U.S. FOOD AND DRUG ADMINISTRATION

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

Conducted by Donald Prater, DVM

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C O N T E N T S

P R O C E E D I N G S

DR. PRATER: All right. Good morning. Good morning to our invited guests and our attendees. If I could go ahead and have your attention now, I think we're going to go ahead and open the session. Thank you. Thank you.

So once again, good morning to our invited guests and attendees in the conference room and as well as those that are viewing and hearing through our live webcast. Welcome to Day 2 of our Part 15 hearing on Partnerships to Enhance the Safety of Imported Food. My name is Don Prater, and I'm the acting Assistant Commissioner for Food Safety Integration in the Office of Foods and Veterinarian Medicine. So I'd like to welcome you here to FDA's Center for Food Safety and Applied Nutrition.

To just give you a little bit of a recap from yesterday, a hearing is one of the administrative tools that FDA can use to obtain information from external experts and stake holders. It's more formal than a public meeting, a workshop or a town hall and, as a result, must be transcribed.

In addition, we have a few other ways that we operate a hearing, and I'll just note that the audience will have the opportunity to ask questions of our FDA presenters, however, only FDA may ask questions of the expert panelists and the folks giving testimony, so just a reminder on that point.

The objective of our hearing this morning is to assist FDA in identifying issues, challenges, and opportunities and will focus on obtaining information on the role of partnerships. These partnerships are ones that we will use to build food safety capacity in other countries, to help operationalize the concept of same level of public health protection in relation to FDA's hazard analysis, preventive controls, and food safety requirements.

It will also serve to enhance risk-based decision making through the consideration of private standards and the recognition of commodity-specific export programs, as well, the implementation of existing systems recognition program.

This hearing consists of four segments. Each one will -- each will begin with FDA's stage-setting

presentations followed by clarifying questions from the audience, guest presenters, followed by questions from our FDA panel of experts, and finish with prescheduled testimony and questions from the FDA panel.

The biographies for FDA and guest presenters are in your information package and are also located at the website at the bottom of the screen. I would like to remind you that the docket will be open until May the 15th, and we encourage you to submit your full written comments to the Division of Documents Management following the instructions in the Federal Register Notice.

The weblink to access the hearing materials is one at the bottom of the screen on our opening, break, and lunch slides. Yesterday, our discussion followed on partnership -- focused on partnerships to improve food safety capabilities via capacity building and partnerships to leverage information from private entities.

Today, we will turn our attention to partnerships that recognize commodity-specific exports and programs and partnerships that recognize the

robustness of an entire food safety system via systems recognition.

To help frame our session today, I'd like to introduce Mr. Mark Abdoo, who will deliver a keynote address. Mr. Abdoo is the Assistant Commissioner for Global Regulatory Policy in the Office of Global Regulatory Operations and Policy. Mr. Abdoo leads cross-cutting activities predominantly relating to food and veterinarian products, including building international partnerships. So please welcome Mr. Abdoo.

(Applause)

MR. ABDOO: Thank you, Don, and good morning everybody. It's a pleasure here -- to be here speaking to you today. As you know, globalization has dramatically shifted FDA's regulatory landscape. We are now in an environment in which food products travel with complex supply chains throughout countries all over the world. Many of these nations, unfortunately, have less developed regulatory systems and capacity than the United States.

FDA-regulated products originate from more

than 150 countries, 130,000 importers, 300,000 foreign food facilities, and food imports compose 15 percent of the U.S. food supply, including 50 percent of fresh fruits, 20 percent of vegetables, and over 85 percent of seafood.

FDA has mobilized a diverse approach as part of its strategy to address the complex issues posed by globalization, including efforts to develop new enforcement and regulatory tools, conduct more foreign inspections, increase collaboration with foreign regulators and other stakeholders, develop internationally harmonized standards and standards convergence, educate foreign industry about FDA requirements, and increase transparency and accountability in the supply chain.

Globalization has made FDA's core mission, protecting the U.S. consumer, more difficult. However, we at the FDA have been steadfast in meeting the challenge in several ways. First, we are committed to our international obligations, one of which is our participation in the Codex Alimentarius Commission. Created in 1963, Codex is an intergovernmental body

with more than 170 member countries.

The Codex mission is twofold: to protect the health of consumers and to ensure fair practices in food trade, which it achieves by establishing and promoting food standards that its members can adopt. Hence, Codex is a collection of internationally established food standards, guidelines, codes of practice, and other recommendations.

It's the world's main intergovernmental body for setting food safety standards. FDA's leadership role in the Codex Committee that sets standards for FDA-regulated foods, helps to shape international food safety standards which Codex member countries adopt by consensus.

In addition to FDA's work in Codex, FSMA gives us two powerful new tools, which you heard about yesterday, to enhance the safety of imported foods. The first is the Foreign Supplier Verification Program, which is based on the principle that U.S. importers are responsible for the safety of the food they import. Importers covered by the rule must have a program in place to verify that their foreign suppliers are

producing food in a manner that provides the same level of public health protection as FDA's Preventive Control Rules for Human Food.

FDA -- FSMA provides FSVP as one mechanism through which FDA can assess whether overseas producers and suppliers are in compliance with preventive controls. The second FSMA tool is the accredited third-party certification. This establishes a voluntary program for the accreditation of third-party certification bodies, which will inspect overseas food facilities for compliance with FDA standards.

Accreditation bodies officially recognized by FDA provide ongoing oversight ensuring that overseas auditors and the companies they work for meet FDA standards as well.

As this audience knows, the FDA has a significant and growing global presence. We have offices in China, India, Brussels, Costa Rica, Mexico, and Chile. We conducted 36 -- 3300, I'm sorry, foreign inspections last year, including 1269 food facility inspections.

In addition, FDA fosters international

partnerships with counterpart foreign government agencies and international organizations. We use several tools to establish and memorialize these partnerships, including cooperative arrangements which include memoranda of understanding and confidentiality commitments.

Currently, we have 81 cooperative arrangements in place. These arrangements memorialize written understandings that FDA establishes with one or more foreign governments or international partners. The arrangements describe the willingness and good faith intentions of FDA and its counterparts to engage in cooperative activities.

Additionally, we have 76 confidentiality commitments in place. These commitments establish a legal framework for FDA to share certain kinds of non-public information, like full inspection reports, with FDA counterparts in foreign countries and international organizations, as part of cooperative law enforcement or regulatory activities.

Lastly, I want to focus on how FDA prevents problems from reaching U.S. borders by our focus on

relevant points along the global food supply chain. In addition to FDA's overseas operations, we recognize the potential value in leveraging the expertise of trusted foreign counterparts to expand FDA's oversight of the steady increase in food imported from around the globe.

Our goal is to work with regulatory counterparts to effectively leverage our inspectional and regulatory resources, particularly in a risk-based manner. We are doing just that in two key areas. The first is systems recognition, which is the topic of today by and large, and is based on a rigorous assessment and conclusion that in other countries food safety regime provide similar protections, oversight, and regulatory standards as FDA's and vice versa.

The result of a positive systems recognition assessment is the establishment of a formal regulatory partnership that allows the parties to rely on each other's regulatory work, including inspections and investigations of foodborne outbreaks.

A systems recognition arrangement involves closely examining a nation's food safety history, regulatory foundation, inspection and audit programs,

and enforcement authority, among other things. Thus far, the FDA has signed two systems recognition arrangements with regulatory agencies in New Zealand and Canada.

The European Commission has also embraced this concept, and we have embarked on work with them towards a systems recognition arrangement with the European Union.

In addition, we see great opportunity for collaboration with foreign partners on specific imported commodities that are particularly high-volume or high-risk. A prominent example is the Produce Safety Partnership, which we lost -- which we launched in 2014 -- we haven't lost it -- with our Mexican regulatory counterparts.

This partnership is based on our common interest in the safety of Mexican produce and our shared commitment to make FSMA's prevention strategy a success.

A second example is our several years of work with China's import/export and food safety agency, the general Administration of Quality Supervision,

Inspection, and Quarantine, AQSIQ, to improve compliance with U.S. limits on the use of animal drugs in aquaculture.

We have invested much effort, and made significant progress by providing education and technical assistance to Chinese producers and regulators. We are also conducting joint inspections with AQSIQ to build our confidence in Chinese government oversight in this area.

More broadly, FDA engages in capacity building which involves education, training, laboratory harmonization, and has been part of FDA's engagement with the international community for many years. This forum today provides an important opportunity to discuss how FDA can build with other nations a common food safety culture of prevention and verification.

We are working hard to continue to expand our reach beyond U.S. borders and to engage with our regulatory counterparts in other countries. That's because we all share three goals. We want food to be safe, we want all consumers to have confidence, and we all want trade to be unimpeded by food safety concerns.

Thank for the opportunity to speak this morning. I'm looking forward to the sessions today.

(Applause)

DR. PRATER: Thank you, Mark. We appreciate those remarks. That will really help frame our discussion for today.

So next, I would like to go ahead and introduce our panel for Session 3. This is the session entitled Partnerships that Recognize Commodity-Specific Exports and Programs. And so for this panel, we are interested in learning about successful models that recognize commodity-specific food safety control systems. These would include export certification programs. We'd like to know how they're established, and how they operate.

In addition, we want to seek comments on and views on the best practices, strengths, and weaknesses of commodity export programs or export certification systems.

We're also interested to learn how commodity recognition programs factor into risk-based inspectional systems and, once adopted, how these

programs are monitored over time. We're interested to know whether and how we should expand our systems recognition framework to include consideration of the recognition of commodity-specific export control programs.

And so to help set the stage for this discussion, I'd like to introduce two of my FDA colleagues who will give us some presentations on how we're working in some different areas with respect to this panel.

So I'd like to introduce William Correll. He's Director of our Office of Compliance at the Center for Food Safety and Applied Nutrition, and he will discuss and share with us some information on the Produce Safety Partnership with Mexico.

In addition, I'd like to introduce William Jones. He's Deputy Director of the Office of Food Safety at CFSAN, and he'll cover some of our aquaculture work. So with that, let me turn it over to Bill Correll.

MR. CORRELL: Thank you, Don. So I'm happy to have the opportunity to share with you about --

information about the Produce Safety Partnership that FDA has with the government of Mexico's food safety authorities. As I'm sure many attending today's meeting know, the U.S. food industry imports a significant volume of fresh produce into the United States from Mexico each year.

Consumers in the U.S. are accustomed to a diverse and readily available supply of fresh fruits and vegetables, and growers in Mexico provide many of these nutritional foods to the U.S. marketplace.

In the summer of 2014, we formed a U.S./Mexico Produce Safety Partnership, or PSP for short, as a partnership between FDA and the National Agro-Alimentary Health, Safety and Quality Service, SENASICA, and the Federal Commission for the Protection against Sanitary Risk, COFEPRIS.

These two Mexican authorities span coverage for products -- or for produce safety on the farm, SENASICA, and after produce leaves the farm, COFEPRIS.

The PSP is the foundation through which we are collaborating with our food safety colleagues in Mexico, much the way we do with our state food safety

partners within the U.S., on education and technical assistance, inspection and compliance, and response to outbreaks.

The PSP provides a strategic framework for us to jointly develop and implement a plan to further our shared goal to promote the safety of fresh and minimally processed produce for consumers in Mexico and the United States.

As I mentioned, the partnership exists between FDA, SENASICA, and COFEPRIS. Representatives from our organizations have met in both Mexico and the United States and participated in a variety of activities, primarily structured around our jointly-created working groups in key focal areas that I'll expand upon shortly.

The PSP also recognizes that working collaboratively with the private sector to advance produce safety is crucial to reaching the desired outcome of safe produce. One such collaborative example, and certainly not the only one, is the Fresh Produce Association of Americas, FPAA's, work to promote produce safety with its members, producing and

trading fresh produce across the United States/Mexico border.

The goal of the PSP is self-evident, and I won't read this slide to you but it's included here for your reference of what the overall goal is.

Now, I'll turn to highlight the five focal points within the PSP around which we've structured our working groups and joint activities. These five focal areas are information sharing, education and outreach, training of auditors and inspectors, laboratory collaboration, and outbreak response. The outcome on information sharing has been that all parties have developed a deeper understanding and appreciation for how produce safety systems function in our respective countries and how we conduct our programs.

It has been a keystone activity to strengthen our partnership. The knowledge and understanding gained through information shared also help to provide a foundation to support the import and export controls that FDA, SENASICA, and COFEPRIS implemented for cilantro shipments from Mexico under FDA's Geographic-Focused Import Alert 2423. Only cilantro producers on

the Green List of FDA's import alert, who must comply with 11 minimal requirements on good agricultural and food safety practices, as part of Mexico's Systems of Risk Reduction of Contamination, SRRC, are excluded from detention without physical examination under the import alert.

The detentions without physical examination for shipments are put in place by FDA on a seasonal basis from April 1st to August 31st. The FDA, SENASICA, and COFEPRIS established these controls under the framework of the PSP. To date, 10 firms have met the criteria for listing on the Green List.

In September 2016, FDA announced that the number of domestically acquired Cyclospora infections in the United States reported in 2016 declined when compared to the previous three years. Education and outreach on produce safety, best practices, alliance training, and standards are available, and in the interest of time I will only briefly mention that here.

For the training of auditors or investigators working group, the partners conducted collaborative activities to gain a better understanding of various

training regiments used by FDA, SENASICA, and COFEPRIS for investigators, inspectors, auditors, and state representatives.

For laboratory collaboration, the partners conducted a wide range of scientific and technical exchanges. Science is the key component of the produce safety system. In the foodborne outbreak response area, the working groups developed and conducted a table-top exercise with Mexico. That exercise included another key stakeholder, the U.S. Centers for Disease Control and Prevention, to conduct the exercise using an outbreak scenario. This laid the foundation to create a bi-national protocol for outbreak response.

To recap, the PSP has a number of accomplishments to promote produce safety for consumers. The investment of the partners, particularly illustrated in the commodity-specific export and import controls framework implemented in the cilantro import alert has furthered our common goal to promote safety and fresh and minimally processed produce.

Our work is not done, and we continue to learn

new and innovative approaches, and I look forward to hearing our speakers this morning. Thank you.

(Applause)

DR. PRATER: Thank you, Bill. Thanks for that information on the Produce Safety Partnership. So now I'd like to go directly to Bill Jones, and we'll hear about some of our work on seafood -- imported seafood and aquaculture.

MR. JONES: Thank you, and good morning. I'm the other Bill sometimes referred to as William, but I prefer Bill.

So Bill Correll has described our activities under the Produce Safety Partnership, and I'd like to share with you some of our activities regarding seafood imports and capacity building.

A large majority of the seafood consumed in the U.S. is imported, with that majority continuing to increase year by year. As you can see, it's climbed from the recently cited over 80 percent to over 85 according to our own data, with National Marine Fishery Service indicating that it's gone even higher to 90, possibly above.

The majority of this imported seafood comes from Asia. That's nearly 60 percent of what comes into the country. Shrimp, as the most popular seafood in the U.S., is a good example. Over 90 percent of the shrimp is imported with more than 60 percent of that being from Asia. And the proportion of seafood that is aquacultured, currently more than half of what we import, also continues to increase.

Here's another representation of the predicted increase in the percentage of seafood that will be from aquaculture in the next decade, when that percentage, too, may approach nearly 60 percent.

We also know that from farm to table, the weakest link in the aquacultured seafood safety chain is at the source, and for aquacultured seafood, that's on the farm.

Seafood safety concerns on the farm include unapproved drug residues, other chemical contaminants and pathogens, among other things, and there's a need and a desire for capacity building activities. FDA has participated in a variety of training programs on Seafood HACCP and global Good Aquaculture Practices.

Some of our activities have been geared to training industry. Other activities have focused on working with the inspectorates of competent authorities to ensure that they have a strong understanding of both our inspectional methods and our regulations.

In this table, you can see our emphasis is in countries with rapidly developing economies, including in Central and South America, as well as in Asia where so much of this product originates. We've conducted quite a few Good Aquaculture Practice train the trainer programs as well as Seafood HACCP programs, and something else that isn't necessarily the focus of this talk, good fishing vessel practices.

An example of our work with the inspectorates of competent authorities comes from our Memorandum of Agreement with China, which forms the framework for cooperation on food safety. It's under the terms of this memorandum, which can be found on our website, that we have conducted several training programs for Chinese inspectorates on aquaculture drugs, and Chinese investigators have had the opportunity to engage in joint inspections with FDA investigators when we

conduct inspections of Chinese firms. And Mark spoke to this as well, the variety of activities we've been engaged in and some significant progress has been made.

The goal of these activities is to ensure that seafood exported from China meets our standards. Part of that goal was in increasing our knowledge and our confidence in the export authorities of partner countries such as China. As we gain understanding, confidence, and experience, we have an interest in incorporating commodity-specific export systems into enhanced risk-based planning.

We are keenly aware of the importance of investing in capacity building, in training, and in developing the means to verify the investments in capacity building and training have taken hold and reflected -- and are reflected in systems that ensure safety of exported foods.

We recognize that in some cases, competent authorities require that exports from their respective countries be certified. I want to emphasize that certification is not a condition of trade. That is, our laws do not require such certification. But I also

want to emphasize that we have worked with, and will continue to work with, export authorities to ensure that exported products meet our standards.

In closing, I would like to highlight that we are interested in how best to measure the success of commodity-specific assurances, including certification programs. We are very interested in hearing more about what assurances consumers feel are appropriate. We are interested in hearing about -- more about what assurances -- learning more about the experiences of other agencies and countries in working with such programs, and we want to hear both about the challenges and the opportunities that are before us.

So your input on all of these topics is going to be greatly appreciated. Thank you.

DR. PRATER: Okay. I'd like to thank Bill Correll and Bill Jones for these opening remarks and for their presentations. I think it's very insightful to see some of the different statistics and the FDA's experience with our partnership programs. At this point, we have an opportunity to have -- ask clarifying questions from the audience.

I recognize it's early in the morning, but I hope that you will have some questions perhaps for our FDA presenters. If you'd like to ask a question, I ask that you come to one of the two microphones and state your name and your affiliation, and please then go ahead with the question. I see we have a question already. That's great.

MR. GREMILLION: Thomas Gremillion, Director of Food Policy at Consumer Federation of America. My question was for Mr. Correll. You mentioned a Green List for cilantro importers and 11 factors that firms on that Green List have to meet. So my question is, who verifies -- what's the verification process for determining who meets those factors? And I guess more specifically, what's the role of FDA inspectors in verifying who meets those factors?

MR. CORRELL: Yeah. Thank you for the question.

So to clarify, the import alert detains all cilantro from a specific geographic region during the time period I outlined. In order to meet the criteria for the Green List, importers -- or exporters to the

U.S. have to meet testimony, you know, to overcome that appearance of adulteration in order to gain entry through the admissibility procedure. And so how that system works is the SENASICA who inspects the farms will have gone out and verified farm sanitary practices are in place, good agricultural practices, and the SRRC program of the risk reduction, which are foundational principles in produce safety, growing, and harvesting.

COFEPRIS, who regulates the exporters, can then control the exports coming to the United States and only approves that for shipment after it's been verified by SENASICA to be okay to go. If it goes through a packing house COFEPRIS overseas, they will also have done that inspection. At the border, they will do Cyclospora sampling now is what we'll do. Thank you for the question.

MR. GREMILLION: Thank you.

DR. PRATER: We have another question. Again, please state your name and your affiliation, and make sure the microphone is on.

MS. CLAVERO: Good morning, and thank you for the explanation. Isabel Clavero, Ambassador for Spain,

Commercial Counselor. My question is for Mr. Correll, as well. As a representative from a Spanish company, most of them from fresh produce, my question is, is FDA thinking of implementing this kind of program for fresh produce, with other countries, for instance Spain or Europe as a whole? And the second question is, how is there relation between FDA and APHIS from USDA when inspecting onsite and crossing the border? Thank you.

MR. CORRELL: Yeah. Thank you for the question.

With respect to expanding, you know, product commodity-specific programs, I think that's part of what we seek from this public meeting, an input from our stakeholders. You know, if you look at the diversity of products around the globe, you know, one can think of literally thousands of potential, you know, commodity-specific programs. And I think that really needs to fit into a risk management system of, you know, how do you prioritize the risk?

The work that we have done with Mexico and the partnership we have there with produce, is not the first time we've done, you know, a commodity-specific,

you know, export control system. You know, in France for instance, many years ago the, you know, cheese for Listeria were on an Import Alert Detention Without Physical Exam.

Our French counterpart authorities and the competent authorities in France, you know, routinely inspect those facilities to then put them on what equates to the Green List to be able to be approved for shipment to the U.S., to provide the assurances that we seek that, you know, proper sanitary controls were in place that manufacture and export. So that's what I would say to you.

MS. CLAVERO: And USDA?

MR. CORRELL: Well, for APHIS we are certainly in partnership with USDA APHIS, you know, and FSIS in many of the activities we do. You know, APHIS, as you know, is, you know, focused around plant health and safety, you know, and so they have some inspectors in country. And where we can leverage that, you know, we have. We specifically did that with mango shipments a number of years ago.

DR. PRATER: Thank you, very much. We have

another question, please.

MS. WEDDIG: Yes, thank you. Lisa Weddig with the National Fisheries Institute. Thank you for the wonderful presentations. I think it's very encouraging to hear about these partnerships. Unfortunately, I think you're preaching to the choir here during this public hearing.

So my question is, you know, we often hear in the media and on the Hill that FDA only inspects two percent of the imported products that come into the United States, and actually even fewer than that is what we hear.

So how would you go about promoting these wonderful partnerships that you're developing in capacity building, so the consumers understand what FDA is doing, and what the Hill -- and that the Hill understands what's going on so we don't see legislation or media calls for FDA to do more inspections?

DR. PRATER: Thank you, very much. I'll ask my colleague Bill Jones to take this question.

MR. JONES: Thank you so much, Don.

(Laughter)

MR. JONES: I might defer to the other Bill and to Mark at some point here. That's an excellent question.

One of the things in the beginning that I always like to mention, when people mention the 2 percent, is that we actually inspect up to 100 percent. And in fact, through the process of the screenings that we do, targeted screenings that we do, and the Import Alerts that we implement, we shift the burden of that to the importer. And when a firm -- when there is a problem and a firm is on Import Alert, that product is being tested 100 percent. So we do cover that gamut.

One of the hopes in establishing, for example, system recognition agreements with other countries, is that once we have established that they're doing something that is approaching, meeting, possibly even exceeding that level of food safety that we achieved through our process that I just described, then we will be comfortable with not having to do that ourselves.

So that's the goal is to make sure we've found a way to establish that those levels of food safety are being met in that same way.

MR. CORRELL: I guess I would add on to what Bill said and, you know, highlight to you that we have worked, you know, rather transparently to explain publicly how our PREDICT system works for entry screening. And it's certainly a risk-based approach focused on, you know, where your highest risk, you know, products are to, you know, do physical examinations, sampling, you know, exams at the border., you know, while we examine, you know, entries, you know, coming through the system.

You know, so I think that, you know, is what, you know, really predicates what Bill said about, you know, we're looking at about 100 percent of the activities but really focusing our sampling and laboratory resources, you know, where it would be most good.

DR. PRATER: Very good. Thank you. We have another question.

MR. MOLLO: Hello? All right, a little better.

All right. So my name is Andy Mollo. I work at Newly Weds Foods. We are, among other things, a

spice company. So my question is primarily for Mark. So in your opening remarks today, you mentioned that FDA values your partnership with Codex, and you have a commitment to working together with Codex.

One area where U.S. regulations aren't entirely aligned with Codex is regards to pesticide MRLs. I'm specifically thinking about spices. I know this is more of an EPA issue than an FDA issue, but do you ever foresee a time when the U.S. regulations would become more aligned with Codex?

MR. ABDOO: Thanks for the question. And you know, our work with Codex is designed to ensure a science-based and risk-based approach as Codex develops its guidance. As you know, under the SPS Agreement at the WTO, countries are allowed to regulate to the level that they see appropriate for their public.

And so there are sometimes discrepancies between what Codex produces and how we go about something. But I think, you know, without predicting the future, which I can't, that our work in terms of the standards development is really what I meant to focus on. I don't know if Bill or William want to add

anything.

MR. MOLLO: Thank you.

DR. PRATER: Okay. Thank you, Mark. Do we have another question?

MR. JONKER: Yes. Jamie Jonker with the National Milk Producers Federation. I think this question is probably also for Mark. When you were talking about the systems assessment, particularly you mentioned beginning discussions with the European Union.

My question for you on that is, do you envision that this is going to be a comprehensive systems assessment of all 27, 28 member states, depending on what point in time that might be, of the EU, or do you see this going as an overview of the EU regulations, and then a country-by-country process?

I think that there are differing ways that their member countries implement their own food safety regulations, some with better success than others, and I'm curious about FDA's thoughts on how that might proceed.

MR. ABDOO: Thanks. And that's an interesting

and helpful question. We are currently in the process of doing an evaluation of EU-wide standards. But we haven't made any final determinations on the extent to which we will look at specific member states or how many member states, all or some portion of them. That's very much something that's under consideration, so I can't answer your question at the current time.

DR. PRATER: Okay. Very good. If there are no more questions in the room, I'd like to turn to the WebEx booth to see if we have questions from the web. Looks like we have one.

MS. MCCORMICK: Okay. We have a question from Rupesh Modi with Red River Foods. "In the produce safety training, we are trained to use the EPA Method 1603 to test water for E. coli. Why did the FDA and PSA limit it to one method? Will there be other methods recommended by the FDA or PSA to test water like MPN methods, which is widely used for Coliform and E. coli tests?"

DR. PRATER: It's a very technical question.

(Laughter)

DR. PRATER: I think probably the best

response that we would generate on a technical question of that nature would be to submit that to our Technical Assistance Network, and we can come back with a good response on that one. So I think that's probably the best way to handle that question, so. We appreciate that question from the web, and we will definitely follow up through our Technical Assistance Network. Other questions? Okay. Very good.

So an excellent session this morning, I think, to set the stage for the presentations that will follow. Very much appreciate all the questions in the room, good questions, and also from the web, and we'll take a break at this point. And we will return at 10:00 a.m. when we will welcome our guest panelists. Thank you.

(Applause)

(Whereupon, a break was taken.)

DR. PRATER: Okay. Just one more minute and we'll get started again. So I'd ask you to please take your seats.

Okay. So welcome back from the break. We'd like to resume our Session 3. We're joined by four

guest presenters who will provide their insights and experiences on partnerships that recognize commodity-specific export programs. And so I will introduce our presenters, and then they will go one by one. So I'd to welcome and introduce Janet McGinn. She's Director of Food Safety Inspection Service at the Department of Agriculture.

Also, we have with us Miles McEvoy, Deputy Administrator at the National Organic Program at USDA. We are also joined by David Plunkett, who is a Senior Staff Attorney at the Food Safety Program at the Center for Science in the Public Interest. And via WebEx, we will also be joined by Shri Mandlik, the Deputy Director of the Export Inspection Council of India.

So I think we have an excellent line-up of panelists, and we are certainly looking forward to their insights. Without further ado, I'll go ahead and welcome Janet McGinn to the podium.

DR. McGINN: Thank you. Good morning. First off, I'd like to thank FDA for the invitation to speak today about FSIS's Equivalence Process.

By way of background, FSIS is the public

health regulatory agency within U.S. Department of Agriculture tasked with ensuring that meat, poultry, and processed egg products are safe, wholesome, and properly labeled and packaged.

To get started, what is equivalence? Equivalence is a process of determining whether a country's inspections system achieves FSIS's appropriate level of public health protection, as applied domestically in the U.S. Equivalence does not mean that a country must implement and develop the same procedures that the U.S. does. Rather, the country must objectively demonstrate that its procedures meet the U.S. level of protection.

Countries wishing to export meat, poultry, and egg products to the U.S. must demonstrate that they have a regulatory inspection system equivalent to that of the U.S. An equivalence determination of a country's inspection system for meat, poultry, and egg products is a pre-requisite of trade for the USDA's FSIS.

FSIS ensures that a country's food safety inspection system addresses FSIS's regulatory-based

objectives. Food safety regulatory-based objectives are the food safety goals for preventing the occurrence of an identified food-safety hazard.

The criteria by which FSIS assesses the equivalence of a country's inspection system can be found in the referenced regulations. In order for FSIS to make an equivalence determination, the central competent authority should document through its self-reporting tool responses and associated supporting documentation that the design of its Food Safety Inspection System achieves an equivalent level of public health protection.

After this, the central competent authority shows FSIS that it can implement the inspection system as described in its self-reporting submission through an onsite verification audit. Equivalent documentation and acceptable audit results will support FSIS to initiate rule making by publishing a proposed role in the Federal Register.

The self-reporting tool is a questionnaire that provides an organized means for the country to demonstrate that its inspection system achieves an

equivalent level of protection. The country's central competent authority is expected to answer all component questions in the SRT in order for an effective determination of equivalence.

The SRT is arranged into six components: government oversight, government statutory authority on food safety and other consumer protection regulations, government sanitation, government HACCP, government chemical residue testing programs, and government microbiological testing programs.

Food safety objective-based safety criteria are the standards that FSIS uses to determine whether the country's Food Safety Inspection System is equivalent. The component questions are the food safety objective-based criteria that FSIS uses to determine equivalence in the form of a question.

FSIS, using food safety objective-based criteria, then reviews the Self-Reporting Tool responses, and associated supported documentation, to determine whether the country's Food Safety Inspection System is equivalent.

When FSIS determines that the country's

documented inspection system meets the criteria, the next step is an onsite verification audit to verify that the CCA implements the inspections system as described in the Self-Reporting Tool.

An onsite verification audit is an audit of the country's Food Safety Inspection System, with a goal of verifying through objective evidence that the country's inspection system has an equivalent level of public health protection. If FSIS determines that a country's documented inspection system is tentatively equivalent, FSIS works with the countries CCA to arrange an onsite verification audit of the country's Food Safety Inspection System.

Audits are conducted by FSIS international auditors. The audit scope includes visual observations of all aspects of the country's Food Safety Inspection System. The audit includes central, regional, and local government offices, exporting establishments and warehouses, and laboratories. After the onsite audit, FSIS sends a draft audit report to the country for review and comment. FSIS then takes the country's comments into account and generates the final audit

report.

Ongoing equivalence is applicable to countries that are listed in the Code of Federal Regulations as eligible to export to the United States, and are shipping meat, poultry, and processed egg products to the U.S. FSIS continually evaluates and verifies the equivalence of an exporting country's Food Safety Inspection System through a three-part process: onsite audits, document reviews, and point-of-entry re-inspection of meat, poultry, and egg products.

FSIS periodically audits every eligible Food Safety Inspection System. These audits will be performed by FSIS auditors and are similar to the onsite verification audits that FSIS does as part of the initial equivalence process.

After equivalence is granted, the CCA on an annual basis must either update its Self-Reporting Tool responses or communicate to FSIS that the CCA has verified its SRT responses and that they are accurate and complete.

All imported shipments of meat, poultry, and egg products that enter the U.S. are presented to FSIS

for re-inspection. If a point-of-entry violation is identified, FSIS notifies the countries and requests and reviews corrective action responses.

The other thing that I would point out is that countries that are equivalent are required to certify establishments that are eligible to export to the U.S. Additionally, they certify shipments of product that are intended to be exported to the U.S. on a shipment-by-shipment basis.

FSIS is the central competent authority and we certify shipments or product that are exported to other countries. We certify on a lot-by-lot basis that they meet our FSIS requirements as well as any additional requirements that the foreign country has in place that are articulated in the Export Library. And with that, I want to thank you.

(Applause)

DR. PRATER: Thank you, Dr. McGinn.

At this time, I'd like to welcome Miles McEvoy to the podium.

MR. McEVOY: Okay. Good morning, everyone. I'm Miles McEvoy, Deputy Administrator at Agricultural

Marketing Service at USDA National Organic Program, and I'm going to give you an overview of the National Organic Program and how we look at imports that are coming into the U.S.

I'm going the wrong direction apparently. Okay. Here we go, that's a little better.

So our mission is to ensure the integrity of USDA organic products throughout the world. We are a global program. We -- there are USDA Certified Products in many countries around the world, and a lot -- there's a huge market in the U.S. A lot of farmers and handlers are trying to access the U.S. market for the premiums that you get in the organic trade.

Our vision, organic integrity from farm-to-table, consumers trust the organic label. Because it's a processed-based standard -- you can't test a product to determine whether it's organic or not -- we are conducting inspection, and having that audit trail all the way from the farm to the marketplace, ensuring there is that clear identity of organic products as it goes from the farm to the distribution chain. And our authority comes under the Organic Foods Production Act

and the USDA Organic Regulation.

Fairly small program, about 45 employees. We have three divisions. One focuses on standards development because we're the scheme owner of the organic standards -- the USDA Organic Standards. We have an accreditation in International Activities Division that oversees the certifiers that are operating around the world as well as our equivalency and recognition arrangements. Then, we have a Compliance and Enforcement Division that handles complaints and conducts appropriate enforcement.

Relatively modest budget of about $9 million over the last few years. There are 81 certifying agents worldwide. Some of them are quite small. For instance, there's three counties in California that run certification programs within their counties. Then there's also global certifiers that certify in more than 50 countries around the world. They're mostly European-based private certifiers that are conducting certification.

Thirty-one thousand certified organic operations in over 120 countries -- the other thing to

realize, of those organic operations, some of those contain hundred, if not thousands, of growers as part of a grower group certification network. So there's -- we calculate about half a million organic farms around the world participate under the U.S. organic system.

The U.S. market is huge. It keeps growing by about 10 percent per year, $43 billion as of 2015, so it's about 4.5 to 5 percent of U.S. food sales.

The way that the system is set up is that we as the scheme owner, we oversee -- establish the standards and oversee the organic control system through certifying agents. So the certifying agents are the ones that are doing the inspections and the verification on the farm, at the distribution and handling component of the distribution chain. And there is a variety of different certifiers. Some of these are government agencies, like state departments of agriculture, but the majority of the certifiers are non-profit organizations or non-governmental organizations. They can be for profit as well. So they're the ones that are responsible for the actual certification, and they're also responsible for

enforcement under their authority over the operations that they certify.

And then we have the certified organic operations, farmers and ranchers, processors and handlers. They're the ones that produce the products, and distribute the products, process the products, and get it into the retail chain.

So there are three options for products to enter the U.S. in terms of complying with the U.S. Organic Standards. One is that the product can be certified -- come from an operation that's certified by USDA accredited certifiers. We have 81 accredited certifiers, and they operate around the world so it could be within the U.S. or outside the U.S. that that USDA accredited certifier is operating.

We also have equivalency arrangements with Canada, which was the first one in 2009, and then the European Union including all the member states, Japan, South Korea, and Switzerland, and we're working with Mexico on an equivalency arrangement and have many other countries interested in equivalency, very similarly to the presentation by Janet. In terms of

equivalency, it's not identical. It's that it functionally meets the same outcomes when we do the equivalency work.

We also have recognition agreements where we recognize a foreign government's accreditation system, and there they are accrediting the certifiers operating within that country to apply the U.S. standards. So it's not an equivalent standard, it's the U.S. standard that these recognition countries are applying. And we have recognition agreements with India, New Zealand, and Israel.

There are many organic arrangements around the world, so it gets to be quite complex. There are -- Europe has a number of arrangements. Canada has a number of arrangements. And as I described the U.S. has a number of arrangements both through equivalency and recognition.

So more specifically on the control systems -- accreditation, certification, and oversight -- the basic international framework in the organic sector is because the U.S. and Europe represent the largest markets by far. Over 90 percent of organic food

products are sold in either the European Union or in the U.S. They form the basis of standards worldwide because countries are trying to gain access to those two markets. So they dominate in terms of the standards discussion, but there's also the Codex Alimentarius guidelines for organic food which is also used as a reference point for standards.

Organic standards around the world are very similar. There are some differences, but in general they are very similar between the EU and the U.S., and other regulatory standards. For conformity assessment, we use the ISO/IEC Standards 17011 for accreditation bodies and 17065 primarily for control bodies.

We have what we describe 10 points of organic integrity, so it's not just the certification that's important in terms of maintaining organic integrity. So clear enforceable standards, communicating about those standards so people know what the standards are, transparent public process in terms of any changes, a quality certification process, an effective complaint process so that if there is alleged problems that can be part of the process, appropriate penalties for

violators, market surveillance, unannounced inspections as component, periodic residue testing is an important part of the organic control system, and then always looking to improve the system through various kinds of reviews and audits.

So the U.S. System, the USDA National Organic Program ensures that all products sold in the U.S. meet the USDA Organic Regulations. Two primary components, certification and accreditation. The certifiers are the ones that verify that the farms and handlers comply with the standards, and then the accreditation body ensures that the certifiers are verifying those production practices, that they are conducting those production sales audit, and ensuring a complete audit trail. So that's how we control -- provide that control through accreditation over the certifiers.

Compliance and enforcement is also important in both certifiers and the competent authorities have a role to play in that. Certifiers enforce the standards for the operations they certify, go through their various compliance procedures, and then competent authorities also need to provide oversight and

enforcement as appropriate.

This is just a picture of providing an inspection and auditing in Argentina, an organic rice operation in Argentina showing both the field observations and the paperwork document review component of those onsite witness audits.

This shows sort of the context of how we, how we approach an audit at a certifier. There's -- we do witness audits to observe an inspector conducting an inspection. We do review audits where we're going out to operations to see that the inspection report was complete and covered all the control points. We're looking at performance evaluations, the criteria that they have for their inspectors, that they are complying with that, that they have thorough and complete inspections when they are conducting their inspections. So qualified personnel, a quality management system, that they have processes and training and processes to provide a thorough and quality certification system.

In terms of oversight and process improvement, we have a number of things that are looking at the U.S.'s program. We do internal audits, management

reviews, kind of standard accreditation process under 17011. We also have peer reviews. We get assessments by foreign governments that we have equivalency arrangements with, as well as conducting assessments of those foreign governments, and of course our favorite Office of Inspector General audits.

Just a little specific on Mexico -- we have been engaged with Mexico for the last few years. Trade of organic products with Mexico is significant and growing. In 2015, U.S. exports to Mexico were $154 million, so it's a significant market for U.S. organic products. Mexicans are -- Mexico as an organic market is growing. And then imports from Mexico, 141 million, led by coffee, avocado, and bananas. The thing to keep in mind is that we only have harmonized trade codes for certain organic commodities. So this is something that we struggle with is not having great data on trade because there's only a few commodities that have an organic trade code because we know that there is significantly more organic products imported into the U.S. from Mexico than the $141 million.

There are a number of NOP accredited

certifiers that operate in Mexico and over 1600 certified operations in Mexico. Mexico has established their own Mexican organic regulations and are in the process of implementing that. We are working very closely with SENESICA. We've been to observe a number of different organic operations there. They've come up here to observe our certifier audits. We've done our peer-review assessment of SENESICA's program using 17011 for the accreditation role that they play, and 17065 for their oversight or the way that control bodies or certifiers are operating.

Ongoing negotiations are underway and we're looking at potentially equivalency arrangement with Mexico later this year. We have signed a Joint Organic Compliance Committee Agreement in the fall of 2016, and this is an agreement to strengthen compliance and enforcement of the organic sector in Mexico, has specific activities to look at that oversight and compliance in terms of tracking complaints, monitoring trends. In terms of what types compliance problems, what violations are we finding. There is a market surveillance component to this organic compliance

committee work. We are looking at how we can support certifiers that are operating in high-risk -- or high security risk areas and then looking at implementing a shipment-by-shipment import certificate for shipments of organic products between the U.S. and Mexico.

Okay. And one last point is there has been research done by Penn State University on what's called organic hotspots. So this is kind of changing topic a little bit to the economic component of organic agriculture, and what they found was that 225 counties around the United States are what are organic hotspots, where this is a lot of organic activity in terms of farms, handling, and processing. And in those counties, they've shown that median household income is $2000 higher, and it has lowered poverty rate by as low as 1.35 percent in those specific counties.

So we're trying to understand better what is happening here, how is organic leading to this positive economic activity. And some of the things that lead to organic hotspot formation that have been identified is that when there are technical assistance that's available through USDA or through other organizations,

or through government organizations, where there are certifiers available. That seems to lead to, or at least assist in the formations of these organic hotspots.

So certifiers that are providing these outreach services, technical assistance to provide that education, and to provide information about those market opportunities in the organic sector.

So with that, thank you very much. I know that was kind of a run through of a lot of information, but thank you very much for your attention.

(Applause)

DR. PRATER: Thank you, Mr. McEvoy. We appreciate that overview of the National Organics Program.

Next, I would like to welcome David Plunkett, and he will give us a presentation as well.

MR. PLUNKETT: Thank you very much. I hope you don't mind. I might pull a Rubio here and drink a little water. I have a bit of a cold, so if you'll excuse that.

But first, thank you very much for the

opportunity to participate on this panel, and participate in this hearing. The Center for Science in the Public Interest, if you're not familiar with us, has provided advice and been an advocate for consumers since 1971, and we focus on nutrition, health, food safety, and our activities include educating consumers, advocating for science-based government policies regarding food, and also countering misleading claims that sometimes crop up with food and, of course, those products that we feel are not advantageous to people's health, putting a little bit of a voice to the consumers about our concerns there.

I've been tasked with providing the consumer perspective on partnerships that recognize commodity-specific export control programs. This is not a well-defined concept as far as I can discover, but as I understand it, the proposal is that when a country whose domestic food-safety program cannot be declared comparable or found to be, you know, be recognized under systems recognition, would be able to create a side-bar program that ensures that exported foods specific commodities meet our safety standards, which

is as much as I know about the program.

I put this in the middle of the comments, but I realized I needed to move it up to the top. But as I talk about this, we need to remember, for consumers the real issue is they want, they deserve, and they expect the food that they serve to their children, the food that they serve to their families, the foods that they eat themselves, to be safe. And it's the FDA's role to oversee the safety of that product, and it's the responsibility of the people who manufacture or grow, or whatever, produce that food to ensure safety of that product.

And so I think we can put -- as we talk about this, maybe put safety over here to the side and say that's a given. Whatever FDA does, it's got to ensure safety and that's why we, you know, we can put that to the side. And what I'm really going to talk about is a little bit more about how reliable do I see these systems as being, and you know, what are the concerns that the consumers would have about them. Sometimes it's dipping over into social concerns, not so much food safety concerns.

While I don't dispute the FDA's authority to do these sorts of programs, I think commodity-specific recognition really provides no real benefit to consumers. That's because of the baseline. For food to go on our market, whether it's imported or produced domestically, it’s required to be safe. Our expectation is it will be safe. So if you're doing commodity-specific recognition, it's not for the consumer. It's for some other purpose.

We ensure the safety of those foods through a number of programs that already exist or will exist such as a cross-hatching requirements of a foreign supplier verification, third-party certification, and then of course foreign and border inspections by FDA.

The potential that I'm worried about is it could make food less safe if it becomes an avenue for FDA to reduce inspections or for the producers to cut corners on things like supplier verification requirements. While a commodity-specific program isn't really discussed in the Foreign Supplier Verification Program's rule, if it is recognized under the exemption for systems recognition programs that is in the rule,

then we've got the potential that perhaps if we haven't structured that program well enough that it's going to lead to potential problems for consumers.

The major benefits of a commodity-specific program, in contrast, all flow really to the foreign suppliers, to the producers of the food, and because they'll gain access to our markets, and easier access to our markets, and of course the importers who are relieved from bearing the cost of doing full foreign supplier verification programs, if the exemption applies.

I'm not persuaded that consumers benefit from a more efficient use of inspection resources. Keep in mind that commodity-specific recognition is merely doubling down on the FDA's PREDICT program, which is also targeted at creating a more efficient inspection program and providing safety without forcing the Agency to look at every item of food that might be out there.

So consumers expect the government to do its job efficiently, but that doesn't mean that they have to make a Hobson's choice between inspections and none. The proposal, in general, has a budget-driven feel to

it, and I don't think we need to do our food safety system on a basis of what our budget can stand, but rather we need to design it around what protects our consumers and then figure out the funding and the best way to do that.

Our system, as I've said earlier, is based on the industry's responsibility for the safety of the products it produces. The public, in contrast, sees food safety as primarily the responsibility of the government. Consumers expect the FDA to keep a close eye on imported food because, frankly, they don't trust imported food. When surveyed, 76 percent have expressed little or no trust in the safety of food from another country. That's according to the International Food Information Council's Annual Survey, and the most recent one.

When asked why, a majority of those people will tell you that it's because they don't really respect those foreign inspection programs. They don't believe that the regulations are as tight. They don't believe the foreign governments are doing the inspections that need to be done. So they all have a

basic mistrust of the very people that we're going to be doing this commodity-specific program with.

At the same time, consumers are eating more imported food. Earlier we were told 15 percent. The most recent figures I had, 20 percent of the food consumed in the U.S. comes from another country. Import shares of food consumption according to ERS, the Economic Research Service, has grown at 2.3 percent annually since 1990, and that's faster than the per capita consumption of food generally, and it's faster than population growth.

So that tells you that we're going to continue to see import foods become an ever-increasing part of our diet. So consumers have a split personality on imported food, distrusting it while at the same time consuming ever larger quantities. The FDA needs to read that duality as a demand for stronger imported food safety programs.

So as I considered this, how consumers would react to recognition of commodity-specific food programs, starting with the assumption that they expect their food to be safe, I have four concerns that I want

to raise.

First, it's unnecessary to do this program. PREDICT does that job already of ensuring efficiency of our border inspections by creating a database based on the history of the products that are brought in and how those products are revealed to be either safe or unsafe. Rather than assisting efficiency, I would anticipate the recognition process itself, because of ongoing monitoring and the need to do the reviews, will consume resources that might be better placed toward doing capacity building in those countries.

Since countries would not have to address the problems with their domestic food safety program, if they have commodity-specific access, it's likely that far more countries would establish and seek to recognize, or have recognized, the commodity-specific programs, thus drawing even more resources to conduct reviews from other activities.

Consider, too, that the basic concept is that we will entrust a government that has demonstrated it has no commitment to food safety in its own country, but nonetheless providing assurances that exports to

the U.S. are safe. And you can see where consumers might not trust that program.

Also, I think the program is morally suspect, and consumers care about this. Rather than improving a country's substandard food safety system, it allows a privileged few to profit by producing for export markets without regard to improving conditions for their general population. So the proposal implies the wrong incentives to the food supply chain.

A better approach would be to incentivize exporters to share the advantages of a strong food safety system with their home country's people. How important is this to consumers? I think that you can look at programs, you can look at certification systems like Fair Trade, where consumers are actually paying more for those products. That will tell you that consumers do have a social conscious about how their food’s produced and about the conditions in the countries where the food comes from.

The proposal will also interfere with markets, and I'm concerned about that. Countries hoping to build their economies will move resources into

producing exportable food, tying up productive land for the export program, creating export enclaves to the detriment of indigenous populations who will lose access to land, lose access to potentially safe food.

The program will do this by acting as a subsidy. Relieving importers who participate from having to bear the cost of assuring the food they import is safe. The subsidy will most likely be paid by the people in the exporting country, who most support or work under this export-control program, if they even want to see any benefit out of it.

Also, buyers will be directed to only those sellers who participate in the export program, and in countries where democratic institutions are not strong, if this is done in such a country, that would mean that you might find yourself purchasing from crony capitalists favored by the government, rather than, you know, really building the economy of that country.

This would be in contrast to a full systems recognition which, by the way, I think is a sound idea, because full systems recognition would improve the chances of access to a healthy, open market of safe

food products in that country.

Finally, the proposal undercuts statutory programs under the Food Safety Modernization Act. It replaces industry responsibility with a command and control government program in the country where it's applied, and that's contrary to the core philosophy of FSMA.

To the extent that the recognition of commodity-specific programs eases access to U.S. markets, it will reduce demands for programs like the Voluntary Qualified Importer Program, which was intended to be designed to again create greater efficiency. That program would also suffer a foreign supplier verification program as I noted earlier would suffer, and I think that there would be impacts on the third-party certification program, even though supplier verification -- you know, the commodity-specific sounds a little bit like third party, which raises another question. Would we be talking about recognizing a private entity as being able to certify to us, or being able to tell us that, that export program is adequate or being the controlling factor in that export program

that we would actually recognize? I would think not, the FDA typically doesn't endorse private programs, but there is a question there that I can't find an answer to.

So for these reasons, I believe consumers, fully informed, would reject commodity-specific recognition as a costly exercise that provides them no value in terms of cost savings, in terms of safety, or in terms of their shared social values with the people of other countries. Thank you very much.

(Applause)

DR. PRATER: Thank you, Mr. Plunkett, for those comments and your perspectives. I think that's useful to us as well.

So now, I'd like to turn to our presenter via the Web. This is Shri Mandlik who is Deputy Director of the Export Inspection Council of India, and I'll turn this over to my colleagues in the WebEx booth that will advance the slides and coordinate the audio.

MR. MANDLIK: Hello?

DR. PRATER: Yes, we can hear you.

MR. MANDLIK: Hello? Hello. Good morning.

First of all, thank you very much for the opportunity you gave to the Export Inspection Council. The presentation is on EIC's Export Control Program in India for Fish and Fishery products. Next, please.

In India, the food control market can be viewed in two ways. We have an internal market, and we can say there is external market. Internal market can be import and domestic, which is looked after by Food Safety and Standards Authority of India, and external market that is export has been looked after by Export Inspection Council. Next, please.

The object of Export Inspection Council is to provide for the sound development of export trade to quality control and inspections and issues related to it. Next, please.

Under the Export Quality Control and Inspection Act, the government of India has the power to notify the commodities to specify the type of quality control within the Food Safety Management System or (inaudible) right inspection to establish and/or recognize the specification of the importing countries so that the export certification then will be

meeting the importing country requirements. And if any contaminants that are non-compliant, then there are powers to prohibit the export of the notified commodity if they're not meeting the requirements of the importing country and the export notification. Next, please.

The actual certification is done by the export inspection agencies. These are the field organizations. They are established in 1966 under the Section 7 of the Export Quality Control and Inspection Act. They are the field organizations of EIC and actually doing the certification. They are located at Delhi, Mumbai, Chennai, Kochi, and Kolkata. They, these export inspection agencies, operate under the technical and administrative control of Export Inspection Council. All these agencies are located at these places are backed by state-of-art laboratories. In addition to that, there are the 30 sub-offices which are backed by the laboratories for the microbiological testing. Next, please.

These are the locations where the offices of the Exporting Special Agencies and the sub-offices --

strategic locations along the coastal line. Next, please.

For any export quality control system to be successful, we need to have the four pillars;, that is, regulation, which is why we have a full quality control and inspection act. And there is an inspection, then testing, and certification. Inspection is done by the Export Inspection Agency, the field organization. The testing is done at the laboratories, which are duly certified by the competent authority. And based on the inspection and the satisfactory testing, the certification is done. Next, please.

The quality provisions for India for export for fish and fishery product, we can say for food safety there is Export Inspection Council. We have the government of India Order 729 which says that fish and fishery products cannot be exported unless it is certified by the Export Inspection Council.

And to implement this order, there is a notification S.O.730, which use the minimum requirements of the product and the requirements of the facility and dos and don'ts for the official control.

With regard to the disease -- aquatic disease control, there is an organization called NBFGR who are under ICAR. It is the Ministry of Agriculture and Farmers Welfare. They undertake the aquatic disease control, and they are the competent authority for this. Next, please.

This government -- this Fish and Fishery Products Order and Notification 730(E), they were amended over a period of time in order to accommodate the requirements of the importing country. For example, 464 was amended for adding the requirement of the (inaudible) 1227 was then for addition of the antibiotics and the heavy metals.

Similarly, the notification was amended to add the requirements of the Fishing Reserves (ph) and other primary production. The primary production, the last amendment was done 497(E) dated 10 March, 2011. We have brought the primary production under the control -- under the official control. Next, please.

The requirements of the aquatic farm, the farms have found the requirements to maintain the minimum imports or the imports which are going into the

farm only permitted chemicals are used. In case they are using any drugs which are permitted with their models, then withdrawal period has to be followed, and they have to keep the record from where the imports were procured and to -- or which establish went to which approved establishment the raw material has been supplied. Next, please.

Similarly, the requirements of the landing site, there has to be adequate supply of the potable water. There has to be a clean ice supply, a raised platform for displaying the fishery product in the auction center, a better waste management system. Then there has to be a hygiene inspector who will inspect the offloading of the raw material from the fishing with the -- and to whom -- to which establishment the products are supplied.

The hygiene inspector is also expected to keep the records of all activities for that auction center or the landing site. Next, please.

The requirements of the fishing -- of the fishing vessels we designed and constructed to ward off contamination, there are holes which are used for

keeping the fishery product, should be cleaned regularly. There has to be a clean ice supply, and they have to maintain the minimum record like the water temperature of the product and to which establishment the raw materials has been sold. Next, please.

The requirements of the establishment where the fish and fishery products are processed, there has to be clean surroundings, and there has to be a raised platform for receiving the raw materials, then provisions for the change room for the male and female workers. Then there has to be a -- a floor has to be a clean, unidirectional floor. There has to be a pre-processing and a processing. They should be well ventilated.

There is a requirement of the approved technologist, which means the Export Inspection Council. He's approving the technologies who will be working on behalf of Export Inspection Agency. He is an extended arm of the Export Inspection Agency, who undertakes the quality control and the implementation of the (inaudible).

There has to be a provision for the wet and

dry chemicals. The high-risk and the low-risk area has to be kept separately here. If there is a booking facility, then this particular clause applies to it. Cold storage facilities and water treatment plants, high supply, these are the minimum requirements of the establishment if the plant has to be approved for export. Next, please.

Any establishment who wishes to export to any country from India, then there has to be a -- there is a procedure for approval and then disapproval leads for two years. And then if it is followed by the renewal approval.

In India, we follow the split system, means an establishment got approved for a particular country. If the (inaudible) that establishment is meeting the requirement of that importing country, then they are given the approval for that specific country.

Similarly we, the split system is also going to the primary production level, so these -- the aquaculture farm, the fishing vessel, the landing sites, when they're improved, the requirements of the importing country are taken into consideration. There

is approval for technologies. In case the establishment wishes to change the scope, they want to go from the freezing to the cooking facility, then they have to have that additional facility approval. Then there is a procedure for granting the Merchant Exporter official control.

Every processor can export. But in addition to processor, then he can engage an exporter who is not a processor. In that case, there has to be approved from the Export Inspection Council that so many processors are attached to these merchant exporters.

Then in these guidelines, there are guidelines for meeting with unsatisfactory test report. If it is unsatisfactory test report of the visits of the official controller, unsatisfactory, how they are (inaudible).

When there is export certification, all the certification is done online very well. The establishment is ready for export, they apply online and the verification is done by the official control by the local competent authority and if things are satisfactory, then the certification is done.

At present, we are printing the health certificate on the physical copy, hardcopy. They have stamps, seal, and export certification is done. If importing country agrees to accept the digital signature, then we are in a position to undertake this digital certification and, in that case, we can do away with the hardcopy.

In case there are quality issues, we (inaudible) the importing country, then we have a detailed procedure how to deal with the issues if the contaminants are back or if they are actually being any quality issues which are observed in the importing country. Next, please.

All approval of this establishment is under Food Safety Management System Certification. It is a self-certification. They have been implemented hazard analysis and critical control points.

During official control, our focus is on the preventative practices. However, if export certification is done based on the satisfactory level to testing in the competent authorities authorized lab. So we follow both way. We have -- there is a

preventive approach, however the end product is tested before the export certification is done. Next, please.

The official control system, we can say we have a feedback system. There is a monitoring visit by the inspector. We can follow, the supervisory visit -- a senior level officer, and a corporate audit from the Export Inspection Council.

Now, this official control is based on the performance of the establishment (inaudible) visits are once in a month. If the performance is satisfactory, if the test results are satisfactory, if there are no issues, quality issues from the importing country, then the frequency of the official control has been brought down. In any case, if unsatisfactory performance has been observed, then the visits are, again, backed -- brought (inaudible) intensive height.

In addition to that, the -- one of the important activities that is national residue control monitoring plan, we implement for all the commodities including fish and fishery products. Six number of samples are drawn from the different area in India. They are tested, and the results are compared with

(inaudible) for analyzing (inaudible) non-compliances from the importing country. And then the -- accordingly, the sampling plan is prepared for the next year. Next, please.

The export inspection, any certification is not complete unless there is a -- there are laboratories in -- with EIC we held full testing laboratories located in Chennai, Kolkata, Mumbai, and Kochi. In addition to that, we have approved 18 private laboratories which are in the official control of EIC.

These -- all these laboratories are in NABL and EIC approved. They are also within (inaudible) all 25 standards. All these laboratories participate in the proficiency testing and demonstrate their technique and competence.

In addition to that, the Export Inspection Agency that is a local competent authority, they have the field offices attached to their sub-offices for routine microbiological analysis. Next, please.

This is a snapshot of the laboratory in Kochi, Chennai, and Kolkata where they have the equipment for

(inaudible), the microbiological facilities. Next, please.

When the consignments are ready, the export certification is done in two parts. First is the export certificate -- a certificate for export (CFE), it is mandatory for every export by the Indian Custom. The copy of the CFE is checked by our Indian Custom, and then there are health certificate which is issued on the secured stationary with the safety features through e-certification. The health certificate is meant for the importing authorities. Next, please.

The health certificates are issued based on the importing country requirements. In addition to that, there is a pre-harvest testing or in-house ELISA testing to check the antibiotic abuse (ph). And in addition to that, there is a pre-export testing we undertake. When pre-harvest and pre-export testing are satisfactory, then the -- and the importing country requirements are satisfactory, then the export certification is done. Next, please.

This is the home page of Export Inspection Council from here. The list of the approved facilities

is available, then their documents related to the fish and fishery product notification order, then the building (ph) inspection. There is a link for e-certification where the exporter can log in and apply to that. Next, please.

Once they log in to e-certification, then he has to use his unique username and password and get into the certificate. Where he wants to export. If he's approved for Country A, then these (inaudible) will be available and then he -- the export certification can be done online.

On the website, the importing authority can also view by keeping -- by putting the reference number of the health certificate and check whether the certificate is authentic or not. Next, please.

We have a robust quality issue handling mechanism. When we receive any quality complaint from any importing country, immediately we place the establishment on the internal alert. It means there is a higher frequency of official control. We immediately undertake the investigation. The investigation is done at the establishment, the laboratory who issued the

test report, the primary production at the farm, or the vessel or the landing site.

When the root cause has been found out, how it happened, and then the corrective actions are taken, there is a verification and increased frequency of the surveillance. If a recall is there, then -- if recall is required, then that step will be taken. Then in case the (inaudible) are non-compliant, then there is a disposal as per the decision of the local competent authority. And definitely there are actions to prevent the reoccurrence so that there is a small threat from India to the importing -- our importing partners. Next, please.

With respect to the export control program, this number of issues, we reviewed from 2009. Though the graph is not consistent, however it is a Hindi figure, and we -- but we examine ourselves for how we stick to our export control program using (inaudible). Next, please.

With regard to India and U.S. FDA -- or USDA -- India has signed the Memorandum of Understanding between EIC and export inspection and U.S. FDA in March

2015. It was followed by signing the Confidenciality Commitment from EIC not to publicly disclose the non-public information shared by U.S. FDA. That was done in June 2016.

We have also initiated the process of equivalience fish and fishery products web-based effective within the Public Health Information System. We are working on it, and when this process is done then India will have the equivalence for export of Siluriformes fish which comes in the purview of USDA. Next, please.

Indian system is often audited by the various -- our importing partners. We have the Food & Veterinary Office Mission from European Commission. They come for ID mission, and (inaudible) mission. Then from custom union we have FSVPS. Then there is a CNCA for food and AQSIQ for the feed.

Vietnam authorities are also coming in verifying our certification program. From Japan we have authority from Ministry of Health, Welfare, and Labor. And of course U.S. FDA also audited our system in 2011 fish and fishery products certification. They

co-audited by a team of U.S. FDA officials. Next, please.

Our views on commodity specific certification program is that different countries have different standards, which makes full certification difficult because when the products are made, they are made for Country A. And then if there are opportunity that it needs to be sent to Country B, then it becomes difficult for the exporter to take a call on that without (inaudible) meeting the requirement or not.

Similarly, when the export is done to Country 1. And after the evaluation, the same product is exported to Country 2, so there is a possibility that the raw materials may not be meeting the requirement of the Country 2. And in that case, there might be a quality issue with the Country 2. However, when they manage (inaudible) exporting, they are exporting with regard to Country 1.

The way out of these two issues is that if every country follows the quality standards, then probably we don't -- an exporter will not face these type of issues. Next, please.

With regard to training and monitoring, we have (inaudible) trainings to the staff, which is in the field. And training is done at the regional and the sub-office level. Our officials have also trained at the international level. Our lab experts are regularly sent for specific training. EU there is a program, CITD and special training for the (inaudible) officials from the laboratory and the field are participating in all these training as they come into the building initially, too (ph).

Our monitoring of the officials is through the supervisory visit. The senior officers are going and checking whether the compliance in effect is done or not. Then there's a corporate audit from the Export Inspection Council to check whether the compliance -- whatever -- what the inspections are sent from the EIC are followed in total or not.

In addition to that, there are unforeseen and unexpected visits to check the compliance. Here, the local competent authority is not aware that the senior officers are visiting the establishments of the local office. Next, please.

Our approvals are end of the Food Safety and Management System certification that is (inaudible) mandatory and our focus is on the preventative requisites. And however, when the export certification is done, then we check the test reports. And if the test reports are satisfactory, then the export certification is done. Next, please.

Thank you very much for your attention.

(Applause)

DR. PRATER: Thank you very much, Mr. Mandlik. We appreciate your presentation.

So at this point, we've heard from a number of panelists and it's time to turn it over to our FDA experts. I'd like to remind them that Mr. Mandlik will be available via WebEx to answer questions as well.

So I will turn it over to Dr. Steven Solomon who is Director of our Center for Veterinarian Medicine and the Chairman of this Panel who will moderate the session.

MR. SOLOMON: Thanks, Don. And let me just add my thanks to all the presenters.

So for this next session, we have a number of

experts from FDA that are going to ask questions to try and probe into the issues that the FDA is trying to get their hand on. I think you've had an opportunity to meet most of them, but let me just introduce them again.

So Mark Abdoo, the Assistant Commissioner for Global Regulatory Policy in the Office of Global Regulatory Operations and Policy; Camille Brewer, the Director of International Affairs Staff; Bill Correll, Director of Office of Compliance in Center for Food Safety and Applied Nutrition; Bill Jones, the Deputy Director, Office of Food Safety, Center for Food Safety; and Caroline Smith DeWaal, the International Food Safety Policy Manager in the International Affairs Staff in the Center for Food Safety.

So I'd ask our experts to -- we'll just go down the line. Please direct who your questions or -- would be, if it's more to one person, and we'll walk through. So Camille, I'm going to start with you.

MS. BREWER: Thank you, Dr. Solomon. I'd like to thank all the panelists as well for very interesting presentations.

My first question is for Dr. McGinn. If you could talk about how countries enter into the equivalence process, is there certainly some degree of self-selection? What's the first screening process? And do countries -- do any countries self-select out of the process and decide not to proceed? Thank you.

DR. McGINN: Thank you for the question.

So the first step of the equivalence process is for the country to officially request equivalence for FSIS, and then FSIS sends them the Self-Reporting Tool. And then a number of countries may not respond to the Self-Reporting Tool, but the next step is for the country to submit the Self-Reporting Tool to FSIS, and typically there is an ongoing technical exchange of information. And then once FSIS determines that the system on documented appears equivalent, we work with the CCA to do an audit.

So there's -- so it starts with a country making the request, and you know, the Self-Reporting Tool is an opportunity where some don't continue to pursue equivalence.

MS. BREWER: Thank you for that. And just a

quick follow-up. Could you give us a guestimate of the number of countries that decide not to take the next step, that you don't hear from?

DR. McGINN: I don't have a good figure off hand to provide you on that.

MR. SOLOMON: Mark?

MR. ABDOO: Thanks. My question is for Miles, and Janet might also jump in if she has insight.

I noticed that in your presentation you said that you have equivalence agreements with both the EU and the member states. And I was wondering if you could fill in some of the thinking behind having that sort of duplicate set of arrangements for the organics program.

MR. McEVOY: Yeah, I must have misspoken. We have an arrangement with European Union, which includes all of the member states. So when we do our assessments of the EU System, then we may go to -- we do go to specific member states to see how the system is being applied in that particular country, but we do not -- we have not assessed each of the 27 or 28 member states. We've looked at specific country systems that

have more significant organic production and sales.

MR. SOLOMON: Bill Correll?

MR. CORRELL: My question is for Miles, as well. In your presentation, I think I gleaned that AMS is working as the accrediting body for the certifiers. Was I correct on that?

MR. McEVOY: Yeah. That's correct.

MR. CORRELL: Could you describe a little bit of the program and criteria that you use for accrediting the certifiers and how that program functions?

MR. McEVOY: Right. The criteria are in the USDA organic regulations, so the criteria are that the certifiers have to be following the certification processes that are spelled out in the regulations, which means annual inspections, qualified review process, they have to do a certain percentage of unannounced inspection. So that's kind of the certification piece. And then there's a number of criteria in terms of the accreditation criteria.

They are similar to ISO Guide 17065, but they're not identical. There's a few differences. So

things like having qualified personnel, having internal review, an internal audit, having a conflict of interest provision, maintaining confidentiality, so all those various elements of ISO 17065 are some of those accreditation criteria for the certifiers.

The process is that they apply for accreditation, and they have to submit a quality manual that describes how they meet all those criteria. Then we do a desk audit to see whether that's sufficient, and then once that's sufficient, then we go out onsite to see that they are meeting those criteria.

MR. CORRELL: A real quick follow-up -- thank you very much for that. Once certified, is there an on function built in the program to, you know, check on the certifiers, audit the certifiers?

MR. McEVOY: Once they're accredited?

MR. CORRELL: Yes, once they're accredited.

MR. McEVOY: Yes. There's a five-year review process. They have a midterm audit and a five-year audit. In addition to that, we do compliance audits if there are problems that are identified during that interim time frame.

MR. CORRELL: Thank you.

MR. SOLOMON: Caroline?

MS. DEWAAL: Thanks. I'm going to pull a Jenny Scott and say I have lots of questions. However, I will -- I'm hoping for two questions. First, for Mr. Plunkett.

You expressed a number of concerns, and I wanted you to think about a couple of scenarios. One is countries with robust food safety systems, those that could be candidates for systems recognition but where trade doesn't justify the amount of time and resources that are needed to actually achieve full systems recognition. Would you continue to have concerns there?

And secondly, countries that commit to sell any products that go through the Export Certification Program on their domestic market in a way that's affordable. Can you just elaborate on if you have the same concerns?

MR. PLUNKETT: Just those two scenarios? Okay. Well, you know, your expectation is that commodity-specific would be no less rigorous than

system recognition. You know, you're looking for the same thing. You're looking for the ability of the country to regulate the safety of its products, then in this case it's a particular product, not all of its products. And so the first scenario, you know, if they have a robust safety system I think that's going to be taken into account, but I don't understand why someone would, you know, say, oh, well we only want to do commodity-specific. Perhaps they have only one export product. But I think the benefits to the country would be to go ahead since you're going to do the same steps and have the same requirements, go ahead and get your system recognized.

As far as export certification and, you know, would a country commit to those export products being available on their domestic market -- that's how I understood the question. Yeah, I think that's nice, but that's not really the concern. You know, the concern is that the country is not living up to its obligation to its citizens, but we're providing them with a way to specify particular products that are going to be safer, and perhaps they'll make them

available to their citizens, perhaps not.

But the more likely consequence of any system like that is that you'll have international corporations going in, purchasing all the land that they can purchase, and growing that export commodity strictly for the export market. Why would you go through the process of getting an export program if you're -- you know, if you're going to expand that program to cover your own citizens, yet you're not going to go ahead and improve your food safety system?

The better approach for FDA in that circumstance isn't to create this export program and say, oh well, this is fine because they're going to share this. A better approach would be to go in and really build the capacity of that country to protect its own citizens so that we know we can be confident that the food they're producing is going to also protect our citizens.

MS. DeWAAL: If you will allow me, I have one important question for the panel. How -- what types of criteria do you use in the organic program and then the USDA program to ensure the strength of rule of law in

countries where you've developed these programs? And also, I'd be interested if our other two panelists have any answer on that.

MR. McEVOY: Well, we have certified organic products that are coming from all over the world, and some of those countries that it's coming from, there's not as -- a very effective government control system, especially over the organic sector. This is a little bit of answering two questions at once through your previous question because what we have seen, especially in Latin America as the organic market has expanded in the U.S., there's a lot of organic farmers and -- or farmers and handlers in Latin America that are going to access to the U.S. market.

And it's mostly small producers that are operating in cooperatives and smallholders that are involved in coffee or cacao or some kind of export commodity. And as the markets have grown -- those export markets have grown, it has built capacity in certain areas and gotten the government's attention so that now there's a number of governments in Latin America that are very engaged in developing organic

control systems in Latin America.

And through an organization called the International -- Inter-American Commission on Organic Agriculture, the goals of that Inter-American Commission on Organic Agriculture are to both strengthen control systems but also to build internal markets. And so they're trying to build technical assistance and various capacity to build that domestic market supply. So there's like -- there's a synergy between the development of market opportunities in international trade that are leading to better governance.

In Latin America in particular, we've seen that with SENASICA's work in organics that's strengthening their system there. They are being able to provide much more of a network of help, not just through the government, but through other organizations that can provide market assistance and technical assistance on the production challenges in growing and distributing organic products.

DR. SOLOMON: Dr. Jones.

DR. McGINN: So our equivalence process, of

course, we're looking at the central competent authority, and one of the components that we look at is government oversight. And you will see that most of our food safety objectives are based on that component. So we do put a lot of scrutiny on that one. We look at it through the self-reporting tool as well as the audits, so we do look at that component very closely.

DR. SOLOMON: Bill.

DR. JONES: Thank you. I've actually got a question for each of you, as time allows, but let me start with Mr. Mandlik to make sure we're keeping him in the loop, if I may.

First of all, thank you for taking on the challenge of joining us remotely. It's working so far, and now I'm going to put it to the test.

We've worked closely in the fisheries products arena with your Marine Products Export Development Authority and your Export Inspection Council, and we've engaged in train-the-trainer programs together for good aquaculture practices with good success. And I'm wondering, in an ideal world with more resources available than either of us happen to have right now

for these activities, what would be the first thing on your list for subsequent activities?

MR. MANDLIK: Thank you for the question.

Once this step has been done, and now what we are planning is that the officials or the technologist who are trained, they will be training down the line. That is the first step we will be taking in this, so that the people who are trained will be training the more people and then you will see the effect on ground because this training, when it was -- it had happened. The response was very high. However, because of the time and, you know, the other issues, we could not accommodate all the people. So that is the next phase we will be doing in early this year. Thank you.

DR. JONES: Thank you.

DR. SOLOMON: Do you have more follow-up?

DR. JONES: I do have other questions.

DR. SOLOMON: Well, why don't we --

DR. JONES: We'll let someone else take a turn.

MR. CORRELL: So Mr. Plunkett raised a real concerns about consumer confidence, and so I'd ask all

three of the other representatives to sort of say -- you described your program, and you described the oversight over the program, and the tools that you used to try and work on the enforcement. But what I didn't hear was how transparent you are when you find problems and address those problems, and how do you translate that to the consumers in order to enhance the confidence level? Dr. McGinn, do you want to start?

DR. McGINN: Sure. So FSIS has a very transparent process. We do have four countries that will be listed for the first time in -- as eligible. We do go through proposed rules. And so, our rationale for why we are recommending to list them as eligible goes through a very transparent process. Also, all of the audit reports are published on the website and are available for review.

MR. CORRELL: And part of my question was about if there's problems identified, you know, once they're in the system, how you make that public and how you make sure consumers are aware of, you know, the rigorous efforts that are undertaken.

DR. McGINN: The audit results, if there are

any issues that are identified during the audit, those are described in the audit report.

MR. CORRELL: Thank you.

DR. SOLOMON: Mr. McEvoy?

MR. McEVOY: Sure. So consumer confidence in organics is really critical since, as I said, you can't test to see whether something's organic or not. An organic apple looks the same as a conventionally produced apple. There are a lot of concerns about imports, so a few years ago we had a lot of concerns about Chinese -- organic imports from China. We did an extensive audit in China to follow four commodities from the farm to the port and published that report, and that seemed to help provide that information.

We do post all the audit reports from the certifier audits that we conduct, as well as the assessments that we conduct of foreign government systems. We also do a lot of enforcement work, so we do a quarterly report in terms of our number of complaints received, number resolved, notices of correction and civil penalties that have been issued, and we also provide some information of specific cases

that are higher profile cases. There was a case last year of a grower, a seed grower in Idaho, selling conventional alfalfa seed as organic alfalfa seed that had somewhat of a high profile.

But there's -- we would like to do a lot more to be more transparent about the enforcement activities that we conduct. We also published fraudulent certificates; they're posted on our website as well.

MR. CORRELL: Thank you. And Mr. Mandlik, anything to add to this?

MR. MANDLIK: No, please. Thank you.

MR. CORRELL: Camille?

MS. BREWER: My question is for Dr. Mandlik, and thank you for staying up. It must be midnight in India. So my question is about your business model.

Is your program 100 percent cost recovery? Is it user fee? How do you support the program? And my second question for you is around your connection to the food safety authorities in India, and I think that the presentation by Mr. Plunkett led me to that question. Is there a connection to the domestic side? What do you learn from one another? Thank you.

MR. MANDLIK: Thank you for the question.

With regard to first part of the revenue, the fee, I would like to say that all the Export Inspection Agency and Export Inspection Council officials are the government officials, and that they are on the payroll of government. In addition to that, the establishments we got approved, and when they are doing the export the local competent authority tries to collect the monitoring fee. There is a fixed monitoring fee based on the value of the consignment, and that's the revenue to the local competent authority.

With regard to the second question about our connections with the Food Safety and Standards Authority of India, although we are in the different ministries, we work closely. We are under one umbrella. There is an exchange of information. Both the officers of both organizations are on the panel and the standard-making bodies. We -- together we share the Codex of the SPS or the TBT platforms, and we (inaudible) of India are (inaudible) duty. Thank you.

DR. JONES: I have a question for Janet and for Miles. So we're evolving our programs. That's

what this hearing's all about. You have well-established systems for equivalents and for accreditation respectively. As these programs have evolved and continue to evolve, what are some of the changes you've made along the way, and what aspects of the process would you like to streamline even further going forward?

MR. McEVOY: Yeah, we've made a lot of changes to the process. The National Organic Program is a relatively new program, so the main changes are more robust systems in terms of assessment, both in our equivalency arrangements and our recognition agreements that they're more thorough. And our audits of the accredited certifiers are more frequent, more detailed, and more robust. So we continue to learn.

The other thing that we do, we do a review each year of kind of the major findings that we have. And so based on that, then we conduct specific training to the certifiers on those, I guess, weaknesses that we see in the system. And then we do have a number of things that we are looking at in terms of strengthening the oversight of the organic sector that we're looking

at doing. One thing in the -- in the organic sector, there are what are called excluded operations, especially excluded handlers.

We find that that's a real weakness in terms of following the audit trail, so those handlers that do not actually pack or re-label a product are not required to be certified, and we find that that's a real weakness because there's a lot of paperwork in terms of the audit trails, so we're looking at how to put improvements in that part of the process.

DR. McGINN: I think some of the changes that we've made in the equivalence process is, we have made a lot of effort in terms of communicating how equivalence decisions are made, so documenting and publishing are directives that describe how we make initial and re-instatement equivalence determinations, how we do audits. So I think a lot of the changes that I think have been impactful have been around being more transparent to help foreign countries understand how we make our decisions, other stakeholders to understand how we make our decisions.

So I would say that just becoming increasingly

transparent is one of the significant things that we've done, as well as development of outreach materials to foreign countries to help them understand as well kind of what types of documentation they need to respond to the self-reporting tool and really understand our process.

MR. PLUNKETT: If I can make one comment about the -- I think your question sort of opens the door to a slippery slope problem with any of these programs, and that is one change that FSIS did make -- not to attack my co-panelist here -- but one change that they did make that was, I think, detrimental to the program is they changed the schedule for doing their in-country audits. And so instead of doing audits every year, they slowed that down and they'll do them every three years perhaps, depending on the safety -- you know, the perception of the quality of the country's program. And, you know, that idea that, okay, we're going to go to, you know, we're going to go to systems recognition or a commodity specific recognition because, you know, we're going to have more efficient inspections, if it's a budget driven then the next step is, okay, well we're

going to slow this, we're going to slow that, we're going to do audits of these systems once every 5 years, once every 10 years.

And so you get into this role where, you know, your initial purpose may have been to create a more efficient system, but your final result is that you're making changes, not on the basis of what assures consumers about the safety of the food, but what your budgets will allow.

And I think that that kind of a slippery slope is a bit of a problem with any of these programs that we talk about for -- at this point increasing efficiency, but ultimately finding ways to do things cheaper sometimes to the detriment of the safety programs that we're hoping to achieve.

DR. SOLOMON: Camille.

MS. BREWER: My question is for Mr. McEvoy. You indicated that the certifying agents have enforcement authority. Can you talk about that a little bit more? What are the enforcement tools? Thank you.

MR. McEVOY: Yeah. A certified operation has

to meet the requirements and is inspected and reviewed on an annual basis to see that they meet those -- all the criteria in the organic practice standards. So during the inspection -- it's a very common that during that inspection they'll find -- there will be findings of noncompliance and record-keeping or something in their system where they need to make improvements.

And so then the certifier issues what's called a notice of noncompliance, and the operation then has the opportunity to provide corrective actions to that noncompliance or to rebut the noncompliance. If those corrective actions are accepted by the certifier, then the certifier has to verify that they are actually implemented. So it's a continual process improvement process.

If it's a significant violation, then it goes into the adverse action process where they would issue a notice to suspend or revoke the certification of the operation. So those are the compliance procedures, in short, that a certifier applies in their enforcement of the standards.

DR. SOLOMON: Anything else from the Panel?

Caroline?

MR. CORRELL: One quick question for Miles. In terms of audits of the certifiers that you do, and you had talked about sort of the frequency of that, is that disclosed, the report -- the audit reports in terms of transparency? It seems to me the strength of these programs and liability for consumer assurances really rest with, you know, overcoming the, you know, the mistrust of such systems.

MR. McEVOY: Right. The certifiers are the key and yes, the audit reports of the certifiers are posted on our website.

MR. CORRELL: Posted?

MR. McEVOY: Yeah.

MR. CORRELL: And if there's a -- you know, I assume there's a process for remedial action with the certifiers if, you know, they fail one too many audits in the future.

MR. McEVOY: Yes. So the way that -- we don't post the reports until the corrective actions have been submitted and accepted, so then that's when they get posted, so it's -- so a reader of the reports can see

what was found during the audit and what the certifier is doing to remedy the finding.

MR. CORRELL: Oh. Thank you.

DR. SOLOMON: Caroline.

MS. DeWAAL: Thank you. I was interested that both in the National Organic Program and the Meat Inspection Program neither of you mentioned the label because you are really built around a USDA mark of some kind. So my question is, how do you -- what type of activities do you conduct at the border to ensure that meat is only coming in from countries that have been recognized or that the organic label really does meet the program requirements? Do you have border activities that do that? Thank you.

DR. McGINN: So all of the meat, poultry, and processed egg products that come into the country are presented to FSIC for re-inspection, and so we do -- every shipment that comes in, we re-inspect and part of that verification includes labeling verification.

MR. McEVOY: Yeah, the National Organic Program is all about the label. It's label approval to use the word organic on an agricultural product. It

has to meet certain requirements.

We have really no oversight at the border. At the point of entries there's no oversight. We're looking at establishing some type of oversight, but the oversight is really at the level of the certified operation. So that's going to be the final handler that is responsible for exporting the product into the U.S. and then the receiving party in the U.S. is also going to be a certified handler that receives the product. And that's where the inspection occurs, but not at the port of entry.

DR. SOLOMON: One more. Last question. Bill.

MR. JONES: Okay. Thanks. I appreciate that. I'm glad we have time for one more because David always asks me a lot of tough questions and I don't want to miss an opportunity to ask him one more.

So you talked about the dichotomous approach of consumers to imported foods. Given our dependence on imported foods -- and I'm going to ask you to suspend disbelief and an alternate reality for you here -- if we came up with what you could potentially see as a responsible and effective program that made the

PREDICT program even more effective and accomplish this through an effective capacity building program that was, of course, morally responsible, how best would we engage the consumer to communicate this to them?

MR. PLUNKETT: Yeah, that's a good question, and I can't really say that I know the absolute answer -- a very tough question in that regard. You know, we're talking about how do we communicate to the consumer that food is safe? I think probably the best way to communicate that is to make sure that food is safe, you know, not have outbreaks, not have reports of illnesses caused by food, allow people to become confident in the food that they're purchasing that it is, you know, it is under regulatory control, that it is going to be safe for them to consume.

People will get comfortable over time. There's some aspects that you will never be able to solve because at least a piece of that mistrust is the fact that a consumer doesn't elect the representative that votes in the government of the exporting country. You know, the consumer doesn't have control over that, and I think that distance is a bit of the problem.

And so what the consumer is going to look at is they're going to look at FDA. And so for FDA you're going to have to have programs that are very transparent, that are very understandable to consumers, and that they're easily discovered. Sometimes we bury our programs and bury our explanations deep in websites and consumers have no way to access that information in a realistic fashion.

So I think that those are sort of the things that you can do. You know, can you start doing television ads and various other communications and run newspaper articles and that sort of thing? I don't know that that would be as effective as simply making sure that you're doing your job properly and that the food that people are purchasing is safe and that they can have confidence in the food safety system in this country, even if they don't necessarily trust some distant power.

DR. SOLOMON: So let me thank our panelists, and I especially thank Dr. Mandlik. We'll let you get some rest now after a long day. And we're going to go to the last portion for this morning which is testimony

from stakeholders who have pre-registered to speak. And we have one, William Jordan, if you'd come up to the microphone, introduce yourself, and then present your testimony.

MR. JORDAN: Thank you.

My name is William Jordan, and I'm here in my capacity as a government affairs consultant to the Equitable Food Initiative. It occurs to me that probably my testimony this morning is more appropriate for a segment to yesterday afternoon's because the Equitable Food Initiative is a non-profit organization that is a private food safety certification scheme-owner. But if you'll indulge me, I'll take a few minutes to tell you a little bit about EFI and make some comments about the issues that were raised yesterday.

EFI is a coalition of retailers, growers and agricultural workers in the produce industry, and EFI and these coalition stakeholders have worked together to develop a rigorous set of standards that covers not only food safety, but also labor conditions and environmental stewardship. And that broad scheme, that

broad set of standards, I think, distinguishes EFI from some other scheme operations as well.

Another thing that distinguishes EFI from other programs is its emphasis on training the agricultural workers on the facilities where fruits and vegetables are being grown. It's the workers themselves who are in the best position, based on all of their knowledge and experience in the fields, literally in the fields, they are in the best position to identify problems and take steps to correct them before they become a serious food safety issue.

So emphasis on training farm workers is at the heart of the EFI program. EFI certifies farms in the United States but also elsewhere in North and South America to comply with the rigorous standards. The EFI is benchmarking the food safety standards that they have developed against the produce safety rule to ensure that any farm that EFI has certified to be in compliance with its regulation is also meeting the FSMA standards as well.

We actually at EFI are very interested in a strategic partnership with FDA. We think that farms

that have been EFI certified and that are re-inspected and audited on a regular basis are ones that pose fewer risks to the food safety program and, therefore, perhaps may deserve to be evaluated differently under the PREDICT program.

We would love to work with FDA to have you all come and look the training programs that we do with the farms that we've certified and figure out how best we can work together. Thank you.

DR. SOLOMON: Any questions from our panel experts for Mr. Jordan?

Okay. Thank you very much.

Okay. With that I am going to turn it back to Don to close us out for this morning's session and just, once again, thanks to the panelists and thank you for my colleagues as expert witnesses.

(Applause)

DR. PRATER: Thank you very much Dr. Solomon, and I'll just add my thanks to the panelists, appreciate all the insights that you've shared with us today. Also, a special thanks to Dr. Mandlik for participating remotely and staying up with the time

difference. So thanks, as well, to our FDA colleagues, the experts and to folks in the audience and on the web.

This will conclude Session 3 this morning, and we will now take a break for lunch and we will reconvene at 1:00 o'clock. I'll just remind you there's a cafe outside the front entrance of the building. Thank you.

(Whereupon, a lunch break was taken.)

DR. PRATER: Okay. If I could ask you to take your seats, we'll start in just one minute. Very good.

So I would like to welcome you back, and open Session 4. This is our session entitled Partnerships that Recognize the Robustness of the Entire Food Safety System: Systems Recognition. For this panel, our objectives are to seek comment on what indicators we should consider to determine whether the program meets expected outcomes and best practices on how to identify robust food safety systems.

So at this point I would like to introduce my FDA colleagues who will provide some remarks to set the stage for this panel. We'll have Ms. Caroline Smith

DeWaal. She is an International Food Safety Policy Manager here at the Center for Food Safety and Applied Nutrition. Ms. DeWaal will explain what systems recognition is and provide an update on where we are with its implementation.

We will also have Karen Swajian, who is a Consumer Safety Officer in the Office of Food Safety at CFSAN, and Karen will describe the international Comparability Assessment Tool, or ICAT.

As well, I'd like to introduce Deb -- Debra DeVlieger. She is a National Food Expert in our Office of Regulatory Affairs, and she will cover systems recognition, audits, and reports.

And finally, I'll introduce Brian Pendleton, a Senior Policy Advisor in our Office of Policy and he will review the impact on the Foreign Supplier Verification Programs and other FSMA requirements.

So welcome to my FDA colleagues, and I'll turn it over to Caroline.

MS. DeWAAL: Thank you, Don. Hopefully I can figure out how to use the -- all right, there we go. Thank you.

Good afternoon, everyone, and I really want to thank everyone for coming to this two days of discussion around a variety of approaches we either have in place or are considering with respect to improving the safety of imports. It's incredibly helpful to FDA.

Systems recognition is a program that we started working on really around 2010, maybe a little earlier. Camille Brewer would know the exact dates. But it really is a partnership. And at the end of the process of systems recognition we have a partnership with a foreign government, which is -- a real -- which is a really strong bond with that government.

But while we're approaching that final outcome, we actually have a number of partnerships. We have partnerships within the Agency itself, because to get to systems recognition you have to achieve consensus across a broad area of technical expertise and programmatic activities across the agency. And we also, in that process, are developing partnerships with the foreign government and between the technical experts of those foreign -- of the foreign government

that we're working with. And so it's really, in a way, the journey is as valuable as the destination.

So systems recognition is a partnership with a foreign government, and it follows an intensive assessment, which we will discuss during the panel. And at the end, the two countries have recognized that their food safety systems are operating regulatory programs that yield similar food safety outcomes. And the goal here is really to benefit both countries as they enable the countries to be more risk-based as we use resources.

We use resources for a variety of activities related to imports. But again, it's a check at the end of the process. And preventive controls have taught us that if we can get earlier in the process, we will have more reliable results.

So systems recognition allows FDA to really focus our resources. And when we think about risk-based activities, that's really what systems recognition gives us a tool to be more risk-based in putting our inspectional resources to use, in using our laboratories and the other tools that we use. We want

it to be risk-based. And so systems recognition gives us that method to do that.

We also -- after we've achieved systems recognition, we really can identify the partners where we're going to rely on them heavily. If we have a problem, if we become aware of a problem with food entering our country that's sourced from one of those countries, we have someone in the government to call and say, we've got this problem right now. What are you going to do to help us fix it? And so that relationship becomes very important.

And secondly -- and lastly, it offers the prospect for additional information sharing, which is a future activity. And we're still in some -- we're still implementing the program, so we haven't fully implemented all the ways that we think it's going to be useful to us. But it does give us the ability to share information more rapidly and more broadly.

I think -- okay. Sorry. So systems recognition indicates -- if you're a consumer and you're hearing about systems recognition for the first time, it really is a signal that the FDA has assessed

that country to ensure that we have the knowledge, confidence, and experience with that particular country, that they can manage their own food safety system.

It's really focused on the domestic food safety system of the country involved, and the standard is not one that they are doing the exact same thing in their regulatory approaches, but that they provide similar -- they're not necessarily identical systems of protections -- and that they are doing similar activities with respect to oversight and monitoring.

Unlike equivalence, FDA is -- systems recognition is not a market access tool. And that is a key take-home message from this presentation. Equivalence is essential if you want to market access for a certain number of products. We saw today with meat and poultry, it is a prerequisite to market access. That's not the case with systems recognition. Countries can still access our markets and it means the tool is actually being used for a different purpose.

The scope of the assessment is very broad. It typically covers all foods that are regulated by FDA.

The exceptions are things like infant formula, molluscan shellfish, Grade A dairy, and dietary supplements that have different regulatory programs within FDA itself. We are considering animal feed for future inclusion in the program. And certain regulatory requirements, things like drug residues, are not covered because they again, have a different foundation in our law and we have to enforce those standards.

So as Don mentioned earlier, we have two countries currently in the program, New Zealand and Canada, and one more in process that hopefully will finish up soon. We have another country, another region actually, the European Commission that was also mentioned earlier today, that will be in process, maybe for a little while. We're much earlier in the process with that region.

We -- so right now, within the Agency and within the team, the partners within the Agency, we're really turning our full attention to implementation. There are a number of members of our implementation workgroup in the room here, and I will discuss that

later on in the presentation. But I did want to just note, before we move on to Karen and Deb and Brian, that at the -- after systems recognition is achieved, we still have work to do.

We have regular consultations with the country involved, and we do a renewal reassessment every five years. So that process is just starting with one of our partners right now, and the other partners we have quite a number of years to go. And with that, I'm going to turn it over to Karen Swajian to give more background on systems recognition.

MS. SWAJIAN: Thank you, Caroline, and welcome. I'll be discussing today the -- not only the ICAT tool, but our IT web-based system that we've implemented in order to capture the information having to do with systems recognition.

Where are we? Sorry about that. Okay. The ICAT is a series of standards used to assess a foreign competent authority's food safety system to ascertain whether it provides a comparable system of regulatory oversight and monitoring, as Caroline had indicated. And through this process, the participant actually

submits responses to each of the standards, outlining their food safety system and program, identifying how it's comparable, not just that it is comparable, but outlining how that is so.

We have a multidisciplinary team consisting of CFSAN and ORA personnel that reviews the responses and the standards, and we review them standard by standard. And actually within each standard we have a series of what we call elements. It's similar to questions, but they're -- we actually refer to them as elements, in which all of the participants or -- and a participant, when I refer to a participant, I mean a foreign competent authority -- as to that, how they are actually satisfying that element.

It's an interactive program with the candidate, so since it's reciprocal, the information, the information is supplied, and our information is supplied in the ICAT so they actually have our information ahead of time so they can assess each element based on the information that -- the element that we provided as well as the reference material that we provided that actually is our -- how we satisfy that

particular element.

The team develops and sends questions regarding the ICAT responses to the candidate for additional information, so if we -- if there is some gaps in the information, we have a mechanism in order to send back questions, and it's a very interactive process in which we work with the participant in order to get a full complement of information to satisfy the standards and the elements.

We also, in addition to the exchange of information through emails or what not, we also have face-to-face meetings, so this is not just through an electronic process. We actually do sit down with the participant and we actually have consultative meetings. It varies depending on the information that's required, as far as how we move forward and how many face-to-faces we actually have, but there are quite a few.

In the ICAT standards, it was originally modeled after the manufacturing food regulatory program standards; however, that's about as far as it goes at this point because we've significantly changed it and altered it from there in order to accommodate our

international participants and their systems to make sure that we've accommodated both our system, as well as theirs, so it's evolved to accommodate the imported products.

And the tool is modified. It is ever evolving and we're working on our next iteration as we speak now, so it is an ever-evolving process to make sure that we're -- it is as up-to-date as possible.

There are 10 standards, and in each standard we have a different set of elements. They vary from 1 element in a standard to 10 elements in a standard. Our regulatory authority, which is our Standard number 1, is our regulatory foundation, that's our most important. That's the foundation. That's where all of our information comes from, and that's the cornerstone to the entire program and where the rest of the standards actually leap off and they build off of that regulatory foundation.

It encompasses -- Standard 1 encompasses laws and regulations whereby the other standards are built. The competent authority outlines their laws, authorities, and regulations that ensure us that they

have a comparable food safety systems.

Standard 2 is training, and that's where the participant would define their training program of the food safety personnel.

Standard 3 is their inspection program where the participants would describe the key elements of their food safety inspection program.

Standard 4 is the program assessment and inspection audit program, and the participants would describe the basic quality assurance reviews necessary to evaluate the effectiveness of the food safety and inspection program. They would recognize -- they would give us information to recognize trends in the inspectional coverage and identify best practices used to achieve quality inspections and sample collections and to protect the public health by ensuring a safe food supply.

Standard 5 is food-related illness and outbreaks. This applies to the surveillance investigation response and subsequent review of alleged food-related incidents and emergencies that may result in illness, injury, and outbreaks. This standard also

applies to the collection and analysis and dissemination of information that may prevent illness and outbreak recurrences.

Standard 6 is the compliance and enforcement program, and this is where they would describe the strategies, procedures, and actions to enforce food safety laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

Standard 7 is industry and community relations, and it describes the elements of industry and community outreach activities developed and accomplished by the competent food safety authority.

Standard 8 is program resources, and this is where we would -- they would describe the elements for assessing the adequacy of the resources available to support the food safety regulatory program.

Standard 9 is our international communication and harmonization, and this describes interaction between the competent food safety authorities and the international community.

And then we have Standard 10, which is our

laboratory support where the elements of the laboratory support of the food safety regulatory programs are described and assessed.

And that takes care of the ICAT itself, that tool itself, and that's what our competent authorities use in order to submit to the program for evaluation and potentially becoming recognized.

In so doing this, we have actually the first couple of countries, Canada and Australia -- I'm sorry, Canada and New Zealand -- was done manually through -- sorry, Bill -- through actually email exchanges whereby a lot of the information was just exchanged through emails.

We've now developed an IT system, and we're very proud of it. It launched in October of 2015. It's quite a feat for us to do that. It actually launched without any flaws. And this is to support the systems recognition program from submission of the ICAT through implementation of the actual program. So it's not just a one-stop shopping of the ICAT, but it's also through the implementation, and anything that actually can occur through the program would actually be done

through this IT system.

We utilize two platforms, two IT platforms in order to accomplish this. We have one external platform which is FURLS -- it's the FDA Unified Registration and Listing System. Both systems are secure, so the external site is secure as well as the internal site. This is the gateway for the participant to access the IT system. Bill, you don't know about it yet, sorry. You will.

So this is the platform that is currently used by industry for programs such as the LACF, the food facility registration as well as Prior Notice. From here, the participant will access their own account, so nobody else could get to it. It's their own account, and they are able to navigate through the system with email accounts, completing the ICAT, submitting documents pertaining to the program, et cetera. And that's again, through implementation -- through submission of the ICAT through implementation of the program.

They can also -- we would actually be -- also be able to interact with the participant through the

site where we can actually upload notifications, updates, and so forth through this system to an individual, as well as to anybody that's recognized.

The CMS program, the platform, is the Compliance Management System. It's an internal platform that is used for FDA-ers only. And that's just where the FDA would -- conducts their work. And that's the review team and anybody that's associated with systems recognition or needs to know about the systems recognition. They have the ability to access and see the documents.

We can interact with the participant as well through the system. We can exchange documents, posting notifications, and appropriate information. Both platforms, as I said, are secure. And since neither system was actually capable at the time that we developed this, they -- neither system was capable of doing the requirements that we were, we actually had to build out a lot of these requirements, which took quite a bit of time and foresight in order to do this, and actually it's worked quite well so far.

The system was also developed to allow

multiple users to work in the system on both sides. So our participants, our recognized participants, have the ability go in, multiple people, considering there could be multiple agencies involved, like CFIA we had multiple agencies that we worked with. They could actually allow multiple -- their agencies to come in, in order to fulfill the commitments of both the ICAT submission as well as the implementation of the program.

There's a locking mechanism through this process as well. So especially through the ICAT submission process, we don't want both the FDA and the participant -- in order -- to work on the same standards at the same time, so there are locking mechanisms that will prevent any of this from occurring. So if the participant is working on a particular standard, FDA cannot access it, and likewise if FDA is working on a standard, the participant can't access it.

We also have a -- we've had plenty of positive feedback having to do with the program from our current user that's in the system now, as well as our FDA folks

who are working on the system, so we're excited that it is working well and not having a problem. And we currently have the one user in the system, and we do look forward to bringing our other recognized partners into the system as soon as we possibly can.

With that, I will turn it over to Deb DeVlieger, who will be talking about reports. And thank you.

(Applause)

MS. DeVLIEGER: Thank you, Karen. And thank you, everybody, for being here this afternoon. I love this topic, so -- but I'm going to make my talk very short. And I think it's interesting that Karen said that there were no flaws with the IT system, but anybody who knows me, I don't know IT systems very well, so I've been flawed within that system, but it's nothing that she reported on.

I'm also going to make sure that I get this right, and I'm going to ask Caroline which button. It's the button with nothing on it.

So as Caroline said, systems recognition is a partnership, and it's almost even more than a

partnership. It's actually, I think, and I could be corrected on this, but I believe it's the only reciprocal arrangement that FDA has, meaning that both countries participate in this program.

But today, I'm only going to be talking about FDA's procedures for assessing the participant's application against our ICAT standards and how we determine if the standards are being implemented in the country. And I'll first talk about audits, and then I'll just touch on reports very briefly.

So in review, once the participant has submitted documentation, our multidisciplinary team, which was described by Karen, reviews each submission and we make a decision of whether or not the participant's written authorities, regulations, programs, and procedures show what we call comparability with the U.S. standards. And again Karen said this isn't just a one-way review. It is a very, very interactive, and that's because it's really important for FDA to understand the participant's food safety structure, all the way from the authorities, to the regulations, to the training, to the inspection,

everything that is in that ICAT because we need to understand that in order to be able to go to that country and determine if the country is implementing their own system.

And so FDA will only schedule that in-country audit after comparability of written programs is determined. So first we're looking for that comparability on paper, it would not probably be worth our while to go and try to figure out the system while we're there. It's really important for us to understand the system as it's written and agree with the system as it's put up against the U.S. standards.

So following that determination of comparability FDA then schedules and performs an in-country verification audit, and this audit is done to verify information that was submitted by the participant and also to determine if the participant can implement their own food safety system. This is looking at their own food safety system.

So as we said, the in-country audit is conducted by a team of FDA scientists, investigators, and subject matter experts that may have specialized in

a particular high-risk a commodity area. During the visit this multidisciplinary team visits government agencies, they visit food processing facilities and laboratories to conduct interviews, observe in-country inspectors and laboratory personnel and review records to verify the implementation of the participant's program and their procedures as were submitted in the ICAT.

During these, particular emphasis is placed on the observation of written policies, including oversight activities and enforcement of food safety regulations within that country. At the competent authority level, standards relating to things like regulatory foundation and food-related illnesses outbreaks may be assessed. While at the food facility level, standards relating to things like inspector training and inspection program implementation and compliance and enforcement programs are assessed. And last, at the laboratory level, the assessments focus on the participant's ability to implement their own laboratory procedures.

So typically -- and you know, understand that

we, I believe, has been in kind of a pilot phase with this, but typically we've sent four teams to do these verification audits, including one team that assesses the competent authority's written authorities and other programs. They usually stay right around the competent authority offices and they ask them to show documents, you know, just to verify what was submitted during the ICAT.

And then another team that assesses the implementation of the laboratory procedures, both of those teams are usually in-country for about a week. And then we have two additional teams that assess the implementation of the participant's food safety system with a focus on inspection and compliance programs. Typically these teams are in-country for two weeks because the attempt is to cover different commodities in different regions of the country.

Like I believe Caroline said, you know, these systems recognition arrangements have to do with all foods in that system knowing that that's a huge systems-based program and not commodity-specific.

So after the in-country verification audits

are complete, and using somewhat a template that we've developed in order to cover all the ICAT elements, each team is tagged with writing their own individual report based on what they saw during their assessment, and each of those teams includes, in that report, their final recommendation to move forward or not.

And those reports all then come together and they are discussed. And once the findings are agreed upon, the information from all of the teams is merged into a final report, which is then cleared by the teams prior to sending it through our Center for Food Safety and Applied Nutrition and our Office of Regulatory Affairs for comment. And then after those comments are addressed, the report is then just sent up clearance.

So I don't want you to make the mistake to think that this process is simple. It sounds simple as I sit here and explain it. It even seem simple to me. But it's complicated, and it really does take time. It's a very, very thorough review, and it's fair. You know, given the complexity of the both the U.S. and the participants food safety systems and the need for us. to understand both of our systems, it only makes sense

that it would take time and that it would be complicated in order to make that final determination of comparability. Thank you.

MR. PENDLETON: Thanks, Deb, and good afternoon everyone. I want to talk a little bit about the intersection of systems recognition and FSMA, in particular, the Foreign Supplier Verification Program regulations, as well as the regulations on preventive controls for human food and animal food. And I suppose the regulations have been out for well over a year. Probably most of you know these provisions pretty well now, but in case you don't, it doesn't hurt to have a refresher for this, and perhaps you might have questions about it following up.

So -- there we go -- FSMA established, of course, new requirements for the production of safe food that apply both to domestic food production, as well as for imported food. And they include requirements for a hazard analysis and preventive controls for manufactured foods, produce safety standards, as well as the foreign supplier verification programs, or FSVPs. And these requirements are

relevant for considering systems recognition, both in the recognition processes itself, as well as in how we treat foods coming from countries that have achieved systems recognition.

FSMA directed importers to conduct foreign supplier verification activities and directed FDA to come up with regulations on FSVPs. Under the FSVP regulations, importers need to establish programs that provide assurances that their suppliers are using processes and procedures that provide the same level of public health protection as those processes and procedures that are required under either the produce safety or the preventive controls regulations, as well as ensure that the food that they import is not adulterated, and for human food, isn't misbranded with respect to the labeling of food allergens.

Among the principal FSVP requirements, the importer needs to conduct a hazard analysis for the food to evaluate the performance of the potential foreign supplier and the risk posed by the food, and to approve their suppliers on that basis, and then to determine and conduct the appropriate supplier

verification activities. That might be onsite auditing of the supplier, sampling and testing of food from the supplier, or perhaps looking at appropriate food safety records from the foreign supplier.

Of course, we do have modified or different FSVP requirements for certain types of importers, such as very small importers, importers of dietary supplements, and importers of food from suppliers in countries that FDA has officially recognized as having a comparable food safety system under systems recognition or determine to be equivalent. Provided certain conditions are met, most of the standard FSVP requirements would not apply to food from such suppliers in these countries, except that these modified provisions only apply to food that will not be commercially processed further before consumption, such as packaged food, as well as fresh produce for consumers, and that restriction is intended to align with the requirements under preventive controls.

Now, if these conditions are met, the only standard FSVP requirements would apply -- that would apply are to use a qualified individual for the things

that you're doing, as I'll talk about in a moment, to maintain records and also to ensure that you, as the FSVP importer, are identified as such for the food at entry.

So to import food under the modified conditions -- and these are set forth in 21 CFR Section 1.513 -- the foreign supplier needs to be in and under the regulatory oversight of a country with a food safety system that's comparable or equivalent. The imported food itself has to be within the scope of that agreement. The -- and we anticipate that our FSVP draft guidance, which unfortunately is not out yet, but we hope to have it out soon -- it will provide guidance on how to obtain information about systems recognition arrangements and the foods that are covered under them, and so that, hopefully, this will be available to importers in a convenient location on our website.

And the third requirement is that the importer needs to be in good compliance standing with the food safety authority with the comparable or equivalent system.

So what does good compliance standing mean?

The regulation defines good compliance standing with a foreign food safety authority as being on a list of producers that the country has established as being in good compliance standing, or any other way that the country chooses to designate suppliers as being in good compliance standing. In addition to determining whether a foreign supplier is in good compliance standing, the importer needs to continue to monitor that status.

And we expect that the draft guidance will provide information on how importers can determine whether a potential supplier that they want to use is in good compliance standing with the country with a comparable or equivalent food safety system. That might be through perhaps links that we might have on our website to the information provided and made available on the website of a foreign country.

So as it currently stands, the first importers, who would be required to comply with FSVP, would happen in late May of this year. And as it currently stands, we have systems recognition arrangements, as we said, with New Zealand and with

Canada. So it would be foods from those countries. As long as the food will not be processed further, that would be eligible for these modified requirements that I just spoke about.

Currently, we don't have any equivalency agreements for which the foods covered under those agreements would be subject to the modified FSVP requirements that I just talked about. We have engaged in equivalence determinations with certain countries, such as Grade A dairy products and bivalve mollusks, but we don't have any equivalency agreements that would fit the conditions for 1.513 at this time.

As we stated in the preamble to the FSVP final rule, we're considering whether and how to recognize commodity-specific agreements as agreements that would be subject to -- for inclusion under the modified requirements.

There are a couple of other provisions in FSVP as well as in the supply chain program provisions of the preventive controls regulations that relate to systems recognition. One provision concerns the evaluation of a potential foreign supplier. If the

supplier is in a country with a comparable or equivalent food safety system, the importer or the receiving facility under preventive controls would consider information about the manufacturer or the farm's compliance with the relevant laws and regulations of that country, the country with the comparable or equivalent food safety system, instead of the applicable FDA food safety regulations, in deciding whether to approve that supplier.

And then with respect to onsite auditing of suppliers that's needed for -- that is conducted for supplier verification requirements, if the foreign supplier is in a country with a comparable or equivalent system, on onsite audit would consider the laws and regulations of that country, rather than U.S. laws. Now, this would apply to food that's not covered under the systems recognition arrangement, but it comes from a systems recognized country, such as maybe infant formula or animal feed, depending on the scope of the systems recognition arrangement.

In addition, there's a provision that allows an importer or a receiving facility to substitute

foreign onsite inspection -- foreign onsite audit, the results of an inspection of a foreign supplier by the food safety authority of a country with a comparable or equivalent system.

And lastly, I just want to mention another aspect of international agreements, not systems recognition, but internal agreements with food safety requirements in the U.S., and that is that we have requirements for importers of juice and seafood under the HACCP regulations. And an importer of juice or seafood needs to either implement written verification procedures for that juice or seafood or obtain the food from a country with an active memorandum of understanding or MOU.

Where an MOU exists, there's no need for the importer of the juice or seafood to perform any independent verification procedures. In that situation, the importer is relying on the foreign regulatory authority to ensure compliance by the foreign processors. And the United States has MOUs with Canada, Mexico, and South Korea concerning shellfish.

And lastly, with respect to MOUs, we are principally interested in two-way agreements -- that is, agreements that will acknowledge the acceptability of the U.S. regulatory system to the foreign government, as well as the acceptability of the foreign regulatory system to the U.S. government. Thank you.

(Applause)

MS. DeWAAL: So we're about to wrap up. We are -- I just want to go over the implementation issues that the Agency is looking at. As may have been mentioned a few times, New Zealand and Canada are our two countries that are already in the program. New Zealand was our pilot. They -- we signed the arrangement in 2012, and we are just starting the renewal process. Canada was signed in 2016, and Australia has also been assessed and is nearing the end of their process.

Our implementation plan has been taken into the Agency. As you saw, there's a lot of technical experts on the ICAT review teams and in-country assessments. We have an equal number of diverse technical SMEs, subject matter experts, on all of these

issues that become part of our implementation plan, and that's moving forward now.

And I just want to mention that performance monitoring and review is a key issue that we hope our experts, who are about to come and speak, are going to talk to us about. We recognize the need to create a monitoring program that has been baselines and indicators to measure the performance of our systems recognition program, and we're really looking forward to hearing the ideas from the expert panel, as well as from the public presents later on.

And with that, I'm going to turn it over to Don.

(Applause)

DR. PRATER: Thank you very much. And again, thanks to Caroline and Karen and Deb and Brian for their presentations and their opening remarks. At this time, we would like to open up to the audience for clarifying questions from our FDA presenters. We'll go to the audience first and then to our WebEx connection. If I could just ask you to approach the microphone. Please state your name and affiliation, and if you can

direct your question to a specific one of our panelists, that would be helpful as well. So we'll start here.

MS. LARRIMER: Natalia Larrimer with ANAB. And my question is kind of to all of you, but I think more pertinent to what Deb has said in her presentation. It's more when you were developing the recognition system program -- I'm going to call it program as a whole -- did you consider or did you even -- did you look at the third-party certification laboratory inspection international system that is already in place? So a lot of the countries already have a similar system that has all of the points that you have mentioned, such as the oversight crustacean facility inspection and, you know, continued oversight like that already in place. Was that system looked at when the FDA recognition system was developed? And if it was, why was it not considered or incorporated? I hope it makes sense.

DR. PRATER: Okay. And before we answer the question, could I ask you just to restate your name and affiliation.

MS. LARRIMER: Sure. Natalia Larrimer, ANAB.

DR. PRATER: Thank you.

MS. DeVLIEGER: See, technologically challenged. I'll start and then probably I'm hoping that my coworkers here can clarify. When the ICAT was first put together, we really looked at it just as looking at FDA's own system. It really gave us an opportunity to look at our own system and see how full and robust it was before we even could compare another system to it.

So the ICAT itself is based on our own authorities, our own regulations, you know, our own training and inspection system, and other things like that. If there was -- we don't, in FDA, I don't think, recognize, in our own system, third party -- and I'm not sure if you call -- for laboratory we may in some instances. That's why I don't want to misspeak. But it's basically our system based on our regulatory framework.

And so as we were developing it, that's what's probably most important to us. If we were looking at a country that had, you know, used third party as part of

their own system, we would have to look at, you know, in tandem with their -- you know, to see if what -- how they used that third party actually was comparable to what we would do in our own regulatory structure.

So I don't think it's been taken off the plate, but for our own program, we don't offer it in our own program as far as, you know, the way that we look at ourselves. Is that right?

MS. LARRIMER: Yeah.

MS. DeVLIEGER: Uh-oh.

MS. LARRIMER: (inaudible) for the unforeseeable future because of some changes that have had happened in the past year, such as the release of the circular OMB A-119 where use of the international standards and private sector conformance assessments is strongly encouraged, as well as possible changes giving out the funding that might be coming with a new administration. Do you think it is something that would be considered, and if so, how much input would you be looking for from the public sector in that area?

MS. DeVLIEGER: Honestly, I'm not familiar with all of what you just said. But I can say that the

ICAT is a -- it's not stagnant. It's something we work on every single time. If FDA is making changes in their own regulatory system based on whatever is coming at us, we would then, you know, revisit the ICAT standards themselves. We might put more information in them. And then, you know, I think Caroline said we assess every five years, but it also can be more often than that if there's changes that are made within each other country's system.

There's a huge amount of dialogue that happens between the two countries. And so something like that, something that comes out at us and that we need to change or that we need to work on with a country that's participating with us, that's what we would do. And we would do it more often than the five-year reassessment, so.

MS. LARRIMER: Thank you.

DR. PRATER: Okay. Thank you. We can go to this side of the room.

MR. LAKE: Does it come through? All right. Thank you. My name is Bob Lake. I and a colleague, Cathy Carnevale, have been working for a while now

under a contract with IIT to develop a training program for the Foreign Supplier Verification Program. It's under the FSPCA umbrella.

And Brian has done a nice job of quickly outlining the implications for the FSVP program implementation that is posed by -- well, what systems recognition means within the context of that rule. And as someone who spent some time obsessing about how this is all going to work, there are going to be questions coming up within a few months, real practical questions at a very long U.S./Canada border, about what foods are covered, to what extent are the exporters in good standing?

And I guess one thing I'm concerned about is whether there has been some effort to develop a combined U.S./Canada training effort involving particularly the regulators, but also others to ease this transition that I think could be -- you know, a lot of stuff goes across the border in both directions. And we're getting close. And I guess I'm just wondering to what extent there's been some thought about some very quick and helpful training for people

on both sides of the border.

But -- well, before you answer, let me thank you all for the presentations. I have found this whole meeting to be very, very interesting. And I think this presentation is getting down to something where the rubber, I think, really meets the road. And I appreciate all of the time into it, and especially Brian's summary of the tests and key points on FSVP.

MS. DeWAAL: Thank you. I'm going to turn it over to Brian, but I just want to say that we are regularly having conversations with both our SR partners right now about that very issue. So Brian, do you have any follow-up?

MR. PENDLETON: Yeah, just to say that -- and those are very good points and we know we need to address this, both in the draft guidance that will come out, as well as to the extent that we can provide helpful information through the training that's going to be very much appreciated. I think there are some things that will be -- well, I know there -- well, I feel there are some things that are going to be in the draft guidance that are probably going to address some

of the questions, but I'm sure that's not going to -- there are people who have others once it comes out, and we will look forward to the comments on that.

But -- I mean, there -- I don't know to what extent we've been talking with the Canadian officials about, the details of application of systems recognition arrangement of Canada under 1.513 in FSVP. But, for example, there are questions -- I know we've talked with New Zealand -- about how they would indicate that their suppliers are in good compliance standing, like would that be on a list of -- they would have a list of suppliers that aren't in good compliance standing. And so an importer could look at that and see those who wouldn't qualify for the modified treatment under these provisions of FSVP, but that's just one thing we've talked about.

But those are the kind of things that we need to provide as much information to importers on our website as we can when we have it.

DR. PRATER: Thank you very much. Okay. A question from this side of the room.

MR. GERMILLION: Hi. Thomas Germillion,

Consumer Federation of America. A comment -- sorry, can you hear?

DR. PRATER: Your microphone?

MR. GERMILLION: Yeah. All right. Thomas Germillion, Consumer Federal of America. A comment -- a general comment -- we're concerned about the public participation in this process. And with FSIS in equivalency determinations, for example, there is an opportunity for public participation before a final decision is made about, you know, approving a country's experts. And so my question is when New Zealand's assessment is renewed, will there be an opportunity for public participation before that final decision is made? And also, have you considered posting online materials like these final audit reports or the finalized ICATs? And if so, why don't you post those materials online? Thanks.

MS. DeWAAL: Thanks, Thomas -- very helpful questions. We do post the audit reports on our website. So for both Canada and -- but the report that supported the finding of comparability, both New Zealand and Canada, are posted, as are the arrangements

themselves. So the -- but with New Zealand, we had a public meeting very much like this one back in 2010 or '11, one or the other. We had one to discuss the concept and the process of the pilot with New Zealand.

And part of the purpose for this public hearing is to also engage with Consumer Federation of America as well as the industry groups here and others on exactly that topic. So this is part of that transparency. But as you did see, we do have a communications component of our implementation, and I think we will be interested in your comments on how we can engage.

I just want to make one final point. You mentioned the process FSIS uses. And I just want to distinguish. Equivalence is a market access process, and that does require -- it requires public participation at a different level. These are partnership agreements. We also have confidentiality agreements with foreign governments. We have a variety of MOUs that we have with foreign governments. So it's really a different animal than what FSIS was talking about this morning. Did that answer your question?

MR. GERMILLION: It's a good start. Thank you.

DR. PRATER: Okay. Thank you very much, Caroline. I would just add it's a regulatory cooperation, too. Other questions in the audience? Okay. If not, I'll go to our WebEx booth to see if we have questions from the web. It looks like we do. So we'll stand by.

MS. MCCORMICK: Okay. We have two questions from folks on the webinar. The first one is in two parts. It comes from Heather Gale with the CanadaG.A.P. program. "There's been much excellent discussion during the public hearing of the concepts of equivalence, comparable systems, as well as processes that allow for the same level of public health protection. Given that Canada and the U.S. have in place a formal arrangement providing for mutual recognition of each other's food safety systems, does this mean that the Canadian producers who demonstrate compliance with Canadian food safety regulations are able to export product to the U.S. without needing to provide their customers with additional evidence of

compliance with specific FSMA provisions, for example, with U.S. specific irrigation water testing requirements set out in the produce rule, or will the Canadian exporters have to show their customers that they meet each element of the rule?"

DR. PRATER: So I was having a little difficulty hearing the question. But it sounds like it's a question of a very technical nature, and it may be one, as with the question we had this morning, that might be more appropriate to be addressed through the Technical Assistance Network. I'll ask and see if any of my panelists want to comment on that, or that one is perhaps best addressed through the Technical Assistance Network. So thank you very much for the question, and we will follow-up on that through that mechanism.

Do we have another question from the web?

MS. MCCORMICK: Yes. The follow-up to that first question, "Does it matter, at this point, that the current systems recognition agreement between Canada and the U.S. was done prior to the finalization of some of the FSMA rules, as well as pre-Safe Food for Canadian regulations?"

MS. DeWAAL: That's a great question. The -- as Karen and Deb both mentioned, the ICAT was a tool developed, but that as we were working through the process, especially with Canada, there was an understanding on both sides of the border that the laws were changing. And so components of FSMA were actually incorporated into the original ICAT, and right now the ICAT is undergoing revision to consider if additional elements from FSMA have to be rolled into it. These are very, very comprehensive standards. And they really do look broadly at preventive controls in both countries.

So we anticipate and, in fact, have already had a number of discussions with our Canadian colleagues on updates in their new laws. Their regulations are a little bit behind ours. And we've also had ongoing discussions with them on the regulations that have come out under FSMA.

So it's -- this is not a one -- a process that has an ending and then you're stuck with those standards. It's a process of ongoing discussion and dialogue with these participating countries. And

sometimes it's weekly -- and sometimes we're having discussions weekly, sometimes monthly. And you know, once the laws are in place, perhaps less often, but we'll see.

DR. PRATER: Okay. Thank you very much for the questions. I see that our time has elapsed for the questions. And so, at this point, we will take a 15-minute break, and we'll come back and welcome our guest presenters at 2:15 for Panel 4. Thank you.

(Whereupon, a break was taken.)

DR. PRATER: Hello. If I could ask you to take your seats, we'll start in just one minute.

Hello. Very good. So if I could just ask you to take your seats, we'll start in one minute. Thank you.

Okay. Welcome back from the break. We're joined now by four of our colleagues that will provide their insights and experiences on partnerships that recognize a robust food safety system. And I'll introduce our guest presenters now. The first presenter will be Andrew Dicello. He's the Senior Technical Director at Management Systems International.

We also have William "Bill" Jolly, Chief Assurance Strategy Officer at the Ministry for Primary Industries of New Zealand; Paul Mayers, Vice President of Policy and Programs, Canadian Food Inspection Agency; Sandra Eskin, Director of Food Safety at the Pew Charitable Trusts; and Sandra Hoffman, Senior Economist, Economic Research Service of the USDA.

Our chairperson for this group -- I'm sorry, so if I could, I'll ask Andrew to deliver the first presentation or remarks.

MR. DICELLO: Thank you very much. So again, my name's Andrew Dicello. I work for Management Systems International. We're a consultant from here in the D.C. area. We specialize in monitoring and evaluation and performance improvement. We work with a number of U.S. government agencies, and in particular, we work extensively with the FDA in applying a results-oriented management approach to support a number of their programs and offices, including a number of the FSMA rules.

So I've been asked to talk a little bit to give a very brief overview of the results oriented

management approach and how that might be applicable to the systems recognition program. So normally, when I would do this -- the last time I was here I think I had about two hours to walk the results oriented management. I've got about ten minutes, so hopefully, it doesn't go over everybody's head. I do have a lot of pictures, so while you'll see a few slides, hopefully, this isn't too painful.

So what is results oriented management? It's really an approach that puts results -- and by results, sort of, it's an umbrella terms to mean outcomes, objectives, goals, impacts at the center of the planning and management process. So by doing this, it sort of facilitates a shared understanding among all stakeholders, internal FDA external, as well what goals of a program are, what the high-level objectives are, and what the strategy is for achieving that. What are the results that need to be achieved?

In doing this, it also allows an organization to align its activities, its resources and its programs to address specific results. And also, when you're thinking about measurements, which the panel will be

talking about, to really frame those in the context of the results or the outcomes to be achieved.

And then that -- the results oriented management system, then allows you to manage to effectively because you're collecting data against results. So you're not just tracking the activities that you do and the timeliness and that sort of standard stuff, but you're actually collecting data against an evidence to support the program's results.

So a lot of organizations implement a program -- a results oriented management system, sometimes it's known as results based management, managing for results, and they have a somewhat similar set of steps. This is fairly generic. But the first step in the process is to define the results or the goals of the program and a strategy. Once those are clearly defined, the next step is to say how are we going to measure that success and identify what the performance measures or performance indicators are.

Those being established, you have to figure out how you're going to collect that information. What's that plan for collecting the evidence to support

your strategy? Then you go through implementation. You're collecting data on a regular formal basis. You're analyzing that data, and you're using that information to then adjust and adapt your programs to improve. So in a little bit more detail, one of the key tools in the ROM approach is a results framework; very similar to a logic model.

And the idea with the results framework is you establish what your goal -- the highest level goal of the project are and you want to connect that to the activities and the intervention of FDA, of its partners, of the different organizations that are contributing to that strategy. So at the lowest levels you have activities, and the framework allows you to understand how those activities contribute to an initial set of outcomes; behavior changes, changes in the way that people think, for example. And how those initial results -- what do I have up there -- say 1.1 or 1.2, in turn, contribute to some higher level outcome. In turn, that next level of results leads us up to our goal in our sort of three-level framework.

So there's an if/then relationship and a

theory of change for how you go from your activities, to initial results, to a broader set of outcomes, and finally, to your goal. And so this is very helpful for talking about communicating. It also helps you if you're trying to figure out what the strategy that we should use. You start at the goal level, and you kind of work down from that to determine what you're theory of change is.

So just as an example, and this is just taking a snippet from, you know, not a comprehensive strategy or framework by any means, but for an illustration. If we said that that highest goal of a program was the improved safety of imported foods, we might ask ourselves well, how -- how would we achieve that result? And one might say well, we have to increase the compliance by foreign suppliers with the FDA regulations. And sort of asking the next question, well, how do we do that?

And to say to do that there's two results that have to be achieved. First of all, FDA has to do a better job of executing its compliance activities. But it's not just FDA. Obviously, the foreign suppliers

have to understand the regulations. So per this theory, if the foreign suppliers understand what they're supposed to do and FDA does a good job of compliance activities, then we'll see an increase in compliance.

Similarly, if you're working down from the more effective execution of compliance actions and you're FDA saying well, how do we do a better job. There's two results that have been identified as being necessary to achieve that. One says, first of all, we have to have really skilled, very knowledgeable FDA inspectors. So their knowledge and skills -- if they know what to do when they go out in an inspection or investigation, then they're going to be more effective, more efficient.

But we also have to go to the right places. We have to go a better job of targeting. So this theory sort of says if we do a better job of targeting and we have skilled inspectors, then when we go out there, we're going to be more effective in our compliance action. So this is just, you know, an example of how this framework would work, this logic

model linking lower-level results all the way up to the ultimate goal, which is improved safety of imported foods.

As I mentioned, sort of the second step is once you're clear about what you're trying to achieve and how you're going to do it strategically, it's thinking about how you're going to measure success. And then sort of -- rather than sort of starting from the standpoint of what do we want to measure, we're really trying to say okay, now that we have these goals, these outcomes that we want to achieve, what are the two or three measures that we would use to objectively confirm that those results had been achieved? And these are just some illustrative measures that could be used. So for each result, there's a set of measures. And those measures, again, are very aligned specifically to a particular result up to the goal level.

The third step is then, as I mentioned, you know, once we have these measures, we go out and develop a plan. Who's going to collect this information? Is this information that FDA has that the

foreign competent authority has? Is this information that comes from industry or other partners? What's that plan for correcting the data? Is it practical? Can we do it? And how frequently do we need that information to be able to make decisions and improve our program? So you develop a plan for monitoring and evaluation.

Step four and five are really about collecting that data on a periodic and regular basis, and using that to make improvements to your project. So on a particular result, you look at the data, not just what we do, but whether we're achieving that result, and you make some determinations about whether your strategy is working.

And the last step, you take that analysis and you make changes. You make improvements. And the ROM process is really about learning and improving. So accountability -- it does allow for accountability, but it really also allows you to adapt your strategy, to adapt your activities based on what the information that you receive or the evidence that you have.

So real quickly, some of the -- so that's sort

of the process. Some of the benefits. Why organizations -- it does take a lot of effort to implement a results oriented management approach. And there's many here in the audience that have been through this process and know it's quite onerous at times. But there are a number of benefits that can be conveyed through this.

First of all, it improves your planning process. Everybody is clear about the results to be achieved. There's a real emphasis in sort of getting consensus about what the program is trying to do and what the strategy is. And then it really allows you to be -- you know, selective about the resources that you want to bring to bear. Are your activities lined up to support the specific results or not? If they're not aligned with your strategy, you don't need to do them and you can reallocate those resources. So it sort of improves your planning process.

From a management perspective, again, as I mentioned, sort of allows you to understand when you get measures back, you have to understand them in the context of the specific result that they're supporting,

as well as the overall strategy. So this -- having this framework and these tools allow you to do that.

The framework also allows you, if you're using a results framework, to communicate perhaps more effectively with internal and external stakeholders. You go from perhaps a very lengthy document that somebody has to read through and sort of decipher to a very concise one-page visual that you can walk folks through. It also allows you to then convey results in a more direct manner. So it allows you to tell your story.

And this might be one of the most important ones, depending on how you design your program, if you're doing it in a very participatory process, then you build sort of shared understanding, increased buy-in with your partners, what you're trying to do, who has what responsibilities, and then how you're going to measure success, and how you're going to collect that data to monitor and understand progress.

So that's my eight- to ten-minute presentation, what you should do in two hours, but hopefully, it wasn't too fast.

So the question is, is this applicable to systems recognition? What are some of the considerations? So I'll just touch on this briefly. I think to the extent that it would be helpful in communicating what the systems recognition program is, what its goals are, and how you achieve systems recognition, or what a successful systems recognition program is, this could be an effective tool, right? How are we going to measure success? It lays it out there for everybody to sort of assess and understand.

I think there's also an opportunity -- again, this approach was used with import controls, FSVP and some of the others. So there's been a lot of work around results oriented management and development of frameworks that could be brought to bear in terms of results, in terms of indicators that have been sort of brainstormed or potentially of being used that could apply for systems recognition.

And then, you know, you have the ICAT tool, which a lot of thought has gone into. How do you assess -- monitor and sort of assess whether a country is able to participate in the program and whether

they're doing a good job? So there's a lot that's already out there that could be leveraged and used with the ROM approach.

So lastly, one thing about this approach is you don't have to take it -- all pieces of it, you can sort of scale it to your particular needs. So, you know, one of the questions is what of -- what are these elements? Which of these benefits is sort of -- will be most useful for FDA, and where do you want to put your emphasis? So you could just develop a framework, and that might be useful for planning and communications. But if you want to use it as a tool to manage and understand progress, then you might use the full -- sort of all the tools and all the steps of the process. So that's sort of an important consideration.

Also, as I've thought about this, you could have a standard template for systems recognition that you use, and maybe attract indicators for each country, you aggregate them. The other thought is that you could apply it to particular countries and adapt the framework. So you might have a framework for Canada, a framework for New Zealand, a slightly different one for

different countries. So it allows a degree of flexibility around that. So those are just some quick comments. Thank you.

DR. PRATER: Thank you very much, Mr. Dicello. We appreciate that presentation and those thoughts that you've shared with us. So now, I'd like to welcome Bill Jolly to the podium, and we'll forward to your presentation or comments.

DR. JOLLY: Thank you. Have we got my presentation loaded? Ah-ha, cool. So today, I thought I'd quickly introduce where or who is New Zealand, who is MPI, why we are relevant, and a bit of a theme -- To-mah-to versus To-may-to. We say To-mah-to, which is a British expression, and you guys say to-may-to, but ultimately, they mean the same thing. So MPI asked me to answer five questions and talk about the prerequisites, indicators of the six implementations, public health benefits, stakeholder communications and the differences between the different tools.

So where and who is New Zealand? We like to call ourselves the California of the South Pacific. But we're already 4.6 million people, and we don't have

Californians, so it's much better. We're not actually down under, but we're at the top of the world. We actually see the new millennia first and every day first. We're number one in the world transparency antics, that is, any corruption transparency of government is doing business, et cetera, an important thing when you start talking about doing business with the New Zealand government.

We're relatively disease- and pest-free. We're at the bottom of the South Pacific, which is the top of the world. And we invented the six-month quarantine period because that's how long it took to get there on a boat. And importantly, food and agriculture are the business of New Zealand.

MPI, we were formed in 2011/2012 from four regulatory ministries. I came from the New Zealand Food Safety Authority, but we will say the Biosecurity Authority Ministry of Fisheries. We have two ministers, importantly, a Minister of Food Safety and a Minister for Primary Industries. And we are New Zealand's single food safety SPS authority. So it's a one-stop shop. We do it all. From animal welfare,

imports, exports, halal, or as I like to say, we do both wine and cheese.

Why is New Zealand relevant? Well, we're really the first to pilot the ICAT with the FDA and sign the comprehensive food safety system recognition arrangement in 2012. The pride of that. We had a long history of close collaboration and alignment. You know, we have had a shared philosophy and a high degree of trust for many, many years. But importantly, we're equally close to the likes of EU, Australia and Canada. And we have comprehensive equivalence system agreements with them. And so this is not unique for us, and it's something we work very hard at is having collaborative agreements with our partners.

So why is New Zealand relevant? Well, we're small, but we're actually one of the world's biggest exporters of agriculture products. Say 15 (inaudible) over all by value, but Number One in dairy, Number One in sheep, sheep meat, kiwi fruit, venison, (inaudible) mussels, and Number Five, in beef, but we also import 25 percent of our food, and we import over a billion dollars' worth of food from the U.S. And again, food

and agriculture are the business of New Zealand.

So the credibility of our regulatory system seems to apply success into our economy. And that's food safety, biosecurity and farm reproduction. So when we start looking at frameworks for identifying robust food safety systems, what do we do? And it's very similar to what the FDA is doing. And we've been through processes in a very similar fashion with the EU many years before we went through it with the FDA. But there's some prerequisites in there. You know, credibility, commitment and fitness appearance of the system is really, really important. At least you're dealing with a competent authority that's in that sort of ballpark. You know, you're going nowhere.

Oversee consistency with relevant international standards makes comparability a lot easier. And the Codex National Food Control System is one of the most up-to-date standards, but there's also the food hygiene and the meat products standards and the dairy standards.

Obviously, having a similarity of the design of the core regulatory elements helps as well as with

science, risk assessment, quality assurance, transparency, monitoring and, you know, a culture of continued improvement. But the most important one of all is a high degree of trust through that existing knowledge, confidence and experience. And again, lots of similarities with the FDA.

So the process -- and I'll skip over these because it's been described by the FDA, and our process is very similar. And it's about describing our own system and then asking countries to describe their system in similar outcome-focused manners. So it's not replication. When we talk about standards, your standard can be an outcome or it can be a process descriptive. We're interested in outcomes. So we're interested in how you actually assure food safety.

So some of the elements -- and again, that list is very similar to the one the FDA put up there. And so when the exporting country describes theirs, it is again, a iterative process. And we try and get them to describe it in their own terms but according to these mega outcomes we're trying to achieve and then looking for those points of comparability. It's not

about replication. Where there are specific differences in hazard or risk profiles, we go into a more in-depth process, and sometimes that will come down to a specific equivalent decision on a specific aspect. But for the most part, we keep it at that high level.

So indicators of a robust food safety system, how do they change over time? And again, I've got to apologize because most of these are qualitative. But to look at the level and type and transparency of operational documentation, regulatory standards systems and records, you know, if that's not on the -- if that's not readably identifiable, you know, it's very hard to maintain a relationship. And the more transparent it is, the more trust there is.

So outcome products standards, which encourage a food safety culture, a buzz word of these days. Right? Governments don't make their food, the industry does. So, you know, we provide the incentive and, you know, encourage that food safety culture, industry responsibility, but also allowing for innovation. The more prescription you have, then the least safe your

food will be because, by definition, you're basing it on assumption and those assumptions won't carried through over time.

So obviously, we look at the level of compliance by the regulated industry with good hygienic practice requirements, operational performance, characteristics and regulated hazard targets. But again, these are all indicators, they're proxies, and they differ between countries. And so you look at how the country is doing it and in their regard, and whether they are doing this analysis and monitoring.

Responses by the competent authority to noncompliance by the industry. And again, you know, demonstrated prosecutions, sanctions, recalls, international notifications, those are all good things. There's no system that operates that doesn't have those things, and so the more transparent they are, the more confidence you have that they are actually on the ball.

So we look at the adequacy of the monitoring systems, analysis of data, consequence responses, both reactive and proactive. If the same problems keep happening year after year and there's no changes to the

system, then there's something wrong with that system. There exists some system audits, and the results of these and associated responses. And again, "trust me I'm from the government," doesn't work. Okay? It doesn't work for me anyway, and I'm from the government. So it's about, you know, checking the checker.

And we heard an intervention about quality systems. We require -- even our government audit verification services to be ISO 17020 accredited. We work inside very tight quality assurance frameworks. And then we have a system audit group that audits them and then we get -- have foreign competent authority that audits the whole system as well. So it's just -- it's a way of checking the checker and getting that quality permit guide.

Obviously, the results of port of entry inspections. And we monitor those. We know how countries around the world are performing in our system and also to other transparent import systems. Willingness to take safeguard actions, and one criticism of New Zealand is we're probably too willing

to take safeguard actions, and we've done a few recalls where there've been false positives in the end. And obviously, policy risk-based and continuous improvement are very important, so again, key things about how you judge the robustness or the time of food safety systems.

One of the points I wanted to make is that the core reason for systems recognition or equivalence agreements is that they provide for a high level of assurance in import inspection or import of leverage systems alone. You know, importer and importer -- importer inspection and importer leverage systems are really quite a blunt instrument. They're not very refined. So they help to ensure risk that managed its source overseen by a competent regulator using a full suite of regulatory tools.

They're a much higher level of assurance. They provide for an increased cooperation calibration, communication, and collaboration, freeing up resources so they can be focused more appropriately. And the risks are managed in the context of which they arise rather than some foreign context, which is often not

relevant.

So we asked about the communication -- stakeholder communication. We got a lot of criticism for going into a deal with the United States. You have not seen as us (inaudible) practice around the world -- believe it or not.

And, but -- but as a regulator, we do see the FDA as being one of the biggest practices in the world. But our consumers were equally concerned about us doing a deal.

So our responses were, you know, again, reinforcing it. It's about, you know, working cooperatively and collaboratively. It's far more efficient and effective. It's about reducing redundant regulation.

Regulations in one country, do not apply transboundary. And then nor should they. I mean, we've all got our own regulatory systems. And so the more we try to transboundary regulate, the more inefficient it gets. And it ultimately provides for a better commercial efficiency and certainty for border issues or where problems are found. So I'm being told

to wrap up. I said I had 12 minutes but I thought -- I think it's been cut down to 8 or 10 so I'll hurry up. And I took out all my funnies.

So it's not about replication. It's not about looking for differences. It's about whether there's a system in place to appropriately address the wide range of risks and whether working together provides for greater assurances.

System equivalence, systems recognition, you say to-may-to, we say to-mah-to, or the other way around. And they're different -- slightly different tools but ultimately achieve similar outcomes.

Commodity control recognitions or equivalence evaluations make sense when you want to, you know, delve into a very specific area.

Couple of last points -- I wanted to highlight some of the international harmonization activity, the (inaudible) standards. Information exchange, which is a very recent standard, which New Zealand chaired with Mexico and Brazil and the current Codex discussion paper on discussion -- on system equivalence, which is being co-chaired between New Zealand, USA, and Chile.

So last two slides, what can the future look like, and can we really inspect that? It's all about cooperation, collaboration in the future. So thank you.

(Applause)

DR. PRATER: Thank you very much, Dr. Jolly. We appreciate those insights. And so now, I'm going to continue to move right along and welcome Paul Mayers to the podium.

MR. MAYERS: Thanks very much. Good afternoon everyone. I'm delighted to be here. I'll hopefully not run over time in terms of responding to the challenge. And let me start by saying, we no more than anyone else have got this figured out in terms of the performance dimension.

But that said the work that we've done in collaboration with our colleagues in the United States around systems recognition has been extremely rewarding.

And the drivers in a Canadian context relate to the fact that between our two countries, the two-way trade in terms of seafood and agro food products are

what presents $47 billion worth of commerce, not insignificant in terms of economic impact but from a volume perspective in terms of the implications for citizens on both sides of the border. These are significant.

And so the importance as both the United States and Canada have been going through the modernization of their food legal frameworks of also having a conversation that doesn't just relate to alignment, but also then relates to true collaboration, I think, underpins then the reason why, not only is there value in pursuing systems recognition, but then in thinking about, well, how do we assure ourselves that the objectives that we set out to meet through systems recognition are being delivered by having a performance frame?

In the Canadian context, we have elaborated a foreign food safety recognition framework and that goes beyond systems recognition alone. It recognizes that there are a number of areas from a policy perspective as we think about the management of imports in relation to food, where, as my U.S. FDA colleagues explained

earlier and I won't repeat, where that significant due diligence gives us the basis for demonstrating that knowledge, confidence and experience that we can act.

We can act at the system level. We are quite confident that we can act at a specific commodity level, which enables them some jurisdictions who will not be able to meet our tests at a full system level to invest in a particular commodity line that represents a significant export to Canada and apply the same principles and, of course, as previously discussed in terms of equivalence.

So let me pause there and talk a bit in terms of both outcomes and results. And I'm not going to suggest that we figured out the measures that we would apply to this because the application of this framework is a piece of ongoing work currently in our context.

But that said, much like my colleagues, the outcome of improving food safety outcomes for Canadian consumers in relation to imported food stands first and foremost.

And in that regard, we recognize that there is also a tremendous benefit for citizens in terms of the

social license that they give us in the activities that we undertake on their behalf to have mutual reinforcement around the strength of our systems.

And systems recognition not only is a confirmation between each other at the regulator-to-regulator level, it is a signal to our citizens of an affirmation of the effectiveness of our system by an independent authority for whom we have tremendous respect.

And so, much as was described earlier in the due diligence approach, well, we did the same thing in relation to the U.S. system. We did the same thing in terms of onsite assessment. And we believe there is value in communicating that to citizens in terms of that affirmation.

But thinking about a couple of key results that we will continue to reflect on within this frame -- and I'll put up a pictograph that basically says what I had in the previous slide in perhaps a simpler characteristic.

There are three key areas that we believe from a results perspective thinking around what Andrew

presented that could be elaborated in that same framework context. One is a stronger risks basis and more preventive stance for the system. And so the volume of trade between Canada and the U.S. means that if we took a one-size-fits-all approach, we would spend almost exclusively our resources looking at each other, which in a recognition context, thought about from a risk basis would say, well, that's the craziest thing to do is to spend all our resources looking at each other. And so we have a tremendous opportunity in that regard.

Taking a more risk-based approach to how we structure and deliver our programs and importantly then how we effectively use the taxpayer dollars that we are stewards of, which is in my mind this second key result area, effective use of the resources in delivering those key outcomes for citizens. And through that, we also have what I see as the third critical result area and that's deepening the partnership with key jurisdictions with whom we trade because going through the exercise that builds on us, as Bill said, the long history of familiarity and trust that we have in each

other and underpins it with a very tangible and evidence based demonstration of that effectiveness has a tremendous power in terms of building not just confidence but familiarity and awareness at a level of understanding that then becomes enabling in a cooperation context.

Through this exercise, we learn things about each other that we might have assumed or might not even have recognized. And there is tremendous value in that. And, so, you know, we look to smart folks like Andrew to then help us in elaborating the detailed measures that associate to results and orientation of these types.

At present, we've only got so far as to thinking about, you know, what are those things in a results context that we can leverage from this that go beyond simply being able to say, so in the exercise of foreign supplier verification that we can discern through a recognition agreement who might be eligible for modified requirements?

In my mind, that's actually, probably the least important outcome, not without value if you

happen to be one of those businesses. But I think from a system perspective the results opportunity is tremendously more powerful than that going forward.

And so that's where our attention will continue to turn as we approach this with colleagues in other parts of the world where we equally will pursue similar arrangements.

As Bill said as he wrapped up, without this, our ability to provide the assurance for our citizens in terms of the amount of product and the number of countries from which they come that will be necessary to meet their needs is going to be a task too large. Thank you.

(Applause)

DR. PRATER: Thank you, Mr. Mayers, very insightful comments and well-appreciated.

Next, I'd like to welcome Sandra Eskin to the podium.

MS. ESKIN: That's the slide so that's what you get to look at. Good afternoon, everyone, and I want to thank FDA for inviting me to participate in this meeting.

Let me begin by telling you a little about the organization I work for, The Pew Charitable Trusts. It is a public charity. It was created by the combination of about seven trusts from the four children of J.N. Pew, Senior. He was the founder of Sun Oil or many of us know as Sunoco. That's right. It is someone's last name. It is not an acronym.

We focus on about, oh, dozens of different areas. We have about 50 -- a little more than 50 separate projects, which can deal with research and/or advocacy. And some of the areas we work in includes health, food being part of that, the environment, state policy, economic and financial issues, and also democracy, elections, and voting. You may have heard about a report over the last few weeks that we authored a few years ago.

And then we also have a separate branch known as the Pew Research Center that does polls. I feel like they release polls about every day, and you will hear them often on the radio and they're cited, so we're pretty busy. And we're located -- our main office now is in D.C. It was originally Philadelphia-

based. There still is a presence in Philadelphia.

So when did Pew get involved in food safety? The first project began in 2008. It was actually outside the organization. It was at Georgetown. And it focused on produce safety. It came about after a series of foodborne illness outbreak linked to spinach and other fresh produce items. And the goal of that project was to focus on getting FDA to put in place regulations under its existing authority.

Well, about a year later, it became clear that there was movement, after many years, in comprehensive legislation to strengthen FDA's food safety authorities, which led to obviously the enactment of the FDA Food Safety Modernization Act. And since that time, we were very involved with other groups in this room and representatives of the food industry.

After getting the law enacted, the hard work began, which was years of proposed and finalized rules and a not insignificant amount of resources spent on getting FDA the resources it needed to do its food safety work. Excuse me. So I'm here to discuss systems recognition at least from a consumer advocacy

perspective.

I never got questions, so I'm assuming that's what you wanted me to talk about. Okay, good, otherwise, it'll be short.

So as a proposition and an important one, I, along with my colleague, David Plunkett, I do believe that systems recognition is one tool, an important tool in the import toolbox.

I'm going to talk a little bit, just make some general points, and then continue with some questions, comments really directed toward FDA staff, which hopefully will address -- and some of them may have been addressed so excuse if they have. I wasn't able to attend earlier parts of this meeting.

So again, that toolbox, if you go to the FDA website, I think there are at least 11 different tools listed, including, obviously, things we've talked about today -- border inspections, foreign facility inspection, registration, various certification programs, bilateral agreements, and, of course, systems regulation.

I believe that, and I think many people share

this view, that the heart of the import oversight system is the foreign supplier verification program. That really is a sea change that was implemented through FSMA and continues to be implemented. Again, I'll use heart. I usually like to use building metaphors. I've used it a couple of times with FSMA because I'm the daughter of a general contractor. But since I'm the mother of a doctor, I'm going to be comfortable using body, and we'll see how that goes.

So it is really the heart and soul of the system, and we've talked to a large degree about how systems recognition is part of that. And certainly the change that was made from the proposed rule to the final rule for FSVP, which really focused on those products that come into this country and are either fresh produce or other food products that are not going to be changed in any way, just consumed here.

You know, it makes sense to have those covered when you've got intermediate steps. You've got lots of processing, lots of other opportunities for issues. It's not as appropriate. So that's really a good thing.

I also noted when I was looking at the FDA website that I always think of systems recognition in the context of FSVP, but that's not the only place it's mentioned. And again, it may have been mentioned more broadly in prior sessions here. But that includes the facility inspections, import field exams, and import sampling. That may currently be the case. That may be in the works. But again, I think some of the presentations we've just heard talked about how important the concept is.

But at the same time, again, I want to make a global statement. There's a lot of tools in that toolbox and some perhaps are either more important than others, or certainly in an environment we've been in recently, and will probably continue to be in when resources for FDA are scarce, we've got to figure out what makes the most sense, what's the most cost effective, how we get the best public health bang for our bucks. So that's important to keep in perspective. Both with systems recognition and more broadly.

And I just want to raise as an example -- so under the law, foreign facility inspections were

supposed to be increasing over the course of five years from a baseline of 600 upwards to close to 20,000.

I don't know exactly where we are. And I'm not -- I understand the FDA's argument has been that these actual foreign facility inspections are costly and maybe not the best way to ensure public health protection, but that's just an example of we've got one tool in that toolbox that hasn't been perhaps fully funded and, therefore, could play a bigger role.

Okay. So let me raise a number of issues regarding mostly FDA's role in the systems recognition piece.

What I didn't -- what I wasn't able to determine, and again please enlighten me if that's wrong, it's sort of is this a quantitative or qualitative process for FDA or both? I'm looking at the, you know, in the ICAT tool there are 10 categories and even evaluating that, are you giving point values, and that's kind of perhaps inappropriate. But I'm just trying to get an understanding of how these terms -- these standards all work together.

Stepping back, you know, is the system you're

evaluating truly prevention-based? Does it have to have the same sort of orientation that we have? Again, not a question perhaps with those countries that have achieved systems recognition but going forward, how is that going to work? You know, how does a system ensure compliance? How robust is their inspection program?

Do they rely more on third-party and audits than inspections, and how does that influence the determination of systems recognition?

And obviously, when it's initially being evaluated and then if it gains systems recognition, how do you evaluate the effectiveness of a system in assuring, improving public health?

When you look at their surveillance system, is it telling us information we want to know? Are illnesses down? Are outbreaks down? And what about just contamination levels? How is that working? This is the same type of issue that FDA has grappled with and continues to grapple with as it determines overall FSMA metrics. And we've been in meetings and discussed this. These are hard issues, and this is very much along the lines of what Andrew discussed at the

beginning of this panel because that's how FDA is looking at it.

So I will underscore a point that Thomas Gremillion from CFA made earlier, which is absolute, complete transparency is essential. I had no problem finding the filled out ICAT questionnaires from Canada and from New Zealand. I wasn't able to find the audits I think that were discussed when Thomas raised the issue.

So I would -- if -- if I -- if you can just show me where those are that would be helpful, and if other people are having problems with it then maybe you need to figure out a way to orient your website so that it's easily accessible. I know I can just imagine how much time is spent on that.

And obviously also raised was this notion of ongoing dialogue, a five-year reevaluation, but is there constant monitoring going on of countries that have reached systems recognition? If you see problems, how do you do this?

And then finally, going forward, I mean, you've obviously mentioned Australia. You've mentioned

the EU and I went back and looked at the 2012 Geo report in which FDA officials were quoted as saying that these expected -- that they expected that few countries would actually seek systems recognition because most countries will not be able to meet our standards. Is that still the case? Have things changed since then, or was that somehow misquoted?

Have other countries beyond the EU and Australia, even if they haven't formally submitted or begun the process, have you had conversations with them? And how does that align with the major trading partners of the U.S.? We inspect a lot of food from a lot of countries who I suspect would not meet systems recognition. Again, it's not a free pass. It's not a market tool. I get that. But it is an important piece in this whole system. Thank you.

(Applause)

DR. PRATER: Thank you very much, Ms. Eskin. We really appreciate your comments, which I think were probably matched by an equal or an exceeding number of questions, so…

MS. ESKIN: That's the best kind of

presentation.

DR. PRATER: Thank you. Thank you very much.

So I'd like to welcome Sandra Hoffman to the podium.

SANDRA HOFFMAN: Thank you. We were -- I was pleased to be invited and ERS was pleased to be invited. The Economic Research Service of the USDA is a research shop. Research is -- are not just our middle name. It's our first name.

And so we are involved -- we are the national counterpart to our state land grant college system and like our sister agency, the Agriculture Research Service, we look at our role not as doing research for USDA or about USDA programs only, but about improving understanding of the food and agriculture system of the U.S. And our clients so to speak, are U.S. consumers and U.S. farmers and anyone involved in the U.S. food system, so that basically includes all of us.

I was asked to come and partially to provide an economics perspective. But as I looked at that in this context, it strikes me that one of the questions that hasn't been addressed here really is the question

of metrics.

I was asked to look at both the ICAT and as well as some efforts to provide quantitative metrics that can be used to evaluate -- have been used to evaluate and measure the outcomes of food safety systems. So I looked at the global food security index from the economists as well as the Canadian Conference Board's world food safety ranking.

And coming away from that, I'm actually quite encouraged by the discussion here today focusing on qualitative analysis. I think there's a level at which our ability to quantitatively measure the outcomes that we're concerned about -- we need to do that, but I think it needs to be supplemented and the role of qualitative assessment is very important. That needs to be transparent. But I think the difficulty I saw in developing quantitative metrics that are going to be meaningful, I think makes it really imperative that you don't lose the qualitative piece.

But now I'm going to turn to the quantitative metrics and some of the issues I face. And like -- like Sandy Eskin, I noticed -- I think these -- the

comments I have to some extent grow out of and apply to metrics that we use nationally. And then I think there's an added level of problem when you try to start using quantitative metrics at the international level.

So we want our quantitative metrics to provide us, you know, at a national level with a way of measuring progress over time. And I think one of the difficulties that we face in looking at this over time nationally is baseline and changing conditions.

You know, I think there's -- the one thing I come away from looking at many types of analysis as an economist is there is a tendency pervasive in humankind -- it seems to think that things don't change. So if you measure something, what you're seeing is measuring the change you want without recognizing there are a whole set of other conditions that may be changing along with it. So when you measure your change, you may not be measuring the result that you're concerned about. You may be measuring -- you may be reflecting the underlying conditions.

For example, if we look at -- one might think measuring the number of illnesses we have in a year,

would be a good metric of how well our systems are functioning. In the U.S., our surveillance system is really based -- conducted at a state level, and the funding for that surveillance comes in part from state legislatures as well as from national legislatures.

So when we went through the 2008 financial -- economic crisis, we saw a very significant cut in the resources available for surveillance. So if we're looking at illnesses across time and we're ignoring the fact that there was a change in the surveillance effort because there was a change in the funding, we're in danger of missing that.

Comparably, as I was looking across the metric across countries, I think that there are similar problems because you need to -- it's not enough to count -- there was -- there were attempts for example to look at illness per capita, a standard type of epidemiological measure. But if one can't normalize for effort, you don't know if you're actually comparing same -- the same thing.

So if you're using that quantitative metric to ask about comparability across systems, there has to be

a way of also looking at effort. One of the -- for example, one of the measures that was used in the Canadian Conference Board measure was the number of recalls per capita.

But it -- but think about this. If I'm counting the number of recalls per capita, what may be driving that? Well, hopefully, what's driving that is if you have a low number, it reflects you don't have much of a problem. But having a low number may also reflect that there's been little effort put forward in identifying the problems. It may also represent lower standards or differentials in standards.

So there's a number of things that have to be held constant for that measure of recalls to be meaningful in comparing across countries. And that kind of problem is pervasive across many of the things that we would consider to be just kind of standard measures of are we being successful in achieving safer food?

There are a couple of other criteria that I would encourage -- want -- encourage authorities to think about in looking at quantitative metrics and this

includes at a national level, not just at an international level.

One of the things is again, the economist in me says, you have to look at the dynamics over time. So one of the issues is, are there trends that you're -- that may be occurring that you need to see that might change what you want to measure?

For example, are you seeing a change in the consumption of a certain commodity over time? That becomes important in looking at, for example, the rate. If you're looking at the rate of illness for, you know, the number of illnesses from a particular product, it matters whether you're eating more of it so the exposure is greater or not.

Another factor that I think has gotten left out nationally that I think is important is sometimes financial risk can be an important thing to look at. At a national level, financial risk in terms of firms and it is a risk factor for firms and inspection, so a company that's undergoing is in a significant change in their financial situation or change in their ownership structure may be in a period of greater risks for

changes in their safety systems, so that may be an indicator you want to pay attention to at a national level.

And similarly one might ask, as we saw in the 2008 economic crisis, are there financial -- are there changes in financial circumstances that could be significantly changing efforts or capacity within a country that needs to be accounted for in trying to develop metrics?

And then I will also back up -- all of the speakers spoke of the importance of transparency, which is critical both nationally and internationally.

I would also say that coming out of -- in the environmental economics literature, there is a great deal of discussion about the importance of whether a system is set up to encourage truthful revelation about information that you're providing to the -- to an authority and that that is also another piece of -- another factor to look at both domestically and also in terms of comparability across countries.

I'll finally say that I'm sure that there are many things that I have not addressed that you may have

questions about, and I worked in this field for going on -- oh my gosh, it is between 15 to 20 years. So I would be more than happy to address questions that I may not have raised in my comments.

(Applause)

DR. PRATER: Thank you very much, Ms. Hoffman. We appreciate those comments.

And at this point, we've had a number of very good presentations, very thoughtful comments and questions. What we're going to do is we're going to take a break at this point for just about 15 minutes, and we will start again at 3:30 and our FDA experts will ask the panel questions at that point, and I will turn it over to Deb DeVlieger to chair the next session, so thank you very much and we'll start again at 3:30, very promptly.

(Whereupon, a break was taken.)

DR. PRATER: If I could ask folks to find their seats, we'll start in just a minute. Okay. Thank you very much.

I'd like to welcome you to the final session of our public hearing. Next we have our FDA panel of

experts who will ask our guest presenters some questions. Deb DeVlieger, who I introduced previously, will be the chairperson for Panel 4 and will moderate this session, and I will join the panel.

MS. DeVLIEGER: Thank you, Don. I really appreciate that. And first, I'd really like to thank our presenters. I know, as you can see, I took a ton of notes, and I don't even get to be the one that asks questions and which brings me to our panel.

I'd like to introduce to you our FDA panel of experts that will be asking the questions, starting with -- and I mispronounced her name before, so I'm going to make it right this time -- Caroline Smith DeWaal from our International Food Safety Policy Manager at our International Affairs Staff here at CFSAN.

Second in line is Karen Swajian. She's a Consumer Safety Officer with our Office of Food Safety here at CFSAN.

Sharon Mayl, Senior Advisory for Policy, Office of Foods and Veterinarian Medicine. Mr. Don Prater, who you've gotten to listen to most of today.

He's our acting Assistant Commissioner for Food Safety Integration, Office of Foods and Veterinarian Medicine.

And Jenny Scott, the Senior Advisor of the Office of Food Safety, here again at CFSAN. And so we're -- oh, and Camille. Camille I do not -- I'm so sorry.

I'm not even sure. She popped in and I'm not even sure I -- but one of my many bosses, Camille Brewer also. I think she's the Director of our International Food Safety staff. So welcome, Camille, and thank you for popping in.

MS. BREWER: (inaudible -- off mic).

MS. DeVLIEGER: Yeah, we were actually just trying to outnumber our panelists, you know. That's always FDA's attempt, right? So we'll just go ahead and get started. I'm just going to start in the middle. I know that the FDA experts already told me they had a lot of questions so we look forward to that.

I'm just going to start in the middle of that panel and ask Sharon, do you have any -- do you want to start with the questions?

MS. MAYL: Sure, I'm going to start with a

question for our regulatory counterparts, Mr. Mayers and Dr. Jolly. I'm wondering if you have agreements or similar types of agreements with other regulatory authorities and if so if you could describe those?

MS. DeVLIEGER: I think the question was directed at Bill Jolly. And I just want to -- the both of them, okay. And just so that our questioners know if you could actually state the name of the person so that whoever's doing the translation knows that you've asked that person the question. And also that there are two Sandra's on the panel, so just make sure you get Sandra H. or Sandra E. Thank you.

MR. MAYERS: Thanks very much for the question. So Canada doesn't have another formal systems recognition agreement of this type, so the agreement with the United States was our first in this regard. However, we do have a number of arrangements with other jurisdictions of related type. Of course, there are a number of equivalence arrangements.

We have a comprehensive arrangement with the European Union that falls into treaty status and, of course, with the Canada-European Union Treaty

Arrangement, CETA, it will roll into a continued very comprehensive frame within which we have a very structured governance framework in terms of how we collaborate with each other.

And Bill and I were chatting earlier about some of the comprehensive arrangements we have as well. So there are a number of arrangements.

We are big fans of partnering in terms of the food safety context because we're big proponents of the view that trying to address the problem at or post border is a pretty limited way of getting the food safety assurances that we desire, and operating upstream is, in our view, the way to go. And so this is a direction that we expect to continue to expand. Bill.

DR. JOLLY: Yes, we have a number of comprehensive agreements, and as I said in my presentation, they take different form.

We have a comprehensive system of growth equivalence agreement with the EU, a sanitary agreement, which covers all animal products from the food safety, from an animal health, and from a

certification point of view, and it's probably one of the most comprehensive agreements anyone has in the world.

We have a comprehensive agreement with Australia. In fact, we share a joint standard setting agency, and Food Standards Australia New Zealand, which does composition and labeling and a couple of other joint standards for us, which help the economic integration. But there's a mutual recognition of each other's food safety systems across the board.

With Canada, as Paul says, we've had a number of commodity-based equivalence agreements for a number of years, and we've had discussions about elevating that to a wider systems equivalence agreement.

We've got a number of agreements which are one-way equivalence agreements whereby countries have recognized the equivalence of New Zealand's systems without the reciprocal being in place, and there's a number in the Middle East to that effect.

And lastly, we've got about 20-odd what we call enabling cooperative arrangements which increase the cooperation between the registry authorities and

provide for recognitions of specific functions. And it's a first stepping stone, if you like, to actually enable it better safe -- more and better safety of food through having a clearer understanding of each other's expectations through communication when there are issues found, cooperation, capacity building, et cetera. So that's the sort of stepping stone type approach.

So it's again, like Paul, we're real friends. We want to work collaboratively around the world. We see it as delivering a much higher level of assurance, communication, and cooperation.

MS. DeVLIEGER: Karen.

MS. SWAJIAN: Good afternoon, and I want to thank you all for your presentations. They were very informative, and we greatly appreciate the information. My question has to do with your performance metrics, and this is directed towards Dr. Jolly and Dr. Mayers.

Having to do with the arrangements that you currently have or in the process of doing, are you assessing the implementation process as well as the actual application process? And if you are, what type

of the metrics and criteria are you actually applying to each? Are you just looking at recalls and illnesses? Are you expanding this to much more information? So how are you actually applying your performance metrics to your processes? Thank you.

DR. JOLLY: I'm going to start this one. Comparability metrics are really, really different because you're just not comparing apples with apples. And even when you start looking at outbreak data or human health data, we all have surveillance systems, and so, I mean, the U.S. has one of the best human surveillance systems.

And so you compare your publicly available data with some other developing economies around the world, it looks as though you got a really bad system. But it's not. It's because you got -- you collect data with the world and same with us. And so the ability that you have comparable metrics, it's really challenging.

The other thing is, most metrics countries collect is procedural compliance metrics. And you know, the attribution of that as far as the impact on

the outcome you're trying to change is often not known. I mean, we all use proxies, too. There's very little direct cause and effect type measurement.

And so how you integrate your own system to achieve that, you know, ultimate impact, that change you're trying to achieve is quite contextual. So again, when we start looking at monitoring these agreements and the outcomes, it's around looking more at those qualitative metrics. It's around continuing that communication, that cooperation.

There's always a little bit of comparability from a point of view of point of entry findings, a little bit of comparability from what other people are finding around the world, a little bit of comparability about how transparent that competent authority is in their interactions when things are happening.

And with all of our partners to date, we've been more than happy with those actions. And again, we have a very active communication with the FDA. There's barely a week or a month goes by that we're not having -- on teleconferences, et cetera, on one thing or another. And the same with the European Union and

other countries such as Australia and Canada where we have very close relationships.

MR. MAYERS: Thank you, and I'd agree with Bill's comments and just add that in my view in servicing the arrangements that we have to date, I would hesitate to characterize that it's within a true performance frame context.

It's more of a verification of the basis of the original assessment. That's what I would characterize it. And that's where, you know, within equivalence arrangements, for example, we carry out regular periodic audits. That in my mind is not a performance measure focused on the achievement of a set of outcomes. It's simply a verification that the basis on which the agreement was originally articulated continues to be delivered in an operational context.

So it's very much in that process dimension. So this is why we're very focused on elaborating a much more dynamic performance framework that's actually focused on measuring and indicating the achievement of outcome.

MS. DeVLIEGER: Thank you. Camille, any

questions?

MS. BREWER: Yes. I want to thank all the panelists for the great presentations. And in particular I'd like to thank Dr. Jolly and Mr. Mayers. They've been such good partners over the years. We wouldn't have systems recognition without the thought -- - thoughtful process that they, in fact, supported years before we got to systems recognition. So I want to acknowledge that, so thank you. I have just two questions. One is for Mr. Dicello.

So you mentioned the possibility of doing an overall performance plan for systems recognition or doing a country specific framework. Having done frameworks, I know how much work they entail, how many hours they entail to get close to right. So is there kind of a middle ground there? Could there be an overall framework that could consider inputs from the various partners? Have you ever seen anything like that? So that's my question for you, and I had one question for Dr. Jolly, and it's about your arrangement -- your agreement with the EU, and does it cover all of the Member States? Thank you.

MR. DICELLO: Great. So I think my suggestion would be that -- and you're right it takes a great deal of effort to sort of come to consensus on what the results are and what a good framework is and what the measure should be around that framework.

I think my thought with the country level framework is that, you know, understanding that that framework may not hold exactly when you apply it in different contexts with different countries, or you can look at it and say within this framework for a certain country, these are the results that require more emphasis, or if you're explaining to countries where they are in this strategy, this is where they really need to focus their effort.

So I think, and you may also find that you need, just in the same way you adjust the ICAT. that your template framework sort of evolves as you learn. In a particular contract, there might be conditions that require you to add a different result that wasn't in your main template.

So I think it's just a bit of an offshoot from the original. I would suggest that you would have one

core template, and then you might be able to adapt it and adjust it, again, the results to some degree but also maybe the measures because, as we said in some contexts, the measures may not be practical to get from every country, and so you might want to look at slightly different measures. So those would be my thoughts on that.

DR. JOLLY: And so to answer your question whether our sanitary agreement applies to all member states, the answer is, yes. And we recognize the European Commission as the essential competent authority. All member states are required to apply the same laws. And there will always be some level of implementational difference just as there's implementational differences across the 50 United States.

But we have a little bit of a safety net if you'd like, and it's more of an administrative standard, but basically it says that if any Member State has taken a safeguard action against another Member State, then it also applies to us. So that way you've got 26 or 27 policemen that are taking actions

before you do. And so if the product is free to move throughout the European Union, then we're happy for it to move to New Zealand. If it's not free to move throughout the European Union, then we want to know why and that's where the conversation starts.

MS. DeVLIEGER: Thank you. Caroline.

MS. DEWAAL: Thank you. I'm going to pose my question to Sandra Hoffman. Thank you very much. Your remarks were really actually very helpful to us. But I'd also like Andrew to listen because I'd like your thoughts on this as well.

Let's say that we're just looking at performance metrics for the U.S. to evaluate our various systems recognition arrangements, so getting away from the complexity of metrics that cross into Canada or New Zealand. So it's country-specific metrics. Sandra, I know you know, as do I, the complexity of some of the adverse events, so outbreak reporting, recall reporting, and import alerts, things of that nature.

I'm wondering, they have many confounders and they can change over time what those trends look like.

My question is should we consider a metrics that puts all adverse events into a single box such that we consider them together? Would that help to get rid of some of the issues around outbreak reporting such that if we're just looking at Canada or New Zealand, we're picking up all adverse events that are being marked against that country and can do some kind of comparison there as opposed to trying to isolate them? What do you think?

DR. HOFFMAN: So I guess I have a question back to you is, what are you trying to measure in doing that? Are you trying to look and see if there's been a change in conditions, or what is the purpose?

MS. DeWAAL: So we're looking for baseline data. So the Canadian agreement, for example, was signed in 2016. It gives us historical baseline data.

(Crosstalk)

DR. HOFFMAN: I don't know that I would want to see them combined.

MS. DeWAAL: Okay.

MS. HOFFMAN: I'm not sure. I need to give that a lot more thought.

MS. DeWAAL: That's okay.

DR. HOFFMAN: The use of multiple metrics and looking at whether they're moving in the same direction might be a stronger indicator than -- I would be more comfortable with that then looking at a single one of the metrics.

So if you're looking at overall trends, you know, are you seeing for a particular country -- so now you don't have to worry about comparability across countries -- are you seeing things moving in the same direction? I think that would be a stronger indicator than a single one. I think this is going to take more thought.

MR. DICELLO: Yeah, I would just add, I mean, a couple -- a way that you can handle that is, yes, if it -- again to the information that you needed for reporting or for management purposes that you're trying to get from that is you could have multiple metrics.

You could also have a single metric but disaggregate it by the types of event, which really gets you to the same point but it just -- it can feel a little bit easier, allows you to look at the data

across the different events in that way.

MS. DeVLIEGER: Don, questions?

DR. PRATER: Thank you very much. And my first question is for Sandy Eskin. So Sandy, I very much appreciated your comments about the toolkit for imported foods that we have, and you -- in addition to systems recognition, you mentioned the facilities inspections, border activities, FSVP. We have a lot of tools in the toolkit at this point.

So as we begin to optimally use our toolkit, we'll also need to describe how we're allocating our resources across these different tools. So what will you be listening for or what do you think the stakeholders will be listening for when we start to describe how we're allocating resources across different tools in the toolkit?

MS. ESKIN: That's a great question. So thank you. Again, to the degree that you can not only identify resources that the Agency is using for each of the 11 or so tools, that's helpful. And, again, I think it creates some of the same questions we've been talking about already. How do you draw -- how do you

connect that particular tool to a particular outcome? So I will give it some more thought, but I also think it's a great question to ask just generally both internally and with experts, particularly, those with economic backgrounds.

I do think that it is important for you, in addition to looking at each tool, to put them all together and sort of figure out on an ongoing basis how they -- how FDA's activities sort of align with each of them and to the degree if there's any way to find out if certain outcomes can somehow be connected. Helpful?

MS. DeVLIEGER: Jenny.

MS. SCOTT: I'm not sure how close I can get to this before it starts ringing in your ears. I have one for Sandra Eskin as well. And I just want to turn a question that you posed to us back on you.

So you talked a bit about monitoring these systems recognition and arrangements. So what do you think are appropriate monitoring activities, frequencies for these arrangements? And also, what do you think should trigger a review or even a discussion in advance of a scheduled one?

MS. ESKIN: So obviously you articulated -- the agencies articulated I think a formal review. Did -- Caroline, did you say five years more or less?

MS. DeWAAL: That's for a renewal.

MS. ESKIN: Renewal. Okay. So I think it would be useful to look at sort of formal activities, analyses done by the actual system that you have recognized. So I'm sure they do annual reporting. I'm sure there's other reporting that's related to the activities, public health information.

So I think using those course -- those normal course of information that they produce, I think it might be interesting to get a sense of what some of the stakeholders are producing. I don't want to say saying. I don't want -- I want there to be some data point there, some information, so in addition to self-reporting by the agency, what stakeholders and other interested parties have reported about the system and its performance.

Obviously, there's material in the press or otherwise that will note food safety problems, recalls, major recalls, foodborne illness outbreak, so that's

also relevant. But I think you're going to have to look at a range of information. How often you do that is going to depend on your other staffing restrictions or resources are because you could obviously have someone watching constantly. That may not be very effective.

Again, the premise here is the system that you have recognized, in fact, provides -- I'll use paraphrasing -- in the same level of food safety outcomes or public health outcomes as ours. So you are going in there with a presumption that it's going to continue to perform at that high level. Nevertheless, you do need to monitor it.

MS. SCOTT: I just want to follow up on that, and I want you to think about this as you develop your comments. You don't necessarily have to answer now, but remember that this is a two-way street. And this is an arrangement that is supposed to help us with resource allocations both ways. And so whatever we say triggers us to go back and investigate more with them, the same things can happen here.

We don't have a perfect system. We have

problems on a fairly routine basis. And so our resources could all be tied up in doing this back and forth, too. So again, we're looking for a balance here as to doing enough to make sure that this arrangement is still appropriate, that we're still achieving the same food safety outcomes and yet using it as a tool to put our resources in the right place.

MS. ESKIN: I agree totally, and again, all of this has to be -- you know, the systems recognition piece has to then also be part of the FSVP and whatever other pieces of the import system that system recognition informs and then the bigger, right, the bigger amount of resources over all the import system because it's, I'm sure, quite an art and a science to figure out in an agency that regulates, you know, so much, even in just the food space, what's the best way to spread out what are always going to be scarce resources.

MS. DeVLIEGER: Don, did you have a follow-up to that? Oh, okay. Go ahead, Jenny, if the rest of the FDA experts' okay with that. Okay -- okay.

MS. SCOTT: Well, I just know that Andrew is

on a tight schedule here and I want to get the question to him before he has to leave.

But you know Sandra Hoffman made a point about mentioning the importance of qualitative analyses. And, I am wondering how well these qualitative analyses fit within the ROM system as a metric, how you do the measurements when you don't have a quantitative measurement?

MR. DICELLO: So that was a great point that Sandra raised, and it's a challenge. There's no question. Some of these are sort of subjective or qualitative in nature, some of these results. I know when we did some work with the FDA we sort of struggled with this.

There are some ways to take qualitative assessments, like the assessment of a panel of experts, and sort of quantify that against some criteria so you can convert that into something a little bit more quantifiably even though you're really getting the opinions of folks.

But more generally what I would say is that while I sort of talked a lot about developing

performance measures, they are -- they don't really tell you why things have changed. They just tell you as a flag-raising exercise that things have changed.

And most organizations also have built into their monitoring evaluation systems some sort of evaluation that goes a little bit deeper than if you're not getting the public outcomes that you want and the indicator data and some other things aren't working, you have an evaluation. You're going out to the field. You're interviewing stakeholders. You're talking to consumers, and you're seeking to get deeper into the why the system isn't working. So the monitoring has a really important piece but it's not the whole story. So you can get a little bit more of that qualitative information.

If you build into your -- you know, some of the things about building in some evaluations at different periods, maybe two years into an agreement, you're going to do sort of a midterm evaluation. And in that process and from the outset, you identify some questions that you might want to learn about. What are some issues now that you would like to explore later?

Some sort of learning agenda questions you might say could also be part of your process to get it some of these qualitative things or some of the things that you don't feel totally comfortable that the monitoring data is providing for you.

MS. DeVLIEGER: Thank you. Caroline.

MS. DeWAAL: Thank you. I want to turn the questions back to our country representatives. And I note that both Canada, New Zealand source food from a broad variety of countries just like the U.S. does. To – Bill, I was really interested in your transparency index, the world transparency index. Can you tell me a little bit about that?

And then also can you both think about or provide some comment on the question I asked earlier about rule of law? And how do we assess rule of law and how it -- how important it is to different countries that we trade with?

DR. JOLLY: Okay. The world transparency index, I suggest you just go on the web to have a look at it. But it is -- it's a measure, and it's updated regularly about corruption, about a number of

parameters as far as reliability of being able to do business with that country or what considerations.

And it's just one other number, but it's one of the more publicized so it's a faraway comment to some extent, but it's something New Zealand takes pride in being in the top three or four regularly for a number of years.

As far as the rule of law, the -- there are two types of systeming. From a competent authority point of view and from a food safety from just a basic consumer right of having safe food, we think it's imperative that you do have a sound regulatory base to build that from, and that regulatory base gives you a number of empowering tools to actually enforce, to set standards, to verify, and to ensure, you know, transparency of community information.

Having said that, then there are a lot of other attributes around that where administrative systems may work. And so there's a lot of administrative systems around the world where maybe there's an attribute about a label claim or a regional claim for a plant pierced or an animal disease or

something like that.

And so, yes, rule of law from a foundation and from a basic attribute, which is not a evaluating attribute, it's a qualifying attribute, which is food safety, it's a pre-comparative attribute. I think's important.

The one other message I just want to say is that all of this -- and it's picking up at the point like Jenny was saying before -- it's about the messaging we give to our importers and our manufacturers. And if the messaging is, if you take a due diligence approach, if you deal with reputable suppliers and look for quality assurance and from reputable countries, then you will be rewarded with an expedited clearance and list regulatory (inaudible) which will have an economic benefit to you.

That's an incentive. And at the same time, you want to actually say, if you don't, if you go for least cost, you know, short term relationships, cheap and cheerful, then we are going to, you know, take a heavier regulatory impact on you.

And do we have that balance right because

again, the system that we've put in place with this systems recognition and some other things, there's actually more cost and there's not a lot of benefit.

Now, we do it because we partner with countries and it's just, as I say, a pretty competitive type thing. But at somewhere down the line, there's actually got to be a benefit for the companies, U.S. companies importing or New Zealand companies importing or the opposite, exporting, so that, you know, that encourages the actual dealings with reputable companies.

And so you know, it's not just about a one-size-fits-all. You've got to set that grade in. That red, orange and green light or multiple variations between them.

MR. MAYERS: And just to add to what Bill has said, in my mind that sense of rule of law is essential tenant to what we're pursuing here, because if it has at all the sense of "a nudge and a wink" as opposed to an effectively demonstrated outcome that is supported on an ongoing basis by confidence, that it means something, then we are undermining consumer confidence.

And there is no upside to that pursuit. And so the due diligence dimensions are all about confirming that the -- what is -- say what you do and then do what you say has meaning, which essentially is simply a demonstration of rule of law. So I see it as absolutely essential.

MS. DeVLIEGER: Thank you. Sharon.

MS. MAYL: Yeah, this is going to be a question for both of our Sandras. Earlier today, we heard some concerns raised by David Plunkett about commodity-specific arrangements versus systems recognition agreement arrangements that went across all food categories, specifically that the concentration on food safety will be toward exports and not necessarily for the people themselves in the country as well as economic impact.

So I was going to ask you first Sandra Eskin, who I call Sandy, but Sandra Eskin, if you share those concerns, if you see benefits to commodity-specific arrangements and then also, Sandra Hoffman, if you see any of that borne out by any data or you think it could be?

MS. ESKIN: So yes, I do share some of David's concerns but I also believe there could be a role in allowing these type of commodities-specific agreements. Uh, I think it will take a little more thought on my part to elaborate on that, but I do understand.

So the question in my mind is, are there ways to minimize any pressures toward or concerns that David articulated in a system that allowed for commodity-specific? I think that's a reality that we do have countries where a limited number of commodities are imported/exported, so it's a recognition if they had a recognition consumer demand.

But also, I believe that there is a role for the values piece of it in terms of ensuring or trying to ensure that everyone's system improves.

DR. HOFFMAN: Now, I wasn't here this morning so I'm not sure that I fully understand that the question is. I mean, -- I -- so yeah.

MS. MAYL: Oh, I do -- sorry. I think we had some -- I heard some concerns that commodity specific agreements could sort of have an economic detriment to some countries that are then just concentrating on

exporting the product. But I'm wondering if you sort of -- if that could be our out or else if you also see some benefits as well?

DR. HOFFMAN: Yeah, yeah, yeah. It would seem to me the economics of the export industry is going to be driven probably more by the private sector and maybe addressed in part through private sector relationships. I would agree that I wouldn't want to undercut the opportunity to try to strengthen the system as a whole.

And that a system -- I think I should say at this point that I'm speaking only for myself and not the Department of Agriculture. And also at this point, I'm not speaking out of research. So, but it would seem to me that where you're looking at a commodity-specific arrangement without focusing on the system as a whole, that that is a more fragile kind, a less robust kind of support because you don't have behind it the strengthening of the system overall, yeah.

MS. DeVLIEGER: Karen.

MS. SWAJIAN: I have a question for Dr. Hoffman in care of Bill Jones.

You mentioned the need to be cognizant of

changes in consumption levels. And we've been trying in some cases to look at illnesses per servings. What are the challenges and limitations for that approach?

DR. HOFFMAN: Well, I think the big challenge is our ability to measure consumption. And what we don't have really good consumption data. I mean, we're -- we have -- I'm thinking domestically at this point.

So we have NHANES, which is a survey and it's limited in the sample size and also limited -- also issues with seasonal variation and geographic variation by season. Otherwise, we're dealing with commodity sales and trying to back it out of that.

So there's, I think, an area where we need to do further work is on that issue of consumption measurement and whether our consumption measures are adequate for what we're now asking it to use it for, you know, whether we have kind of the same level of -- comparable level of confidence in that data that we do in our disease data.

MS. DeVLIEGER: There might be time for about one more question. Don?

DR. PRATER: My question would be for Bill and

for Paul. So I want to pick up on a theme that one of our FDA presenters mentioned this morning about where we can go in the future with systems recognition in terms of adding even more volume and recognizing the fact it's not a static relationship but affords us an opportunity to share additional types of information.

Can you reflect on any types of information that we might share in the future that you think would be beneficial?

MR. MAYERS: Well, I might turn it around that there's very little information that I can think of that there wouldn't be a benefit in sharing.

Fundamentally -- and I go to one of the results areas that I talked about, about deepening partnership. As I said at the end of my presentation, the more that we move to seeing a more integrated perspective on the role of regulatory systems and delivering for consumers not as individual jurisdictions but in a collective context -- and no better place to demonstrate that than in the North American context because I can assure you there are lots of Canadians who, given our current weather,

frankly reside in Florida.

I still care about their food safety outcomes. And in caring about their food safety outcomes, I'm dependent on what you do to deliver that. Much the same is the case when Americans come north.

And so the more that we see the role of the regulator, not just in defending an individual jurisdictional interest but in delivering on a food safety outcome, then the less we get worked up about so what info do we share and what info don't we share. And so you know, maybe it's a bit too pie in the sky to envision a complete partnership because we each operate different legal systems that legitimately protect certain components' information for a very good reason.

But beyond those -- and that's a pretty limited set -- my view is we should be working towards maximizing information sharing because our focus is on those outcomes.

DR. JOLLY: So you asked about the future, and I'm going to be inspirational and -- the -- I'll be incremental first of all and just say, from the current safety systems recognition arrangements, a little bit

wider scope would be worthwhile. But one of the things we've done with the European Union is we've seconded people and we've seconded people inside their food and (inaudible) office, so we've done joint audits together, and they've come out and spent some time with us and done joint audits. So it's part of that calibration exercise.

And where we want to get to in the future is lots more mutual recognition assessments. I mean, when you do a veterinary drug assessment, why should we have to do veterinary drug assessment? When you do a risk assessment on lead, why can't we pick that up -- or arsenic -- and the same with, you know, food additives or claims or a variety of other things -- so we actually share resources a lot more and we have more of a mutual recognition.

Where we've got to with Australia is in that sort of line, inasmuch as if it's legal to sell it to one country, then it's legal to sell in the other. And where we've put in our own law from an international standard point of view, if there's an issued tolerance in Codex, then irrespective of what our tolerance is in

our law, we will accept for imports the Codex standard.

And again, because we recognize that we're not about managing hazards, we're about managing risks. And once we get away from that sort of focus on hazards and procedural compliance and look at that wider risks framework, there is so much more opportunity.

So getting out of our silos and looking at the world being a global marketplace because your consumers are no different from mine. You know, my kids have lived over here, my kids have lived in Europe, so to think --I want the same as my neighbors want.

And so I think the future is about less differences and the least focus on procedural differences and more focus on risks management and cooperation and sharing.

MS. DeVLIEGER: Thank you very much. We're going to conclude the question session now. And I'd like to thank the FDA experts for the great questions that you asked and the panelists for the great answers that you have given.

We're going to turn now and invite testimony from our stakeholders who have pre-registered to speak.

And the first person that would invite to the microphone is Thea Emmerling Minister, Counsellor, Head of Health, Food Safety, and Consumer Affairs Section, European Union Delegation to the United States of America. Thea?

MS. EMMERLING: Does it work now? Yes, yes. Thea Emmerling from the EU delegation to the United States. The European Union has a single market of over 500 million consumers and is committed to very high standards of food safety and consumer protection.

In the EU, consumer protection comes first. The EU has harmonized sanitary and phytosanitary legislation which applies equally in all the 28 EU member states.

An extensive body of EU food laws covers the entire food production and processing chain from farm to fork within the EU in one consistent whole.

These laws also ensure the safety of imported and exported foods. Our food safety system is based on three pillars: First, hygiene requirements throughout the food chain; second, animal and plant health requirements that guarantee the prevention,

surveillance, and control of animal and plant diseases; and third, residue and contaminants provisions for which we have the world's strictest monitoring system.

We have three layers of control in the EU Food Safety System. First, food handling businesses have an obligation to self-control. They are responsible for the safety of the food and feed that they produce, transport, store or sell. They have to put self-controls in place and document them.

They have to identify and regularly review the critical points in their processes and ensure that controls are applied at these points. They must notify authorities of the activities incorporating official controls.

They must ensure traceability of ingredients and products. They have to immediately inform the authorities if they have a reason to believe that their food or feed is not safe and immediately withdraw unsafe food or feed from the market.

In these aspects, you will note that the emphasis is very similar to that of the Food Safety Modernization Act.

The responsibility lies on the food business operator. Second layer, the EU member states or, in case of imports, the administration of the country where the business operates have the responsibility to put official control systems in place to verify the effectiveness of the self-controls.

This responsibility comes directly from the applicable and uniform EU legislation, which is binding across the EU. The EU Member States are responsible for the enforcement of the EU law throughout the entire food and feed chain, in the same way as state-based agency officials enforce U.S. federal rules in their states. Competent authorities must organize official controls that reflect the risk of respective product categories and verify that the activities of the businesses and the goods placed on the EU market comply with all requirements. All EU Member States welcome the basis of transparent and coordinated control plans.

Three, a unique feature of the EU Food Safety System is the third layer of oversight and auditing. The European Commission audits the control and

inspection systems of the EU ember States, and verifies that they are effective from the farm to consumers.

This is one of the tasks of the Director, General for Health and Food Safety, at the European Commission. All audits carried out by the Commission service are publicly available on the internet to ensure full transparency.

In case of findings, the Commission starts a rigorous follow-up process with the respective country to remedy shortcomings. The Commission can also start infringement procedures against EU Member States, which means bringing them to the European Court of Justice in case of late or noncompliance with EU law.

Countries importing food from the EU can thus rely on the EU three layers control system as just outlined --a rigorous system that no other exporting country or entity offers. Therefore, import of EU products in the U.S. have an additional layer of consumer protection that exists nowhere else.

The EU and the U.S. have a long history of safe trade in food. We welcome partnerships that recognize the robustness of the entire food safety

system, which the FDA calls systems recognition.

The EU and the U.S. are currently actively engaged and well-advanced in the mutual systems recognition exercise. We see the U.S. as a natural partner in food safety. We share the same values of high food safety standards and consumer acceptance. We also have similarly focused systems that place the ultimate responsibility for producing safe food on the food business operator. We see many advantages in a close regulatory relationship through systems recognition.

Systems recognition will allow the U.S. to fully utilize and leverage on the assurances that the EU Food and Safety System highlighted just some seconds ago provides for U.S. consumers of EU imports.

The track record and high food safety standards of EU producers allow more of a close working relationship of the Commission and the FDA will facilitate the, hopefully, successful completion of the formalized systems recognition program between the FDA and the EU. It will allow both to focus their scarce inspection and audit resources on where the risks are

greatest and will, therefore, also directly benefit public health. Thank you.

MS. DeVLIEGER: Thank you very much and before you go if I could just ask the panel if you have any questions? No questions. Okay, thank you very much.

The next person that I would like to invite to the microphone is Ralph Ichter from Euroconsultants Incorporated.

Okay. And then moving on from that because I don't see Ralph in the audience, I would invite Tamara Rasbury from the Japan External Trade Organization.

MS. RASBURY: Thank you very much. My name is Tamara Rasbury from Japan External Trade Organization. I would like to say a few words about JETRO'S partnership with FDA since today's theme is partnership.

One of JETRO's missions is to promote the export of Japanese food to the United States in addition to supporting Japanese companies operating here in the United States. We would like to thank the FDA for providing us with many kinds of information that helps us with this mission. Last year, we had an

official from FDA come all the way to Japan to give a lecture about FSMA. Thank you so much.

We believe it is important to keep Japan informed about information regarding FSMA, and we would like to ask FDA to continue to give us timely information about it as far in advance as possible.

Our partnership with FDA is indispensable for the important task of establishing a system that can quickly respond to increase from Japanese companies wanting to export food to the United States.

We would like to maintain this partnership to help ensure that Japanese companies comply with FDA regulations, including FSMA. Thank you so much.

MS. DeVLIEGER: Thank you. Any questions for Tamara? No, okay, thank you so much.

That's going to conclude the testimony session of this, and I'm going to turn this back over to Don Prater so he can offer concluding remarks. Thank you, Don.

DR. PRATER: Thanks, Deb. On behalf of the FDA panel, I'd like to thank all the speakers for their presentations and I'd like to thank everyone in the

audience, both in person and by webcast, for your attention.

We've had two very full days of interesting and insightful discussion that will be considered by FDA, along with the comments and the docket. I'd like to offer a special thanks to the International Affairs Staff and CFSAN, the IAS team who have been the arms and legs, to use the people analogy, behind this hearing. And especially I'd like to thank Susan Berndt, Wade Woolfolk, and Sandra Boston.

I'd also like to thank Juanita Yates and her team for all their logistical support. Thank you very much and that final plug, please submit your written comments to the docket by May 15th.

Again, thank you for your participation and this concludes our public hearing.

(Whereupon, the public hearing was concluded.)

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I, Natalia Thomas, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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