of stakeholders as that work progresses.

MS. BREWER: Brian and then Mike.

MR. BEDARD: You go ahead.

MS. HEINEN: Okay. First, I wanted to go back to the previous commentator just for a second, and while there was kind of a gloomy reply of five years we wouldn't have much done, I think it is important to remember that we do have a safe food supply in this country, and this is just a change in how we are approaching things to make sure that we keep it to that standard. And so to get that message across the whole world will take time, but it's -- the system has worked us well and continues to work well. So let's not forget that and not take home a gloomy message.

Regarding this question. Just note that the G20 ministers this year, agricultural ministers this year did focus on small producers and sustainable agricultural development. So I think that there is a

growing recognition that we have to take all of these elements, energy, safety, production into account as we move forward with our initiatives in Africa and other places knowing that there are millions of small farmers who are part of the food supply system. So it's growing.

MS. BREWER: Thank you. Brian?

MR. BEDARD: Thank you very much. Thanks, Kristian, for that highlight. I'd like to get down on the farm for a minute, and I think if we're looking at safe food in the U.S., when I talk to the people who are in the know, where is the highest risk? I mean, in fact, what we are trying to do is use this Global Food Safety Partnership to focus on the initial high-risk foods being imported into the U.S., for example, and how do we get at that?

Well, the high-risk foods, it's not canned foods; it's fresh produce or seafood. So where are the good agricultural practices? Where are the good aquacultural practices that we need to put in place? And I guess, the questions I ask, sort of practical questions, well, you have, USAID, for example, that has a mandate to work in developing countries to do

development work, to work with farmers and they have a very good approach to value chains and the way they approach many of the agricultural markets.

How are we marrying what needs to be done to address the domestic needs and import needs? Is there any sort of collaboration with USAID and other donors in terms implementing good agricultural and good aquacultural practices in addition to all of the other things we're doing in terms of institutional laboratories and all of those things? One of the things I'd like to see is more of our investments down on the farm in many of these developing countries so that -- and not only for the domestic markets, the Cargills and Wal-Mart’s are in discussion with us now about how can they bring their farmers together to produce safe food, not for export, just for the local market. So I think that's one of the critical issues that we may be overlooking here. Thank you.

MS. BREWER: Mike, did you have a final comment?

MR. TAYLOR: Just, again, I think it is

important to bring together the considerations of how we have a sufficient food supply from a food security standpoint as well as one that is safe from a public health, consumer protection perspective. These are connected issues, particularly in the produce sector.

You know, I don't think these values are in conflict. I think they have to be worked on together. I think for our part, and, again, just the mandate that we've got from Congress is to establish a framework for produce safety that recognizes all that diversity and recognizes difference in risk across different practices and commodities and uses of commodities, and to have a system that reflects that, that's adaptable and achieves the food safety goal in a way that it is not -- does not undermine the ability to maintain the diverse production system that we've got. We'll put proposals out and people will comment and we'll see how we've done, but the two are connected and I think we understand that at FDA. It's got to make a practical difference for food safety. It's got to be feasible, and that's what we're working on.

MS. BREWER: I'd like to thank all of our panelists. This is very stimulating, but before we part, I do want to give you the opportunity to give one last comment, something you'd like to add, any closing statement or remarks. Steve?

MR. HALLOWAY:No, thank you.

MS. BREWER: Brian?

MR. BEDARD: No, thank you very much.

MS. BREWER: Sue?

MS. HEINEN: I look forward working with you.

MS. BREWER: Okay, thank you.

Mary?

MS. SOPHOS: I look forward to working with you too.

(Applause.)

MS. BREWER: Well, well done, and thank you all. We're going to take a break for just 15 minutes. I have 11:05. So we will meet back here promptly at 11:20. I promise that we'll end the day on time.

Thank you, enjoy your break.

(Short recess.)

MS. BREWER: We are about to resume.

Okay. Let's begin again, and I want to just remind folks that this is being transcribed so please speak directly into the microphone.

So for this section, we're going to continue to do a bit of setting the stage. We're going to focus down on two FDA initiatives, principally FSMA and the imports work, and we're also going to be talking about global products safety, a very, very important initiative for FDA.

We have Dr. Kate Bond and Kate is the Associate Director for Technical Cooperation / Capacity Building in our Office of International Programs at FDA.

I've introduced Roberta Wagner already. She is our Assistant Commissioner for Field Operations within our Office of Regulatory Affairs.

So, Kate, are you ready to take us through the FDA's pathway to global product safety?

FDA's PATHWAY TO GLOBAL PRODUCT SAFETY AND QUALITY AND THE ROLE OF REGULATORY SYSTEMS STRENGTHENING - KATHERINE BOND, ASSOCIATE DIRECTOR

FOR TECHNICAL COOPERATION / CAPACITY BUILDING,

OFFICE OF INTERNATIONAL PROGRAMS, FDA

DR. BOND: Thank you, Camille. I want to echo the thanks that have been expressed this morning to all of you for coming, for sharing your time and your input. I co-lead the international capacity building work group with Dr. Julie Moss and we are absolutely thrilled to see such interest in this effort, and also to hear the rich discussions this morning. It's a bit difficult to follow that kind of a discussion, but I wanted to be rather explicit that as we develop this plan, it's really important for all of us to have a very wide-ranging comprehensive understanding not only of what the complexity of the issues are to regulatory capacity, but also the extent of efforts that are already underway to address this important area, and I think this morning's panel really helped to do that.

And so what I'm going to do now is to shift gears a bit and talk about the FDA's globalization efforts, particularly FDA's pathway to global product

safety and quality, and also the role of regulatory systems strengthening in building that global product safety net. It's a great honor to be here to represent the FDA'S Directorate for Global Regulatory Operations and Policy and the Office of International Programs.

You heard already from this morning's discussions just how many opportunities globalization of the supply chain brings, but also the challenges in terms of the products that FDA regulates. Globalization really addresses a whole wide range. It potentially increases risks to consumers and really demands a major change in the way FDA fulfills its mission.

And, historically, FDA products were primarily manufactured domestically; the volume of imports was low; the movement of goods across country was minimal, and today, as you all know, U.S. consumers demand products from all regions of the world. The volume of products continues to grow and regulators worldwide are really grappling with the increasing complexity of supply chains.

So this morning, I'll talk about the globalization challenges and realities FDA faces, what

we're doing to address these challenges, some thoughts about moving forward, and then the role of regulatory systems strengthening.

So the world was a different place when Franklin D. Roosevelt established the modern FDA in 1938. Today we grapple with challenges of global supply chains, international trade and foreign sourcing of products. And just as public health leaders have long-recognized that diseases no know borders, we now see that product safety and quality can no longer be contained within our borders.

FDA is transforming from a predominately domestically-focused agency operating in a globalized economy to a public health regulatory agency fully prepared for a complex globalized regulatory environment.

We can see a few statistics here. Global production of FDA-regulated goods and materials has really exploded over the last 10 years. We can no longer distinguish between domestic and imported products and we must regulate global product supplies.

FDA-regulated products originate from more

than 150 countries, 130,000 importers and 300,000 foreign facilities. Twenty-four million shipments arrive at more than 300 U.S. ports of entry annually and this was up from six million 10 years ago. The trend for imported products will undoubtedly increase. And not only are more finished products imported, but manufacturers increasingly use imported materials in the U.S.-based plants. So this trend, again, makes the distinction between domestic and imported products obsolete.

Complex supply chains also present real opportunities for both safety and security problems and globalization greatly increases the risks of the unknown with respect to quality and integrity. Who has handled the product? How is it manufactured, packed, distributed, stored? Who supplied the ingredients? Complexities of language, time differences and distance also add to the risk and the complexity of ensuring safety and quality.

We heard from Deputy Commissioner Mike Taylor this morning, and some of the statistics related to foods that were consumed in the U.S. Again, I'll

repeat 10 to 15 percent of all foods consumed by U.S. households are imported. Approximately 60 percent of fresh fruits and fresh vegetables are imported. 80 percent of seafood eaten domestically comes from outside the United States. We see food imports increased an average of 10 percent per year from 2005 to 2011, and 70 to 85 percent of food import refusals of produce and seafood were for potentially dangerous violations including the presence of pathogens, chemical contamination and other sanitary violations.

And we saw from Sue Heinen this morning the growing graph of global trade; this is what it looks like for FDA in terms of imports. You can see the exponential increase which grew, if we look at the products combined group, 13 percent per year in years from 2002 to 2009. And the compound annual growth rate for 2002 to 2009 for foods was 9.5 percent. For veterinary products, 6.7 percent.

And we know that imports will continue to grow. Between 2007 and 2015, it is estimated that imports will triple corresponding to a 15 percent growth rate.

So what this tells us really is that we must treat like risks in equivalent ways regardless of their source.

Deputy Commissioner Mike Taylor described the complexity of the supply chain, and I can see for those of you looking at the screen, you may not realize that there is actually a world map behind those lines of fish in cans. And what I would like to describe is that the tuna is caught in the South Pacific and processed into frozen pieces. It's then transported to New Zealand for pre-canning or canning before being sent on to Southeast Asia at point No. 3 for further canning or processing. Then, it is shipped to the U.S. East Coast at point No. 4 for distribution throughout the United States, where consumers buy it for meals.

So within our global supply chains, we are seeing increasing numbers of firms involved in the production of one product, ingredients components from dispersed sources, increased product mobility, again, all of which lead to different kinds of challenges.

Increasingly, the agency, as well as

industry, must contend with ever more sophisticated threats of fraud, product adulteration and even terrorism along the supply chain. And the reality is that manufacturers and others in the supply chain around the world may place economic gain above safety and public health or possibly have more malevolent intentions.

So what is FDA doing to address these challenges? Recognizing the effect that globalization has had on the FDA's work, the agency has had some great accomplishments over the last few years. These and other efforts have set the groundwork for the FDA's new strategy to assure global product safety and quality.

To address these challenges, the Commissioner created a new Directorate, the Office of Global Regulatory Operations and Policy. It combines the Office of International Programs with the Office of Regulatory Affairs. And the Directorate will make FDA's response to globalization challenges and import safety a top priority in the years to come.

OIP leads and manages and coordinates FDA's

global engagement work and serves as a primary liaison with foreign governments while ORA provides FDA leadership on imports, inspections and enforcement policies and maximizes compliance and minimizes risks associated with FDA-regulated product.

So this will help ensure that FDA integrates its domestic and international programs, again, recognizing that products know no borders.

I'll describe a little bit about what FDA has been doing to date. Since 2008, the FDA received a special congressional appropriation to establish offices overseas. We have expanded our work also globally by increasing the number of foreign inspections in country primarily in the areas of food and medical products. We deployed dedicated cadres of foreign inspectors in certain commodity areas including foods and specialized product inspectors.

FDA also uses the PREDICT system to improve import screening and targeting to prevent the entry of adulterated, misbranded or otherwise violative goods into the United States and to expedite the entry of non-violative goods.

PREDICT uses automated data mining, pattern discovery and open-source intelligence to identify risk factors allowing FDA to better target FDA-regulated products offered for entry.

The FDA has established bilateral relationships with trusted counterparts to assist in global regulatory efforts and has increased efforts to share information via confidential arrangements and information-sharing platforms.

And in today's global economy, the multilateral organizations are increasingly important as partners, particularly as countries work to strengthen regulatory systems and begin to view regulatory systems and standards as essential elements to their larger public health and health care delivery systems. And I think the discussion we just heard this morning is a great reflection of that.

So you can see from this map -- it's a little bit better resolution -- FDA's foreign presence includes 13 foreign hosts. So you can see we have offices in China, Beijing, and Qingdao and Shanghai. In India, we have two posts, in Mumbai and New Delhi.

In Latin America, we have three posts, San Jose, Costa Rica, Mexico City, Mexico and Santiago, Chile. In Europe we have three posts, Fermi, Italy, Isa, London and UK imbedded in Yuna and in Brussels, Belgium. And the Middle East and North Africa, we have one post in Amman, Jordan, and, finally in sub-Saharan Africa, a post in Pretoria, South Africa. So these posts really provide a great deal of opportunity to refine our approaches and to maximize our global impact including implementing provisions in FSMA. You also have a dramatically high increase in the number of inspections globally from less than 1000 inspections in 2008 to more than 2,000 in 2011. And we're considering other means to increase the oversight of foreign firms showing inspections reports with counterparts, which you'll hear more about from Roberta Wagner.

Many of these efforts are actually summarized in a recently released FDA report entitled "Global Engagement," the cover of which is pictured here. So we encourage all of you to read the report for more details, but you will see it covers a range of areas the FDA has been actively involved in the last several

years.

So what does the future hold for us then? We must change the current paradigm so that we get to the point we're fully addressing all the challenges of globalization. We must remain transparent about our efforts to transition from a domestic agency into a global public health agency. We need to remain vigilant in inspecting foreign firms and maintaining equal expectations of standards for both domestic and foreign firms. And at the same time, we need to develop international operating models that rely on mutual reliance, enhanced intelligence, information-sharing platforms, data-driven risk analytics and smart allocation of resources to partnerships.

In late 2010, Commissioner Hamburg established the globalization steering committee, which is a cross section of agency-wide experts tasked with developing a framework and action plan to guide future regulatory strategies to address the explosion in the number of imported FDA-regulated products.

The committee envisioned the future as a public health safety net for consumers around the world

administered by global coalitions of regulators.

The globalization steering committee put forward the pathway to global product safety and quality report which sets forth a plan for the FDA to move from a reactive approach, in which we intercept harmful products, to a proactive approach where we anticipate and prevent the arrival of harmful products to the U.S. market.

So this is a picture of the pathway reports' front cover, and it is available through the FDA website if you search pathway report. I'll describe the contents of the report now.

It lays out key strategies coupled with cutting-edge investigative tools in four distinctive areas of what we refer to as pillars, specifically creating global coalitions of regulators, building global data systems, advancing intelligence, information gathering and risk analytics and leveraging the efforts of public and private third parties.

So what do we mean by global coalitions of regulators. FDA's traditional approach has been close

cooperation with a series of regulatory partners via bilateral agreements. We now envision a deeper engagement beginning with a core group of partners. For example, a primary goal of the coalition could be to develop procedures for more comprehensive and systematic information sharing, the coordinated appointment of resources and acceptance of common science-based standards.

This will be achieved by focusing on comparability and confidence building, identifying elements of a regulatory system that will produce comparable safety outcomes to a benchmark system.

The ultimate goal for us, as Deputy Commissioner Mike Taylor stated this morning, is mutual reliance. In other words, we don't need to do everything, nor do we do it alone. By working together with other countries, as well as third parties, we can avoid duplication of efforts and leverage resources globally to expand the safety net. Likewise, we can learn from each other's operating and governance models.

The next is global data information systems.

It is essential here for the agency to have the capability to aggregate and utilize multiple sources of information and intelligence from around the world to inform regulatory decision making. These efforts help to identify emerging trends, intercept potential threats and prevent contaminated products from entering the supply chain. Ideally, equipping the agency with an intelligent data information system that can analyze multiple sources of inputs or data bytes extends beyond FDA. The ultimate goal must be the creation of global information-sharing platforms.

To do this, we will need to identify critical data elements, better standardize our reporting, create properties for regular systematic information exchange, and this includes unique facility identifiers, for example, the DUNS numbers that could enable us to cross walk our data proving the real potential to work with other governments to potentially combine numbers and identifiers for more global systems.

In terms of the focus on risk analytics, FDA must first identify the signals and warnings of potential risks for monitoring and then help focus the

agency's work in collecting intelligence and data that would help us to effectively monitor the signals. As we monitor and analyze the signals, we must work proactively to identify vulnerabilities and increase our analytic capabilities to interpret and act on such data.

FDA has been engaged in risk analytics for a long time, but we want to take a more proactive and global approach to make effective decisions. To build the necessary support infrastructure, FDA will focus on creating or identifying IT tools that allow experts to quickly access and analyze data across various information sources.

At the heart of FDA's effort to be a smarter, more proactive safety agency like having the analytical horsepower to make timely, effective decisions.

And, finally, the fourth pillar of the pathway is the leverage of third parties. One of the most fundamental changes that FDA will undertake is the more effective deployment of its own resources and leverage the use of third parties against risk-based priorities.

The agency will continue to execute the broad range of surveillance, intervention and enforcement activities that are currently in its toolbox to prevent harm-related efforts. However, we need to think more creatively to ensure our standards are well understood and fully applied to foster best practices in the industry and advance innovation to drive safety and quality.

Likewise, we appreciate that we can't, nor do we have to be the one to do it all. FDA intends to establish an infrastructure to verify and audit the integrity of the information that it receives from public and private third parties, and to ensure that appropriate corrective actions are taken where needed.

The ultimate goal is to move from a primarily domestic orientation to one that treats like risks in like ways regardless of their geographic location and regardless of who is doing the work.

So we fully recognize that in order to achieve the pillars of this pathway, stronger regulatory systems globally will be a key element of our success.

Stronger regulatory systems, as we heard this morning, can also contribute benefits to other countries' health and well-being, as well as expanded access to markets and economic development.

And with this in mind, the FDA asked the U.S. Institute of Medicine to undertake a consensus study that would engage two partners in select countries to identify major issues and gaps in their regulatory systems and to design a strategy for how the FDA, along with other regulators and stakeholders, including development banks and other development partners, can help to strengthen regulatory systems. The study is entitled, "Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad."

And I'll just briefly highlight what some of the findings were in terms of gaps. You've heard some of them this morning. Looking across the range of FDA-regulated product areas, the IOM consulted with a wide range of stakeholders around the world representing a range of disciplines in countries. They remarked how common the gaps that they identified in countries were across the world no matter whether they were emerging

economies, large emerging economies or lower-income countries.

Regulators shared challenges adhering to international standards and controlling supply chains, infrastructure deficits like clean water, electricity, transportation, and communication and internet access severely inhibit their ability to carry out core functions, and some have limited legal foundations, as we heard again this morning.

Many regulatory systems lack a consistent professionalized workforce, and outdated equipment, minimal surveillance systems inhibit their ability to track and monitor products. In many places, there's a lack of political will to invest in stronger regulatory oversight or simply a lower priority in light of other competing challenges.

The IOM Committee posited that successful regulatory systems meet the higher standards, their responses focus on outcomes, they're predictable and independent, they allocate resources proportionate to risks and they recognize, collect and transmit evidence when breaches of law occur.

More specifically a food and medical product regulatory system assures product safety by requiring compliance with good manufacturing, clinical, laboratory and agricultural practices. It offers staff development and training to enable them to stay abreast of scientific advances, monitors and evaluates product quality using laboratory, inspects products throughout the supply chain, conducts risk assessment analysis and management and responds to emergencies.

And the IOM also states that the emerging consumer awareness in developing countries and emerging economies are a key driver to demanding stronger regulatory oversight.

The report also makes very clear, as you heard this morning, that strong regulatory systems reside at the nexus of global health, economic development and trade. And it is in our collective interest to collaborate, share information and strengthen systems globally.

The report puts forward a strategy with an emphasis on global public health. It discusses risk-based investments, suitable market incentives and the

need for international coordination, many of the same principles mandated in Section 305 of FSMA.

Together there are 13 recommendations for international and domestic actions, just to state a few, that may resonate in the presentations that preceded as well as those that will follow. The IOM recommended that intra-governmental organizations should invest more in strengthening the capacity of regulatory systems in developing countries. And we applaud the Global Food Safety Partnership as an example of this kind of investment and leveraging of resources.

The IOM recommends that U.S. development partners should work to strengthen surveillance systems in developing countries, and there are considerable examples of how this is being done in partnership with the World Health Organization and other multilateral organizations.

The IOM also recognizes the need to professionalize the regulatory workforce and calls on a global curriculum for regulators and I think that we heard this morning about several efforts to define the

core competencies of the system, to share those with governments and also the kinds of resource pooling such as the PTIN that we heard about this morning as also promising signs in that direction.

Finally, U.S. policymakers should integrate the medical products safety objectives into their international economic development, trade, harmonization and public health work. We heard a bit about that from USDA this morning. The USAID contributions of the Global Food Safety Partnership, I think, is another positive example, as has been the FDA's long-standing work in Codex Alimentarius.

So I would like to conclude by saying that over the next decade, FDA will continue to transform from a predominantly domestically-focused agency operating in a globalized economy to an agency fully prepared for a regulatory environment in which FDA-regulated products know no borders. It's a monumental effort. It will take a long-term investment of time and resources, however, the payoff will be added safety and security for American consumers.

We also recognize that regulatory capacity

efforts are essential to meeting our collective goals for food safety, public health and economic development, and we have a great opportunity with FSMA to advance food safety systems through the kinds of partnerships you've heard about this morning. Thank you.

(Applause.)

MS. BREWER: Thanks , Kate. So we'll move directly, and, Roberta, are you ready?

IMPLEMENTING TITLE III of FSMA - ROBERTA WAGNER, ASSISTANT COMMISSIONER FOR FIELD OPERATIONS, OFFICE OF REGULATORY AFFAIRS, FDA

MS. WAGNER: Good morning. I guess it is almost good afternoon, and I know that I'm standing between you and lunch and we're a little off-schedule so I'll do my best to get us back on schedule.

I am Roberta Wagner, and I see a lot of familiar faces in the audience and some of you might be asking so when did Roberta move from the Center for Food Safety and Applied Nutrition? It's been about a year now. I'm now in the Office of Regulatory Affairs,

so you're not imaging things. I did switch positions.

Today I've been asked to summarize this morning's conversations and layout the framework for this afternoon. So I'm going to. A lot of this should be review for the majority of you in the audience, and if you've been around and listening to FSMA presentations, I apologize for the repetitiveness, quite frankly, but hopefully there will be a tidbit of new information that I provide.

I'm going to go over why we need FSMA at this particular point in time, and then I will focus on the import provisions in FSMA, so Title III. And then I'm going to talk to you a little bit about the implementation accomplishments to date relative to Title III, the import provisions, and also some of the outreach activities that we've done, again relative to the import provisions in FSMA.

And, again, obviously the reason we need FSMA at this particular time, there is a public health imperative here. Foodborne illness continues to be a significant burden in this country, and we have the current CDC or Center for Disease Control statistics up

on the screen. You know about 48 million people, one in six Americans, get sick each year from food. 128,000 are hospitalized, 3,000 die from foodborne illness. So these numbers are significant. You know there are certain populations that are more susceptible to foodborne illness and the effects of foodborne illness infants and children, pregnant women, older individuals and those that are immunocompromised.

I also just want to point out, and, again, most folks in this room understand this, a foodborne illness is more than a stomach ache. I mean, there could be life-altering diseases that result from foodborne illness, arthritis, kidney failure, just to name a few.

I'm not going to say too much about this slide because I think Kate described why globalization is such a driver for FSMA at this particular point in time. You know, the statistics are all over the place, but about 15 percent of our food supply is imported. You heard that about other certain categories or foods are imported in a much higher

volume. 80 percent of the seafood that we eat in this country is imported. Two-thirds of the fruits and vegetables we eat in this country are imported.

One of the stats that has been thrown out there recently, there's been a 10 percent increase in import food line entries, those are the entries coming into our borders each year for the past seven years, and it just continues to increase.

As you heard from Kate, we expect to see over 24 million lines of FDA regulated products coming through our 300 land, sea and air ports this year alone. And of that about 10 million of them will be line entries of foods, so almost half.

Food imports are coming from 150 countries plus, and they're coming from over 240,000 registered foreign food facilities.

Another reason why FSMA was needed, and, again, I feel like I'm preaching to the choir here, but the food supply is more high tech, more complex. People demand different types of foods in the marketplace. I mean, all you have to do is walk through your produce aisle and look at the

varieties of produce you have available to you now even versus five or ten years ago, and it's amazing. But with these new types of foods and all the importation of foods, we're seeing some new hazards. We're seeing new pathogens that are causing foodborne illness. We're seeing old pathogens in new foods and in new environments. So with that, that variety has -- we've paid for that a little bit.

And then, of course, shifting demographics. We know that this country is aging, a lot more of our population is designated as the elderly, and, obviously, foodborne illness can impact them and make them very sick.

Again, I think if you haven't seen this slide, you just haven't been around. I'm just basically going to say there are four main themes, or, again, we use that word pillars of the FSMA legislation, prevention, enhanced partnerships, inspections, compliance and emergency response and import safety, and we are focusing on import safety at this particular meeting, although I have to say that enhanced partnerships is a piece of what we're about

today, as well.

And, again, the import food safety provisions in FSMA have been described collectively as having the ability to produce the most groundbreaking shift in our food safety system. FDA has traditionally, as Mike mentioned this morning, relied on port-of-entry inspections to basically assure that food is safe. In other words, when the stuff arrives at our borders, we're out there doing field exams. We're out there collecting samples, and that is how we are basically assuring that the food is safe.

Quite frankly, there are 10 million lines of food coming in with no added resources of substantive nature; we cannot use that approach anymore. We are not -- we simply are not assuring that the food coming in from overseas is safe. So, again, what FSMA does is it provides tools to shift from a focus on port-of-entry interventions to a systems approach with supply chain accountability.

For example, FSMA explicitly states that importers are responsible for ensuring that their foreign suppliers have adequate preventive controls in

place, and that the foods that are entering into the United States are as safe as those foods that are produced domestically. FSMA says that explicitly.

So what I am going to do in the next couple of slides is I'm going to go over the sections in Title III of FSMA, and, again, these are the import food safety provisions. There are actually nine sections, specifically Sections 301 through 309. You are going to see something up on the screen. I'm going to actually read language that gets into a little bit more detail that has been cleared, so I'm going to read it very specifically as I know this is all being recorded.

I think they worry about me; they try to keep me scripted.

So Section 303 is titled, "Foreign Supplier Verification Program," acronym FSVP, requires importers to verify that each of their suppliers use risk-based preventive controls that provide the same level of protection as U.S. standards, and that the food they import is not adulterated or misbranded.

Section 302 is titled, "Voluntary Qualified

Importer Program." The acronym is VQIP, that's what you're hearing, V-Q-I-P. It requires that FDA establish a voluntary expedited review and entry admissibility program for importers that have provided assurances that those they import from are consistently producing safe foods and are in compliance with U.S. standards.

Importers will have to apply to be accepted into this particular program and facilities from which such importers acquire products; they will have to be certified as in compliance with applicable U.S. standards by an accredited third party. So, in other words, a program for the best of the best importers.

Section 303, it's titled, "Authority to Require Import Certifications for Food." In some venues I've heard people say mandatory certification. I think you need to read those provisions very carefully because it mentions certification, but also assurances. So I'm not going to use the word mandatory certification here.

Section 303 provides FDA with the

discretionary authority to require, as a condition of granting entry into the U.S. of certain high-risk foods, certifications or assurances of compliance with applicable U.S. regulatory requirements.

Okay. We'll move on to the next three provisions. Section 304 is titled, "Prior Notice of Imported Food Shipments." This requires that when a foreign entity intends to ship a food product to the U.S. that has been previously refused entry by another country, that during the prior notice submission or process, that's the FDA's prior notice submission process, they have to provide that information to us including the identification of the country that refused the food.

Section 305; the entire afternoon will be spent on Section 305, Title III of FSMA. It's titled, "Building Capacity of Foreign Governments with Respect to Food Safety," and it requires FDA to assist with expanding the food safety capacity of foreign governments and their respective food industries from which foods are exported to the

U.S. And I'll go into a little bit more in detail -- well, I'll talk a little bit more about the very specific language in Section 305 in a few minutes.

Section 306 is titled, "Inspection of Foreign Food Facilities," and I want to emphasize that foreign food facilities are also addressed in Title II of FSMA in Section 201. So I'll talk a little bit about both of them very quickly.

Section 306 gives FDA the authority to refuse admission of imported foods from foreign establishments where FDA is denied access for inspection. So if a foreign facility will not allow us to inspect, we can deny entry of their foods at the border.

Section 306 also mandates that FDA direct resources to inspections of foreign facilities, suppliers and food types that present the highest risk.

Section 201 of FSMA is where they tell us how many inspections we're supposed to be doing in the foreign arena, and, more specifically, they basically said in year one of enactment of FSMA, which has already passed, you must do a minimum of 600 foreign food facility inspections. And then for the proceeding

five years, you are to double that number every year. So in other words, year one, we did 600; year two, you have to do a minimum of 1200, 2400, 4800. The number goes up to over 19,000. And, again, remember we did not get any extra resources.

Okay. In the last three sections of Title III of FSMA, Section 307 titled, "Accreditation of Third-Party Auditors." This requires FDA to establish a system for the recognition of accrediting bodies to accredit third-party auditors to certify that foreign food facilities and/or foods meet applicable U.S. requirements.

Certification of foreign facilities meeting applicable U.S. standards from an accredited third party will be required from importers that want to participate in VQIP, as I mentioned.

Certification by an accredited third party may be required if FDA invokes its discretionary authority to mandate certification for certain high-risk foods.

Section 308 titled, "Foreign Offices of the FDA." And you heard a lot about that, again, from

Kate. It requires that FDA establish offices in foreign countries to, in part, provide assistance to the government entities of such countries relative to food safety measures, particularly for foods that are exported to the U.S.

So, in short, FSMA basically tells us that we should be using these foreign posts in part to do capacity building.

Section 308, mandates FDA to submit a report to Congress describing the basis for selection of FDA foreign posts to date, the accomplishments of these posts to date and our plans for establishing additional posts.

Section 309, the last section in Title III, is titled, "Smuggled Food" requires FDA to, in coordination with our Department of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the U.S.

Okay. So a little bit more detail about Section 305 and, again, this is to lay the foundation for this afternoon. The charge provided to FDA in

Section 305 is to develop a comprehensive plan to expand the technical, scientific and regulatory food safety capacity of foreign governments and their respective food industries that export foods to the U.S. The due date for this comprehensive plan as per the statute is January 4th, 2013. This statute says specifically, we have to consult with certain folks when we're developing this comprehensive plan, and there's the list of the varied -- it's a bunch of different government agencies, food industry reps, foreign government officials, non- governmental organizations and other stakeholders.

305 also basically lays out and tells us when you see "shall" in the statute, it means basically must. That as appropriate, we must include certain things in the plan and that includes recommendations for bilateral and multilateral arrangements and agreements including provisions to provide for responsibility of exporting countries to ensure the safety of food, provisions for secure electronic data sharing, provisions for mutual recognition of inspection reports, training of foreign governments and

food producers on U.S requirements for safe food, recommendations on whether and how to harmonize requirements with Codex, and then provisions for multilateral acceptance of lab methods and testing detection techniques.

So I am going to summarize. This is a summary slide and tells you a little bit about these provisions and how we envision them all working together. You know, as has been mentioned, FSMA does represent a major paradigm shift in the area of imports. For the first time importers will have explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place and that the food they ship to the U.S. is as safe as food produced in the U.S.

The agency has the power to establish a third-party program for certifying that foreign food facilities comply with U.S. food safety standards to require certification as a condition of entry for high-risk foods and to reject entry if food at the foreign facility or the country refuses an inspection by FDA or a designee of the FDA.

Significantly and relative to this particular meeting, FSMA explicitly encourages arrangements with foreign governments to leverage resources such as mutual recognition of inspection results, sharing electronic data and training of foreign governments to build their regulatory capacity relative to the oversight of food safety. Such capacity building efforts will be coordinated and carried out in concert with donor organizations and, in part, by staff in FDA's foreign offices and elsewhere.

So our implementation approach, again, a lot of this information will be repetitive for those of you in the room, but we have been implementing FSMA, or pieces of FSMA, for almost 18 months now. Our implementation focus has been on those provisions that will give us the biggest public or have the biggest public health impact.

Transparency continues to be a priority and stakeholder engagement continues to be a priority. And that's why we're all sitting in the room now. We have a comprehensive capacity building plan that is due in January 2013, and as folks have said prior to my

presentation, we want to engage the appropriate people to make sure that plan is the best that it can be.

And this diagram is -- again, it doesn't -- you can't see most of it unfortunately, this just represents the FSMA implementation structure. I think folks should know that when FSMA was enacted, almost 18 months ago, we set up an implementation structure. All the names in these boxes, they have other day jobs for the most part, but everybody has been committing a lot of time, at least part time and some full time, to FSMA implementation.

There is an implementation executive committee, chaired by Mike Taylor. The other folks on that committee are the senior leaders from the FDA components involved in food and feed work. So your Center Director from Center for Food Safety; your Center Director from Center for Vet Medicine; your Associate Commissioner for Regulatory Affairs, my boss, they're all part of this implementation executive committee.

We set up six teams principally around the

pillars. We have prevention, inspection and compliance, imports, federal, state integration, fees, reports and studies. We have team leads and, again, all of the team leaders have day jobs, but everybody is fitting this in and doing a good job, quite frankly, of juggling.

Under each of the teams, we have multiple work groups and those work groups have work group leads. The team leads and the work group leads are, again, managers and subject matter experts from across those FDA components that are involved in food and feed work. So, again, our CFSAN, CVM, ORA, and, of course, Office of Foods has played a critical role in all of this.

I just want to mention that I am currently the lead of the imports team. I was actually co-chair of the inspection and compliance team when I was in CFSAN. When Dave Elder departed, I took his place as the lead of the imports team, and I just want to point out that we do have an international capacity building work group, and a lot of the folks that are presenting today or this afternoon are from that particular work

group.

So what have we completed to date relative to FSMA implementation and Title III import provisions? Section 304, we did get an interim rule on prior notice of imported food, out May 2011, and, again, this just requires that those that are trying to bring in food that was refused from another country, report that during the prior notice process.

Section 308, we did a report to Congress on FDA foreign offices, February 2012. Again, it basically describes our 13 foreign offices. It describes what those offices have been doing, and also describes what some of the challenges are with setting up foreign posts.

And then Section 309, we have with the assistance of the Department of Homeland Security, put out an enhanced anti-smuggling strategy.

Outreach. And, again, this is Title III, FSMA import-related outreach. What we're doing today is one of those outreach initiatives, and, again, we really look forward to your input through the docket. For your input this afternoon, we put out a

document on the website, I believe, on Friday. I think all of you got it, and it basically outlines the elements that will be in the comprehensive capacity building plan and questions that we'd really like your input on so, again, we can -- this plan can be the best that it can be.

So, import-related outreach; we've had public meetings on imports, March 2011. Public hearing on comparability assessments and import practices March 30-31, 2011. We're having this capacity building meeting today, and, additionally, we've had 40 listening sessions and meetings to date. And we've done a lot of foreign government outreach through embassies and briefings.

And so I'm going to close with this. I just want to make sure everybody knows that we are diligently maintaining a FSMA webpage on the FDA website. Any information - this thing is kept very, very current - and any information you need on FSMA is up here. This is your go-to relative to FSMA. And I thank you for your attention.

(Applause.)

MS. BREWER: I want to thank both of our speakers. We're a little bit late for lunch, but I do want to give you the chance to ask one or two questions. So I'll take two questions. Please come to the microphone, sir.

PARTICIPANT: My name is (inaudible) and I represent the French food industry. My question relates to shifting the burden of implementation of this to the importers. We heard this morning that there about 130,000 importers. I would assume at least 100,000 of them are very small structures. We are not talking about Kraft here; we're talking about small and very small companies who don't have general counsel, who don't have a staff of 45 to address these issues. In our experience as exporters has been that in the security area, when 6- pack was implemented, the concept is the same and it is to be implemented in a very uneven fashion in the sense that some imports can have a piece of paper involved and some on the contrary, will have stalled in entry.

And the second point I would like to make is that sometimes, and this might be my experience, we as

export or exporter trade associations often inform the U.S. import of what's going on in FSMA. So, you know, my question is how do you address the situation of very small structures, importer structure, and do you have any specific outreach program for these very smallest companies, that don't have the means or the interest to, you know, to go into a website and read all the information. Thank you.

MS. BREWER: Thank you. Roberta?

MS. WAGNER: First, let me say that the VQIP program has not totally and completely been constructed. We have something framed out, and we were actually talking -- we will probably have some sort of public meeting around what we think we are going to propose relative to that. So, certainly, we want to get stakeholder input there too.

Relative to CTPAT, you know, it's kind of interesting because segments of the industry like it. Other segments don't. And so we are having those types of conversations, but where we're going to end up, you know, some folks say that to be part of VQIP you have to be part of CTPAT. We haven't made any decisions

yet. We are having those types of discussions. You know, relative to the small importers, I have that written down. We do have to do better outreach for the smaller players, absolutely.

VQIP is not mandatory, it's voluntary, and so, again, you basically will apply and be admitted into the program based on, again, we have to specify criteria so that you can become part of the program.

So it's not going to be for everyone, quite frankly. The foreign supplier verification program standards will apply to all importers. They will have to be in compliance with those, but we actually envision VQIP being for a segment of the importers and not applicable to all.

MS. BREWER: Thank you. Caroline?

MS. SMITH DeWAAL: This is a really quick question for Roberta. The law, as I recall it, has provisions for the use of cooperatives, I think in the third-party certification area. Has FDA really considered how agricultural cooperatives, which are commonly used to organize small agriculture sectors, may be used to implement FSMA? Thank you.

MS. WAGNER: I don't want to speak to something I don't have explicit knowledge about, but I can pass that question on to Charlotte Christian, who is working on the third-party accreditation piece.

MS. BREWER: Very quickly, Audrey?

MS. TALLEY-RUSH: Audrey Talley-Rush, and I am former USDA -- I'll leave it at that. I have a question -- I guess my question is very specific about -- your time frames are very short. The gentleman was very explicit about small company involvement, and, I guess my question gets to the issue of -- since we are talking about imports, how will you look at -- as you roll out these requirements notifying them, providing adequate time to get input from a broader audience, and when I say notification I mean because if some of these will address SPS issues, some of these will address TBT issues, which, obviously will impact trade of small and medium size economies. So I guess my question is, as you proceed through the process, and I don't expect an answer, but I think we should consider that. Thank you.

MS. WAGNER: Again, thank you very much. And

so noted, and we need to figure out how we're going to better outreach to the small and medium players.

MS. BREWER: And just to add to that, it is our obligation to notify measures and we've been very consistent about that as we progress through FSMA, so that will continue.

So it's time to eat. Is anybody hungry besides me and Carlos over there?

(No verbal response.)

MS. BREWER: So what I'd like to do, because we're running a little bit late, I'm going to truncate our lunch period a bit, but you will have time to eat and check your BlackBerry. We're going to start talking at 1:10.

This afternoon is very much the nuts and bolts of our recommendations, so we'll see you back here promptly at 1:09 because we'll start at 1:10. Thank you.

(Whereupon, at 12:25 p.m., the meeting was recessed, to be reconvened at 1:10 p.m.)

A F T E R N O O N S E S S I O N

MS. BREWER: We are talking at 1:09. I have

1:09. I know that it was very, very crowded downstairs in the food court, so I want to be a little fair, so why don't we give folks another couple minutes. I see people coming in now. So let's just take another five.

(Short recess.)

MS. BREWER: Okay. We're going to go ahead and get started. Now, this afternoon, we're going to focus in on the FDA draft recommendations and considerations for capacity building. Using 305 and those six elements as a roadmap. We'll have speakers that will address all of those elements.

We're going to start with Dr. Julie Moss, who with Kate Bond, is the co-chair of the capacity building implementation team. And I want to give kudos to that group for organizing this meeting, and getting you all to come. So thanks very much to that working group.

We're going to start out with an overview of 305, how we're looking at it; how we are addressing those elements. We'll move directly into a discussion of elements 1, 2 and 3. We'll pause for stakeholder consultation.

I note that we have another group of experts

on stage with us. We have Nalan Yuksel from Canada, who is the Senior Food Security Analyst for the Canadian International Development Agency, CIDA.

We have Janie Dubois, who is the Manager for the International Food Safety Training Lab within JIFSAN. Julie Howard, Chief Scientist in the Bureau for Food Security, USAID. Josyline Javelosa, Agricultural Attaché from the Embassy of the Philippines. Kelly Johnston, Vice President of Government Affairs, Campbell Soup. Christine Strossman, Director, Trade and Scientific Capacity Building Division from FAS, USDA. And Caroline Smith DeWaal, Food Safety Director from CSPI.

Later on today, Keith Brown, the Senior Vice President of Programs for MSI, will be joining us as well.

What I'd like to make clear is that the stakeholder panel will have the opportunity to ask specific questions of the FDA speakers about the elements. You will also have that opportunity as an audience.

We are especially interested in your

comments, your feedback, your reactions. If you have a question, we'd like to keep it to clarifying questions. It's your perspectives that we're most in need of hearing.

So with that, I'll turn it over to Dr. Moss.

FDA INTERNATIONAL CAPACITY BUILDING PLAN OVERVIEW - JULIE MOSS, DEPUTY DIRECTOR, INTERNATIONAL AFFAIRS STAFF, CFSAN, FDA

DR. MOSS: Thank you, Camille, and welcome everyone. I am Julie Moss; I'm the Deputy Director for the International Affairs staff within FDA's Center for Food Safety and Applied Nutrition. I'm also the co-lead with Kate Bond for the International Capacity Building work group. And Kate and I together are leading the work group to begin to implement Section 305 and develop the capacity building plan.

Many of our work group members are sprinkled within the audience today, and two of them will be following my presentation today to give a little bit more input into the specific elements of the plan.

So what I'd like to do today right now is to

share with you some overarching thought to lead into and to begin doubling down into the current thinking of the capacity building plan. And also build off the document that you have in your packets and echo some of the thoughts that are in your packet for the documentation that answers questions that we'd like to hear from you to gather some input to be able to continue developing this plan.

So, first off, I'd like to share with you a little bit of background of our thoughts with regards to capacity building, and FSMA wasn't necessarily the impetus for us to step back and pause and to rethink how FDA Foods Program wanted to do its capacity building efforts. We actually began rethinking our process in the spring of 2010, and we asked various U.S. Government counterparts to come and share with us what they do with regards to capacity building and training efforts. How they do they evaluate their effectiveness and so forth? We had representatives from USAID. We also had representatives from the Foreign Agricultural Service and the Food Safety Inspection Service out of USDA. And we also had

internally representatives from our ORA within FDA, and this was a great opportunity to see what other organizations are doing with regards to capacity building and training efforts.

We also looked at several global evaluations of food safety training and capacity, that being from FAO, from the World Bank and other global reports that shared thoughts and insights about what works well in the capacity building realm.

One of the overarching themes that we found was that it is necessary to be proactive with your capacity building programs in order to be impactful.

I have to say that was something that FDA needed to step back and really realize and look at our own programs to see what we were doing. To tell you the truth, currently our programs are quite reactive in nature whether it is a regulatory problem that pops up, an outbreak of some sort, and then we need to -- we'd like to go in and do some training or capacity building efforts or a mere request to come in to work with another country on some capacity building aspect.

And so that was very reactive in nature, and

we'd like to pause there with that and really make a change to becoming more proactive, and FSMA is going to allow us to that as well.

So at that point, at the end of 2010, we were in the midst of developing a capacity building plan or developing an affirmative agenda, I should say. And then, voila, FSMA passed. And this actually gave us quite a bit of credence with regards to the capacity building thought process that we had already in place.

This is the first time that capacity building has actually been called out in legislation. It was quite monumental for us, and this is really a fantastic opportunity for us to be proactive with our technical assistance in capacity building programs that we want to do for food safety capacity building.

Now, there have been previous speakers before me that have shared the charge for Section 305. So I won't necessarily repeat, outside of I do want to call out that it states that FDA shall develop a comprehensive plan. And I highlight the term comprehensive because we're really taking that literally, and we're interpreting that to be able to

develop a plan that's a little bit more broad and far-reaching compared to what is specifically called out in Section 305. And I'll explain that a little bit more in a couple slides down the line.

We do have a specific due date that we are keeping in mind, January of 2013.

I also want to echo a thought -- some slides that Roberta Wagner shared earlier, and that is that this plan will also help FDA's foreign offices to be able to implement their charge in Section 308 that cites -- gives them the onus to provide technical assistance with regards to food safety through other foreign governments. And this plan will be able to help guide and direct all foreign offices to move forward and helping them to implement Section 308.

FSMA is also very specific in terms of whom we should consult with, and this has already been called out previously. There are very specific U.S. agencies that Congress directed us to work with. However, we are also considering -- we also think USAID and the Environmental Protection Agency are also very valuable U.S. agencies to interact with. Food industry

representatives, foreign government officials, non-government organizations representing consumers and then other stakeholders in general.

We also think another stakeholder group, and that is academia, not being included here, but we also think that is a very important stakeholder group to engage as well in developing this plan, and then also implementing this plan as well.

And so you will see many of these stakeholder groups, representatives reflecting in the stakeholder panel before you today, as well as the speakers earlier today.

This is the list of the six elements that FSMA Section 305 calls us, FDA, to consider in developing our capacity building plan.

The plan shall include as appropriate. And I'd like to just focus on the terminology "as appropriate." We had some advice from our lawyers and we are interpreting this to mean that we can delve into these six elements a little bit or a lot, as long as we give some reasoning and rationale as to why we're doing so.

Our intention is to address all six elements in some form or fashion. In terms of looking at these six elements too, we took a lot of time to be able to focus in on why these six elements were called out.

We dissected them individually. We dissected them wholeheartedly. So I think there is a nod to looking at this from a broad perspective in terms of the aspirational node of the high-level perspective of what is Congress actually asking us to do and how these six elements are to work together. And then from the other perspective, a more detailed notion of looking at each individual element together, and this is where we would love some input from all of you and from the stakeholders about how to address these individually or collectively.

We see the first three elements as more of the mechanics of capacity building, that is the agreements, secure electronic data sharing and recognition of inspections reports. Those are more of the mechanics of how to do capacity building.

Then Elements 4, 5 and 6, which is actually the training of U.S. requirements, recommendations on

whether and how to harmonize with Codex and provisions of multilateral acceptance of lab methods and so forth. We see those more of a substance that can incorporate capacity building activities.

I also have highlighted in Elements 3 and 6, some key terminology. For Element 3, provisions of mutual recognition. Mutual recognition is a term that we asked our lawyers for some insight on in terms of how we should define that term. It's a pretty heavy-hitting term. So how should we be defining it?

And the same goes for Element 6 with provisions for multilateral acceptance. Multilateral acceptance, again, is a fairly heavy-hitting term, and how should we be defining that and using that?

And some general guidance that we received from counsel is that we can define it as we so wish so long as we explain how we are defining it and how we are using this. Again, if there are any specific thoughts from our stakeholders, this is where we'd love to hear it.

I'm going to stop with regards to those particular six elements and let my colleagues, who are

part of the FSMA international capacity building work group to delve a little bit more deeper into these specific elements. But I wanted to give you just a broad sense of high overarching thought process of what we are thinking with regards to the six elements.

With regards to the consultations. We have had several to date, and we are taking these consultations wholeheartedly that Congress has directed us to. We've had five to date, the first one being in March of 2011 where we had our first panel session at an existing FDA public hearing and we had some initial insights on how to implement Section 305.

We also had some more -- another consultation in July of 2011, which was an information session or a working shop session with regards to the Pew Charitable Trust that hosted a meeting in July of 2011, and that was very helpful to get some insights from the consumer and industry perspective.

March 21st of 2012, we had an information session with our U.S. Government colleagues to begin the discussions with our U.S. Government counterparts to gain some insights.

March 30th of 2012, we did an information session at the Standards and Trade Development facility in Geneva, Switzerland and got some fantastic insights from various government representatives as well as non-government organizations.

In April of 2012, we did another information session at a meeting in Panama City, Panama through a meeting called the Executive Leadership in Food Safety, and there were representatives from food safety experts from the Americas, North America, Central America and South America, and we also got some very nice insights.

And then, of course today. This is the most -- our next consultation session with all of you where we are looking for specific insights in how to develop this plan. And the next one that we have in line is an information session at an upcoming Codex commission meeting in Italy in early July of 2012.

To give you some flavor of some of the insights that we've received so far, in the detail end of things, we've received insights specifically on the secure IT systems and where we received insights that whatever IT systems that FDA develops, that we should

have an auto save feature because some countries often lose electricity and power without notice, and they don't want to go into and refill in all of the fields, and so forth.

On the other spectrum, the more broader spectrum, we received lots of general insight to continue working in collaboration with a country's competent authority to implement FSMA even if the law doesn't direct us to work directly with the competent authority. Say, it directs us to work with the importer to make sure that we are still discussing what we're doing with the competent authority of other countries.

And then another type of input that we received is previously we hadn't had a physical document for folks to react to, and that's exactly why we have in your packet today the questions posed to you, what FDA's current thinking is and that's directly in response to some initial feedback that we got from the previous consultations.

So going back to my initial thought a few slides ago in terms of this comprehensive capacity

building plan, and this is where we are interpreting the term comprehensive to be a little bit more open-ended and broad, and we are suggesting to include several different additional considerations into our capacity building plan above and beyond the six elements that Congress directs us to do.

We are intending to incorporate additional things associated with evidence-based decision making, partnerships and design for effectiveness. For the first one, evidence-based decision making, the crux of this consideration is utilizing data to informed decision making. While the best attempt was always to have data in mind in terms of our decision making in the past, it wasn't always available, and sometimes it was just going with the most common sense approach. And we're really going to step back and really put a push towards having the data drive the decision making, and that is where this is coming from.

A prime example here is with regards to when we're working with another country, whether bilaterally or multilaterally, is to really focus on a country's food safety systems' assessment and to have the

adequacies or the inadequacies of a food safety system to be part of a discussion in order to drive the priorities and the capacity building activities moving forward.

With regards to establishing partnership, this is key to FDA, as you've heard from the various speakers early on in the day, and, as you know, FDA is not missioned as a training organization. We're not missioned as a donor organization, so it's important for FDA to recognize what we can bring to the table.

What we can bring to the table is the expertise in food safety, the expertise in nutrition, the expertise in food safety systems, and then it is important for us to bring that to the table and to leverage that with current partners and future partners.

And, again, just to echo the speakers from earlier today, is that we're not alone in this and that we're all in this together.

And I also want to echo some comments that Mike Taylor said earlier today, as well, is that while various stakeholders have different motivations for

being engaged in capacity building, we do have a common sense in that we want to have safe foods. And then lastly, we want to design a program for capacity building around effectiveness. At this point, we really can't answer the question, are our capacity building efforts impractical to FDA's public health mission? We can't really answer that right now, and we would love to answer that. So we are moving forward and trying to answer that question. So what we're looking at is to be able to see where FDA's capacity building efforts impact the foreign supply chain and also where it can impact U.S. public health.

So we want to be able to link our capacity building efforts to public health outcomes, and we're beginning that process.

The next several slides are what you have in your packet that I'm going to read for the transcript purposes verbatim. And these are FDA's recommendations regarding the additional considerations above and beyond the six elements.

So with regards to evidence-based decision making, FDA's recommendations are that FDA's capacity

building plan should focus on preventing unsafe food from entering the U.S. marketplace.

FDA should gather and obtain information that is country and product specific. Such information should help set the agency's capacity building priorities along with additional information FDA obtains.

So this really gets back to data-driving priorities, driving decision making.

To continue on with FDA's recommendations for evidence-based decision making, FDA should use data from multiple types of self assessments, whether it's a formal process or an informal process to inform its planning process.

FDA will seek assessment results of other countries and encourage discussion about the identified adequacies and inadequacies of those countries food safety systems. And these results should inform FDA decision making.

Again, this really gets to the point, it's not necessarily important what FDA thinks is the issue, it's really important to hear what another country

feels is important to them and recognize and acknowledge that.

FDA's approach to capacity building should account for the interest of individual countries in collaborating with FDA, their ownership of such undertakings and their willingness to adjust the needs identified through assessment tools. Again, this is acknowledging a country's willingness to partake in capacity building and collaborating together.

So the discussion questions for all of you, as well as our stakeholder panel before us, is what data should FDA consider in setting capacity building priorities? How should FDA assess a country's food safety system and what tools should FDA use in doing so? Are there other considerations for prioritization that FDA should consider?

Moving on to establishing partnerships. FDA's recommendations here, FDA should seek greater coordination with other global safety actors in pursuing global and regional food safety capacity building efforts.

FDA should encourage development agencies or

organizations to invest in food safety systems as part of their agricultural and economic development efforts - and such a model that you heard about already is the Global Food Safety Partnership.

In our discussion questions for all of you, who should FDA partner with and why? Are there partnership models that FDA should consider? And how should FDA engage development agencies or organizations?

And then the third additional consideration is designed for effectiveness, which I'm not going to address at the moment. That's going to be part of my last presentation of the day, and so I'll address it then.

So it is at this point where we really need your input. The capacity building plan is a work in progress, and this is an opportunity where you can help us to design and craft this plan. We are all ears at this point. We welcome your input, comments, ideas, data, thoughts. You can either share it today or you can share it in writing through the formal docket process. Your input is extremely important to us, and

I really want to reiterate that, it's very important to us. So, thank you.

(Applause.)

MS. BREWER: Thank you, Julie.

Julia Guenther will go over the first three elements of the plan.

FDA INTERNATIONAL CAPACITY BUILDING PLAN -ELEMENTS 1, 2, 3 - JULIE GUENTHER, POLICY ANALYST, OFFICE OF FOOD DEFENSE, COMMUNICATION AND EMERGENCY RESPONSE, CFSAN, FDA

MS. GUENTHER: Thank you, Camille. My name is Julia Guenther; I'm a Policy Analyst at the U.S. Food and Drug Administration, and I am a working member of the international capacity building work group. I'll be going through just high-level explanations or descriptions of the Elements 1, 2 and 3, and now we're going to through the recommendations that we have come up with so far for each of those elements, followed by the discussion questions. And after I've completed all three, I believe we are going to open it up and Camille

will facilitate the stakeholder panelists' inputs and comments as well as potentially time for those of you in the audience if time allows.

So moving on to the first element and, again, I apologize, I usually don't like to read slides, but for the purposes of the transcript, they are asking us to read the slides.

For Element 1, recommendations for bilateral and multilateral arrangements and agreements including provisions to provide for responsibility exporting countries to ensure the safety of food.

A little bit of background of where we were thinking and what we were thinking with respect to this element. In considering how we will look at bilateral and multilateral agreements and how those agreements could help us with our capacity building efforts, we looked at existing agreements and memorandums of understandings that FDA currently has. Last count, FDA has food-specific cooperative agreements and MOUs with about 20 countries. Those are both broad, meaning that they affirm commitment and document intentions for improving food safety, as well as technical where they

address a narrowly defined problem or risk.

An example or a few examples of broad agreements are the U.S.-Canada Regulatory Cooperation Council, the RCC, that was formed in 2011 to increase regulatory transparency and coordination, as well as the confidentiality agreement between FDA and the Canadian Food Inspection Agency, CFIA, Health Canada and the Joint Committee on Food Safety.

Another example of a broad agreement, if you will, is our bilateral partnership with Mexico creating a High-Level Regulatory Cooperation Council, HLRCC, to enhance the economic competiveness and economic well-being amongst the two countries.

So those are examples of some broad agreements and then one example of a technical agreement is one what we have with Mexico, their National Service of Agricultural Food Health, Safety and Quality, or SENASICA, and the goal of that MOU was to establish and build confidence in a system that ensures safe importation of cantaloupes to the United States.

So those are just some of the examples of

existing agreements that we looked at to learn from and, obviously, there are lot more that have been successful, but we looked at those few specific ones and we definitely welcome your input on how other agreements have worked in your capacity and how we can approve capacity building by using such agreements.

Another form of agreement that I wanted to mention was the White House Food Safety Working group. That's mainly an agreement or a discussion among U.S. agencies, but we see that as another opportunity, as Julie mentioned. FSMA requires us to do consultations with our sister agencies so that is another avenue of using agreements to build capacity around food safety.

So that's kind of the background that we looked at in coming up with some of these recommendations, and so I'll go ahead and actually read the recommendations and then also the discussion questions.

The first recommendation. In pursuing new arrangements and in re-evaluating existing agreements, FDA should seek opportunities with exporting countries and with other Federal Government agencies that

optimize FDA's ability to leverage resources, rely on the findings of other government entities and support joint capacity building activities.

To ensure effective arrangements, FDA should seek agreements and arrangements that are specific, goal-oriented and offer a gain for all parties. In developing new arrangements, FDA should focus on agency need and anticipated U.S. public health incomes outcomes.

Additional recommendations. FDA should also seek informal arrangements, which can be highly effective in promoting collaboration and technical exchange. Formal agreements and arrangements are not always necessary, although some signs may be required by our counterparts.

Then FDA should prioritize the role of arrangements to ensure the safety of food imports.

So those are the recommendations that we've come up with so far for the first element on bilateral and multilateral agreements.

The discussions questions, which you have in your packet, are as follows: Are there instances where

cooperation and information-sharing efforts have been particularly effective? How can models of effective agreements and arrangements best support capacity building and how can agreements and arrangements allow parties to leverage each other's resources?

What are the anticipated goals and gains that FDA should seek in these types of arrangements, and do you find informal or formal agreements to be most effective -- or more effective?

So that was Element 1 regarding recommendations for use of bilateral and multilateral arrangements and agreements.

Moving on to Element 2, which is provisions for secure electronic data sharing. And, again, in looking at Element 2, and the requirements set forth by FSMA, we obviously looked to what we already know and so we understand that fostering and in maintaining open regular dialogue with other countries is crucial to advancing our goal -- our mutual goal of ensuring food safety.

So in looking at some of the examples of

data exchange mechanisms, we looked at the eLEXNET, which is a secure network that shares laboratory analysis, although eLEXNET only currently is a domestic-sharing mechanism.It doesn't go beyond the U.S. Government.

However, another tool that we are familiar with and are aware of is the FOSCOLLAB, which is the WHO tool to facilitate the sharing of WHO and FAO databases, as well as databases made available from national competent authorities around contamination in foods, risk assessment, et cetera.

So in considering how we are going to include provisions for secure electronic data-sharing within our capacity building plan, we looked to some of these existing mechanisms. However, we understand and we know that as FDA implements additional parts of FSMA, for example, the imports provisions that Roberta mentioned before lunch, we understand that we need to keep in mind that we are working in a global environment and there are limitations as well as opportunities for FDA to share information and share data so that we can all get to a safer food supply.

So moving on to Element 2's recommendations. Sharing key information with regulatory counterparts and with multilateral organizations, as appropriate, to support scientific and technical exchange of information, facilitate regulatory follow up and communicate rapidly during an emergency.

As FDA implements the import related sections of FSMA, the agency should continue to analyze the capacity of current IT systems and determine whether any needs exist for system integration or the development of new systems to facilitate and enhance data sharing.

So those are the recommendations. And our discussion questions that we would like feedback on, what factors should FDA consider in providing for secure electronic data sharing?

Are there any technological or other challenges related to data sharing such as challenges related to inter-operability and system compatibility?

What kinds of information should be shared in

a secure electronic data-sharing system?

What factors would enable greater information sharing?

And lastly, Element 3 looks at provisions for mutual recognition of inspection reports. And, as you can imagine, this is one of the more challenging elements for us. However, we did look at some of our sister centers within the FDA, specifically looking at pharmaceuticals as well as veterinary drug registration, looking at some of the models that exist currently in some of the other FDA centers for models that we can potentially emulate in looking at mutual recognition of inspection reports.

One specifically that we are looking closely into is PIC/S which stands for Pharmaceutical Inspection Cooperation Scheme. The genesis of PIC/S was in the 1970s, the European Free Trade Association founded the pharmaceutical inspection convention. The title of that was, "The Convention for the Mutual Recognition of Inspections in Respect of the Manufacturer of Pharmaceutical Products."

So you can imagine it's a similar model that

we may want to look into and may want to emulate. The goal of PIC/S is to foster international development, implementation and maintenance of harmonized good manufacturing practice, standards and quality systems of inspectorates in the field of medicinal products.

So that is just one of the examples of a model in the pharmaceutical world that we in food and food safety may want to look at or have looked at to draw from lessons learned and potentially implement in the world of food safety.

With regard to the recommendations that we currently have, I believe we only have one here, but it is broad in scope. FDA should continue exploring the issues surrounding mutual recognition of inspection reports with the intent of expanding reliance on inspection reports from other countries that have demonstrated strong inspectional programs.

Then the questions associated with Element 3 that we would like your feedback on, what are examples of effective models for mutual recognition of inspection reports?

What preconditions must exist to ensure that

a system for mutual recognition of inspection reports ensures confidence?

How should a system for mutual recognition of inspection reports assign responsibility for regulatory follow-up actions where an inspection report indicates the need for such follow up?

So that is a brief, brief overview of each element as well as our current recommendations and the discussion questions that Camille will lead.

(Applause.)

MS. BREWER: Julia, thank you very much.

I'd like to turn first to our stakeholder panel and ask are there any questions of clarification? And I'd like to start on the left and our convention will be to work towards me. If there are none, just please say pass.

(No verbal response.)

MS. BREWER: SO we get the award for clarity, thank you very much.

(Laughter.)

MS. BREWER: So next we have posed a set of questions to our stakeholder panel. Again, I'd like to

start from my left, and if you could please address the questions. We're going to start first with Element 1. So, please just address Element 1.

STAKEHOLDER CONSULTATON

MS. DUBOIS: I just wanted to reiterate something we've heard about this morning, and that was actually an excellent model, the UNIDO data use going into --

MS. BREWER: We can't hear you.

MS. DUBOIS: Can you hear me? Okay. I thought this morning we had some information given about the UNIDO use of data from import alerts or import actions. And this was a good model of information sharing where the data comes from the different organizations that look at the imports, but it used to guide the capacity building in the particular country individually. So I just thought this was worth mentioning as a good model for how cooperation and information sharing can really be an effective model to guide capacity building.

MR. JOHNSTON: Thank you for the presentation. I just wanted to mention, and you already

touched on it so I'll be very brief, and that is the beyond the border program between the U.S. and Canada. I might also say there is one bilateral between the U.S. and Mexico. If you read the food safety part of the action plan between the U.S. and Canada, it really lays out exactly what we're trying to achieve. I would just simply caution that that is actually a newer plan than the Food Safety Modernization Act, so it's not really in place yet. So to the extent that it is an effective model, I would say it is to be determined, but, clearly, the goals purposes of that serve, I think, as a wonderful precursor to what you might do going forward for other countries.

I think it is more of a management approach. Try not to bite off too much of the apple, start with Canada where you've already got a plan in place or a team is already assembled, the stakeholder process and discussions well underway before you start to go other countries around the world. Try to build a good pilot program, a good model first knowing full well that no country is going to be the same. What issues we may have in China or may have in Mexico would not be the

same necessarily in Canada.

And also I'm mindful of the fact that you want to take a very risk-based approach, and we don't have a lot of risk with Canada. I mean, there are other parts of the world where there risks are much higher. So -- but I do want to commend that as an example, and try to make that work first and foremost. It's already in place and well underway.

MS. SMITH DeWAAL: I'm going to look at the broad set of questions you provided here. First of all, we see an urgency of action. The FDA should not suffer from paralysis by analysis. You need to -- the language within the Food Safety Modernization Act provides certain flexibility.For example, the use of the term "arrangements" or "agreements" give you flexibility as to how -- how formalized these have to be. I think there's the opportunity for rapid harmonization between the U.S. and other high-performing systems. So I would take advantage of your opportunities with Canada, with the EU, perhaps Australia, New Zealand, maybe Japan, other countries that are considered high performing in this area. But

there is also a critical hurdle that I think you need to overcome, and that is the hurdle that where the U.S. does have arrangements and agreements especially in the area of information sharing, the U.S. also requires other countries and foreign officials to sign confidentiality agreements. And that will be a hurdle to you having successful arrangements and agreements. So I just wanted to point out that you may need to address that as you move forward.

MS. HOWARD: Thank you. I also have a few general comments before a specific comment on Element 1. First of all, since I'm coming from USAID, I want to note that USAID very strongly supports the development of this comprehensive plan by FDA to expand technical, scientific and regulatory food safety capacity of foreign governments and their respective food industries recognizing that these are the sources of many foods which have been exported to the U.S.

A word on USAID's role in this area. USAID is responsible for coordinating the implementation of Feed the Future, which is the administration's initiative to reduce global hunger and poverty. Feed

the Future is a whole of government effort involving many agencies and improving food security and improving safety is a priority in most of our 19 Feed the Future focus countries, so we see a real possibility for a collaboration with FDA and other agencies in this area.

FDA's proposed capacity building plan, we see would strongly complement USAID's efforts. Food safety improvements across the global food supply chain contribute to economic growth in exporting countries as well as enhancing the safety of foods imported into the United States.

And so, again, we welcome the opportunity to work with FDA on developing and implementing a food safety capacity building strategy for developing countries.

Now, just a brief comment on Element 1. USAID's food safety capacity building program's focus on alignment with international standards and on Codex Alimentarius standards in particular. I wanted to comment a little bit on informal versus formal arrangements. We work in both of these spheres and feel very much, it depends on the situation; it depends

on the need.

In Africa, we are providing support for food safety capacity building as part of programs to promote regional trade integration. So, again, feeling that there's got to be some kind of demand for it. Demand regionally for trade sort of spurs interest in food safety as well as the possibility for export to the U.S. and other countries against first interest in food safety improvement.

I wanted to share with you a little bit about the importance that we place on a very strong institutional partner, on the ground partner to train with and a partner with whom we feel that the institutional responsibilities for food safety will ultimately reside.

So let me share an example with COMESA, that's the Common Market for East and Southern Africa, a large trading block, maybe of you will know, in East and Southern Africa.

So USAID and other U.S. Government agencies have worked for many years with COMESA to develop a

regional framework for trade, for food safety and for commercialization of commodities including bio-engineered crops. When it is approved, this framework will apply consistent safety standards and risk assessment processes across the region and will ensure that new bio-engineered crops and other commodities meet international food safety standards.

So USAID has really taken a long-term approach to development of this program and really to building capacity on the ground. We've been working with scientists, policymakers and regulatory agents on the ground for several years to advance this framework. So, I guess, you would say we're working with international formal standards, but also sort of in the business of creating new formal standards on the ground with new partners.

MS. JAVELOSA: Good afternoon. Thank you very much, FDA, for inviting the Philippine Government to present its perspective and get input from us into the U.S. international food safety capacity health building plan.

Before I give my general comments, allow me

to give some context to my general and, perhaps, more detailed comments later on. You know, the Philippines is a small, but significant partner of the U.S. be it economically, politically, culturally or historically.

The Philippines last year exported about 1.4 billion worth of agriculture and fishery products to the U.S. And to compare it with the USDA FAS figures earlier, that's about 1 percent of the total imports of the U.S. for agriculture and fishery products.

Now, most of the Philippines' food exports are targeted to our Filipino-American group here, which is about 3.4 million considering some other mixed races Fil-Am and others. And although there is increasingly a strategy by some food companies, they also want to reach the mainstream U.S. market. So we are small, but to the Philippines this industry is also important as a lot of people to rely on agricultural and food production. It's important to our economic growth and to have inclusive growth especially in the rural areas.

Now, the speakers have highlighted the eagerness of a lot of trading partners to comply with the U.S. regulations and various initiatives to improve

food safety.

Now, the Philippines is one of those eager countries, as evidenced by many activities they have been participating in at the multilateral level, as a WTO member, OIE member, IPPC and Codex, and we also have an E-U-P-R-T-H, a regulated technical assistance project in Asean. We also have some safety capacity building initiatives, and recently with FDA, Asean has a capacity building on agriculture safety.

And, of course, in APEC, as mentioned earlier, and if I may recap what Mary has presented, with all the initiatives in APEC, the Philippines has an improved national food safety system. The capacity building initiatives have helped us have a basis for our national food safety law, have a contaminants moratorium program, and increased confidence across the board.

So, in sum, what I'm saying there is so many food capacity building activities that the Philippines has participated in, and we feel the next steps for having this bilateral arrangement with FDA is to recognize these capacities that we have developed, and

in the long run recognize the competence that we have built in making sure that our exports are safe.

Correct me if I'm wrong, and maybe if you correct me, you could correct me privately, but I'm not aware that our exports have been associated to any foodborne illness. So not that -- because our Philippine exports are safe, but maybe the U.S. Government also has a good system in place that they're able to reject those that do not meet the safety standards.

And UNIDO too was mentioned earlier, that could be a very good tool in also focusing what has to be worked on in developing countries as to what areas have to be strengthened.

So in developing this bilateral engagement, it would be appreciated if FDA could have a devoted officer to sit down with us, let's review what we have. We have both formal and informal arrangements, and I think they've been working. And as far as we're concerned, we don't want to -- if there is no problem, we don't have to fix it. If it could strengthen it, it would be good to have some strengthening. And we know

you have your website, you always post there the new regulations, but sometimes it is hard to follow, so if there could just be a devoted officer with FDA to sit down with us and make us be prepared of what changes there could be that would affect our exports that would be greatly appreciated. Thank you.

MS. STROSSMAN: I think Sue Heinen from FAS spoke this morning and presented some of the general perspectives that we have related to trade in the national capacity building. So I'll get right into specifics related to this particular element related to bilateral and multilateral arrangements.

In our experience, conducting capacity building programs, we found -- and I think this has been mentioned previously -- it's important to maintain flexibility and respond to individual circumstances and not necessarily adopt a one size fits all approach. It has also been our experience that it is often cost effective and efficient to build upon and complement existing structures and initiatives wherever possible, and we've heard about some of those this morning and this afternoon already.

So we have had situations where a formal agreement or arrangement was necessary and desirable, and in other cases where it was not.For example, USDA has a long-standing memorandum of understanding with China's Ministry of Agriculture dating back to 1978 and through that arrangement and over time, we've developed a scientific cooperation exchange program which facilitates U.S. and Chinese research team exchanges to promote bilateral scientific and agricultural cooperation development and trade. And the cost of these exchanges are shared between the two countries.

In collaboration with USAID, USDA also supports capacity building in support of free trade agreements. That was also mentioned by Sue Heinen this morning, such as the CAFTA DR, FTA and the Peru Trade promotion agreement are a couple of examples where we have conducted food safety-related capacity building together with our USAID counterparts.

So we have these more formal arrangements and also -- but I'd also like to emphasize that we have many other capacity building programs, large and small, without any particular formal arrangement and those

also work quite well. Thank you.

MS. YUKSEL: Thank you very much. I just wanted to build on what Julie Howard from USAID had said just earlier because I'm also coming from a donor agency at CIDA Canadian International Development Agency so I'll be giving more of a development perspective in the capacity building, and I leave it to my colleague from the Canadian Food Inspection Agency, who is also in the room, to give the more technical on the food safety side. But I just wanted to say that Canada is one of the many donors in developing countries that endorse the Paris Declaration on Aid Effectiveness, and I think this is a very important approach that aims to be a more comprehensive attempt to change the way donors in developing countries do business together.

It is based on five principles of partnership: country, ownership, alignment, harmonization, managing for development results and mutual accountability.

And this new model addresses not only one

aspect of development, but the political, economic, social and institutional dimensions of development. So it stresses the importance of getting governance rights, the proper sequencing of reforms, the need for capacity building to ensure sustainability and engaging with civil society.

So at CIDA, we recognize the following concepts to be crucial to the way we do development in developing countries. Local ownership, like I said, which means that development strategies, if they are to be sustainable, must be developed by recipient countries, the government and their people, and that they must reflect their priorities. So improved donor coordination.

As someone else had mentioned, there's a lot of donors out there that are working already in developing countries. How can we better coordinate our activities on the ground is going to be crucial.

Stronger partnerships, we've talked about this before. It's been brought up earlier today. There are a lot of partners out there not only in industry and government, but civil society and

academia. How can we work together to form stronger partnerships?

Results-based approach is going to be crucial with ensuring proper monitoring evaluation of the development programs. And greater coherence, and this is all of government coherence program where policies are coherence with domestic and international would be very important.

In line with that, there's just three considerations for technical assistance and capacity building of food security based on these principles is consideration has to be given to greater coordination and cooperation of how technical assistance and capacity building is dispensed in developing countries.

Priorities and needs assessments are crucial to identify where opportunities exist not only for short term, but for longer term. This was mentioned before, as well. You have to build in the longer term training needs on food safety systems. And improved communications to avoid overlapping duplication and to maximize the use of limited resources that is going to benefit both developed and developing countries at the

same time. Thank you.

MS. BREWER: Thank you all. Julia and Julie; do you have any questions back to the panelists? I actually have one for Caroline.

Could you just expand a little bit on how you see a confidentiality agreement as being an impediment?

MS. SMITH DeWAAL: We were at a conference, I think it was last week, maybe two weeks ago. The Trans-Atlantic Consumer Dialogue invited both high-ranking officials from the European Union and also the U.S. to gather for a conference that was held in Washington earlier this month. And at least two of the European speakers mentioned that one of the hurdles they have with reaching agreements for information sharing with the U.S. is the requirement to sign these confidentiality agreements which are designed, Camille, if I understand them properly, they are designed to protect our industry from the possibility that confidential business information might somehow leak out to perhaps their competitors. I'm not exactly sure what the -- I know it's a non-food safety-related rationale. It's more a trade rationale that these

confidentiality agreements are required. But, at least, among the -- I was struck by the fact that this was mentioned by at least two senior officials, including the Executive Director of FSOC. Mike correct me, if I'm misremembering that, but it was mentioned twice by high-ranking European officials who have had the opportunity to have to negotiate these kinds of agreements. So the bottom line is, these systems, these new systems are going to be built on information sharing and it may be electronic information; it may be public health information; it may be facility inspection information, but I think you may need to address this non-food safety, non-public health hurdle that has given rise to these confidentiality agreements.

MS. BREWER: Thank you. Julie, Julia?

MS. MOSS: I'm good.

MS. BREWER: Okay. Let's move on then to Element 2 and, again, starting at my far left.

MR. JOHNSTON: I just, again, have a brief comment. I think the data-sharing course, and I'm not expert on this area, but I just have one conceptual

area where I think this is very important and it relates back, absent the Bioterrorism Act, of 2002, 2003 when we first like confronted the issue intentional of food safety issues and food contamination concerns. I think it is important to incorporate data sharing as an element of the Section 302, which, of course, is the voluntary qualified importer program. This can't be a data-sharing system that is government to government because one of the things we experienced is the government loves lots of data from companies on what's going on, and some of it confidential and some of it not. But it is real hard for us sometimes to get the data back to know what are the threats that are out there that you're looking at so we can plan accordingly as well. So I would encourage you to consider having data sharing be a part of any voluntary qualified importer program so we, therefore, know in exchange for us providing additional information, to be a trusted importer.

On the other hand, we also have access to data you have as governments to know where some of the threats may be so we can also plan and prepare

accordingly with your prevention law. That's my only comment.

MS. SMITH DeWAAL: So for this one, I want to also highlight the fact that there are a couple of platforms that we consider quite good for information sharing. One is run by WHO, INFOSAN. The other is the rapid alert system in use in Europe, and these are designed to circulate information very rapidly among government agencies on existing threats. So I want to highlight the fact that those are existing and the Trans-Atlantic Consumer Dialogue two weeks ago approved resolution calling on the U.S. to also support and even further develop these types of information systems for getting sharing public health information more rapidly.

I think there is another opportunity here and that is also in a FSMA provision dealing with traceability. The FDA will have the opportunity to start to craft trade stability requirements for food products especially high-risk food products. However, that's defined under the regulations when they come out. And so I think that you might look for opportunities within the traceability area to

understand some of the existing platforms that are being used by industries for information sharing because I think the private sector is way ahead of governments in terms of capturing this kind of information and putting it into platforms that are useable while still protecting whatever secret information they need to protect within their own company.

MS. HOWARD: So a quick comment on infrastructure. In USAID experience, many countries suffer from a lack of adequate technology infrastructure and so we encourage FDA to explore the use of cell phones as part of its alternative communication technology platform. So we're finding in much of our work, turning more and more to cell phone technology especially in Africa cell phones tending to be much, much more widely available than computers and sort of standard Internet connections. Thank you.

MS. YUKSEL: Just a quick comment of some of the work that we do on the agriculture side. It's always been a big issue for us of actually getting the data. So, I think, it's kind of the elephant room, but

saying the first challenge is actually to address the capacity of the country, to actually have a data system that is up to date, relevant and effective. So does a data system that can be shared actually exist? I mean, that's the first part. And if it doesn't exist, then there's a lot of capacity and a lot of money that has to actually go into actually collecting that data. So before delivering on data sharing, you must first look at what they are able to do now and then use that as your gauge in going forward.

MS. BREWER: Anything to add?

(No verbal response.)

MS. BREWER: Okay, then, let's move on to the third element, provisions for a mutual recognition of inspection reports.

Comments, response to the question starting from my left.

MR. JOHNSTON: I do want to comment on this one. I think it's important that you look at our world, if you will, as we are a very highly integrated industry in so many ways, not just in terms of where and how we make products, for example, with the U.S.

and Canada and the U.S. and Mexico, and, in particular, in North America, we make things together. But we are also highly integrated with each other. My competitor on one aisle of the store may also be my customer on another and vice versa. So we do things for each other; we're very, very highly integrated.

As a result of that, if you walk and talk to anyone like my company's plant manager or any plant manager for most companies of any size, if you have, for example, a dual inspection plant in the U.S., you've got a USDA inspector there on a continuous basis. You've got the once-a-year or so drop by FDA. It's more than a drop by, it's a real inspection. Number three, is you have multiple inspections from our customers. We sometimes have 9, 10, 12, 13, 15 or more inspections a year from our third-party inspectors who sometimes have the toughest inspections of all. So when you look at mutual inspection regimes, please do look at the third party. I know it is part of the law, but please do look very seriously and respect the very robust third-party inspection system which is really involved in pretty important ways over the last 10-12

years. It's better; it's stronger; it's got a ways to go in some respects, but it's a very good tool for helping to get mutual recognition for inspection reports. This, again, can't be just government, but look at the private sector and what we've done already over the last many years in inspecting each other.

You might want to comment.

MS. SMITH DeWAAL: I think Kelly just made an excellent point, and that is that realistically FDA and even probably a number of the other government inspection agencies may not get to these facilities very often, but their customers will get there. And so trying to develop systems where you're receiving signals when there are adverse findings, I know there are provisions in the law, for example, for FDA to be receiving laboratory, adverse laboratory results from the certified labs. And also getting immediate notification of conditions from third-party auditors. And, again, those are two systems that are already built into FSMA, but that you may need to be utilizing and plugging in to this system. I know it may be on another branch of that diagram of how you're analyzing

the law, but it is critically important that you bring these different elements together to make sure you have the most robust system for data collection and for capturing those signals.

So I think that that's an excellent point. I think that this whole question is one that's going to be rich for public comment and written comments, and I know my staff will probably be looking at these questions in great depth. So I'm going to wait until we do written comments to really give you my -- our full thinking on this. But I would be -- it would be wrong for me not to mention two things in this discussion. One is that you should be looking and consulting with FSIS on how they manage this issue of shared inspections, whether they rely strictly on their in-country audits or whether there is an inspection-sharing mechanism under the FSIS model.

And, finally, the issue that's very important to consumers, the issue of transparency and making sure these information systems work for the public, not just for the industries and the agencies because, you know, given different countries and different cultural

context, you can hide a lot of information. So it is very important that you consider the issues around transparency of inspection information which is vital for public health, and I'm sorry, I took a little long on that. Thank you.

MS. JAVELOSA: Yes. From the Philippines perspective, we think that a workable way for the FDA to expand the technical, scientific and regulatory food safety capacity of the Philippines is by validating and recognizing our inspection systems and food testing laboratories. Perhaps we could have some visits from U.S. FDA to the Philippines and observe how we do things there and work towards having a validation of our systems and vesting procedures, and over time we would like also to have recognition of our export certifications. This would help facilitate the entry of all products into the U.S. We'd reserve our detailed comments later on in writing. Thank you.

MS. BREWER: Okay, then. Thank you. So now it's once again your turn. So I will open the floor to clarification questions on any of the elements and also to responses to any of the questions that we posed. I

would just ask you to indicate again your name, affiliation and let us know what element you are addressing. The floor is open.

Dr. Carnevale, please?

DR. CARNEVALE: And my name is Catherine Carnevale; I'm an independent consultant on food safety, international food safety and a former employee of the Food and Drug Administration.

I do have one question, I guess, that is a clarifying question. It does not need to be answered right now, but I do think it would be helpful in getting comments on the plan to explain the differences between a formal agreement -- and I am addressing my comments to the first item on agreement.

To explain the differences, informal agreements and informal agreements and why are we even making the distinction. But -- can I go on with my comments?

MS. BREWER: Please.

DR. CARNEVALE: And sort of relative to that point, And I think some of the panelists mentioned the amount of resources that go into establishing a formal

agreement can be massive. It can involve a lot of bureaucracy and may not be done in a very timely way. So I think that in making comments on this that you need to take into account if you are going to have formal agreements or maybe even informal agreements the resources in establishing them and maintaining them. And, therefore, the agreement must have a significant purpose from the standpoint of advancing the goals of FSMA and the goals of food safety.

So I mention that as one comment. There are 150 countries after all that you are getting food from, so if there is an expectation that you are going to have even one agreement which each one of those countries that's an enormous amount of resources.

Another comment is that you need to think about the incentives for the exporting country. Their needs -- I know there's talk about having gains for all parties whether it is unilateral or multilateral, but you need to think in terms of the incentives for the parties in negotiating these agreements.

And I think the last thing I want to say, which is -- I guess I would consider the most important

is the inter-connectiveness of the various elements of FSMA. In the past when we've talked about agreements with other countries, we have had a different paradigm with regard to imported food. We are changing that paradigm from one where FDA has essentially relied on the foreign food producer and exporter to know what the U.S. standards are and to make sure that they are complying with them.

Two, a system where we are looking to the importer who may be in the U.S., but is in the U.S. to have a preventive control system. So where does the foreign government -- what's their role? Where do they fit into the system? So you're going to need to kind of take a totally different mind-set on why you are having these agreements with other countries. I'm not telling you anything you haven't thought of already. But it's a different approach and so, therefore, I think these agreements may be more limited in terms of what you are trying to do and you may want to have a very specific purpose for the agreement. And, you know, to one where maybe there are problems or in

establishing relationships with the other country for when a problem does occur. And I'm done.

MS. BREWER: Thank you, Cathy. Kristian, are you coming to the microphone? Oh, I'm so sorry; I didn't see you. Please.

MS. DAWSON: Just a little bit about my interest in how --

MS. BREWER: Can you speak into the microphone?

MS. DAWSON: I'm so sorry, thank you. My name is Laura Dawson and I'm a small business owner. I'm also a nutritional specialist. I've been a stakeholder on several Codex Alimentarius panels for a number of years. I've also been a member of the Food and Nutrition Services Outreach. I'm also currently on a project with the Red Cross locally to do mass care feeding in an event of emergencies and disasters, and we're writing a statement of understanding with local pizza places. I mean, so we do those type of legal documents on the grassroots level here in the United States where we may even involve food safety and inspection requirements and safety for people that are

sheltered in emergencies and disasters. So I have taken a lot of this into consideration as I bring thoughts about each one of these points that you brought up today. And in doing so, I think that one of the -- several of the things I thought in the first one, the first item about trusted systems that I had seen work already, and I think that the Codex Alimentarius system is an excellent standard because it includes so many countries, even developing countries of providing input to the parliamentary process that's being established to determine how much of vanilla you can put into a manufactured product, which I'm not sure all of us are excited about doing all that hard work, but someone is doing that. It is happening. So I think rather than reinventing the wheel, these folks at Codex have great diplomatic entrees already by knowing some of these government organizations that FDA could be partnering with at some point. So I think that's a strong thing that we need to look at in the first aspect of working multilateral and singular agreements and understandings.

And then also on the next point on security

of Internets on Item 2, I'm going to just hit a bullet because I'm going to write mine. I did that; I helped to write the food guidelines in Washington, D.C. with the Center for Nutrition Policy and Promotion in 2005 and I wrote most of my comments. But I think that broadband.gov is a great initiative in the United States that's reaching out to rural areas in order to create a network of Internet connections that are secure to a population that's in a rural area so that they get good information for health care purposes, food safety, education, et cetera.

I think it can be patterned as a means for other countries so that we can start expanding and creating that type of environment because with our electronic health records that we're implementing in the United States, we're also working to incorporate that worldwide. And having worked with the NIH on the e-coli outbreak in 2007, we had international meetings in which we were able to discuss outbreak and numbers of people that have been impacted and carry on in an international conference sitting in our own offices in our own countries.

So I think there are a lot of resources that we can learn to share. We can learn to share a Cloud. More governances are learning to share Cloud Internet services. It's far more economical than physically transporting individuals and web cameras and microphones will break that social barrier that may come up with trust. And then -- so broadband was the initiative there.

On the last one on the trust factor -- I think I'll just leave that one for writing. So thank you so much for your time and the work, the generous work and concerns that you put forward. I'm grateful.

MS. BREWER: Thank you.

MR. MOELLER: Kristian Moeller with GlobalGap. On the issue of sharing data. Thank you for the recommendation on the private sector and the audits -- priority company audit. They're not going to share that data, but we do have accredited certification which is ISO 65 accredited. I know that this already a good level of sharing or from caring. We at GlobalGap, we have more than 100,000 audits every year in more than 100 countries. What that means to recognize those

on a level, there is some experience which we bring and submit in writing, but one of that is we talk about many different languages when you want to interpret these audits. So that needs to be taken into account.

Secondly, I think the ownership of these audits, when you talk about confidentiality, and, yes, I'm from Europe, so there are these concerns. We don't have our criminal record on the Internet so there is protection of those companies. And what we have dealt with is we give constant or instant access to these operators that own their own audit reports and they can share like with your Facebook with a certain group of people, with your best friends, with your family, with the public. So you have it always at your fingertip how much you want to share, and then you can make a condition if you want to supply to the U.S. FDA or share that piece of information with FDA. Part of that is for your quick access, for example. So ITEAS makes it possible to that and have an opportunity as a third party for more dialogue. Often with governments something is published and then we can react and respond to it. I think also there should be also opportunities

for operators. They have often good reasons. And there's some data out there to have an opportunity, if it's public, also to be able to defend in public.

Those are my comments.

MS. BREWER: Thank you. We have a question. Mary?

MS. SOPHOS: Kristian, I do have a clarifying question. This is Mary. You had just mentioned the audit report owners sharing those reports. Does that system already exist or is that just -- it does already exist?

MR. MOELLER: Yes.

MS. SOPHOS: Okay. Thank you.

MR. LAFONTAINE: Yes. I'm Dan Lafontaine with the HACCP Consulting Group, a private consulting group. My comment relates to what I believe Caroline mentioned a little bit ago. Looking at the U.S. FDA FSIS model, which has been in existence for -- a broad-based system for 30, 40, 50 years.

The point I want to make is take -- use the systems approach. Look at the governmental agency, regulatory agency of these countries and their

effectiveness. Audit, for the lack of a better word, or evaluate that system and also validate that system by actually looking at plants and seeing if what they put on paper is, in fact, working.

The counterpoint is, you do not want to chase individual plants; you'll never get there with the hundreds of thousands that you're talking about. The bottom line that I'm mentioning is concentrate your resources on your partners' governmental agencies and evaluate their effectiveness. And, in turn, if there are countries that are not effective systems, then you, in turn, can work with them to build their systems and actually look at individual plants.

So look at the model that the FSIS has been using very effectively on the effectiveness of their system, and, in turn, the system they use to evaluate plants as far as their food safety effectiveness. Thank you.

MR. DE MONTIS: Thank you. Eric De Montis (ph) from the Protected Agriculture Growers Organization of Mexico. And my comment is on Element 1, the second question of how can models of effective

agreements support capacity building? I believe there is a very effective model coming from bi-national agreements with USDA-APHIS where they actually give accountability to the organizations to manage these agreements. One of the issues is always resources from the governments. So by giving this accountability to the organizations, they support the management, the generation of information, the lobbying with the government, their own governments. So I believe that's a very effective model.

Today there are 12 bi-national agreements with APHIS, USDA-APHIS and Mexico. They work through 12 different organizations, private organization of growers or industry members. So I believe this model could actually support this.

MS. BREWER: Okay. Thank you very much. I would like the stakeholder panel to stay put, and I'd like to invite Dr. Elizabeth Calvey to come join us and discuss Elements 4, 5 and 6.

FDA INTERNATIONAL CAPACITY BUILDING PLAN - ELEMENTS 4, 5, 6 - ELIZABETH CALVEY, TEAM LEADER, LIAISON AND PARTNERSHIP TEAM, CFSAN, FDA

DR. CALVEY: Hello, this afternoon. Us short folks cause problems with the IT folks.

I'm here, as Camille said, to talk about a little more in-depth on Elements 4, 5 and 6, and I will follow the same format that Julia followed where I state the element number and then talk a little bit about our thinking behind the recommendations that we put down, and then I will read the recommendations for the transcript.

So Element 4, Training of Foreign Governments and Food Producers on the United States Requirements for Safe Food. Our recommendations for Element 4 are based, in part, on our past experiences in technical assistance and capacity building efforts.

In drafting these recommendations, we consider the need for training efforts to be effective and sustainable as well as the need for such efforts to have to have multi-faceted reach.

FDA has been involved in technical assistance capacity building for many years as part of the U.S.

Government's obligations under its various trade agreements, in particular Article 9, the agreement on the application of sanitary and phytosanitary measures or, as we say in shorthand, the SPS agreement.

We realize that there are many different methods and modalities for effective technical assistance and training and the training should be geared towards the appropriate audiences along with farm to table continuum in the appropriate language in ways that are effective for a particular audience, thus we utilize a variety of approaches in our technical assistance and training efforts including face-to-face, web-based training and train the trainer courses.

We also recognize the collaboration of experts from industry, government, academia and consumer groups increases the quality, accessibility and the use of training materials in both the public and private sector.

FDA currently disseminates information on our food safety laws and regulations to our diverse stakeholders in multiple ways. Through our foreign offices, we provide assistance to countries that export

to the U.S. with respect to requirements for exported products that are regulated by the FDA by posting documents and videos on our website, not only in English, but other foreign languages including Arabic, Chinese, French, Japanese, Korean, Portuguese and Spanish.

And in 2011, FDA began utilizing YouTube for video hosting.

We also, as you heard this morning, with many of our speakers, work with a variety of organizations in food safety capacity, including the U.S.D.A. Food Agriculture Service program, the APEC PTIN, the new World Bank Global Food Safety Partnership and our own Joint Institute for Food Safety and Applied Nutrition.

We also recognize that other countries are actively engaged in food safety capacity building, and we are engaged in conversations with Canada and the EU countries to help minimize duplication of effort and foster complementary activities.

Recognizing the broad impact of the new requirements on FSMA, FDA is actively engaged in public/private partnerships and alliances with other

groups representing academia, industry and other U.S. Government agencies to provide growers and producers with assistance to the development of standardized curricula.

Besides the Seafood HACCP Alliance, which was created in 1994 and the Juice HACCP Alliance, which was created in 2001 to help deal with our HACCP rules, we have established within the last three years three new alliances. The Produce Safety Alliance was created in 2010 with the USDA Agriculture Marketing Association, Cornnel University, by its reaching out to all the players of produce safety.

The Food Safety Preventive Controls Alliance, which was created in 2011 with the Illinois Institute of Technology. I'll have to call it National Center for Food Safety and Technology because I don't know the new umbrella organization; it is still new to me. And we also created the Sprout Safety Alliance at NCFST, Illinois Institute of Technology. And later this afternoon you'll be hearing a brief presentation from Julie Moss on our efforts to implement a framework that will help assess the effectiveness of these capacity building efforts.

So based on all this data gathering and past experience, we are recommending as resources are available, FDA should facilitate the provisions of technical assistance and should participate in capacity building activities focused on preventive controls, produce and seafood safety and U.S. food safety requirements.

FDA should prioritize its training and capacity building activities according to risk assessments and the needs of identified countries as appropriate.

FDA should continue to develop materials, i.e., web-based and classroom-based about U.S. food safety requirements, including materials about FSMA.

Similarly, FDA should refine the existing materials on U.S. food safety requirements.

The discussion questions for Element 4 include, what are the best ways to ensure that developing countries are engaged with any training efforts?

What training methods, modalities and models are effective and why have they proven effective?

What are potential obstacles to be effectiveness of training efforts and why?

And now I'll go on to Element 5 -- oh, two more questions for Element 4.

How should FDA assure that its training efforts are sustainable?

How should FDA training plan be designed in order to ensure the multiplier effect, i.e., train the trainer type programs?

Now, we go on to Element 5. Recommendations on whether and how to harmonize requirements under Codex?

Our recommendations related to Element 5 are based on our long-standing participation in Codex. As you mentioned several times, FDA has engaged in Codex since 1963 when Codex was inaugurated, and FDA participates in all committees of Codex.

Some of the committees -- I'll just highlight a couple of committees that we are U.S. delegates on -- the U.S. delegate on, and that is the Contaminants and Foods Committee, the Food Hygiene Committee, Food Additives Committee, Food Labeling Committee, Methods

of Analysis and Sampling, Residues and Veterinary Drugs and Foods. We are also on several of the ad hoc -- a delegate for several of the ad hoc task forces on antimicrobial resistance in animal feeding.

And FDA contributes not only as members of the delegation of these Codex committees, but contributes to the technical, scientific experts to help develop many Codex food safety standards, particularly those relating to microbial pathogens and food contaminants and food additives.

And we also work with the standard-setting activities and other scientific bodies within the Codex standard-setting activities, and that's the Joint Expert Committee on Food Additives and Commodities and that's the Joint Expert Committee on Food Additives and Contaminants, the Joint Meeting on Microbiological Risk Assessments and Joint Experts Consultations.

So based on our continuing activities in Codex, we are recommending that FDA should continue its active participation in Codex, assisting in developing science-based standards where appropriate.

FDA should provide continued support to the

U.S. Codex office and support the development and implementation of Codex-based capacity building programs.

FDA should support the Codex Trust Fund and active participation by other countries, and FDA should seek to harmonize its requirements with Codex, where appropriate.

In the discussion question associated with Element 5, what are your thoughts on Codex engagements, example, mentoring and how can U.S. Codex with FDA participation help other countries?

On to Element 6. Element 6 states, provisions for the multilateral acceptance of laboratory methods in testing and detection techniques.

In drafting our recommendations for Element 6, we considered our participation in a host of domestic and international laboratory networks and reviewed the laboratory training efforts of country counterpart agencies within the U.S.

Some of these networks and consortia that we participate in include, but are not limited to, the Laboratory Response Network, which is charged with the task of maintaining an integrated network of public

health laboratories that can respond to bioterrorism, chemical terrorism, and other public health emergencies.

The Food Emergency Response Network, which integrates U.S. food testing laboratories, local, state and federal into a network that can respond to emergencies involving contamination of food resulting from bioterrorism events or public health emergency such as a foodborne outbreak.

The Global Foodborne Infectious Network, part of WHO's efforts to strengthen capacity of its member countries in the surveillance and control of major foodborne diseases, and to contribute to the global effort to contain antimicrobial resistance in foodborne pathogens.

We also are actively involved in the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance, which advises WHO in the development of harmonized schemes for monitoring antimicrobial resistance.

These networks recognize the need to harmonize methods so that surveillance data from

different laboratories can be compared.

In a regulatory environment, it is important to know what the laboratory data will be used for in order to develop laboratory methods based on performance criteria for a given outcome such as for screening purposes or for taking regulatory action, and validating, appropriately, for their method intended use. For example, the contaminants above or below or a limit or the need to actually quantify a contaminant.

And an example of why we need to look at the different -- the intended use is, when you're developing microbial risk assessment models, there is a need to have data that reports the quantity of a pathogen and not just determine its presence or absence to have an effective risk assessment model.

FDA recognizes that that these fit for purposes methods, methods based on performance criteria for a given outcome, need to include a range of appropriate technologies, that is, it has to deal with basic intellectual technologies such as thin-layer chromatography and ELIZA technologies to

instrument intensive technologies such as liquid chromatography and mass spec detection to address the needs within the domestic and international food safety testing laboratories.

In order to fulfill the mission of the laboratory networks, I mentioned above, they include training components for its members. Other laboratory methods training venues include courses through the EU's Better Training for Safer Foods, the APEC PTIN, as mentioned earlier this morning. University of Maryland's JIFSAN International Food Safety Training Laboratory, which is a dedicated teaching facility developed through a public/private partnership primarily focused on those who export to the U.S.

And the recently announced U.K. FERA IFSTL, which will primarily train those concerned with exported foods to Europe.

The U.M. JIFSAN IFSTL and the FERA IFSTL are the beginning of an effort to establish a global network of dedicated training facilities on analytical methods for testing for food contamination.

The training facilities within that will

coordinate and share expertise. As new facilities, if they are added in the future, they will also coordinate and increase the knowledge in the use of global best practices.

To improve transparency with regard to the methods FDA uses for compliance purposes, FDA posts on its website its methods, including the Bacterial Analytical Manual. And the FDA also posts its methods validation guidelines for the validation of chemical methods for the food programs and for the validation of analytical methods for the detection of microbial pathogens. If people would like those links, I can give them to them later.

Based on just all this information, the recommendations for Element 6 include, FDA should encourage the adoption of laboratory methods based on performance criteria for a given outcome and validated appropriately for their intended use.

FDA should have methods available that are not only fit for purpose, but also useable in various sectors within a country.

FDA should partner with training institutions

and domestic and international laboratory networks to conduct outreach and education about fit for purpose laboratory methods with a goal of increasing multilateral acceptance and use of these current best practices by the international community.

FDA should continue to be transparent and share its methods for compliance purposes.

The discussion questions related to Element 6 include, what are the needs for mutual recognition of laboratory methods? What role should industry laboratories have and how should FDA coordinate with such laboratories? And what role should organizations, for example, WHO and ISO, have? What are the opportunities and what are the impediments? Thank you.

(Applause.)

MS. BREWER: Thank you, Beth.

Look at us, we're back on time. What I'd like to do is just take any questions of clarification, then we can go to break, and then we can come back and hear from the stakeholder panel. Is that fair?

(No verbal response.)

MS. BREWER: Okay. Clarification questions?

(No verbal response.)

MS. BREWER: None. People want to go to break.

(Laughter.)

MS. BREWER: Anyone?

(No verbal response.)

MS. BREWER: Let's go to break and we'll back in the room promptly at 3:15. Thank you all.

(Short recess.)

MS. BREWER: Let's take our seats, please.

I'd like the stakeholder panel to come back to the stage, please, and also I'd like Keith Brown to join us.

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MS. BREWER: Okay, then. We will follow the same format. We will first hear from the stakeholder panel and we'd like them to address, first, Element 4. We'll just go down the line. Then Element 5, then Element 6. If you want to pass, that's fine. But if you have comments to the questions, we want to hear them. And I think I'm missing Caroline. Is Caroline here?

(No verbal response.)

MS. BREWER: Caroline.

All right. Let's get started and she'll join us.

MS. DUBOIS: So just to give an introduction for those who don't know JIFSAN, the Joint Institute for Food Safety and Applied Nutrition is a partnership between the University of Maryland -- you are the only one who can't hear me.

(Laughter.)

MS. DUBOIS: So the institute is a partnership between the University of Maryland and the FDA. We've been providing resource outreach and a lot of training activities over the last 16 years. So looking at the training is, of course, very interesting for us to be able to bring our point of view in that.

On the first element on the training methods modalities and models that are effective, one of the elements that we found over the years to be very important is a combination of training that happens in country and where trainees are brought into the United States or another country to update their training.

There are several advantages to both besides the cost of travel. For example, training in the United States benefits from the availability of a large number of experts, and we were talking earlier about using FDA expertise to train our foreign governments or for industry, and there's only so many people and only so far they can travel, and only so many trips per year. So gathering people here allows us to pool some resources in a very cost-effective way for the U.S.

When we do training in country, in the United States I mean, it also enables a lot of networking between the people who come for the training and a larger number of experts from our own government organizations. This is an essential component for continued interest, but also for improvement.

The training in country, however, and what we call in country is when we send trainers to deliver the material. This can reach, of course, a greater number of participants, but it will always use a limited number of trainers, therefore, a set of expertise that will be a little more limited. And then we have to be extremely careful about selecting the trainers because

of the restricted fields of expertise and then these trainings become so specific, it's hard to deploy in a very large scale.

And we were talking this morning about deploying worldwide in a scheme such as the Global Food Safety Partnership, and it's very important that we consider how we can use as much expertise as we can in the most cost-efficient manner.

We talk about web conferencing for participation in the development of all sorts of things, including regulation, and, of course, web delivery is an important component that should be included as a method for training, delivering training. However, one danger in web training is to just make material available and hope for the best. Assume that it will be used because it is there, and there is no such guarantee.

We talked about language. Elizabeth detailed some of the language issues and what has been done about these issues, and delivering training again on the web in single language or a small number of languages limits how many people will go to it. But my

point here was more that - there has to be some management of the web-delivered resources to make sure that there's an understanding of who is taking advantage and who is not. Training is not done just because it's available.

And then the obstacles -- I'm sorry, I'm taking longer, but I passed a couple of times, so I was banking my time.

(Laughter.)

MS. DUBOIS: The last element that -- and I just flipped all the way through that I wanted to address was -- and it's been mentioned already, a one size fits all, does not work. It is very important to engage the right partners to establish long-term relationships to engage industry. The governments, of course, but industry, as well, and academia. And academia is essential in some developing countries where there is not the knowledge, and we talked about the data also to conduct risk analysis. So it's very important to engage multiple different partners from different backgrounds and with different intents in the end. Thank you.

MR. JOHNSTON: Thank you very much. I just want to mention there were several times in the presentations or in the FDA outline you've seen the word "leverage." There is one area that I think that FDA can leverage a lot of private sector activity is in the area of training. I'm going to bring myself back in time here. Peggy Rochette is here from Grocery Manufacturing. Peggy and I worked together for the National Food Processor Association before they merged. And one of the things that I was responsible for at NFPA was something called the Food Processors Institute, FPI, which is a tiny program for people in side companies to do food safety, including certification.

I would strongly encourage you to look at certification as an incentive to get people who need training to be trained because if you are certified in a valid, legitimate program that meets some of these things, you will make yourself more marketable, one, to companies like mine, but also to help enhance the capacity of operations and private sector and public sector in other countries. So I would encourage you to

look at that.

I would also look at carefully involving participation and training or certification programs, again, as part of a voluntary qualified importer program because, again, you want to create the incentive for people to be in the VQIP program so they'll be subscribing to perhaps even higher standards, more information sharing and having training as part of that, I think, is pretty important.

MS. SMITH DeWAAL: The training element of the plan is really the opportunity, I see, for FDA to seed the concepts, especially within university systems in foreign governments. The critical problem with training across national and cultural boundaries is, of course, they're not only language differences, but they are differences in understanding.

If you traveled in India or almost any developing country, there are differences. There are differences in acceptable levels of sanitation. There are differences in just cultural understanding, and so you need to seed the information within an environment where it can grow.

So what I would recommend for FDA to consider is identifying the important partners whether they be at WHO, FAO, the organization, the U.S. Industrial Training Organization that was here represented today, whether they're at the University of Maryland or Minnesota or Michigan State, but identify a key -- one or more key partners. But then as you look to do in country training that you actually have those entities partner with universities in those countries.

You will grow their food safety programs within the universities; you will create the knowledge base that you need to make sure that the concepts that are really principle concepts within risk analysis around food safety generally, but the FSMA concepts are captured more broadly in the system. Thank you.

MS. HOWARD: Thanks. Well, I gave up my opportunity to comment on one question in the last session, and I'm going to make up for that now. And I'm also going to use that word "leverage" and say I'm really excited to learn about the private sector, the opportunities for leveraging private sector skills and what's out there in third-party institutions. I think

that is something that we in USAID need to follow up for our programs and look forward to continuing that discussion with USDA and, of course, with FDA and other partners about how to do that effectively.

I wanted to talk a little bit, maybe give a couple of examples of the kinds of capacity building we've been involved with, and sort of highlight characteristics that we think are important as it's going to go forward. And then I'm going to sort of end with sort of five maybe principles that we use as kind of guiding principles in our programs.

First, I think -- I mean, the incentive, you know, whether it was certificate or, you know, incentive in terms of, you know, what you realizing in terms of improved income, the financial aspects. It's important for the individual who is getting trained, for the farmer, but also important for governments to invest in a system.

So one example of this is the mango market development project that we have and with other partners in the State of Maharashtra in India. And this was a project that focused on building capacity

among mango farmers and processors who had to really meet very high standards for product quality and safety for domestic and export markets. And we really focused in this project not only on the food safety dimensions, but also on, you know, what did it mean in terms of what the farmers got back out of that. So we found that growers who were able to produce these certified products, mangoes, received 20 to 30 percent, at least that amount, greater returns on mangoes in this very high-value domestic market and 50 to 60 percent greater returns on mangoes sold to exporters. So I just hold that out because that's a very important figure to take to governments, and we were trying to institutionalize that system.

Another aspect I wanted to comment on briefly is just what it takes to how you know you're successful in institutionalizing a system? And we've had collaborations, we call the Partnership for Food Industry Development in Michigan State, Ohio State, probably University of Maryland, Louisiana State have all been involved with this over time. But Louisiana State and a couple of countries through its leadership

in the meats, seafood and poultry component of this project has been working in Ukraine and then in Moldova. And the Ukraine managed to establish an International Institute of Food Safety and Quality. Now, we know that's successful now because that itself, the IIFSQ has established itself as a repository for the region now. So it's addressing food safety and quality assurance sectors not only for Ukraine, but, you know a number of the other countries of the former Soviet Union. So I think this is some of the aspect that we were talking about in the previous conversation, how can FDA and partners, and willing partners be active not just at the retail level of the individual plants, but, you know, really focus on developing these trainers -- trainers of trainers in institutions that will train the trainers of trainers.

So we're quite pleased about that. So let me just turn briefly to what do we think are kind of the essential approaches to ensure long-lasting success?

And first and foremost, and I can say this 10 times, taking a medium- to long-term approach to building capacity. So we just find over time when all

trainings and workshops are rarely successful in trying to invent this very complex kind of training that needs to be done. So training really needs to be sustained over several months to years, if not institutionalized in a home institution.

Secondly, it's important to provide mentoring and extensive training to the key individuals, the champions, you know, that can act as leaders within their countries or regions, and really drive the development and implementation of science-based standards and regulations. So, you know, it's really sort of, you know, maybe partner with the private sector, and just identify, you know, who are likely to be the champions over time and really do our best to mentor them.

Thirdly, and, again, I could say this probably 10 to 20 times, capacity building efforts should include the development of standards regulations as well as the implementation and operationalization of processes. And how many projects do we all know of that sort of stop at the standards and regulations and declare a victory, and then you sort of go back and you

wonder why nothing happened. Well, you know, really, operationalizing means everything from going to training, parliamentarians, training folks in agencies, training the private sector, training the border officials, and all the steps need to be done or you don't have successful change.

Fourth, you really need to tailor capacity building activities to each country's needs. I won't dwell on that because I think we've said time and time again this morning. So as an aspect of that is recognizing that the processes may not directly transfer from the U.S., but we may need to look at models, for example, we're increasingly looking at South Africa, what South Africa is doing as a model for our work in Africa, and it's helpful, we think, also to promote this south-south collaboration and information sharing and look forward to working with our donor partners to see how we can do some more of that, I think.

Lastly, again, going back to the mango example, supporting not only the training, but the research and the economic analyses that demonstrate the

benefits at different levels of appropriate food safety standards and processes. This is really going to help to gain the support of policymakers to enact new laws, regulations and procedures as well as the support of farmers.

MS. JAVELOSA: Yeah. A couple of inputs from our food bureau, agriculture and fisheries product standards that have been active in the APEC food safety capacity building as project proponents, as conveners or organizers and also as recipients of technical assistance on specific food safety issues.

On the best methods to engage developing countries, they identified bringing together experts and having exchange programs and one example provided was one which was done during the food APEC defense project where food and participants went to the University of Minnesota for the food defense exchange program.

Another method identified was through USDA-FDA internships to expose regulatory officials of developing countries on how the U.S. manages their food control system with surveillance and risk assessment.

And one good training model identified as well was the training on the risk assessment conducted by Food Standards, Australia, New Zealand and sponsored by APEC requiring groups to conduct local group studies within six months after a five-day training. And within the six months experts conducted one on one mentoring with each of the groups via e-mail.

Food Standards, Australia, New Zealand conducted a follow-up workshop to report on the outcome of the group case studies later on. And those were a couple of comments provided by the Philippine Bureau of Agriculture and Fisheries Product Standards.

MS. STROSSMAN: Thank you. Just to provide some general feedback and also some examples for FAS's experience providing capacity building related to SPS in general and food safety. Generally, we have found that in terms of -- there's been a lot of talk about partnership and collaboration, and I just want to emphasize that. As different government agencies and donors, we can have different objectives, but that we can gain mutual benefits by collaborating on our activities.

For example, FAS's capacity building activities are generally geared to support our agency's trade and food security objectives. We're also closely collaborating with USAID, State Department, FDA and others to provide U.S. FDA expertise in support of some of the overlapping development in public health and foreign policy objectives, as well. So I think that was mentioned by Julie and others that we need to kind of find that common ground and leverage what each other are doing.

And in terms of kind of the elements that we have found important when conducting training on U.S. requirements, one very important one is having that buy in and commitment from our foreign government partner. And if that's not done effectively and not understood up front, it can be an obstacle to success. So we need to make sure that we have that.

On the flip side, we need to have the commitment and the available resources such as the qualified trainers in the relevant U.S. regulatory agency to be able to provide the training over a relevant period to make sure that it's sustainable.

We need to ensure the sustainability through mechanisms such as training the trainer has already been mentioned, incorporating the private sector or academic sector into activities and leveraging those resources using technology. We heard about some of the limitations of that, but, certainly using the various means possible including webcasts and websites to maintain information so that there's not just a one off when you've provided the information.

We find that there's a lot of turnover of key personnel in some of the countries where we work, so we need to address that issue and find ways to make the training sustainable given that constraint.

We found that it's important that with our partners in the countries where we are conducting training that we jointly agree on objectives and how to maximize resources to meet those objectives.

We found that targeted programs with clear objectives tend to work better than broader less well-defined initiatives. One model that I could mention is our support, our capacity building supported by USAID to assist countries in achieving meat equivalence with

the United States and the way we have carried that out is working with technical experts through kind of a four-step process, which I think gets to the issue of having kind of a sustained longer term view starting out with providing seminars on the regulations to ensure that our foreign stakeholders understand the provisions. And also doing an initial assessment of the systems, for example, the inspection and food safety laboratory systems to define the needs.

And then as a second step, providing specific training targeting the areas that have been identified.

As a third step, after the specific training, performing a second review of areas for improvement and additional needed training.

And then as a last step, performing kind of a mock audit to confirm that these systems are in order before an official audit would be. And so this mock audit by -- in a capacity building context before an official audit would be undertaken.

So this model allows USDA to educate the foreign public and private sectors regarding the U.S. regulations, policies and laws while at the

same time helping countries build the capacity that will allow them to participate in international trade. Thank you.

MS. YUKSEL: This is always the beauty of going last, because everybody has always said all the points that you wanted to say, but it also allows me an opportunity to actually reinforce some of the points that I think are really important and try to be innovative and try to think of ways of strengthening some of the things that have already been said. For example, and I'm going to stick very much to being a development person and working for development agency, our areas are very much in the poorest of the poor, so this is where I'm coming from, and this is to be understood, that when we're looking at -- we need to understand that there is dramatically different levels of human capacity. It was mentioned not only between countries, but it really needs to be emphasized that it's even within countries and within institutions in those countries that have dramatically different levels of human capacity. And it varies from region to region, even district to district within a country.

So what this means is it's difficult to make a plan from Washington, and what you really need to do is have someone go into the country. This is an investment in time, in resources, and actually getting local individuals who understand the capacity constraints within institutions, and also the cultural and sort of the political nuances that you might not understand from this side of the ocean. This also makes the needs assessment especially important.

It needs to be made in advance and it needs to be flexible enough so that when you go into the country that you need to make sure that it's relevant, the training material is relevant to the specific country.

I also want to differ a little bit on what was said about the training and I understand on some food safety and laboratory training, it's necessary to be in country here, but when we're talking about training with international trainers, and I'm really talking from experience of our work in CIDA in talking with our Canadian Food Inspection Agency, that some of the best trainings that we've had in our experience is

when international trainers and experts are done in country, if possible, and as appropriate so that the international trainers can really understand and adjust to the local condition.

We may make an assumption that we can do sort of Internet and web now, but I've spent five years working in East Africa, living in East Africa, and my contact at the ministries -- I mean, their e-mail accounts were Yahoo and Hotmail. So we have to understand that for them to have access on a daily basis is limited. And when you're there and working with them in country, you can understand that and change that appropriately.

We mentioned the importance of train the trainer approach is crucial. But the thing the train the trainer does allow you to do is that it allows you rely on local trainers and resource persons to ensure local ownership of the project, so gradually transferring responsibilities of the project implementation to local partners. Therefore, you are actually building your capacity in country because you're depending on local experts that you're training

to then carry forward.

So in terms of what we have found in Canadian experiences is that the hands-on practical training provides the best opportunity in advancing training on food safety and the like.

Now, classroom training, we found in our experience, is not very effective, and so how to be a bit more innovative in how you are approaching the training is crucial.

Attendance at the training sessions, it can be facilitated by good coordination between the food control agencies in developing countries. So working closer with them to make sure that the people that are coming to your training session are the right people that you need in the session.

And some of the ways is looking the selection process of who is coming to your training will be crucial. Also, I have to really say the incentives and certifications need to be built in. It was said already, but I just want to emphasize that. The trainers need to see this as advancement in their career. And in doing so, you also take the ownership

into the institutions where then they value that training into their institutions and they'll carry that program forward after you leave. Not as -- it's very, very important that not only the people value it, but that the institutions value that knowledge.

Also, another point is the joint training initiatives involving other developed countries, donors, countries that are also working and delivering international training courses at workshops were out there, as well. And I think there is really innovative projects and workshops that perhaps donors can do together and to be cost effective, as well, and learning from what other donors are doing in country, I think, is crucial.

I think USAID has a lot of experience on the capacity building and working in developing countries, so you can get a lot of those knowledge from them.

The last thing I want to say is capacity building will be enhanced if the recipient countries have a sense of ownership in their activities. And, as I said before, and I want to reiterate that they are prepared to invest in a long-term process and including

the appropriate human and monetary resources for infrastructure development has to in country otherwise it's not going to be sustainable. Thank you.

MS. BREWER: Thank so much for those important themes and principles. I'll turn to working group, you're okay. You've given us a lot to think about, so I really want to thank you for that last session.

Now, we'll turn to Element 5, which is regarding Codex Alimentarius, so to my left.

MS. DUBOIS: Obviously, Codex has an important role to play in -- I don't want to repeat what everybody knows, but one small detail that I think we have to be careful about is that Codex is an international initiative. It is meant to be something that a lot of countries agree on, and if we start picking and choosing what we use Codex to deliver, it might not look like the appropriate use of Codex, and by that I mean if a standard that we use in the United States is not necessarily exactly the same as the standards prescribed by Codex, are we going to separate ourselves from -- just on that particular element. I

think we have to, and we have in the past, and we have to continue, to take Codex for the spirit of its creation which was agreement between a very large numbers of countries.

MR. JOHNSTON: I'll be very quick. I think if there is one role where we really need FDA, not just in the membership, but leadership is in Codex. And Codex is an essential part of trying to harmonize and develop common approaches on food safety, so we very strongly support FDA's work and leadership in this area.

MS. SMITH DeWAAL: Well, Camille, I just can't help it, but with Codex there's the good, the bad and the ugly. And I think in my years of participating in Codex, I've seen all of it. The good is when they can get a standard through in two years as when the Japanese took on vibro vulniferous. I mean, pretty amazing.

The ugly, I won't even describe here, but it happened quite recently. The thing that I note, and I participate in three different Codex committees and often miss planes together with Camille all the time,

so -- but the thing that I note that is that when Codex is actually working on a standard, for example, they recently developed a standard on melons. What's interesting to me is literally the melon experts from the government agencies all over the world are at that meeting. I mean, they literally send their technical experts. And that would be a pretty awesome time to do a training workshop. I mean, if somehow we could create the training workshops to align with these Codex meetings, you would get pretty broad international representation.

So I just want to put that out there. And then, of course, the U.S. can contribute to Codex, number one, by providing papers. I was really interested. Codex took up this work up on produce safety, but at the last food hygiene meeting at the pre-meeting where they discussed what will be on the agenda for the next meeting, it was like pulling teeth to get someone to advance a paper dealing with produce. And we had a whole list, but apparently no one in the countries had had time to actually work on the paper. So, again, thinking through strategically how to use

those Codex meetings to get the papers written and advanced, but maybe also to have the workshops around them.

And then, lastly, support of the Codex Trust Funds is vital if you're going to get participation of developing countries.

MS. HOWARD: Great. Well, just briefly, USAID supports FDA's continued active participation in Codex. We think it's also very important for all the reasons that have already been mentioned. And we support the development of implementation of Codex-based capacity building programs. So -- also, FDA leadership and the whole idea of a set of common standards reminds me of what my colleague from CIDA was saying about aid effectiveness and the crop principles and it may be, you know, building on these comments we just heard, you know, that Codex may be one of those organizing platforms where we as donors and private sector can combine resources to sort of strategically make progress not only on standards, but training at the same time, and put our resources together that way. I think that's going to become increasingly important

as we're finding resources constrained for all kinds of things, to learn how to use them more effectively. So this might be one of those organizing polls and FDA can play a really important role.

MS. JAVELOSA: On how U.S. Codex with FDA participation can help other countries. One idea is for U.S. Codex to provide technical expertise in developing country positions, but to get those positions requiring risk assessment. And another specific request is for mentoring in developing discussion papers with Codex.

MS. STROSSMAN: Just to kind of add my voice to some of the things that have already been said on Codex. FAS supports harmonization with Codex to facilitate international trade and assist developing countries to participate more fully in the standard-setting process. We have worked very closely with our colleagues in the U.S. Codex office and FDA to implement an international outreach program to help build developing countries capacity to participate in and benefit from Codex.

The types of activities that we've included

in that program that we found very useful have been bilateral capacity building workshops, which are designed to strengthen our recipient countries' Codex capabilities. We have also carried out regional colloquia, as we call them, bringing together countries from a particular region to focus on improving regional harmonization and providing an understanding as key issues for upcoming Codex committee meetings, as well as explaining the science behind some of the proposed standards.

We've also carried out a mentoring program for Codex delegates from Africa and so this is, again, one of those ongoing programs that we find has been successful and sustainable and has helped promote fair trade practices and improve consumer safety in countries around the world.

They've strengthened U.S. relations with many countries while at the same time facilitating trade.

And just to comment on the idea that was raised in terms of taking advantage of countries gathered -- experts gathered together for a particular meeting like the Codex meetings, we have employed that

model in many cases where we look at where countries are gathered for particular international meetings where it makes sense to kind of tack on an additional day and conduct a workshop on a particular topic. That is a model that we see quite successfully and is a great way to kind of leverage the fact that you have all of these people together in one place. Thank you.

MS. YUKSEL: Just quickly. For the government of Canada, we are also quite supportive of the Codex and supportive of your activities towards it.

MS. BREWER: Okay. Thank you. So let's move on to the last element, which has to do with laboratories, so Dr. Dubois, would you start us off?

DR. DUBOIS: The requirements for mutual recognition of laboratory methods, I think, of course, starts with the accreditation of laboratories and, therefore, understanding the methods. We can agree, and all we want on the methods if they're not performed the way they're meant to be, the outcome is going to be whatever it is. So I think the accreditation of the laboratories is extremely important.

We talk about certification. I think there's

going to be a certification of some people in the laboratories as well that is with competency, testing and to relate it back to what was just mentioned. It's very important for these to work, especially in the area of training, to ensure that there is a positive outcome for the person, a positive outcome for the laboratory itself, that they gain a position by participation in the training and in the steps that are required for mutual recognition.

The -- it is important to use equivalent methods, and, of course, the equivalence has to be demonstrated and that hasn't always been the case, but I think it's going to be -- there is a misunderstanding in some countries that a method absolutely needs to be used as opposed to a method that provides an equivalent result, and I think that will be important to remind people.

And, finally, the use of certified standards will have to be promoted, and that's extremely difficult in developing countries where those standards -- you know, they're very expensive for everybody, and in some countries they are absolutely impossible to

obtain even for reasons as simple as shipment. So that's something that will have to be taken into consideration.

MR. JOHNSTON: The issue of multilateral acceptance of lab methods and techniques is a very, very important issue to our industry. I don't know of a single company that imports or exports that doesn't have at least one horror story of a false lab report either from a food safety authority or a company or whatnot that proves to be false, but in the process enormous resources get lost, product gets wasted and all because of, again, poor lab work or poor incompatible standards and whatnot involving lab testing around the world. So this is a hugely important area. I know it's also a tremendous challenge of trying to get different companies, different cultures, different entities around the world to agree on many of these. I don't think it is impossible. We've heard from one association this morning it can play a very important role. There are lots of other stakeholders, I would encourage FDA to consult, for example, International Life Sciences

Institute would be a good place to go, International Food Technology, other groups. Private sector NGO's, other associations that have a lot of professional expertise in this field that can help contribute to getting us to that goal.

But if there's one area that we think that's absolutely critical to the success of international capacity building in building trust around the world on food safety, this is one area that's really important.

MS. SMITH DeWAAL: And this is one area where I would say the industry and consumer associations are in complete agreement. This is the issue of standardizing laboratory techniques and methods and getting broader acceptance is vital.

I would point you, though, to the efforts that the World Health Organization, they have done a huge amount of work at capacity building in the area of labs and especially foods labs. They also have a project on antimicrobial resistance. It goes by the tag name AGISAR, which is an effort to coordinate surveillance efforts across public health, food and live animals looking at antimicrobial resistance. But

the important thing about looking at that project is, in fact, the issues around whether appropriate sampling methodologies, sampling techniques, how to trust the sampling, types of sampling that are coming out of different systems and there's really an effort through that process to get broader acceptance. I will note as well that a lot of -- a lot of the report on those particular questions were written by FDA employees, as well as people from USDA, but Pat McDermott has played a really major role in that. So I think -- and the last point I want to make on this is that FDA should not forget the issue of public health surveillance. It's often a forgotten component to this, but public health surveillance systems that track foodborne illness in country -- in developing or foreign countries are vital to effective -- both effective food safety systems to monitoring what are the actual hazards in those systems, and also from our standpoint for effective import control because you need to know what you should be managing when it comes to different hazards.

So I think as you look at the last questions, you shouldn't forget public health surveillance.

MS. HOWARD: Thanks. Well, this is an area where USAID also thinks the establishment of multilateral labs, they're very important and encourage further conversation with FDA, collaboration with USAID, other partners can help leverage resources to develop these food and feed safety testing laboratories including, but not limited to government laboratories that will be able to offer a range of access to appropriate technologies and conduct outreach and education about fit for purpose laboratory methods, not one size fits all.

I wanted to point to one example, a collaboration that we have with USDA as part of the African Growth and Opportunity Act, sanitary and phytosanitary capacity building program that we're jointly implementing in East and Southern Africa. We are both supporting the establishment of regional reference laboratories, so we have one in Boricua for food safety, one in Zambia for animal health and a laboratory in Kenya for plant health. And so the beauty of that -- it's a bit of a closed circle, you have the regional reference lab, the then, multilateral

standards, and this is all part of the SPS annex of the SAFA, Southern Africa development community, EAC and COMESA tripartite free trade area. So it is actually helping to establish standards and laws that the countries themselves have put into place. So I think it is, at least, a double or maybe a triple win for us. Thank you.

MS. JAVELOSA: I would just like to give a general Philippine interest in working with the U.S. in having our food testing laboratories validated and results recognized. And we look forward to working with you on this. Thanks.

MS. STROSSMAN: Thank you. Just a quick comment in this area. FAS has also been involved in capacity building efforts to help laboratories meet standards, as well as providing training on good laboratory practices, which I think is some of the issues that were raised about maybe false results or poor practices leading to incorrect results and specific diagnostic methods that are required by importing countries.

In our laboratory capacity building, we've

used a series of different methods of delivering training. We've carried out hands-on training in specific diagnostic methods such as training to ensure that foreign labs are able to perform e-coli and salmonella detection methods required by FDA and FSIS.

Methodologies vary by agency depending on the product. For example, the method used for testing salmonella in poultry would vary from the one used to test melons.

Another approach is assessment of gaps in laboratory systems. A company then buys related training and technical assistance targeting those identified needs. And also workshops for the key stakeholders to understand what is necessary to achieve certification on a lab.

And these trainings, I think, are very -- have been complemented with training for farmers and good agricultural practices and for food processors, for example, in HACCP, so that you address some of these contamination issues before they happen. Thank you.

MS. YUKSEL: Okay. Last again. I'm going to just base -- it's great so that I don't have say everything everybody just said. My comments are based on a discussion that I had with the Canadian Food Inspection Agency and some of the sort of lessons learned. We talked about a lot about labs and skills, but one thing that they were also -- we were discussing was that labs are often lacking in equipment, as well. And trying to meet that capacity, it can be difficult. However, that being said, providing lab equipment is usually not aid effective, and I think there is a lot of examples out there where you may provide equipment and then come back and it's still sitting in the box.

So I'm glad everyone is nodding. Or that there will be no money to actually fix the broken equipment or the training on proper use down the line isn't there, so we all know that - yet somehow sometimes it creeps back in, and then we end up supplying infrastructure. So supplying infrastructure and lab equipment does not work.

So what are the innovative ways of thinking whereby you can then improve the labs in the countries

that you're working in, put it into the government institutions where they have that ownership of that equipment, and then you build in the training long-term so that they'll sustainably use it over time, I think is crucial. Thank you.

MS. SMITH DeWAAL: Sorry, there was one kind of lesson learned out of the AGISAR process - is another component of this question that FDA probably needs to address - is the issue of identifying a common platform for uploading information. If you're going to take information from different lab systems, from different countries, you need to have an agreed upon set of elements that are -- need to be uploaded.

The platform that AGISAR has been looking at is called tunet; it is out of Boston. I should know this. Sorry. It's called tunet. It's a common platform if you just look it up. But, again, identifying what is the right platform once you do have the lab information that you want, how you actually communicate it to other people, and in a way that's comparable.

MS. BREWER: All right. Thank you all for those really important and relevant points. I'm going

to just plant a seed before I turn it over to the broader audience. I want to ask our stakeholder panelists, did we miss any important questions, and, if so, let us know. But think about that while we turn to the audience.

So, first, are there any clarifying questions or comments to the questions we posed for Elements 4, 5 and 6? Eduardo? Ladies first?

MR. SANTOS: Ladies first.

MS. PAPPAIOANOU: Good afternoon. My name is Marguerite Pappainanou and I'm with Development Alternatives, Inc., DAI, although I worked at CDC for many years. I just wanted to underscore the comment that was made about surveillance. Both -- I know that outbreak information in terms of the type of data, but I'd also like to underscore the importance of information on foodborne infections mortality. Unless countries have that data, they are absolutely powerless against the forces that be with huge amounts of money available for AIDS, malaria, TB, integrated disease surveillance, all of the other diseases that get money for surveillance. It's virtually -- very few

developing countries have any kind of surveillance for foodborne and waterborne infections, and, therefore, it is very hard within the country to muster the political will to actually do something about it because this has been commented at this session, trade is very important and, obviously, food safety is very important to them for a trade.

But as was mentioned, much of the food is actually kept within the country and, therefore, having the capacity and building the capacity to execute disease surveillance is important. And also, not only just how we do it, but the whole public/private sector.

We're talking not only human surveillance, but, obviously, surveillance in livestock from poultry that brings in the private sector and sharing information with the public sector. And it also speaks to the need to integrate both human and animal surveillance systems.

And the last point I'll make on surveillance and building capacity for surveillance is also incorporating what people would do with the information. It's not enough just to collect the

information and share it, what's really needed is to help those who would have the information, use it for prevention, for better control, so it is often assumed that that will happen, but actually it's very important to incorporate those elements in capacity building efforts. Thank you.

MR. SANTOS: Thanks, Camille. Eduardo Santos, formerly with the Chilean Embassy for many years and now working with a D.C.-base trade and SPS consultancy company.

Camille, I'd like to add a little bit of Latin American flavor to some of the comments on issues that have been raised this afternoon here. And actually, I have to be very candid and say that I'm surprised that apart from the colleague from the Philippines, I haven't seen or heard any comment from any other embassy, and I'm quite surprised because this meeting is supposed to deal with international capacity building, and I would have thought that embassies somehow should have been interested in making contributions. So although I do not represent the Chilean Embassy, as you know I left the embassy a few

years ago, I still have some ideas about what's going on in the region. And a couple of points and then a suggestion in the area of training methods.

First, please don't wait any longer. I mean, I know that Caroline suggested that we have already used a year-and-a-half of FSMA. We only have six more months. You may miss the top priority, but whatever you do with your training program, I'm pretty sure you are going to keep other priorities in this area. There are too many things that need to be done and done now. So, please, don't spend more time thinking about what to do and how to do it, just do it. There are too many things to do.

(Laughter.)

MR. SANTOS: I'm sorry, you know me, but that's the reality of most countries, poor countries anyway.

Capacity building, I don't know whether it is a language problem, communication problems, but I have the impression, and that's my personal impression that most of what has been said today has to do with training. I may be mistaken, but that's what the word

that I have heard more and more, training, training, training and training. And I can tell you without strong institutions, at least in the regions, the countries that I know you won't be able to do any training and it will be self-sustained and that it will be successful. You need strong institutions. We don't have strong institutions. Somehow, some way, but not strong enough to do the kind of things that FSMA requires. Please, that's plain language, but that's the reality.

Another issue that has been mentioned here, but I'm going to give you a little bit of inside information on that, which is the equivalence program of FSIS, very successful program, very interesting, very useful, and extremely useful especially to changing the mentality of people working in the inspection service, somehow, some way, the system asks you to look at the system as a whole, not bits and pieces here and there, have a look at it. Use it.

In the case of Chile, there are not many countries that you know that have full equivalence for poultry and meat, and as far as I know that meet full

equivalence, there are only two countries, Canada and Chile. In the case of Chile, change the mentality of the people working in the inspection system. Change the system. Build a new system. And they have a very useful instrument. This is an assessment tool, which is the stuff you need to use when you begin equivalence. Have a look at it. It's extremely useful as a training tool because it forces people asking for equivalence to look at the system as a whole.

And to finish, also a little bit on equivalence. We had about a year ago a very successful experience and this has to do with training methods, which was basically -- this was in cooperation and financed by a multilateral organization of Latin America. They organized a working workshop for two days where the whole team that did equivalence in Chile was taken to a different country and worked for two days with the inspection system of that country and they told them how to work, how to do it, what was required, how they should be working, and it was really stimulating. Using real organizations, using the experience, the local experience, governments,

universities, local institutions very useful. And you have a bonus, you have the language and the culture, and there are plenty of good institutions throughout Latin America that you can use to do training and capacity building. Thank you.

MR. YUDIN: I'm Richard Yudin; I work for an Irish company called Fyffes. We have subsidiaries in the United States that make us one of the largest importers of cantaloupe melons, which is a high-risk product. I want to address Point 6, which is the equivalence of lab standards. What I would request is that you maintain flexibility, that you do not prescribe certain methods that may not be executable in smaller countries which don't have a big lab structure.

You should also be flexible and permit testing done either on arrival or in neighboring countries that do have the infrastructure. Thank you.

MS. CARNEVALE: Catherine Carnevale, independent consultant. And I wanted to address Element 5. And Element 5 has an interesting wording to it. It's recommendations on whether and how to harmonize requirements under the Codex Alimentarius. I

was reading that to mean that FDA would harmonize with the Codex Alimentarius, but most of the recommendations actually pertain to training other countries, mentoring other countries, continued support for the U.S. Codex office to support development and implementation of Codex-based capacity building programs, et cetera.

So I draw that to everybody's attention that this can be read as FDA harmonizing with Codex or it could be read as whether and how to -- for FDA to promote harmonization of Codex Alimentarius, and I don't know whether I should be asking that as clarification question.

But I will also mention that the first bullet of the recommendation which is, FDA should continue its active participation in Codex that is a requirement, as a WTO member, to be an active participant in Codex. And I'm sure you're well aware of that, but all countries who are WTO members are required to be active participants in Codex to the extent they can within

their resources.

And, lastly, as a real honest to God comment, I would -- I don't know whether FDA was sort of avoiding in making these recommendations, but the difficult issue of FDA harmonizing its standards with Codex, but -- and it is a very difficult thing to do, but from my standpoint, I think that is the important thing that FDA should look into doing, however it is done. Thank you very much.

MR. ROBACH: Thank you, Camille. Mike Robach with Cargill. A couple of points on training and to repeat something that was said earlier. One of the things that really struck me as I heard the presentations and the comments was kind of a notable lack of collaboration and cooperation with the private sector, and that concerns me a lot.

We do capacity building around the world. We do it each and every day. Our supply chains extend around the world and we're forced to do it. And it is something that I really think we need to talk more about. We have academia contacts around the world in countries where we do training. As I said earlier,

we're a global company, but we operate locally. And I think there's a lot of experience and there's a lot of infrastructure in place that could be more effectively leveraged as we go out around trying to educate and train both the private sector participants in the supply chain and regulators.

And right now for GFSI, we have a regulatory working group that's doing just that. It's really showing regulators what we're doing around systems that are based on Codex OIE and IAPPC. And I would also urge that you not create redundant training; the training modules already exist. They're there. It's a matter of us, you know, just sitting down and getting together and looking at what's out there, and then using what's out there because there's no need to go out and reinvent the wheel, as has been said a couple of times.

And I also think that one of the things you need to do is make sure that these training programs do become locally sustainable, and we've got examples of that in the private sector where we've seeded training programs with local universities and then local

universities take it out into the marketplace and it becomes a self-sustaining program. So I think there are numerous opportunities to do that. We've done that in China; we've done it in India; we've done it in other parts of the world.

I'll quickly go to Codex. The principles, guidelines and recommendations that come out of Codex. I think everybody has seen -- well, you've seen my process map anyway with the WTO standards and how industry through an ISO framework has taken those principles, guidelines, recommendations into a useable food safety system. I would urge FDA to continue looking at that, and I would urge FDA to harmonize their standards against the Codex standards. I think it is the right thing to do. I think it puts us all on a level playing field and moves us all in the right direction.

And, again, we're working with the supply chain, I think is extremely important. And, you know, FDA should seek to harmonize its requirements with Codex, where appropriate. I mean, I wrote down a note, I said, when would it not be appropriate? I'll just

throw that out there. It just makes sense to me.

In my thoughts on Codex engagement teaching mentoring from the FDA, I would be very, very careful with that because I think FDA goes out and it gets to be a bit presumptuous that you're going to mentor other countries around Codex. So that's just a word of warning from my perspective having plants in 66 countries.

And the last thing on laboratories, consistency around GLPs, I think, become an important element that we can all work together on because analytical data often becomes actionable information, and so we have to be very, very clear about, you know, how that information was generated and what it is being used for. And I think through a GLP system that can work.

And around capacity building, in laboratories, we've got a number of examples where we've worked with governments to build capacity. The best one I can think of is in Thailand in 2004 when we trained the Thai Government how to use real time PCR for the detection of H5N1, highly pathogenic avian

influenza. So there's numerous examples out there how that can work together in a very collaborative way. Thanks.

MR. SOTO: This is Sergio Soto, Minister of Economy of Mexico based here in Washington.

Well, first of all, I would like to thank you -- thank the FDA for putting this together. I mean this meeting that we usually plan together. I think it is very important for developing countries to have this technical assistance. I share the urgency mentioned by my friend from Chile on his question. I believe we are working on this. I'm aware of some actual actions of FDA in Mexico. Their examination of the content of the law and the requirements of the USDA to import products to the market.

I just want to call the attention of FDA to one single element on the technical assistance, and it is the question of small business or small producers. In many cases in developing countries, big business don't need technical assistance. Small business, they need technical assistance. Small business, small producers and many people here, and especially in

developing countries know - besides me - that who needs more technical assistance are the small producers. They don't have a big capacity; they don't have financial resources; they don't have the technical means to get to reach on technical assistance, so I think we should review this concept in the technical assistance recommendations. And then we can have much more success in this activity.

Perhaps other elements we would also take into account is the regional harmonization. I mean the countries that have regions, which are very developing in the production of useful instance or other kind of foods that are producing in the very high standards. We have other regions in which that is not the case. So I leave this to a concept to be introduced, your recommendations. And thank you very much.

MS. BUCK: I'm Patricia Buck with the Center for Foodborne Illness, Research and Prevention, and I really paid attention to a lot of the comments that were made about the training, and I thought some of them were very excellent. One thing that CFI has recognized for a long time is that both food production

and, you know, preparation are really intrinsically personal issues, and that's why it's hard to teach it in a classroom setting.

If you're going to change behavior, you really have to go beyond just what we can post on the web or what we can do in a classroom. So some of the comments that were made, I thought were very significant.

One big issue that I don't think -- I think we've all talked about it a little bit, but with training, one of the thing that has to happen is we've got to gain the trust of the people we're trying to train. And the trainers have got to learn how to engage people so that they are trustworthy. And I know there's a whole lot of research out there on, you know, how to build trust, and I think that's very, very important for FDA to be looking at. You certainly can look at some of the successful programs that have already been put in place.

The other comment I would like to make is that CFI has a young group that is really trying to push improvement and research on foodborne illnesses.

I totally support the coordination of laboratory standards and methods. I can't emphasize that enough.

And we also are for, you know, public health surveillance. These are crucially important things that we're facing serious food safety challenges in this century. And, as was mentioned this morning, FDA, as all of us in the room, we have to become more accelerated in our actions and, of course, I think your meeting will help us all do that. Thank you.

MR. WILD: Good afternoon, Lawrence Wild with Vega. Thank you, panel. Vega is an NGO based here in D.C. We are a consortium of 18 other NGOs working in economic growth fields heavily focused on agricultural development. To give you a sense of active globally, give you a sense of our work in agriculture in 19 future countries. We have 250 programs, more or less, through our members, and the interesting part of that is that all of our programs integrate pro bono experts.

And that hits upon some of the points you mentioned on training, trust and working with small and medium size enterprises. The programs we incorporate, we have long-term staff; we have paid consultants, but

we also use pro bono experts, practitioners from the U.S. all along the agro business supply chain. So you might have -- which have a different set of experience that they can share. The recipients have a higher level of trust with a volunteer than they might with a consultant.

We have had volunteers that are from McCormick Spice, the Vice President from McCormick Spice; the president of a dairy cooperative in Wisconsin, you name it. So they have a set of -- they're actually implementing all the things. They have to deal with the same rules and regulations here in the U.S. and you're talking about operationalizing some of that training. That's what those volunteers -- that's the experience that they have that the consultant might not have. So I just wanted to introduce the use of those types of pro bono experts. Thank you.

MS. BREWER: Thank you very much.

Audrey?

MS. TALLEY-RUSH: I will make this fast.

Audrey Talley-Rush, Rush Options Consultancy.

MS. BREWER: I'm sorry; I'm getting all kinds of signals. What?

MS. TALLEY-RUSH: I'll make it very fast and it's just three points I wanted to make. Being a former FAS manager in the area of food safety, processed products, technical regulations, office of foods science -- Office of Food Safety and Scientific Affairs, which has since changed. I wanted to give us credit for working on some of the issues that you brought here today and encourage the forum to take a look at some of these systems that have been identified here. One is the FSIS public health information system which FAS was every instrumental in helping to get the industry up and running, and even provided some money in the early stages to develop the feasibility study to make PHIS a fully operable system.

It uses a UN platform, and if we're talking about global systems, we need to look more globally and look at ways in which we can look across countries. That system is also able to talk to Europe through their TRACES system, so I encourage you to look at the

PHIS system as well as the EDTV system which is where countries who cannot get electronic certification, get it in paper format. So that's the first -- that's the one thing I wanted to sort of mention.

The other thing is, Caroline, I really liked your comment about Codex, the good, bad and the ugly because I've experienced all three myself. And having said that, one of the things that I find that Codex does very well is it helps countries come around and converge on terminology at global markets.

So a fairly long term is used here. There are terms that are defined internationally that I hope that as we look into creating these systems that we look at terminology so when you're talking across international borders, that we're talking about the same things that you were saying.

And, finally, working with FAS, I worked on a number of these training programs, and one thing I really think that we need to look at is looking across countries to follow up with some of the training that we have done.

Canada has done some excellent training in

some of the same areas that we've trained in, and it would be, I think, helpful, as we move towards the paradigm to coordinate across our sister countries to do the next step, take them to the next level and then do some follow up. Thank you.

MS. BREWER: Thank you.

MS. ROCHETTE: Peggy Rochette from the Grocery Manufacturers Association. I have a couple of comments that I want to make. First of all, I think it's very important to underscore something here about forums. Cathy Carnevale mentioned earlier the inter-consecutiveness of FSMA. And we've heard a lot this afternoon about Codex; we've heard a lot this afternoon about capacity building; we've heard a lot about the various elements of FSMA and what's required in it, but I think that we need to step back and look at the big picture and how we can leverage all of the policy goals of FSMA through a number of forums out there other than just capacity building as it relates to FSMA.

We've talked about the alignment between the APEC goals and the FSMA goals. Kelly earlier brought up the importance of using the RCC, the Regulatory

Cooperation Council. We've got the same thing going on with Mexico. Europe, obviously, higher on the regulatory dialogue. We've got the TPP in which we're working on SPS plus text, and we've got Codex. And said we need to think more strategically in Codex. I think I'm paraphrasing, but he referred to strategizing Codex and there are, in fact, document, guidelines, principles going forward in Codex that would help advance the goals of FSMA. And that specifically -- there is a guideline for national food control systems. There are principles for testing and sampling in international trade. There are other documents that are going forward in Codex, and so I think it's important to think outside the FSMA box and into the global foreign box a little bit.

So saying that, I would encourage FDA to think along those roads. But I also want to say that I've listened to the whole discussion today and I've read through the recommendations, and there certainly are some solid recommendations here. And other things have come out from the panel in front of us, but, in fact, the requirements -- the mandate isn't a plan for

January 4th, 2013. And much of what's in here is not very action formatted. And so I guess my question is what would be the next steps to turn this into action?

I've heard the Philippines say, they would like their inspection systems recognized. Well, so would we like to know who's going to be recognized, and how, and what the deliverables are and what the outcomes are, and how FDA will prioritize the leveraging.

So I'd like to know from FDA what are the next steps and how do we go from these recommendations to an actual plan because the devil will be in the details. Thank you.

MS. BREWER: Thank you for that, Peggy. And, indeed, this is the first step and our duty is to develop a plan. In looking at the steps towards that plan, it was very important to get the elements out there for discussion, to put forward a draft plan based on the input that we received, and then move forward towards action.

So I appreciate all the comments. We are running a little bit late. I did plant one seed. I do

want to turn back to the stakeholder group. Were there any important questions that we need to include as we move forward?

MR. JOHNSTON: This may not fall into the category of an important question, but I think as you look at developing your plan, it's part of a magic process. There is one thing that we do in the private sector that I think is a good lesson for government, and that is, we always ask what's working? What's not working? And what does success look like? And so I encourage you as part of your plan to define what -- at least, what you think success looks like in all of these elements.

MS. BREWER: Thank you. Any other questions that we should include as we move forward?

(No verbal response.)

MS. BREWER: All right. With that, we are indeed, at time, but we do have one final important presentation. Julie Moss is going to talk about measurement and developing plan programs that will be impactful. I'd like to invite Keith Brown to join us up front and we'll do this last presentation, do a

final round of questions and then I hope no one will miss their airplane. So, Julie.

SPECIAL PRESENTATION: ENSURING EFFECTIVENESS OF CAPACITY BUILDING EFFORTS - JULIE MOSS, DEPUTY DIRECTOR, INTERNATIONAL AFFAIRS STAFF, CFSAN, FDA

MS. MOSS: Thank you, Camille.

I wanted to address the third and final additional element that I introduced at my first talk today. The three additional elements that I highlighted before are evidence-based decision making, establishing partnerships and design for effectiveness. And it's the design for effectiveness that I would like to share with you now and FDA's current thinking. And this gets to the point of linking our capacity building activities to public health outcomes. And we really can't answer that question right now, so we're looking internally at a process of what we can do to begin to answer that question and instill that discussion and thought process and prioritization within our capacity building programs.

So what we've done is we are looking at a

results-based approach that we hope to institute within the imports program and we are looking at utilizing a performance measurement system to be able to track the performance or activities, not just the output, but the outcome of our activities.

This is what is going to help us, that we believe, to focus from what's being done or an output focus, you know, we've done X number of trainings in X region or X country, rather moving towards looking at the progress towards an intended outcome or an intended result that we want to see moving forward.

FDA -- this is new to FDA, especially the foods program. This is new to me, myself, as well, so we have brought in a contractor to help us with this process and Keith Brown is from Management Systems International that is helping us with this process. His company has also been involved with the USAID and FAS on a similar process, as well.

So the purpose of a results-based approach is multiple fold. What it's going to do is to help us to link our capacity building activities to the achievement of public health outcomes. Hence, we are a

public health missioned agency and that's where we want to make sure to link our activities rather than assuming or making the best possible common sense approach in the hopes that it's going to see the public health gain that we want.

We really want to make sure that we are making that connection and that link. This is going to be able to provide us the ability to measure and evaluate the performance of capacity building, not necessarily only from FDA, per se, but also collectively the prevention of problems in the foreign supply chain.

This is also going to help us to more effectively communicate and share information, both internally within FDA and also with our external stakeholders because it will be very clear and very obvious of what the intentions are; what are public health outcomes; what our goals are that we want to achieve.

This is also going to provide information to support evidence-based decision making, which is one of the first additional elements that I previously called out. And it is also going to allow us to focus and

prioritize our capacity building activities.

So what we've done in the last year-and-a-half is we have developed an import safety results framework that highlights the relationship of FDA's efforts in achieving the goal of protecting the public from unsafe imported foods. That's our highest level goal that we have identified for ourselves. And in order to achieve that goal, we have three areas of focus. One, is we want to better prevent food safety problems in the foreign supply chain. If we can't do that, then we go to number two. That is, we want to reduce the entry of unsafe products into the United States. And if that doesn't work, then we want to prevent the consumption of unsafe foods by U.S. consumers, within Americans, within you and I.

And let me show you what this looks like in the results framework. And I recognize that this is not the prettiest picture before you today, so let me walk you through this. The box on the top is the highest level goal that we want to achieve. We want

to protect the public from unsafe imported foods as our highest goal.

The three boxes below that are the three streams that I just shared. On the very left side is better prevention of food safety problems in the foreign supply chain. If we're not able to achieve that, then we go over to the middle at number two, in which we want to reduce the entry of unsafe food into the United States. And if we're not able to do that, then we go over to the right, outcome three, where we want to prevent the consumption of unsafe imported foods to U.S. consumers.

And if we do all of those three things, then we can achieve protecting the public from unsafe imported foods.

And whether you're familiar with the results framework or not, let me just share with you a couple pieces of information about how to read this. Each box that you're looking at is a particular result or an outcome that we want to achieve. The boxes on the bottom are the lower level results or outcomes that feed into the highest level results.

And it was important for us to really think about the imports program so that we can exactly see where international capacity building fits into this larger picture. And once we've created this results framework with the highest level goal of protecting the public from unsafe imported foods, it became very clear that international capacity building activities fed into the very left-hand side that is better prevention and food safety problems in the foreign supply chain. So that is where the capacity building working group is focusing on.

The next slide is going to be a little bit busier than this, but I will share with you just some high-level thoughts about it, and we're not going to go through it in all of the detail.

This is what the results framework looks like that we have developed. I know it's very confusing looking at. What I want to call out is some very overarching things to consider. On the very top is our highest level goal, better prevention and food safety problems in the foreign supply chain.

On the very bottom are capacity building

activities that feed into the lower level or the foundational results. The foundational results then feed into the intermediate results in the middle of the page, and then the intermediate results feed into the higher level results at the highest part of the page.

While not directly called out or recognized, I also want to highlight some points that were mentioned earlier today. Consumer demand is also driving this as well, and also the better prevention and food safety problems in the foreign supply chain.

So this is what we're working to be able to instill and move forward. This is a learning process for FDA. And given the nature of this slide, I created it to be color coded, but, unfortunately, you're not able to see in front of you. But on the left-hand side is the affected stakeholders which is focused on the industry, in the middle the affected stakeholder is FDA's responsibility, and on the far right the affected stakeholder is the partner country responsibility and where FDA is looking to partner with other countries in order to move this

issue forward.

Each individual box that you see before you, as well, will also contain various indicators or metrics that will then tell us whether we are reaching our anticipated result or anticipated outcome.

And the next slide is just an indication or an illustration of some of the potential indicators that we are looking at. So what I'm looking at here on the very top is better prevention of food safety problems in the foreign supply chain, and we can achieve this by doing two things. One, increasing use of best practices by industry and priority countries. And we can also increase compliance with regulated standards by industry in priority countries and commodities.

And a couple of example indicators that could be utilized to meet these respective outcomes is on the left-hand side for result one. We could look at the number of growers and processors for which third-party audits confirm their use of recognized standards, whether those standards are U.S. standards, the national standards, international standards, private

standards or what have you.

On the right-hand side, an indicator to tell us if we're meeting our outcome for increased compliance of regulated standards, we could look at the number or the percentages of firms that come off import or some other type of import statistic. So this is just to give you a flavor of what we're looking at with regards to trying to measure and evaluate whether our capacity building activities are doing what we intend them to do.

And we are at the very beginning stages of this. We're hoping to pilot it in the very near future focused on seafood and produce so that we can begin to tailor our capacity building aspects and build our program moving forward.

So with this particular designed for effectiveness attribute within the capacity building plan, I'm going to read to you the FDA's recommendation here.

FDA should develop strategic results frameworks for partner countries and high-risk commodities with the aim of preventing food safety problems in the foreign supply chain.

This strategy will be used to inform decision making in FDA about strategic programming.

And so our questions to you are, what types of data should FDA consider for measuring public health outcomes? What are effective strategic planning models? What are effective strategic models that link public health outcomes? And what are effective ways to measure or evaluate capacity building programs? And we welcome your ideas.

MS. BREWER: Thank you, Julie.

I think those questions are very dense. I would like to turn to our stakeholder panel. Any reactions, comments? Would you like to take on these questions?

STAKEHOLDER CONSULTATION

MS. DUBOIS: Just a very brief comment on the evaluation of capacity building program. I think it's been said before; it's very hard to see a result of individual activities. Once we integrate more largely, it will be easier. And we have to keep the concept of risk analysis and risk management at the heart of this evaluation of our capacity building programs.

Are we changing the outcome? Is the risk -- are we moving the risk around or are we reducing the risk? We want to reduce the risk. And the -- so it's very important -- that's really the point. It's very important to keep the risk analysis at the center of the evaluation of our capacity building programs. It's not how many people we train, it's how much they've retained and what a difference they can make.

MR. JOHNSTON: This is the first time I've had a chance to really look at this, and I'd love to give more thought to this and better input, which I will be happy to do as, I'm sure, many others in the room. I would say you are definitely headed in the right direction. And I'm very excited about the fact that you're moving from what's being done, see all the things I'm doing. My kids do that at home a lot, and I end up seeing the results sometimes, but going more by real, results-oriented performance culture, which is exactly what's needed. It's consistent with FSMA clearly. So I like where you've headed. I want to give more thought to what exact metrics you're going to use for this. What really are good measurements for

success, but also benchmarks for what needs to change or be adjusted when we will evaluate those. Those are also pretty important, as well.

MS. SMITH DeWAAL: What always troubles me is the absence of real baseline date, and, I mean, I just know that's the environment in which you are operating. And I think we all struggle with it.

It is vital that FDA have an understanding of domestic public health in the countries where we import food from.

The hazards here may not be the same as the hazards there, so if you have a really good control system here, it may not fit those hazards. So we -- you need a much better understanding. So I guess that's the challenge. How are we going to -- as you develop these metrics and you're going to be developing them on the fly. You are, because the programs need to be in place already or very shortly. You need to still start building that food surveillance infrastructure to make sure that you have your hazard analysis. You know where the next melamine is coming from or the next, you know, serious danger that we just weren't thinking

about. And the best way to know that is in country surveillance tools.

CSPI has been working on one based on, you know, informal reporting systems. It's really messy, but we're capturing data and we're publishing it. We'll have a poster at IAFP this year. We're happy to turn over to you everything we know. We could look up the Philippines, for examples, but I won't do it here. But that's -- I mean, we need to start working on real systems for monitoring hazards, and this, I believe is actually not a job for FDA. I think it's a job for WHO. But they need to be transparent about it and not keep it hidden the way they do right now.

MS. HOWARD: Well, this is somehow looking very familiar to me because it's a part of the Feed the Future initiative USAID has also put a huge focus on. Not only USAID, but our whole of government partners put a huge emphasis on developing performance indicators and establishing these results framework. And we will be very, very pleased to work with you, and I think a lot of our experience can be relevant to this issue of how do you measure our capacity building

proposal?

I also think we have some things to learn there, as well. But it is also important to think, you know, as we collaborate on programs, we're going to need some congruence in a way that we are measuring. And I just want to put out a couple of ideas on the baseline. I mean, this has also been a really important issue for us and we spent a lot of resources and thinking that's very, very important, and it is hard, but very, very necessary if you want to do a valid measurement. So I applaud that point.

I think also for us to think a little bit about so what does the results framework look from the country standpoint? We've had that theme raised a couple of times, you know, it's different in many cases, but we shouldn't -- you should forget that we also need to have that if we're going to have a real country-driven program that can be sustained over time.

MS. STROSSMAN: Thank you. Just a quick comment. As was mentioned, we've also in FAS been looking at these same issues in terms of tracking results and measuring impacts. And we have found that

results frameworks are quite useful. It requires kind of a new way of thinking and designing projects to really focus on the ultimate result and how you're going to measure that question of what does success look like?

And it's also a good way to kind of monitor progress along the way and see how you're doing and see what adjustments need to be made.

I would definitely reiterate what has been said about the data, the importance of the data, and also the difficulty that's -- really the most difficult thing is finding the data. We talked about how there is a lack of data in many places. And so finding the baseline and then identifying what data you're going to use for your indicators is a big task. And then just to, again, reiterate what was said about how do you -- we talked a lot about partnerships and leveraging and, you know, how do you connect your framework with your partners and what they're doing?

And I've certainly -- in many of our programs we're working -- we're doing a program that can meet multiple objectives whether it's a trade objective, a

public health objective, a development objective. A single program could contribute to all of those things. So how do we link these things up and track them individually or jointly? Thank you.

MS. BREWER: And so I'll again turn to the audience. If you have specific comments on this design for effectiveness element,

MS. DAWSON: Very briefly. The only concern that I have with the bottom line, not just for this portion of it, but all of it. If we could get the cleanest, safest food into the kitchens of wherever it may be, maybe here in the United States, but if we don't have a good model in which -- in the house, people know how to use the food, how to prepare them. If that food hits the floors or if the hands aren't washed. All of that is lost and then the blame still falls on the regulatory bodies for having not met those needs. And so that may be an issue in education.

MS. BREWER: Thank you again. We'll take comments on just this element. Madam?

PARTICIPANT: I have been struggling for one day -- for the whole day and I'd now really love to make

make some speech from my dear colleague.

My name is Sabrina and I come from a Chinese laboratory, and here we make our proposal to this meeting. First, I'm so pleased to be here on my second trip to D.C. The last time, it was September, we sent two of our colleagues to have the training. So I have to come back to China and we'll make some information for the producers in the -- most of them have gone. (Inaudible) Notice from the FDA, they want to do -- conduct the factory inspection, but all of them don't know how to go past or go through the inspection process. So we actually came here and to ask questions about what should we prepare or where we can find the information to get a (inaudible) inspection. And now we just -- we can the proposal to have international capacity building through our import (inaudible).

The evaluation of risk -- of exported food from China to America? The first priority with capacity building must be the equivalence of testing and inspection in our food safety plan.

The key elements of food safety (inaudible)

imported included how to satisfy the need for multinational of acceptance of laboratory methods.

MS. BREWER: Madam, excuse me, I think what we'd like to do is to accept your comments and we will place them in the docket. We appreciate your braveness at waiting until the end of the day. Your comments are very important for us. We're simply out of time. So what I'd like to do is to make sure we include your comments in the docket.

So if you could just hand them to the lady in front of you, we'll make sure that we include them. Thank you.

So I do need to end on this element. And we have Keith here, so I wanted to make sure that we included any comments you had on this particular subject?

MR. BROWN: I just wanted to say one or two things. A couple of the comments that the panel made earlier this afternoon really reflect well in the work that FDA's done here, and one of the things that one of the panelists said that, you know, training is not a one off thing, and it needs to have a long -- or

medium to long term perspective.

I think it also has to be placed within the context of a broader set of objectives and goals, and both of those pieces are what's included in the results framework that Julie showed you. But also in that approach, the overall approach to performance-based management really places training in a broader -- the broader efforts of capacity building in the context of results, change and outcomes that they drive.

The second thing that was mentioned is that, you know, one size doesn't fit all. Different countries and different districts within countries and different skill sets and different capabilities and competencies of what we see everywhere.

Julie presented one as a sense the template framework, but FDA, one thing that she mentioned in a bullet that perhaps just could benefit from one additional word is that FDA is going to roll this out at a sort of country and commodity level. This would be a starting point and then adjustments would be made to a country context to the situation, circumstance of any given country so that the strategy has great sort

of management relevance and the ability to really drive change in that country. So it isn't one size fits all. But what you were presented with today was the template approach, that is the point of departure for each country's consideration of what will work for them or even within different commodity groups within a given country.

And, lastly, just a comment about the fact that you have to know where you're going; you have to focus on results. I think that was made by a gentleman from Campbell's. And one of the things that has been exciting for me as being part of this process is just how focused the conversations are about getting away from just delivering training and understanding exactly where FDA wants to be at the end of day. How to understand measurements so mid-course adjustments can be made so learning can happen throughout the process so at the end of the day FDA gets to that goal and doesn't just spend five years spending money delivering training. That's all I want to say.

CLOSING COMMENTS

MS. BREWER: Thank you. We are at the end of

our day. I want to thank you all for your participation for the excellent comments. I apologize to our colleague from China. We will include your comments, I promise.

We had a fabulous stakeholder panel, so I want to give them a round of applause.

(Applause.)

MS. BREWER: I would be remiss if I didn't talk about all the people that put this meeting together starting with the capacity building work group, Dr. Moss and Dr. Bond are our co-leads. We have members from that working group here. Could you please stand up so we might see you? You can stand. We want to thank you all.

(Complying.)

(Applause.)

MS. BREWER: And, of course, Juanita Yates who always keeps us together for our public meetings and to our AV team from FDA.

So, again, thank you so much. Safe travels home. We look forward to your comments. Comments are due -- the docket closes July 20th. The written

comments are very important to us. Please comment in writing.

Thank you so very much.

(Whereupon, at 5:00 p.m., the meeting was concluded.)

CERTIFICATE OF TRANSCRIPTION

I, Loretta Rodd, certify that I am not the Court Reporter who reported the following proceeding and that I have typed the transcript of this proceeding using the Court Reporter's notes and recordings. The foregoing/attached transcript is a true, correct and complete transcription of said proceedings.

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