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U.S. FOOD AND DRUG ADMINISTRATION

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Public Hearing: Strategic Partnerships to Enhance the

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Safety of Imported Foods: Capacity Building, Risk-Based

6

Decision Making, Recognition of Commodity Food Control

7

Programs, and Systems Recognition

8

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Conducted by Donald Prater, DVM

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1 P R O C E E D I N G S

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

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

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

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

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

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

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

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

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

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

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

1 robustness of an entire food safety system via systems
2 recognition.

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

12 (Applause)

13 MR. ABD00: Thank you, Don, and good morning
14 everybody. It's a pleasure here -- to be here speaking
15 to you today. As you know, globalization has
16 dramatically shifted FDA's regulatory landscape. We
17 are now in an environment in which food products travel
18 with complex supply chains throughout countries all
19 over the world. Many of these nations, unfortunately,
20 have less developed regulatory systems and capacity
21 than the United States.

22 FDA-regulated products originate from more

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

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

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

1 with more than 170 member countries.

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

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

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

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

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

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

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

22 In addition, FDA fosters international

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (Applause)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 trading fresh produce across the United States/Mexico
2 border.

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

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

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

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

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

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

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

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

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

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

22 Our work is not done, and we continue to learn

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

3 (Applause)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 MR. GREMILLION: Thank you.

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

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

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

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

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

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

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

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

13 MS. CLAVERO: And USDA?

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

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

1 another question, please.

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

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

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

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

21 MR. JONES: Thank you so much, Don.

22 (Laughter)

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

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

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

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

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

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

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

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

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

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

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

11 MR. ABD00: Thanks for the question. And you
12 know, our work with Codex is designed to ensure a
13 science-based and risk-based approach as Codex develops
14 its guidance. As you know, under the SPS Agreement at
15 the WTO, countries are allowed to regulate to the level
16 that they see appropriate for their public.

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

1 anything.

2 MR. MOLLO: Thank you.

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

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

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

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

22 MR. ABD00: Thanks. And that's an interesting

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

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

12 MS. MCCORMICK: Okay. We have a question from
13 Rupesh Modi with Red River Foods. "In the produce
14 safety training, we are trained to use the EPA Method
15 1603 to test water for E. coli. Why did the FDA and
16 PSA limit it to one method? Will there be other
17 methods recommended by the FDA or PSA to test water
18 like MPN methods, which is widely used for Coliform and
19 E. coli tests?"

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

21 (Laughter)

22 DR. PRATER: I think probably the best

1 response that we would generate on a technical question
2 of that nature would be to submit that to our Technical
3 Assistance Network, and we can come back with a good
4 response on that one. So I think that's probably the
5 best way to handle that question, so. We appreciate
6 that question from the web, and we will definitely
7 follow up through our Technical Assistance Network.

8 Other questions? Okay. Very good.

9 So an excellent session this morning, I think,
10 to set the stage for the presentations that will
11 follow. Very much appreciate all the questions in the
12 room, good questions, and also from the web, and we'll
13 take a break at this point. And we will return at
14 10:00 a.m. when we will welcome our guest panelists.
15 Thank you.

16 (Applause)

17 (Whereupon, a break was taken.)

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

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

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

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

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

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

22 By way of background, FSIS is the public

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

5 To get started, what is equivalence?

6 Equivalence is a process of determining whether a
7 country's inspections system achieves FSIS's
8 appropriate level of public health protection, as
9 applied domestically in the U.S. Equivalence does not
10 mean that a country must implement and develop the same
11 procedures that the U.S. does. Rather, the country
12 must objectively demonstrate that its procedures meet
13 the U.S. level of protection.

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

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

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

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

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

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

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

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

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

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

22 When FSIS determines that the country's

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

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

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

1 report.

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

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

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

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

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

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

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

17 (Applause)

18 DR. PRATER: Thank you, Dr. McGinn.

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

21 MR. McEVOY: Okay. Good morning, everyone.

22 I'm Miles McEvoy, Deputy Administrator at Agricultural

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

5 I'm going the wrong direction apparently.

6 Okay. Here we go, that's a little better.

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

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

1 and the USDA Organic Regulation.

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

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

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

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

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

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

1 enforcement under their authority over the operations
2 that they certify.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 enforcement as appropriate.

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

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

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

1 reviews, kind of standard accreditation process under
2 17011. We also have peer reviews. We get assessments
3 by foreign governments that we have equivalency
4 arrangements with, as well as conducting assessments of
5 those foreign governments, and of course our favorite
6 Office of Inspector General audits.

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

22 There are a number of NOP accredited

1 certifiers that operate in Mexico and over 1600
2 certified operations in Mexico. Mexico has established
3 their own Mexican organic regulations and are in the
4 process of implementing that. We are working very
5 closely with SENESICA. We've been to observe a number
6 of different organic operations there. They've come up
7 here to observe our certifier audits. We've done our
8 peer-review assessment of SENESICA's program using
9 17011 for the accreditation role that they play, and
10 17065 for their oversight or the way that control
11 bodies or certifiers are operating.

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

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

6 Okay. And one last point is there has been
7 research done by Penn State University on what's called
8 organic hotspots. So this is kind of changing topic a
9 little bit to the economic component of organic
10 agriculture, and what they found was that 225 counties
11 around the United States are what are organic hotspots,
12 where this is a lot of organic activity in terms of
13 farms, handling, and processing. And in those
14 counties, they've shown that median household income is
15 \$2000 higher, and it has lowered poverty rate by as low
16 as 1.35 percent in those specific counties.

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

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

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

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

12 (Applause)

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

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

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

22 But first, thank you very much for the

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

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

1 is as much as I know about the program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 to raise.

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

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

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

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

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

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

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

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

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

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

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

1 food products in that country.

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

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

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

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

11 (Applause)

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

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

20 MR. MANDLIK: Hello?

21 DR. PRATER: Yes, we can hear you.

22 MR. MANDLIK: Hello? Hello. Good morning.

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

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

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

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

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

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

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

1 strategic locations along the coastal line. Next,
2 please.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 There has to be a provision for the wet and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 These -- all these laboratories are in NABL
13 and EIC approved. They are also within (inaudible) all
14 25 standards. All these laboratories participate in
15 the proficiency testing and demonstrate their technique
16 and competence.

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

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

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

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

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

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

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

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

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

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

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

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

13 Next, please.

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

19 Next, please.

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

1 2015. It was followed by signing the Confidentiality
2 Commitment from EIC not to publicly disclose the non-
3 public information shared by U.S. FDA. That was done
4 in June 2016.

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

11 Next, please.

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

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

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

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

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

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

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

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

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

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

8 Thank you very much for your attention.

9 (Applause)

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

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

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

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

22 So for this next session, we have a number of

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

6 So Mark Abdoo, the Assistant Commissioner for
7 Global Regulatory Policy in the Office of Global
8 Regulatory Operations and Policy; Camille Brewer, the
9 Director of International Affairs Staff; Bill Correll,
10 Director of Office of Compliance in Center for Food
11 Safety and Applied Nutrition; Bill Jones, the Deputy
12 Director, Office of Food Safety, Center for Food
13 Safety; and Caroline Smith DeWaal, the International
14 Food Safety Policy Manager in the International Affairs
15 Staff in the Center for Food Safety.

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

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

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

7 DR. MCGINN: Thank you for the question.

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

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

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

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

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

6 MR. SOLOMON: Mark?

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

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

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

1 have more significant organic production and sales.

2 MR. SOLOMON: Bill Correll?

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

7 MR. McEVOY: Yeah. That's correct.

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

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

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

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

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

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

16 MR. McEVOY: Once they're accredited?

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

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

1 MR. CORRELL: Thank you.

2 MR. SOLOMON: Caroline?

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

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

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

20 MR. PLUNKETT: Just those two scenarios?

21 Okay. Well, you know, your expectation is that
22 commodity-specific would be no less rigorous than

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

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

1 available to their citizens, perhaps not.

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

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

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

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

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

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

1 control systems in Latin America.

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

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

21 DR. SOLOMON: Dr. Jones.

22 DR. MCGINN: So our equivalence process, of

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

8 DR. SOLOMON: Bill.

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

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

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

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

3 MR. MANDLIK: Thank you for the question.

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

15 DR. JONES: Thank you.

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

17 DR. JONES: I do have other questions.

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

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

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

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

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

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

22 DR. MCGINN: The audit results, if there are

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

3 MR. CORRELL: Thank you.

4 DR. SOLOMON: Mr. McEvoy?

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

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

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

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

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

11 MR. MANDLIK: No, please. Thank you.

12 MR. CORRELL: Camille?

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

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

1 MR. MANDLIK: Thank you for the question.

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

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

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

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

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

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

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

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

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

22 So I would say that just becoming increasingly

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

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

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

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

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

16 DR. SOLOMON: Camille.

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

22 MR. McEVOY: Yeah. A certified operation has

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

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

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

22 DR. SOLOMON: Anything else from the Panel?

1 Caroline?

2 MR. CORRELL: One quick question for Miles.

3 In terms of audits of the certifiers that you do, and
4 you had talked about sort of the frequency of that, is
5 that disclosed, the report -- the audit reports in
6 terms of transparency? It seems to me the strength of
7 these programs and liability for consumer assurances
8 really rest with, you know, overcoming the, you know,
9 the mistrust of such systems.

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

13 MR. CORRELL: Posted?

14 MR. McEVOY: Yeah.

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

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

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

3 MR. CORRELL: Oh. Thank you.

4 DR. SOLOMON: Caroline.

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

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

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

1 has to meet certain requirements.

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

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

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

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

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

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

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

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

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

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

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

5 MR. JORDAN: Thank you.

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

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

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

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

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

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

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

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

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

12 Okay. Thank you very much.

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

17 (Applause)

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

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

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

9 (Whereupon, a lunch break was taken.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 Unlike equivalence, FDA is -- systems
13 recognition is not a market access tool. And that is a
14 key take-home message from this presentation.

15 Equivalence is essential if you want to market access
16 for a certain number of products. We saw today with
17 meat and poultry, it is a prerequisite to market
18 access. That's not the case with systems recognition.
19 Countries can still access our markets and it means the
20 tool is actually being used for a different purpose.

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

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

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

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

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

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

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

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

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

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

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

1 particular element.

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

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

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

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

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

9 There are 10 standards, and in each standard
10 we have a different set of elements. They vary from 1
11 element in a standard to 10 elements in a standard.
12 Our regulatory authority, which is our Standard number
13 1, is our regulatory foundation, that's our most
14 important. That's the foundation. That's where all of
15 our information comes from, and that's the cornerstone
16 to the entire program and where the rest of the
17 standards actually leap off and they build off of that
18 regulatory foundation.

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

1 have a comparable food safety systems.

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

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

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

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

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

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

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

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

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

22 And then we have Standard 10, which is our

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

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

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

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

1 through this IT system.

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

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

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

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

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

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

22 The system was also developed to allow

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

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

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

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

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

9 (Applause)

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

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

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

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

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

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

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

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

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

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

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

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

22 So typically -- and you know, understand that

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

9 And then another team that assesses the
10 implementation of the laboratory procedures, both of
11 those teams are usually in-country for about a week.
12 And then we have two additional teams that assess the
13 implementation of the participant's food safety system
14 with a focus on inspection and compliance programs.
15 Typically these teams are in-country for two weeks
16 because the attempt is to cover different commodities
17 in different regions of the country.
18 Like I believe Caroline said, you know, these systems
19 recognition arrangements have to do with all foods in
20 that system knowing that that's a huge systems-based
21 program and not commodity-specific.

22 So after the in-country verification audits

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

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

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

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

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

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

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

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

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

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

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

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

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

5 So to import food under the modified
6 conditions -- and these are set forth in 21 CFR Section
7 1.513 -- the foreign supplier needs to be in and under
8 the regulatory oversight of a country with a food
9 safety system that's comparable or equivalent. The
10 imported food itself has to be within the scope of that
11 agreement. The -- and we anticipate that our FSVP
12 draft guidance, which unfortunately is not out yet, but
13 we hope to have it out soon -- it will provide guidance
14 on how to obtain information about systems recognition
15 arrangements and the foods that are covered under them,
16 and so that, hopefully, this will be available to
17 importers in a convenient location on our website.

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

22 So what does good compliance standing mean?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (Applause)

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

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

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

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

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

14 (Applause)

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

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

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

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

1 MS. LARRIMER: Sure. Natalia Larrimer, ANAB.

2 DR. PRATER: Thank you.

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

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

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

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

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

9 MS. LARRIMER: Yeah.

10 MS. DeVLIEGER: Uh-oh.

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

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

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

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

17 MS. LARRIMER: Thank you.

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

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

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

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

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

1 on both sides of the border.

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

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

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

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

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

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

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

22 MR. GERMILLION: Hi. Thomas Germillion,

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

3 DR. PRATER: Your microphone?

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

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

1 themselves. So the -- but with New Zealand, we had a
2 public meeting very much like this one back in 2010 or
3 '11, one or the other. We had one to discuss the
4 concept and the process of the pilot with New Zealand.

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

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

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

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

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

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

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

16 Do we have another question from the web?

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

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

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

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

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

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

10 (Whereupon, a break was taken.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So there's an if/then relationship and a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 So why is New Zealand relevant? Well, we're
16 small, but we're actually one of the world's biggest
17 exporters of agriculture products. Say 15 (inaudible)
18 over all by value, but Number One in dairy, Number One
19 in sheep, sheep meat, kiwi fruit, venison, (inaudible)
20 mussels, and Number Five, in beef, but we also import
21 25 percent of our food, and we import over a billion
22 dollars' worth of food from the U.S. And again, food

1 and agriculture are the business of New Zealand.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 relevant.

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

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

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

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

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

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

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

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

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

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

5 (Applause)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 Thank you.

14 (Applause)

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

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

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

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

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

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

1 based. There still is a presence in Philadelphia.

2 So when did Pew get involved in food safety?

3 The first project began in 2008. It was actually
4 outside the organization. It was at Georgetown. And
5 it focused on produce safety. It came about after a
6 series of foodborne illness outbreak linked to spinach
7 and other fresh produce items. And the goal of that
8 project was to focus on getting FDA to put in place
9 regulations under its existing authority.

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

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

1 perspective.

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

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

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

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

22 I believe that, and I think many people share

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (Applause)

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

22 MS. ESKIN: That's the best kind of

1 presentation.

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

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

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

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

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

1 of metrics.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 And similarly one might ask, as we saw in the
5 2008 economic crisis, are there financial -- are there
6 changes in financial circumstances that could be
7 significantly changing efforts or capacity within a
8 country that needs to be accounted for in trying to
9 develop metrics?

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

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

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

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

5 (Applause)

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

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

17 (Whereupon, a break was taken.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MS. DeVLIEGER: Karen.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MS. DeVLIEGER: Thank you. Camille, any

1 questions?

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

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

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

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

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

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

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

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

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

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

6 MS. DeVLIEGER: Thank you. Caroline.

7 MS. DEWAAL: Thank you. I'm going to pose my
8 question to Sandra Hoffman. Thank you very much. Your
9 remarks were really actually very helpful to us. But
10 I'd also like Andrew to listen because I'd like your
11 thoughts on this as well.

12 Let's say that we're just looking at
13 performance metrics for the U.S. to evaluate our
14 various systems recognition arrangements, so getting
15 away from the complexity of metrics that cross into
16 Canada or New Zealand. So it's country-specific
17 metrics. Sandra, I know you know, as do I, the
18 complexity of some of the adverse events, so outbreak
19 reporting, recall reporting, and import alerts, things
20 of that nature.

21 I'm wondering, they have many confounders and
22 they can change over time what those trends look like.

1 My question is should we consider a metrics that puts
2 all adverse events into a single box such that we
3 consider them together? Would that help to get rid of
4 some of the issues around outbreak reporting such that
5 if we're just looking at Canada or New Zealand, we're
6 picking up all adverse events that are being marked
7 against that country and can do some kind of comparison
8 there as opposed to trying to isolate them? What do
9 you think?

10 DR. HOFFMAN: So I guess I have a question
11 back to you is, what are you trying to measure in doing
12 that? Are you trying to look and see if there's been a
13 change in conditions, or what is the purpose?

14 MS. DeWAAL: So we're looking for baseline
15 data. So the Canadian agreement, for example, was
16 signed in 2016. It gives us historical baseline data.

17 (Crosstalk)

18 DR. HOFFMAN: I don't know that I would want
19 to see them combined.

20 MS. DeWAAL: Okay.

21 MS. HOFFMAN: I'm not sure. I need to give
22 that a lot more thought.

1 MS. DeWAAL: That's okay.

2 DR. HOFFMAN: The use of multiple metrics and
3 looking at whether they're moving in the same direction
4 might be a stronger indicator than -- I would be more
5 comfortable with that then looking at a single one of
6 the metrics.

7 So if you're looking at overall trends, you
8 know, are you seeing for a particular country -- so now
9 you don't have to worry about comparability across
10 countries -- are you seeing things moving in the same
11 direction? I think that would be a stronger indicator
12 than a single one. I think this is going to take more
13 thought.

14 MR. DICELLO: Yeah, I would just add, I mean,
15 a couple -- a way that you can handle that is, yes, if
16 it -- again to the information that you needed for
17 reporting or for management purposes that you're trying
18 to get from that is you could have multiple metrics.

19 You could also have a single metric but
20 disaggregate it by the types of event, which really
21 gets you to the same point but it just -- it can feel a
22 little bit easier, allows you to look at the data

1 across the different events in that way.

2 MS. DeVLIEGER: Don, questions?

3 DR. PRATER: Thank you very much. And my
4 first question is for Sandy Eskin. So Sandy, I very
5 much appreciated your comments about the toolkit for
6 imported foods that we have, and you -- in addition to
7 systems recognition, you mentioned the facilities
8 inspections, border activities, FSVP. We have a lot of
9 tools in the toolkit at this point.

10 So as we begin to optimally use our toolkit,
11 we'll also need to describe how we're allocating our
12 resources across these different tools. So what will
13 you be listening for or what do you think the
14 stakeholders will be listening for when we start to
15 describe how we're allocating resources across
16 different tools in the toolkit?

17 MS. ESKIN: That's a great question. So thank
18 you. Again, to the degree that you can not only
19 identify resources that the Agency is using for each of
20 the 11 or so tools, that's helpful. And, again, I
21 think it creates some of the same questions we've been
22 talking about already. How do you draw -- how do you

1 connect that particular tool to a particular outcome?
2 So I will give it some more thought, but I also think
3 it's a great question to ask just generally both
4 internally and with experts, particularly, those with
5 economic backgrounds.

6 I do think that it is important for you, in
7 addition to looking at each tool, to put them all
8 together and sort of figure out on an ongoing basis how
9 they -- how FDA's activities sort of align with each of
10 them and to the degree if there's any way to find out
11 if certain outcomes can somehow be connected. Helpful?

12 MS. DeVLIEGER: Jenny.

13 MS. SCOTT: I'm not sure how close I can get to
14 this before it starts ringing in your ears. I have one
15 for Sandra Eskin as well. And I just want to turn a
16 question that you posed to us back on you.

17 So you talked a bit about monitoring these
18 systems recognition and arrangements. So what do you
19 think are appropriate monitoring activities,
20 frequencies for these arrangements? And also, what do
21 you think should trigger a review or even a discussion
22 in advance of a scheduled one?

1 MS. ESKIN: So obviously you articulated --
2 the agencies articulated I think a formal review. Did
3 -- Caroline, did you say five years more or less?

4 MS. DeWAAL: That's for a renewal.

5 MS. ESKIN: Renewal. Okay. So I think it
6 would be useful to look at sort of formal activities,
7 analyses done by the actual system that you have
8 recognized. So I'm sure they do annual reporting. I'm
9 sure there's other reporting that's related to the
10 activities, public health information.

11 So I think using those course -- those normal
12 course of information that they produce, I think it
13 might be interesting to get a sense of what some of the
14 stakeholders are producing. I don't want to say
15 saying. I don't want -- I want there to be some data
16 point there, some information, so in addition to self-
17 reporting by the agency, what stakeholders and other
18 interested parties have reported about the system and
19 its performance.

20 Obviously, there's material in the press or
21 otherwise that will note food safety problems, recalls,
22 major recalls, foodborne illness outbreak, so that's

1 also relevant. But I think you're going to have to
2 look at a range of information. How often you do that
3 is going to depend on your other staffing restrictions
4 or resources are because you could obviously have
5 someone watching constantly. That may not be very
6 effective.

7 Again, the premise here is the system that you
8 have recognized, in fact, provides -- I'll use
9 paraphrasing -- in the same level of food safety
10 outcomes or public health outcomes as ours. So you are
11 going in there with a presumption that it's going to
12 continue to perform at that high level. Nevertheless,
13 you do need to monitor it.

14 MS. SCOTT: I just want to follow up on that,
15 and I want you to think about this as you develop your
16 comments. You don't necessarily have to answer now,
17 but remember that this is a two-way street. And this
18 is an arrangement that is supposed to help us with
19 resource allocations both ways. And so whatever we say
20 triggers us to go back and investigate more with them,
21 the same things can happen here.

22 We don't have a perfect system. We have

1 problems on a fairly routine basis. And so our
2 resources could all be tied up in doing this back and
3 forth, too. So again, we're looking for a balance here
4 as to doing enough to make sure that this arrangement
5 is still appropriate, that we're still achieving the
6 same food safety outcomes and yet using it as a tool to
7 put our resources in the right place.

8 MS. ESKIN: I agree totally, and again, all of
9 this has to be -- you know, the systems recognition
10 piece has to then also be part of the FSVP and whatever
11 other pieces of the import system that system
12 recognition informs and then the bigger, right, the
13 bigger amount of resources over all the import system
14 because it's, I'm sure, quite an art and a science to
15 figure out in an agency that regulates, you know, so
16 much, even in just the food space, what's the best way
17 to spread out what are always going to be scarce
18 resources.

19 MS. DeVLIEGER: Don, did you have a follow-up
20 to that? Oh, okay. Go ahead, Jenny, if the rest of
21 the FDA experts' okay with that. Okay -- okay.

22 MS. SCOTT: Well, I just know that Andrew is

1 on a tight schedule here and I want to get the question
2 to him before he has to leave.

3 But you know Sandra Hoffman made a point about
4 mentioning the importance of qualitative analyses.

5 And, I am wondering how well these qualitative analyses
6 fit within the ROM system as a metric, how you do the
7 measurements when you don't have a quantitative
8 measurement?

9 MR. DICELLO: So that was a great point that
10 Sandra raised, and it's a challenge. There's no
11 question. Some of these are sort of subjective or
12 qualitative in nature, some of these results. I know
13 when we did some work with the FDA we sort of struggled
14 with this.

15 There are some ways to take qualitative
16 assessments, like the assessment of a panel of experts,
17 and sort of quantify that against some criteria so you
18 can convert that into something a little bit more
19 quantifiably even though you're really getting the
20 opinions of folks.

21 But more generally what I would say is that
22 while I sort of talked a lot about developing

1 performance measures, they are -- they don't really
2 tell you why things have changed. They just tell you
3 as a flag-raising exercise that things have changed.

4 And most organizations also have built into
5 their monitoring evaluation systems some sort of
6 evaluation that goes a little bit deeper than if you're
7 not getting the public outcomes that you want and the
8 indicator data and some other things aren't working,
9 you have an evaluation. You're going out to the field.
10 You're interviewing stakeholders. You're talking to
11 consumers, and you're seeking to get deeper into the
12 why the system isn't working. So the monitoring has a
13 really important piece but it's not the whole story.
14 So you can get a little bit more of that qualitative
15 information.

16 If you build into your -- you know, some of
17 the things about building in some evaluations at
18 different periods, maybe two years into an agreement,
19 you're going to do sort of a midterm evaluation. And
20 in that process and from the outset, you identify some
21 questions that you might want to learn about. What are
22 some issues now that you would like to explore later?

1 Some sort of learning agenda questions you might say
2 could also be part of your process to get it some of
3 these qualitative things or some of the things that you
4 don't feel totally comfortable that the monitoring data
5 is providing for you.

6 MS. DeVLIEGER: Thank you. Caroline.

7 MS. DeWAAL: Thank you. I want to turn the
8 questions back to our country representatives. And I
9 note that both Canada, New Zealand source food from a
10 broad variety of countries just like the U.S. does. To
11 - Bill, I was really interested in your transparency
12 index, the world transparency index. Can you tell me a
13 little bit about that?

14 And then also can you both think about or
15 provide some comment on the question I asked earlier
16 about rule of law? And how do we assess rule of law
17 and how it -- how important it is to different
18 countries that we trade with?

19 DR. JOLLY: Okay. The world transparency
20 index, I suggest you just go on the web to have a look
21 at it. But it is -- it's a measure, and it's updated
22 regularly about corruption, about a number of

1 parameters as far as reliability of being able to do
2 business with that country or what considerations.

3 And it's just one other number, but it's one
4 of the more publicized so it's a faraway comment to
5 some extent, but it's something New Zealand takes pride
6 in being in the top three or four regularly for a
7 number of years.

8 As far as the rule of law, the -- there are
9 two types of systeming. From a competent authority
10 point of view and from a food safety from just a basic
11 consumer right of having safe food, we think it's
12 imperative that you do have a sound regulatory base to
13 build that from, and that regulatory base gives you a
14 number of empowering tools to actually enforce, to set
15 standards, to verify, and to ensure, you know,
16 transparency of community information.

17 Having said that, then there are a lot of
18 other attributes around that where administrative
19 systems may work. And so there's a lot of
20 administrative systems around the world where maybe
21 there's an attribute about a label claim or a regional
22 claim for a plant pierced or an animal disease or

1 something like that.

2 And so, yes, rule of law from a foundation and
3 from a basic attribute, which is not a evaluating
4 attribute, it's a qualifying attribute, which is food
5 safety, it's a pre-comparative attribute. I think's
6 important.

7 The one other message I just want to say is
8 that all of this -- and it's picking up at the point
9 like Jenny was saying before -- it's about the
10 messaging we give to our importers and our
11 manufacturers. And if the messaging is, if you take a
12 due diligence approach, if you deal with reputable
13 suppliers and look for quality assurance and from
14 reputable countries, then you will be rewarded with an
15 expedited clearance and list regulatory (inaudible)
16 which will have an economic benefit to you.

17 That's an incentive. And at the same time,
18 you want to actually say, if you don't, if you go for
19 least cost, you know, short term relationships, cheap
20 and cheerful, then we are going to, you know, take a
21 heavier regulatory impact on you.

22 And do we have that balance right because

1 again, the system that we've put in place with this
2 systems recognition and some other things, there's
3 actually more cost and there's not a lot of benefit.

4 Now, we do it because we partner with
5 countries and it's just, as I say, a pretty competitive
6 type thing. But at somewhere down the line, there's
7 actually got to be a benefit for the companies, U.S.
8 companies importing or New Zealand companies importing
9 or the opposite, exporting, so that, you know, that
10 encourages the actual dealings with reputable
11 companies.

12 And so you know, it's not just about a one-
13 size-fits-all. You've got to set that grade in. That
14 red, orange and green light or multiple variations
15 between them.

16 MR. MAYERS: And just to add to what Bill has
17 said, in my mind that sense of rule of law is essential
18 tenant to what we're pursuing here, because if it has
19 at all the sense of "a nudge and a wink" as opposed to
20 an effectively demonstrated outcome that is supported
21 on an ongoing basis by confidence, that it means
22 something, then we are undermining consumer confidence.

1 And there is no upside to that pursuit. And so the due
2 diligence dimensions are all about confirming that the
3 -- what is -- say what you do and then do what you say
4 has meaning, which essentially is simply a
5 demonstration of rule of law. So I see it as
6 absolutely essential.

7 MS. DeVLIEGER: Thank you. Sharon.

8 MS. MAYL: Yeah, this is going to be a
9 question for both of our Sandras. Earlier today, we
10 heard some concerns raised by David Plunkett about
11 commodity-specific arrangements versus systems
12 recognition agreement arrangements that went across all
13 food categories, specifically that the concentration on
14 food safety will be toward exports and not necessarily
15 for the people themselves in the country as well as
16 economic impact.

17 So I was going to ask you first Sandra Eskin,
18 who I call Sandy, but Sandra Eskin, if you share those
19 concerns, if you see benefits to commodity-specific
20 arrangements and then also, Sandra Hoffman, if you see
21 any of that borne out by any data or you think it could
22 be?

1 MS. ESKIN: So yes, I do share some of David's
2 concerns but I also believe there could be a role in
3 allowing these type of commodities-specific agreements.
4 Uh, I think it will take a little more thought on my
5 part to elaborate on that, but I do understand.

6 So the question in my mind is, are there ways
7 to minimize any pressures toward or concerns that David
8 articulated in a system that allowed for commodity-
9 specific? I think that's a reality that we do have
10 countries where a limited number of commodities are
11 imported/exported, so it's a recognition if they had a
12 recognition consumer demand.

13 But also, I believe that there is a role for
14 the values piece of it in terms of ensuring or trying
15 to ensure that everyone's system improves.

16 DR. HOFFMAN: Now, I wasn't here this morning
17 so I'm not sure that I fully understand that the
18 question is. I mean, -- I -- so yeah.

19 MS. MAYL: Oh, I do -- sorry. I think we had
20 some -- I heard some concerns that commodity specific
21 agreements could sort of have an economic detriment to
22 some countries that are then just concentrating on

1 exporting the product. But I'm wondering if you sort
2 of -- if that could be our out or else if you also see
3 some benefits as well?

4 DR. HOFFMAN: Yeah, yeah, yeah. It would seem
5 to me the economics of the export industry is going to
6 be driven probably more by the private sector and maybe
7 addressed in part through private sector relationships.
8 I would agree that I wouldn't want to undercut the
9 opportunity to try to strengthen the system as a whole.

10 And that a system -- I think I should say at
11 this point that I'm speaking only for myself and not
12 the Department of Agriculture. And also at this point,
13 I'm not speaking out of research. So, but it would
14 seem to me that where you're looking at a commodity-
15 specific arrangement without focusing on the system as
16 a whole, that that is a more fragile kind, a less
17 robust kind of support because you don't have behind it
18 the strengthening of the system overall, yeah.

19 MS. DeVLIEGER: Karen.

20 MS. SWAJIAN: I have a question for Dr.
21 Hoffman in care of Bill Jones.

22 You mentioned the need to be cognizant of

1 changes in consumption levels. And we've been trying
2 in some cases to look at illnesses per servings. What
3 are the challenges and limitations for that approach?

4 DR. HOFFMAN: Well, I think the big challenge
5 is our ability to measure consumption. And what we
6 don't have really good consumption data. I mean, we're
7 -- we have -- I'm thinking domestically at this point.

8 So we have NHANES, which is a survey and it's
9 limited in the sample size and also limited -- also
10 issues with seasonal variation and geographic variation
11 by season. Otherwise, we're dealing with commodity
12 sales and trying to back it out of that.

13 So there's, I think, an area where we need to
14 do further work is on that issue of consumption
15 measurement and whether our consumption measures are
16 adequate for what we're now asking it to use it for,
17 you know, whether we have kind of the same level of --
18 comparable level of confidence in that data that we do
19 in our disease data.

20 MS. DeVLIEGER: There might be time for about
21 one more question. Don?

22 DR. PRATER: My question would be for Bill and

1 for Paul. So I want to pick up on a theme that one of
2 our FDA presenters mentioned this morning about where
3 we can go in the future with systems recognition in
4 terms of adding even more volume and recognizing the
5 fact it's not a static relationship but affords us an
6 opportunity to share additional types of information.

7 Can you reflect on any types of information
8 that we might share in the future that you think would
9 be beneficial?

10 MR. MAYERS: Well, I might turn it around that
11 there's very little information that I can think of
12 that there wouldn't be a benefit in sharing.

13 Fundamentally -- and I go to one of the
14 results areas that I talked about, about deepening
15 partnership. As I said at the end of my presentation,
16 the more that we move to seeing a more integrated
17 perspective on the role of regulatory systems and
18 delivering for consumers not as individual
19 jurisdictions but in a collective context -- and no
20 better place to demonstrate that than in the North
21 American context because I can assure you there are
22 lots of Canadians who, given our current weather,

1 frankly reside in Florida.

2 I still care about their food safety outcomes.

3 And in caring about their food safety outcomes, I'm

4 dependent on what you do to deliver that. Much the

5 same is the case when Americans come north.

6 And so the more that we see the role of the

7 regulator, not just in defending an individual

8 jurisdictional interest but in delivering on a food

9 safety outcome, then the less we get worked up about so

10 what info do we share and what info don't we share.

11 And so you know, maybe it's a bit too pie in the sky to

12 envision a complete partnership because we each operate

13 different legal systems that legitimately protect

14 certain components' information for a very good reason.

15 But beyond those -- and that's a pretty

16 limited set -- my view is we should be working towards

17 maximizing information sharing because our focus is on

18 those outcomes.

19 DR. JOLLY: So you asked about the future, and

20 I'm going to be inspirational and -- the -- I'll be

21 incremental first of all and just say, from the current

22 safety systems recognition arrangements, a little bit

1 wider scope would be worthwhile. But one of the things
2 we've done with the European Union is we've seconded
3 people and we've seconded people inside their food and
4 (inaudible) office, so we've done joint audits
5 together, and they've come out and spent some time with
6 us and done joint audits. So it's part of that
7 calibration exercise.

8 And where we want to get to in the future is
9 lots more mutual recognition assessments. I mean, when
10 you do a veterinary drug assessment, why should we have
11 to do veterinary drug assessment? When you do a risk
12 assessment on lead, why can't we pick that up -- or
13 arsenic -- and the same with, you know, food additives
14 or claims or a variety of other things -- so we
15 actually share resources a lot more and we have more of
16 a mutual recognition.

17 Where we've got to with Australia is in that
18 sort of line, inasmuch as if it's legal to sell it to
19 one country, then it's legal to sell in the other. And
20 where we've put in our own law from an international
21 standard point of view, if there's an issued tolerance
22 in Codex, then irrespective of what our tolerance is in

1 our law, we will accept for imports the Codex standard.

2 And again, because we recognize that we're not
3 about managing hazards, we're about managing risks.

4 And once we get away from that sort of focus on hazards
5 and procedural compliance and look at that wider risks
6 framework, there is so much more opportunity.

7 So getting out of our silos and looking at the
8 world being a global marketplace because your consumers
9 are no different from mine. You know, my kids have
10 lived over here, my kids have lived in Europe, so to
11 think --I want the same as my neighbors want.

12 And so I think the future is about less
13 differences and the least focus on procedural
14 differences and more focus on risks management and
15 cooperation and sharing.

16 MS. DeVLIEGER: Thank you very much. We're
17 going to conclude the question session now. And I'd
18 like to thank the FDA experts for the great questions
19 that you asked and the panelists for the great answers
20 that you have given.

21 We're going to turn now and invite testimony
22 from our stakeholders who have pre-registered to speak.

1 And the first person that would invite to the
2 microphone is Thea Emmerling Minister, Counsellor, Head
3 of Health, Food Safety, and Consumer Affairs Section,
4 European Union Delegation to the United States of
5 America. Thea?

6 MS. EMMERLING: Does it work now? Yes, yes.
7 Thea Emmerling from the EU delegation to the United
8 States. The European Union has a single market of over
9 500 million consumers and is committed to very high
10 standards of food safety and consumer protection.

11 In the EU, consumer protection comes first.
12 The EU has harmonized sanitary and phytosanitary
13 legislation which applies equally in all the 28 EU
14 member states.

15 An extensive body of EU food laws covers the
16 entire food production and processing chain from farm
17 to fork within the EU in one consistent whole.

18 These laws also ensure the safety of imported
19 and exported foods. Our food safety system is based on
20 three pillars: First, hygiene requirements throughout
21 the food chain; second, animal and plant health
22 requirements that guarantee the prevention,

1 surveillance, and control of animal and plant diseases;
2 and third, residue and contaminants provisions for
3 which we have the world's strictest monitoring system.

4 We have three layers of control in the EU Food
5 Safety System. First, food handling businesses have an
6 obligation to self-control. They are responsible for
7 the safety of the food and feed that they produce,
8 transport, store or sell. They have to put self-
9 controls in place and document them.

10 They have to identify and regularly review the
11 critical points in their processes and ensure that
12 controls are applied at these points. They must notify
13 authorities of the activities incorporating official
14 controls.

15 They must ensure traceability of ingredients
16 and products. They have to immediately inform the
17 authorities if they have a reason to believe that their
18 food or feed is not safe and immediately withdraw
19 unsafe food or feed from the market.

20 In these aspects, you will note that the
21 emphasis is very similar to that of the Food Safety
22 Modernization Act.

1 The responsibility lies on the food business
2 operator. Second layer, the EU member states or, in
3 case of imports, the administration of the country
4 where the business operates have the responsibility to
5 put official control systems in place to verify the
6 effectiveness of the self-controls.

7 This responsibility comes directly from the
8 applicable and uniform EU legislation, which is binding
9 across the EU. The EU Member States are responsible
10 for the enforcement of the EU law throughout the entire
11 food and feed chain, in the same way as state-based
12 agency officials enforce U.S. federal rules in their
13 states. Competent authorities must organize official
14 controls that reflect the risk of respective product
15 categories and verify that the activities of the
16 businesses and the goods placed on the EU market comply
17 with all requirements. All EU Member States welcome
18 the basis of transparent and coordinated control plans.

19
20 Three, a unique feature of the EU Food Safety
21 System is the third layer of oversight and auditing.
22 The European Commission audits the control and

1 inspection systems of the EU member States, and verifies
2 that they are effective from the farm to consumers.

3 This is one of the tasks of the Director,
4 General for Health and Food Safety, at the European
5 Commission. All audits carried out by the Commission
6 service are publicly available on the internet to
7 ensure full transparency.

8 In case of findings, the Commission starts a
9 rigorous follow-up process with the respective country
10 to remedy shortcomings. The Commission can also start
11 infringement procedures against EU Member States, which
12 means bringing them to the European Court of Justice in
13 case of late or noncompliance with EU law.

14 Countries importing food from the EU can thus
15 rely on the EU three layers control system as just
16 outlined --a rigorous system that no other exporting
17 country or entity offers. Therefore, import of EU
18 products in the U.S. have an additional layer of
19 consumer protection that exists nowhere else.

20 The EU and the U.S. have a long history of
21 safe trade in food. We welcome partnerships that
22 recognize the robustness of the entire food safety

1 system, which the FDA calls systems recognition.

2 The EU and the U.S. are currently actively
3 engaged and well-advanced in the mutual systems
4 recognition exercise. We see the U.S. as a natural
5 partner in food safety. We share the same values of
6 high food safety standards and consumer acceptance. We
7 also have similarly focused systems that place the
8 ultimate responsibility for producing safe food on the
9 food business operator. We see many advantages in a
10 close regulatory relationship through systems
11 recognition.

12 Systems recognition will allow the U.S. to
13 fully utilize and leverage on the assurances that the
14 EU Food and Safety System highlighted just some seconds
15 ago provides for U.S. consumers of EU imports.

16 The track record and high food safety
17 standards of EU producers allow more of a close working
18 relationship of the Commission and the FDA will
19 facilitate the, hopefully, successful completion of the
20 formalized systems recognition program between the FDA
21 and the EU. It will allow both to focus their scarce
22 inspection and audit resources on where the risks are

1 greatest and will, therefore, also directly benefit
2 public health. Thank you.

3 MS. DeVLIEGER: Thank you very much and before
4 you go if I could just ask the panel if you have any
5 questions? No questions. Okay, thank you very much.

6 The next person that I would like to invite to
7 the microphone is Ralph Ichter from Euroconsultants
8 Incorporated.

9 Okay. And then moving on from that because I
10 don't see Ralph in the audience, I would invite Tamara
11 Rasbury from the Japan External Trade Organization.

12 MS. RASBURY: Thank you very much. My name is
13 Tamara Rasbury from Japan External Trade Organization.
14 I would like to say a few words about JETRO'S
15 partnership with FDA since today's theme is
16 partnership.

17 One of JETRO's missions is to promote the
18 export of Japanese food to the United States in
19 addition to supporting Japanese companies operating
20 here in the United States. We would like to thank the
21 FDA for providing us with many kinds of information
22 that helps us with this mission. Last year, we had an

1 official from FDA come all the way to Japan to give a
2 lecture about FSMA. Thank you so much.

3 We believe it is important to keep Japan
4 informed about information regarding FSMA, and we would
5 like to ask FDA to continue to give us timely
6 information about it as far in advance as possible.

7 Our partnership with FDA is indispensable for
8 the important task of establishing a system that can
9 quickly respond to increase from Japanese companies
10 wanting to export food to the United States.

11 We would like to maintain this partnership to
12 help ensure that Japanese companies comply with FDA
13 regulations, including FSMA. Thank you so much.

14 MS. DeVLIEGER: Thank you. Any questions for
15 Tamara? No, okay, thank you so much.

16 That's going to conclude the testimony session
17 of this, and I'm going to turn this back over to Don
18 Prater so he can offer concluding remarks. Thank you,
19 Don.

20 DR. PRATER: Thanks, Deb. On behalf of the
21 FDA panel, I'd like to thank all the speakers for their
22 presentations and I'd like to thank everyone in the

1 audience, both in person and by webcast, for your
2 attention.

3 We've had two very full days of interesting
4 and insightful discussion that will be considered by
5 FDA, along with the comments and the docket. I'd like
6 to offer a special thanks to the International Affairs
7 Staff and CFSAN, the IAS team who have been the arms
8 and legs, to use the people analogy, behind this
9 hearing. And especially I'd like to thank Susan
10 Berndt, Wade Woolfolk, and Sandra Boston.

11 I'd also like to thank Juanita Yates and her
12 team for all their logistical support. Thank you very
13 much and that final plug, please submit your written
14 comments to the docket by May 15th.

15 Again, thank you for your participation and
16 this concludes our public hearing.

17 (Whereupon, the public hearing was concluded.)

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