UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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PLENARY SESSION

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January 16, 2013
9:00 a.m.

Patriots Plaza III
355 E Street, S.W.
Washington, D.C.

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Administrator
Food Safety and Inspection Service

MODERATOR: MR. KEITH PAYNE
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ALSO PARTICIPATING:

MR. TONY CORBO

I-N-D-E-X

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

(9:00 a.m.)

MR. PAYNE: Could I have everyone's attention? It's 9:00 now. We'll go ahead and get started with our meeting.

Well, good morning again and welcome for being here in D.C. on this nice rainy day. And I understand there are delays on the red line, so we do have some folks who will be probably joining us a bit later.

But my name is Keith Payne. I'm with the Office of Outreach, Employee Education and Training's Outreach and Partnership Division, and I'll be the moderator for the National Advisory Committee Meat and Poultry Inspection meeting today and tomorrow.

What I'd like to do first is turn over the meeting to our Committee Chair, Mr. Al Almanza, the Administrator of FSIS, who will give a welcome to you. And then after that, we'll have Dr. Elisabeth Hagen, our Under Secretary for Food Safety from the U.S. Department of Agriculture, give

some opening remarks.

So with that said, I'll turn it over to Mr. Almanza for a welcome.

MR. ALMANZA: All right. Well, good morning. I want to thank everybody for being here, all the new members and as well as all the old members, as well.

Boy, it's been a while, Art, hasn't it? Good to see you, yeah.

And so the discussions that you have here are really valuable to us and are always beneficial to bring new perspectives into the conversation.

Man, we have so many gadgets here, it makes me a little bit nervous that I'm going to knock something over, somebody's iPhone.

But I think that that's the beauty in these and that's one of the things that Dr. Hagen and I kind of miss about having regular meetings, is the discussions that occur and the things that this Committee brings to us and the ability to make decisions in the Agency. And you helped us, this Committee has helped us work through major issues

such as HACCP validation, making better use of the data we collect, and with pre-harvest interventions.

So the one thing that we can count on is that everybody's not going to agree. But that's not what this is about, right? It's not about everybody agreeing. It's about having an open and honest discussion of the important questions that we bring to you. That discussion will help us in our decision making, and it also will help the public and other stakeholders come to a better understanding of these complex problems.

So today we have a number of important topics to cover, over the next 2 days. In addition to the issues, we're also asking for your input on some other things which Dr. Hagen will speak to us in a few minutes about. We're also going to provide you with an update on international equivalence and the public posting at the establishment level with their data. These are both very important topics for the Agency.

And I want to thank Todd Reed and Mary Stanley for presenting them. I also want to

thank our Office of Outreach, Employee Education and Training, Michael and your staff, for coordinating this meeting and handling the logistics.

So again, I want to welcome you and thank each one of you for being a part of this, and I'm looking forward to a productive 2013.

With that, Dr. Hagen, your turn.

DR. HAGEN: Good morning and thank you for coming. Thank you for being part of this.

As Al said, it's always good to see some old faces that I haven't -- it's not old faces, right? That's terrible.

(Laughter.)

DR. HAGEN: So old friends. No, that's not good either. Some familiar faces. And some new folks here with us. It's good to get a new mix.

I will say that I think the Advisory Committee process, it can be -- I know it can be painful, right, the application process and the waiting and the selection and all that kind of stuff. And as Al said, not everybody always agrees. But I think the process and the concept itself is a

real gift. I think it's a gift to us as we make public policy. It's a gift to us, those of us who engage in the crafting of policy and the consumers that we all work for, who benefit from our public policy. It's to get the opportunity to have this diversity of perspectives and to be able to step outside of our own way of thinking.

You know, things can get a little bit insular and it's really good to be able to step outside of the way that we're viewing something and to hear what a diverse group of people has to say about where we should be headed. So I really think that it's a gift to us and I appreciate you all being a part of this.

And I know the Secretary really appreciates it as well. He's taken a great interest in the entire Advisory Committee structure, you know, wanting to make sure that the committees that we do have are truly functional and really informing very important decisions that we make, not just in food safety, but across the various missions at USDA. So I know he really appreciates the work that you're

doing here as well.

So collaboration. It's not just a talking point for us. Everybody in government talks a lot about the need for collaboration. We really believe that it matters, for all the reasons I just told you. And I think if you look at our strategic plan and you see that we've kind of staked it out there, too, and said how important it is to us, when you put it in a plan and when you make corporate measures that you're going to hold yourselves accountable to, whether you succeed or fail, you're telling the world that it's important to you. So this is part of what we would call enhanced collaboration with external stakeholders. That's what you'll find in the strategic plan.

So as Al has already alluded to, there are no easy answers to complex problems. We deal with that every day and we know that well. That's why we need your help to think through some of these complex issues. Over the next couple of days you're going to consider two very important topics. We're going to run through some things that you've heard

about before, and there are a couple of key questions we're going to ask you to turn your attention to.

Anybody who's paid attention to what we have been up to for the last couple years, or what we've been saying for the last couple years, as you've heard me talk a lot about prevention, as you've heard me talk a lot about data and the importance of data, how we make better use of data, how we develop policy that's based on good, sound scientific data.

So as you all know, the data that our inspectors gather in the field is a tremendous resource. Advancements in the collection and the use of this data has the potential to help us devise new innovative and preventive-based policies.

So now that PHIS has really been implemented, the Agency has a more comprehensive and, I think, complete picture of the work that our inspectors are doing at establishments. Collecting the data is just the first step. So the new challenge is really determining how we use it

effectively to identify problems in the establishments and prevent contamination and illness.

So in addition to helping us consider how we make better use of our data, you're also going to help us address the issue of the high percentage of positives for non-O157 STECs in veal establishments.

As you all know, we began our verification testing for six of the non-O157 STEC sera groups in June of last year, and this testing has found a higher percent of positives for veal than for other slaughter classes. So we've set out, as an Agency, to learn more about this trend. Through our food safety assessments and our on-site visits, we found several common deficiencies in the areas of sanitary dressing and antimicrobial interventions in veal slaughter establishments.

So today I'd like you to discuss how to correct those deficiencies and also how we communicate those changes to establishments, many of which are small or very small.

So over the past few years we've made a lot

of significant progress in implementing these prevention-based policies, among them, you all know, as I just mentioned, zero tolerance policy for raw beef products with the six non-O157 STECs; tougher performance standards for *Salmonella* and for *Campylobacter* in poultry; testing of additional components in our ground beef program; certainly a test-and-hold program. These are just a few that people are familiar with.

I'm proud of this work that we've done and I certainly think that we have a lot more to do. You hear me say it all the time. When it comes to preventing food-borne illness, we all have a role to play. Producers, packers, processors, consumers, educators, communicators, everybody's got a role to play. And we might not always agree on how we best solve these solutions, but I think we all agree that we need to do better than we've done before, and we all benefit by getting together and discussing new and more innovative ways to approach these problems.

So with that, I want to thank you again for giving your time, for being willing to be part of

this, and just know that it matters. People rely on the work that we do to keep them safe, to keep their families safe, and the work that we do is certainly supported by the work that you all are doing here today.

So I wish you all a very productive meeting. Al and I can't stay for much of the morning today, but you'll be here for 2 days and hopefully I'll be able to come back and visit with you all and just eavesdrop a little bit on what you're doing and what your deliberations are.

So thank you very much. And I look forward to working with all of you.

MR. PAYNE: Thank you, Dr. Hagen and Mr. Almanza.

And now I'd like to go over just some housekeeping measures for the meeting here. First of all, we have the staff, most of the staff from our Outreach and Partnership Division here to assist you, and I'd like to introduce them.

Ms. Sally Fernandez. I don't know if she's here in the room or outside. Dr. Jane Johnson and

Ms. Lindia Howell, who are at the desk, registration desk on the outside there.

And by the way, anyone who would like to make a comment during the public comment period, please sign up there at the registration desk.

Ms. Natasha Williams, who is standing up right here. Ms. Beatrice Herbert, here in the back. Ms. Diane Jones. She may be outside. Commander Jeff Tarrant. There's Diane over there. Jeff Tarrant. And Ms. Sujin Park and Ms. Songhee Lee, who I believe are outside.

If you have any questions about where to go, the most important thing, the restrooms, it can be a bit convoluted here, but there are restrooms here on this first floor. And I understand, I found out this morning, that whoever decided to start painting today in the hallway over there, it was unbeknownst to us, so we do apologize for that. We're trying to cease that operation, so it's not going to hinder progress to the restroom.

There are restaurants in the area, so during the lunch break, please feel free to ask our

staff here on recommendations. I know for the Committee members, I believe, in your binders there is a list of places for a quick bite to eat.

And if there's anything else you need, please ask them, ask us for help and assistance. We work here in the building, we know the area, we know the building pretty well, so we're here to assist and make you feel as much at home as possible, away from your home.

And now I'd like to introduce first, before we go around the table, is introduce the ex officio members of the Committee. And starting over here to my right is Dr. Arthur Liang from the U.S. Centers for Disease Control and Prevention. Dr. Liang is the senior advisor for food safety in the Division of Foodborne, Waterborne and Environmental Diseases. That's within the National Center of Emerging and Zoonotic Infectious Diseases of the CDC.

We just found out, we were going to have Dr. Jeff Farrar from the Food and Drug Administration, but just found out recently that he

could not make it. He's our other ex officio member. Dr. Farrar is the Associate Commissioner for Food Protection in the FDA, where he oversees and coordinates various efforts in the Office for Food Safety.

And then over here, she may rise, Dr. Danah Vetter. She's representing the National Association of Federal Veterinarians. And sitting next to her, to her right, is Mr. Justin Rhee. He's representing the Asian Pacific American Network in Agriculture.

We're very pleased to have you all with us.

Now for the operation of the microphones on the table. A very simple procedure. There's a button, should be a button in the middle. The red light means you're simply muted. But when you need to speak, just push the button, it turns green, that allows you to talk, at least to be heard across the whole room.

And so if we may start, for the record, just to start from my left here, just announce your name and affiliation, going around the table. And

we get to practice using the -- here we go. And I think the button is on the front side of the --

DR. HAGEN: Hello. Good morning. Elisabeth Hagen. I'm the Under Secretary for Food Safety and USDA.

MR. ALMANZA: Al Almanza, Administrator for FSIS.

MS. HARVEY: Good morning, everyone. Sherika Harvey from Mississippi. I'm a consumer safety inspector with the Mississippi Department of Ag and Commerce. And nice to meet all of you.

MR. WINCHESTER: Leonard Winchester, Local Public Health, Seattle, King County, Washington State.

MS. GAPUD: Veneranda Gapud, aka Veny Gapud, with Process Management Consulting.

MR. WARSHAWER: Steve Warshawer. I farm and ranch in New Mexico at Mesa Top Farm, and I'm also the food safety coordinator for the National Good Food Network of the Wallace Center at Winrock International, based here in D.C.

MS. KLEIN: I'm Sarah Klein. I'm a senior

food safety attorney at the Center for Science in the Public Interest.

DR. REINHARD: I'm Bob Reinhard. I'm Vice President of Food Safety for Hillshire Brands Corporation.

MR. WALDROP: Chris Waldrop, Director of Food Policy at Consumer Federation of America.

DR. CHEN: Fur-Chi Chen of Tennessee State University.

MS. BUCK: Patricia Buck from the Center for Foodborne Illness Research and Prevention.

DR. TILDEN: John Tilden, Michigan Department of Ag and Rural Development.

DR. MARCY: John Marcy, a professor at the University of Arkansas Center of Excellence for Poultry Science.

DR. RYBOLT: Mike Rybolt, Director of Food Safety and Quality, Hillshire Brands.

MS. DONLEY: Nancy Donley from STOP Foodborne Illness, formerly Safe Tables Our Priority.

DR. SHULTZ: Craig Shultz. I'm the

Director of the Bureau of Animal Health and Diagnostic Services, Pennsylvania Department of Agriculture, and I was a public health veterinarian in the FSIS field for 17 years.

DR. LORENZEN: Carol Lorenzen, a professor at the University of Missouri, and I have a teaching, research and extension appointment, and I work with small and very small processors and meat sites.

DR. LIANG: Art Liang, CDC, Atlanta.

MR. PAYNE: Okay, thank you. Now we've hopefully learned how to use the microphones.

And just for the new members, this is to the Committee. The way when we get into the discourse of comments among the Committee, when you want to make a comment, simply turn your tent card upright and I'll make note of it, to keep the order of the comments. And when you're done you can just simply put them back down in their location.

We do have a couple brief updates, as Mr. Almanza had mentioned this morning, and with some short questions and answers afterward. And

then we have the two issues to put forth to the Committee.

All questions should be directed to the Chair of this Committee and that is FSIS Administrator Mr. Al Almanza, or his designee if he is not present here. So any requests for announcements to make or to put anything out on the table, please go through the Chair of the Committee or his designee.

During the public comment periods that we have today and tomorrow, again, I would like to encourage anyone who wants to make a public comment to sign up outside so we have you on the list. We'll go down through the list in the order in which they're listed. And depending on the time, we may have to limit the time for comment to about a few minutes, but we'll gauge that as we go along, and we want to make sure that everybody has a fair shake at making a comment.

So with that said, I think I've covered basically most of the housekeeping measures. And just one final reminder. If there are any cell

phones, please turn them on mute or vibrate, so that it's not disturbing the meeting progress.

We'll start with our first update from Ms. Mary Stanley, who's the Director of the International Policy Division within the Office of Policy and Program Development of FSIS. She's going to give an Update on International Equivalence.

And Mary, I think we can get your presentation up here.

MS. STANLEY: Okay, thank you, Keith.

And it's a pleasure to have this opportunity to update you on recommendations that were made from this Committee from discussions, a 2-day discussion on international equivalence, as far back as 2008.

So I would assume some of you were not involved in the Committee at that time. But what we have done is taken into consideration the recommendations that were made. And so I will update that.

During the meeting in 2008, we requested guidance on whether the elements of the triad of

protection should be changed, and whether regulatory information and compliance history from the foreign countries should affect the audits and the reinspection activities at the port of entry in the United States; and as well, whether the scope and frequency of the on-site audits and the port of entry reinspections should be adjusted based on the capability of a country to share their regulatory information as well as their compliance history.

And those of you that may not be familiar with the triad of protection, that essentially is the approach that FSIS has historically taken for many years, dating as far back as the 1980s. And it's taking into account document analysis, the information on the verification activities from on-site audits, as well as the information from verification activities from port of entry reinspection.

And the Committee did recommend that FSIS should maintain that three-part approach to equivalence. And the Committee also directed the Agency -- that FSIS should direct the Agency

resources according to relative risks and historical compliance that each of the eligible foreign food regulatory systems have.

And so over the past couple years, FSIS has been very active in developing a performance-based approach for determining the scope and frequency of on-site audits as well as how we approach our port of entry inspection.

One of the other recommendations that the Committee made to us was standardization of its methods for collecting information from foreign governments. And so the Agency has developed what we are calling a self-reporting tool, which is a system that is designed to collect the information that the countries provide in relationship to their equivalence determinations. This starts at the initial equivalence, but it's also an ongoing equivalence.

And historically, we had approached equivalence with five risk areas. So with the updating of the self-reporting tool, we now comprise this or organize the information in six components,

and those are the government oversight, the statutory authority, and the food safety regulations that are in place in the foreign countries, sanitation controls, their HACCP systems, and then their chemical residue and microbiological testing programs that are in place.

This self-reporting tool is organized in three components and so that it's organized so that we have the component authority module, which collects the information in regards to outlining the country's system. The second module is a laboratory module, which collects the information in regards to their laboratory profiles, that conduct the analysis in the foreign country. And then the third module is set up to capture the establishment profiles for the foreign countries.

And this self-reporting tool provides the criteria in which we're making the assessment for equivalence. And then it also provides the ability -- we can take many modules and push those out to the foreign countries, so when policies change in the United States, we can collect the

information very quickly. And then as information changes with the foreign inspection systems, they're able to update this information to us.

So another recommendation that was made is specific elements incorporating the ongoing verification activities that are important for the success of this three-tiered approach.

So in relationship to the document reviews, we have developed a system that is going to assist us in regards to assessing the exporting country's ongoing ability and willingness to share data. So as I indicated, the self-reporting tool provides a vehicle in which the countries can transmit that information and we can house it.

But there's also a very important assessment that needs to be done, that we have developed a tool that is effectively called a level of advancement. And so that provides the ability, and it's designed in order for us to analyze the information as well as quantify the level of which the country is in compliance with our regulations.

The second area for the three-tiered

approach is in the area of audits. And in this area we standardized the application of the audit criteria and as well have established a mechanism to collect the historical information and evaluate that in association with the exporting country's audits.

And so what we have developed in this area is a component analysis and verification format, which is providing a systematic way of analyzing and verifying the principal components, the six components that I had outlined earlier, in regard to the foreign inspection system. And it also provides a new mechanism in which we can document those verification findings, which drives the end results of the outcomes, which is in a report from the audit activity that we have conducted, which is made publicly available.

And then, as well, another recommendation was for port of entry reinspections, is to target the sampling of high-risk products and high-risk imports. And that recommendation has been embedded in the updating of the Public Health Information System and the release of the import functions this

past May.

So as an Agency, we have developed a *Federal Register* notice that's outlining this new approach. And it is summarizing in a bit more detail, in regards to what the Agency is doing in this area. And that is currently in clearance and should be posted.

So if there are any questions or comments?

MR. PAYNE: Yeah, John Tilden's got a question.

DR. TILDEN: Can you help me understand the difference between a performance-based approach versus a risk-based approach? How are they similar or different?

MS. STANLEY: Well, the performance-based -- yeah, sorry -- the performance-based approach is based on the activities that are ongoing in the foreign country, in regards to their controls and how they meet the criteria. You know, taking, for example, the zero tolerance for *Listeria*. So we assess the performance of their system to be able to manage that and then factor that into the analysis

that we do. And that will drive, you know, how much testing we would do at the border, as opposed to -- and whether or not we feel a need to go into the foreign country to do an on-site audit and verify their controls.

MR. PAYNE: Mr. Waldrop, you're next.

MR. WALDROP: Thanks.

I wasn't on the Committee when this was discussed, so this is my first time coming to the Committee. So since I wasn't part of that discussion, I was a little surprised to learn that FSIS had made a lot of these changes prior to sort of post getting input from the Committee, but prior to any kind of *Federal Register* notice or public input or public comment.

And we saw that some countries, FSIS was determining that they wouldn't go and do in-country audits for 3 years and it wasn't really clear how those determinations were being made or what the basis of that was, and considering the importance of actually going into countries, seeing that the self-reporting that they're doing is accurate and valid

and you can verify that what they're saying they're doing is what they're actually doing.

When you do *Federal Register* notice, are you going to explain how FSIS will be making those decisions in the future, in terms of how often you'll be going into a country and how many times you'll be doing those sorts of in-country audits? Will that all be explained and described in the *Federal Register* notice?

MS. STANLEY: Do you want me to --

MR. ALMANZA: Go ahead.

MS. STANLEY: Okay. Yes, but perhaps not to the level of in-depth discussion that you seem to be seeking at this point.

And there is a companion document that will -- it's a performance-based audit and port of entry explanation that goes into far more detail, that will be available, that is linked with the *Federal Register* notice when that comes out.

MR. WALDROP: Okay, thanks.

MR. PAYNE: Okay, thank you.

Ms. Klein and then Ms. Donley.

MS. STANLEY: I think that --

MR. PAYNE: I'm sorry.

MS. STANLEY: -- Al wanted to follow up.

MR. ALMANZA: Yeah. But I mean, I think that some of the questions that you're asking are very relevant, I mean, because I do understand, not only for members that weren't part of the Committee, but for just the public in general, to kind of understand how we got to where we are. And I think that that's very critical to getting people to understand, okay, yeah, these decisions were made, but why were they made?

And so yeah, I'm for including some of that and also explaining exactly why some country -- we may be in some countries every single year, I mean, but it's going to be based on their history, based on the products that they're exporting to the United States. So it's not going to be just a uniform we'll be there every 3 years, but I think that we need to explain that in the *Federal Register* notice.

But obviously we're interested in the comments that you provide us, so that we can address

those and so that everybody will have a comfort level with what it is that our expectations will be.

MR. WALDROP: I think it's a matter of understanding your thinking and your reasons and rationale for doing it and what data you're going to be relying on to be able to make those decisions. I think that's the sort of stuff that I think the public needs to understand so that they can know that we'll go into this country once a year, we'll go into this country every 2 years, and what is the reason and the data and the analysis that helps back that up.

MS. KLEIN: Thanks. I have a question and I move for the Administrator's point of order.

So the first is a little clarification on -- I know that there's the in-country audit system. But then, when we have a particular plant in a foreign country that is found to be in violation, is there an automatic on-site revisit? So not just self-reporting after an identified problem is what I'm trying to figure out.

MS. STANLEY: I would avoid the use of the

word automatic. Certainly there would be situations where the -- there may be a situation where we would need to go back in. But keep in mind, the FSIS approach is a systems approach. And so we're evaluating the system and the controls of that national food safety system and the regulators in that country and their ability to deliver the program that we found to be equivalent to ours.

And so if we find, either through audit process or through port of entry violations, noncompliance, the expectation is an immediate communication to that foreign government and then they take the corrective actions that are necessary. And then we would verify that either through document review or, if warranted, it may trigger an on-site audit to verify it, depending on the situation.

MS. KLEIN: Okay. Just a point of order. Is it appropriate to recognize members of the public to ask questions? Is that allowed as part of the Committee deliberations?

MR. ALMANZA: Yeah.

MS. KLEIN: Yeah?

MR. ALMANZA: Yeah. I don't know if --

MS. KLEIN: Well, I just wasn't sure if there were specific questions. I did want to kind of draw people's attention to some specific information that was released yesterday from Food & Water Watch, that highlighted specific instances where this process seems to be falling short. I didn't know if Tony wanted to ask a specific question about that, but I wanted to give him the opportunity to do so.

MR. CORBO: Tony Corbo from Food & Water Watch.

I was designated to fill in, in 2008, parallel on that Committee. On this Committee. And never in my wildest dreams did I think that FSIS was going to scale back its international program, which consumer groups have held up as a model for FDA.

So instead of bringing the FDA up to the FSIS level, we seem to be going toward the FDA model, where we're going to let countries escape for periods of time.

We released some information yesterday of three countries -- two countries where audit reports were left off of the country audit reports that had been posted, one for Australia and two for Canada.

In the Australian audit, the auditor in 2011 visited a plant that was part of a pilot project to privatize inspection and your auditor, aside from the fact that the plant employees who were doing the inspection were part of a profit-sharing plan that the company was using to pay, which your auditor said pointed to a conflict of interest. But in the audit report that you posted for us that year said Canada continues to be a problem.

In 2006, the USDA Inspector General criticized the Agency in the way it was enforcing its equivalency standards on Canada. So what do you do? In 2009 you audit Canada. You don't go back to Canada until last year and it happened to coincide with one of the largest recall in the beef markets, a beef recall. Canada has a number of experiences. It also spilled over to us. And the plant that was

involved in that recall was the XL Plant 38. In 2009 you found major problems there. You did not go back until 2012. And the audit points out the fact that a 2009 audit of that plant pointed out some of the same issues, some of the same issues that the Canadian Food Inspection Agency cited in its internal review after the 2012 recall.

And then we're going to eliminate the border inspection program for meat coming in from Canada. You're involved in discussions with the Canadian government to eliminate border inspection and you want to do a pilot project.

So one of the plants involved in the pilot project is Maple Leaf Foods Plant Number 1 in Canada. In 2009, there were major issues, major food safety issues, in addition to the lack of -- in that plant, and you guys decided to take that plant as your model.

Excuse me. You're trying to deregulate the food inspection process for imports, just as you're trying to deregulate inspection -- and I really object to what's going on.

One other point. Mary, I want to ask you a question. How long have you been working in the policy division?

MS. STANLEY: How long?

MR. CORBO: How long have you been not in OIA, but in the policy division?

MS. STANLEY: Since about 2009.

MR. CORBO: 2009. So the reorganization of OIA started in 2009. All right, thank you.

MR. PAYNE: I'm sure there was a question.

MS. STANLEY: Okay.

MR. PAYNE: Ms. Donley, you're next.

MS. DONLEY: I actually have a couple questions. When this was discussed back in 2008, was there any -- was it recommended and/or is FSIS doing any weighting of the various elements, the three, the document reviews, audits, and port of entry reinspections? Is that being weighted in any way, as far as determining equivalency?

MS. STANLEY: The short answer is no. But the details of how we're approaching the analysis is outlined in the paper. So I'm not really prepared

to really go into the details at this point, but they all are equally important, in regard to making sure that the documents and all the results are factored in.

MS. DONLEY: Okay. And then this kind of dovetails to what Sarah was asking about, if I understood Sarah's question. And I've written down, is there anything in the program was similar to trigger a food safety assessment, you know, that is in the domestic arena, that there would be some event that would automatically trigger FSIS to conduct additional audits or whatever is necessary?

MS. STANLEY: Well, that is factored in, in regard to the level of advancement and the tiers that we have built into that, in regard to how well the plant -- excuse me -- the foreign inspection system is performing. And so that is modeled after the same principles within the food safety assessments that we use. And so that would feed in, in regard to the decision making, to whether or not we go on site or if there's an alternative mechanism to look at the noncompliances and the corrective

actions.

MS. DONLEY: Okay. Then my last question is, is back in 2008 -- and I'm grasping for -- the USDA, they're changing where point of entries, they're not -- what's that program? The international North -- you know, they're talking with Canada and with Mexico about not having inspections at the borders, the inspections. Do you know what I'm talking about? The White House, whatever they put together.

How does that figure into what you came up with back in 2008? That program, particularly with point of entry, there are going to be things where they get well into the -- this is my understanding of this program, which I cannot for the life of me remember the name of it -- where inspections are not going to be at the border or point of entry. It's going to be deeper into the distribution system.

Has FSIS kind of had any different discussions about point of entry inspections, where are they going to occur and how is this going to factor in on making these assessments about

countries? Because it's going to be further down the pike. And I don't know. It's a concern that I have because we're not going to be catching -- the point of entry inspections are going to be deeper into the distribution system and production system in the United States.

MS. STANLEY: I believe what you're referring to is the pilot program that Tony mentioned, in regard to beyond the border initiatives.

MS. DONLEY: Right, right.

MS. STANLEY: And certainly no decisions have been made and the pilot has not been initiated. And at this point, in-port establishments are located in close proximity to the ports of entry or the border crossings and the inspection activities are conducted there and through dedicated FSIS employees that are staffed.

MS. DONLEY: Okay. And I'm sorry, I missed that point about Tony bringing that up. I must've blanked out.

MR. PAYNE: Okay, we have a comment from

Ms. Buck and Mr. Reinhard and Mr. Warshawer, to round out this session here.

Ms. Buck?

MS. BUCK: My question is a little more specific and I don't know if you can respond to it right now. But I'm just a little bit concerned about our foreign equivalencies, okay? And I found that very surprising, that there is a Canadian beef establishment, from what I understand, that is now allowed to run a ham-style inspection. And evidently, again, from what I understand, that was predicated on a pilot study on pork.

How does FSIS go about determining how they will design something to be equivalent in a foreign country that we have not particularly accepted, such as ham-style inspections for beef in this country? I'm just a little confused as to what was the justification.

MR. ALMANZA: There were a number of things that occurred, Pat. So to determine equivalence doesn't necessarily mean that it has to mirror exactly what is done in the United States. Their

system has to be equivalent.

So it isn't that it has to be exactly as we do it in the United States. In fact, there aren't a whole lot of other countries that do it exactly like we do it in the United States. But the equivalence process, that's how they supervise, how they oversee the application of regulations, how they -- in the process of their inspection, how it is equivalent to what our expectations are domestically.

So it doesn't have to be exactly as we do it here, but it has to be equivalent to what our system is. And it's not proscriptive in how we determine their equivalence being exactly like ours, but it has to be determined to be -- the system has to be -- we make that determination.

MS. BUCK: That's helpful, Al, but you can understand my concern.

MR. ALMANZA: Yeah.

MS. BUCK: Because when I look at the food safety systems throughout the world, I know that the United States has its share of problems, but we still are the country that is helping to set the

standard.

So if we have not found something or proven something to be, let's say, acceptable as a way of doing business with slaughter, or with any other food, but it's just I find it curious that we would accept it from a country who has shown some proven food safety deficiencies, as far as I'm concerned, you know.

So I just wonder, is there a criteria that FSIS has set for establishing that equivalency? I realize there's always going to be differences and they're never going to do it exactly the way we do it. But surely we must have a broad set of they must have this, this, this, this and this.

And I would think there would be an amount of skepticism if a company from a foreign country was going to use an inspection style that we had not validated for use here in the United States. I caution FSIS to move too rapidly on things like that.

Thank you.

MR. PAYNE: Mr. Reinhard?

MR. REINHARD: I have just two quick comments. And first of all, Mary, I want to thank you. I do think it is great that FSIS comes back to the Committee with a topic that came up several years ago and updates. I think that's a great way to go about it to make sure we continue to move forward. And I know a lot of things came up in those years and in that time and sometimes, you know, remembering and getting back to it is difficult, but it's really appreciated.

And then my two comments, just for everyone on the Committee. First of all, I commend FSIS, because it was said, and maybe not directly enough, that you are the model when it comes to international equivalency and how you handle trading partners and imported product in the United States and what we go about to make sure that they are meeting our standards. And other countries and other agencies throughout the country try to model what you do. And so you should be commended for that.

My second comment is more for education of

Committee members, and that is that it isn't a one-legged regulatory stool that FSIS does for international equivalency. So if you are an importer or if you are a manufacturer of imported products, a further processor of importer products, there are other regulatory burdens that play a part in how that goes.

And so while international equivalency is one broad part of the process, there are very specific requirements on anyone who is importing product or anyone who is further processing or manufacturing imported products that are a critical part of the food safety system.

And so while there are challenges with all things, it isn't one-legged. And I just wanted everybody to know that it is very, very actually good, the way the systems work together and how the process is.

MR. PAYNE: Mr. Warshawer.

MR. WARSHAWER: I was not part of the Committee back when this question was brought, and I really appreciate it coming forward. But that also

means I may be somewhat ignorant of how the questions were addressed previously. My immediate impression is that what you're describing is a way of auditing each country as a system and based on that audit, making determinations as to how to proceed in that country with further verification.

I think there are some globally accepted standards as to how to audit systems. And I put forward ISO 9000 as an example. And I can't imagine an audit of a system that doesn't include an annual review. Whether that annual review dictates on-site follow-up is a product of the audit itself. But I also have never heard of an annual system review that didn't have some spot check involved.

So I think there are -- if we're auditing these countries as systems, there are some standards that need to be adhered to and we need FSIS to validate its system approach and needs to recognize and adhere to these standards. There may be a better one than ISO 9000, but I just mention that as a model.

And then I also want to know, because I'm

certainly new to this whole process, where does it go from here? If a *Federal Register* notice is made, first of all, background information with that notice is crucial for those of us who are newly in the loop or have been out of it for some reason can't engage that notice. And assuming that notice is complete with sufficient background information to elicit comments, what is then done with the comments?

I think it's super important, as we move into the -- continue to move into higher and higher percentage of product moving across borders, that our systems be accountable and then our verification of systems be accountable.

So I just expect this question to be a living question. It won't be done and we don't want to just hear nothing about it for five more years. So how will that aspect of the process be addressed?

MR. DERFLER: This is Phil Derfler.

When we publish the notice in the *Federal Register*, I mean, it will provide a broad context in which -- I mean, we're presenting our new approach.

We will be presenting our new approach to the world. So it is to provide an opportunity and provide the information I think you will need to comment on. On the basis of any comments that we get, we will publish a second notice that responds to the comments that we receive. If on the basis of the comments we think that there are changes to what we're doing that are necessary, we'll certainly make them. But the whole idea is to provide people with a broad picture, a broad context on what we're doing and provide an opportunity for public comment on it.

MR. WARSHAWER: Okay, I didn't get a response to the part about system auditing. And you know, I'm trying to be brief because I know we have 2 days of a lot of work ahead of us. I can't conceive of a system audit that doesn't include annual review, in nature, and annual on-site spot check.

So I'm asking that some summary of and rationale for the system approach that's been chosen, be part of the background and especially some explanation of the annual or cyclical and

preferably annual in-country presence.

Every system I at least personally have been exposed to does involve some kind of annual physical presence, and I can't think of a rationale that would eliminate that. So if it is not happening, there has got to be some explanation of why.

MS. STANLEY: Yeah. And I'll quickly respond because I know we have to move on, but I didn't want to leave you with the impression that we're not doing spot checks. And in lieu of ISO guidance for audits, we refer to the Codex guidance, which we were very active on the committee that developed the guidance for audits in the most recent updates. But there are multiple ways of auditing on-site, visual as well as the documents and supporting evidence. So that's all outlined in the *Federal Register* notice, moving forward.

MR. WARSHAWER: Thank you.

MR. PAYNE: Thank you, Ms. Stanley, and thank you all for your questions and comments on that topic.

Moving on, we are going to give an Update on the Public Posting of Establishment Level Data.

On the agenda, we had Mr. Jeremy Todd Reed. Unfortunately he's not able to be here today. So in his place we have Mr. Christopher Alvares. Mr. Alvares is the Director of the Office of Data Integration and Food Protection's Data Analysis and Integration Group. And I will try to bring up his presentation. No presentation?

UNIDENTIFIED SPEAKER: No.

MR. PAYNE: I'll just minimize this. I think it's just temporary. Okay.

MR. ALVARES: Okay, good morning, everyone. I don't have slides for the group today. I think really it's more of a kind of progress report and update. I think really the materials that everyone's going to want to see at the end is the actual kind of work products that we're finishing up internally now and starting to move through our governance process.

But we have been working on this for a while. This was a topic that was brought to the

Committee, I believe, 2 years ago and we've been doing a fair amount of work in the meantime. And we felt it was an appropriate time to brief the Committee, let you know where we're at in this process, and answer any questions that you have.

So just a little context for everyone. Again, I'm not sure if all of the Committee members here today were on the Committee earlier, but we had come to NACMPI with an issue topic about public posting of establishment data in 2011, I believe. And we got a number of recommendations. I think it was a very lively discussion, a lot of different perspectives. But we also got some recommendations, that it was in some ways a bigger topic than we could handle or that the Committee could really do justice to in just a 2-day session.

And one of the recommendations that came out of that was to reach out to some other groups that have experience in data posting, that could give us a in-depth assessment and look at perspectives in greater detail.

So what we did was we went to the National

Academy of Sciences and we asked them to also help us with this topic. I think one of the things that came out of the Committee is that posting establishment data sounds very simple in concept or in that sort of mission statement. But when you get down into the details, it can get a lot more complex.

So NAS in, I think, late 2011 had a series of meetings. They prepared a letter report, which they gave to FSIS, and in there they made a number of a recommendations. They did speak to a couple of other agencies as well. I know that they got input from a variety of stakeholders. And there are a number of issues.

One of the issues that really kind of, to us, came to the forefront is that we really need to have a data release or data posting plan. This process really started with kind of a charge to identify some datasets as part of data.gov and some of the open government initiatives. But really kind of what we heard from NAS is that we have to have a plan, we have to have a clear strategy that everyone

understands, that's kind of transparent, open to public comment, public understanding, public review. And so that's what we've been doing, you know, based on that report.

They also had a number of other comments about things like supporting that data that's posting in a variety of ways, documentation, infrastructure, IT support, and issues like that.

So we had a couple of -- in 2012, pretty much throughout this past year, we had a couple of meetings. We did some listening sessions with a number of stakeholders. Industry was one, consumers was another one. We also met with a couple of internal FSIS and some other kind of sister agencies, to talk about what their data posting policies were.

So we met with representatives from CDC and from FDA. We met with, actually, some representatives from Mine Safety, who post a lot of data publicly. We also talked internally with our FOIA office to understand issues that they go through when they're responding to FOIA requests. A

lot of FOIA requests involve submitting data to the public and having to address issues such as corporate confidential information, redacting PII and other types of information. And so we got input from them.

One thing I should mention is that when I say we, I'm talking about a workgroup that was formed within FSIS and has representatives from all of our program areas, whether they're generating data, analyzing data, writing policies based on data, whether they're involved in consumer outreach or training. So we have some representatives from all of our programs area that are also providing input into this process.

So where are we at right now? We sort of wrapped up some of our discussions at our meetings with stakeholders. We've gone through and kind of gone back to the desk, started writing and started drafting a strategic plan for data posting. We're really at the stage now where we've finalized a draft. We're ready to put that in front of our management and go through an internal clearance

process. We've committed, I think, through NACMPI and NAS and other conversations, to have a comment period. So what we'd like to do is once we've cleared this internally, we'd like to again put this plan out for comments, receive input, and then ultimately finalize it and use that as our guiding document for going forward.

So what's in this plan? I can't give you a whole lot of specifics. I don't have a draft that I can hand out today. But I can give you some big general areas that we're going to try to address in this strategic plan.

One area is guidelines. We want to put in writing some specific instructions for how to handle and how to identify PII, how to handle things like free text fields, sort of the level of data granularity or even the level of data aggregation. So some very general guidelines about what data needs to be pooled together when we say we want to release a dataset.

We're also going to put some instructions in there about documentation. One of the things

that we heard from NAS and from this Committee is, well, it was that it's probably not sufficient to just put a dataset out there and then kind of leave it to the public to figure out what it means, what to do with it, how to interpret it, or maybe, unintentionally, how to misinterpret it. And so there were several recommendations to provide context to that data.

So we're going to try to include the information about the data was collected, maybe what we see as some key sources of variability or things that we're familiar with, you know, or kind of pitfalls in analyzing the data that other consumers of the data might be interested in or should be aware of, things like associations to other datasets.

So if we're posting sampling data and it has some link to illness data in CDC, we'll try to incorporate some of those things, ways that we commonly use that data in the context of other data.

We're also going to define some criteria for data release. How do we identify all the data

that we have, what to release first, how do we prioritize, and how do we go ahead with those postings? And so we're going to try to identify or define some criteria to help us decide, is this ready to go, how much is it going to take to do this, and what are the process steps that we need to do?

And then, finally, there's the release process. So we have a couple of different forms where it can be released through data.gov, through the FSIS website. I know many people want to have machine-readable formats for data. So formatting of data was one area that was also brought up as a consideration.

Infrastructure support, as well, can be an issue. If we post it on our websites, we have to be able to make sure that they can be downloaded and that they're accessible and consumers don't run into issues with actually being able to use the data.

And then we also have, as with a lot of organizations, security issues that we have to keep in mind. We have to make sure we conform to our

security policies for posting data and allowing consumers to have access and those sorts of things.

So at a very high level, those are sort of the main themes that the report is coalescing around. And as I mentioned, we're finalizing that draft. We're getting ready to move it through clearance. I think it will probably be moving through our clearance process in the next quarter or so. So I think, publicly, we should be moving forward sometime this year. At least that's the timeline that we're working on right now.

So that's the update that I have. I'm happy to entertain any questions from the Committee or from the audience as well.

MR. PAYNE: Ms. Buck --

Mr. Waldrop?

MR. WALDROP: Thanks. Chris Waldrop, Consumer Federation.

I wanted to echo Bob's earlier comment about the usefulness of these updates for things that the Committee has previously deliberated on, to kind of give us an update of where you are now. So

I appreciate Chris coming here and providing that.

I also wanted to commend the Agency for sort of this deliberative and methodical approach you're taking to this, because I know it's a very complex issue. It sounds simple, but it's not. And I know there is a lot of stakeholder interest in it. So I think you're taking a very appropriate approach in trying to navigate those waters.

I can definitely see a lot of relevance to posting this type of data, particularly for the whole food safety community, when it comes to research and sort of making a lot of data available, particularly to researchers, who could then use it and help us get places where normally we couldn't or normally the Agency couldn't.

Just one quick question.

MR. ALVARES: Sure.

MR. WALDROP: In terms of, you know, you're looking at posting establishment-specific data. The Agency also posts a whole lot of aggregate data right now.

MR. ALVARES: Um-hum.

MR. WALDROP: Is the intention to continue to post that aggregate data and make sure to continue that process as well as this new one?

MR. ALVARES: Yeah, I think the short answer is yes. I don't see that this process would change in any way the data that we're currently posting or any sort of summary reports or analyses that result in postings that we do as well.

I don't think the intention of this is to move away from the Agency providing its own kind of summaries of data. You know, quarterly reports, annual report-type things I think will continue. Yeah.

MS. BUCK: I would have to echo, of course, what Chris said. This is very helpful.

This is Patricia Buck from the Center for Foodborne Illness.

I would think, at this particular point in time, that CDC has a huge backlog of data that needs to be released into the community.

Will this plan involve like a timeline of groups of data that will be coming out? Or how are

you, I guess, setting your priorities?

MR. ALVARES: Um-hum. So we won't have -- the plan won't have a specific list of datasets and timelines. I think that once we kind of -- once the plan is cleared and we can agree on a set of criteria for selecting datasets, I think then we'll have to go through the process.

We did get some feedback from, I think, NAS in particular, that they sort of felt that the most -- kind of the low-hanging fruit might be sampling data and those kinds of things.

So that may be where we're going, but I can't really say that we've got a deadline yet for when to post.

MS. BUCK: Has there been any input, like from the White House food safety group, working group, to provide you with some guidance for the specific needs of particular areas that maybe should be put on your priority list?

MR. ALVARES: We haven't received any direct guidance from the food safety working group or the White House, that I'm aware of.

MS. BUCK: Maybe that's something you should look into, because I think that there might be some topics of interest that might be beneficial to move this along quicker.

Thank you.

MR. ALVARES: Okay, thank you.

MR. PAYNE: Mr. Reinhard, then Dr. Tilden.

MR. REINHARD: So Chris, thank you. I just really have one comment and it is around the documentation when data is released. And this was extensively debated, I think, both by this Committee and NAS. And the Agency feels that they need to provide comment around the data.

I would continue to, as I have in the past, caution the Agency that providing data and trying to explain to the public what it means isn't necessarily your role. You may want to say how the data is collected and what the data represents. But to then go through and try to explain it, particularly when you look at releasing all kinds of establishment data, doesn't make practical sense to me. I think that is something that there are

numerous groups in the public that will do their own analysis and come to their own conclusion and will comment to FSIS or to others on what the data says. So I just caution you on that.

MR. ALVARES: That is a good point. I think that came up in our discussions with the Committee earlier, is what role the Agency would take in -- I don't know if facilitating is the right word, but participating in public analysis of data. And that's going to be, I think, a real challenge for us. I don't know that we've -- I don't know that we're really prepared right now to engage in analysis projects with a lot of academic organizations and such, or any of the kind of public stakeholders. So that is an issue that we're going to have to address.

MR. PAYNE: Dr. Tilden.

DR. TILDEN: Yeah, here we go. Coming at it from a state agency's perspective, I do think you've already heard the questions about all of the new systems that are evolving, credible in the eyes of external stakeholders. And I think it is part of

readership to be able to, using the buzz word transparency, to be able to articulate how information is being used and how it can be verified. And I think both FSIS and FDA share the same challenges of using limited resources to cover as much of the waterfront as you can.

MR. ALVARES: Um-hum.

DR. TILDEN: I don't see a way that you can get around being able to articulate what data points you're using to make decisions.

And I really do applaud FSIS for what you're doing with sticking with this. I would urge you to continue to come up with timeframes where people can see the fruits of your labors. I think if we go another year or two or three and we still have a plan that's under revision and data isn't -- even the low-hanging fruit, as you mentioned, isn't up there and available, the most useful, the most broadly interpretable information should be getting up there sooner rather than later.

MR. ALVARES: Okay, I appreciate that. I do think, you know, one area that's -- documentation

and context is really important and maybe one way that we may be able to judge whether data is ready to be released at the very granular detail level is maybe based on the level of documentation that we have out there already.

So we have put out a number of sampling plan documents and that may not be sufficient. I don't want to put those out as sort of the materials that would support those datasets. But to the extent that we have a lot of documentation out there, that may make it easier to move forward with those kind of datasets.

MR. PAYNE: Dr. Liang.

DR. LIANG: Art Liang, CDC.

And you may have said this and I'm just too old to remember a few nanoseconds ago. But did you seek -- of the people you sought advice from and consulted with, did you talk to anybody at NCHS, the National Center for Health Statistics?

MR. ALVARES: So I don't know which group within CDC the workgroup spoke to. I do know they spoke with representatives from CDC, but I can

follow up with you.

DR. LIANG: This is more for you than the --

MR. ALVARES: Um-hum.

DR. LIANG: They just have a long history of at least getting vital statistics and turning them into public-use data tapes. They'll probably have some experience with having this publicly available data that everyone is grabbing, whether it's researchers in academic centers or, you know, lay interest groups. So they just may have some things you can benefit from, what it would take to do the care and feeding of something like that.

MR. ALVARES: Okay, thank you, I appreciate it.

MR. PAYNE: Ms. Klein?

MS. KLEIN: Sarah Klein from CSPI.

I don't know whether this -- I don't think this was already addressed. But is the intention to go back in time to provide data that was gathered over the last 5 to 10 years, or just to be providing data contemporaneously going forward?

MR. ALVARES: Well, I think that will have to ultimately be part of the decision-making process. Just in a general concept, I don't see why we wouldn't be able to release historical data. But the more you kind of go back in time, the more you get into what I imagine is sources of variability or things that you have to be careful about with the data.

Even our sampling data, the way that it's organized in terms of data and things like project codes that have changed over time, and unless you're really familiar with some of those, you really need -- the further back you go, the more context you need as to whether data can be combined or whether it can't or whether our approach to sampling establishments was a simple random sample at this time and now it's a volume-weighted approach this year.

So those kinds of things, you're right. I mean, historical data would be good to release, but it does also add more complexity to what we have to put out. But I don't think that this approach would

involve sort of starting from this point and going forward.

MS. KLEIN: Okay, thank you.

MR. PAYNE: I see no further questions or comments.

Thank you, Mr. Alvares --

MR. ALVARES: Thank you.

MR. PAYNE: -- for your comments and questions.

We're running slightly behind schedule, so I'll pose a question to the Committee and our designated Committee Chair now, Mr. Philip Derfler. Do we want to take a break or plow straight through?

MR. DERFLER: Yeah.

MR. PAYNE: A break, okay. If we can abbreviate the break to try stay on schedule and get caught up. Five minutes. Does that sound enough?

Just ask the staff here where the bathrooms are or if you need anything.

(Off the record.)

(On the record.)

MR. PAYNE: There's a lot to accomplish for

the rest of the day. Okay, we've got a few remaining members who are coming in now.

Okay, we'll resume with the first issue we're presenting to the whole Committee. We have Dr. William Shaw here, who's the Director for Risk, Innovations and Management Division of the Office of Policy and Program Development, who will give an overview of the charge of considering the unique circumstances of Strengthening Verification of Sanitary Dressing and Antimicrobial Interventions for Veal Slaughter.

So Dr. Shaw, you can use the clicker here or use these arrows to advance your slides.

DR. SHAW: Okay. Good morning, everyone. And so we're going to talk about veal this morning. And I think this is a really exciting, sort of, opportunity for the Committee to provide us some input.

And so I'm going to -- just some objectives of what I'm going to talk about this morning. I'm going to talk about some identification of problem, how we came to realize the problem that we

identified with veal slaughter and veal products. I'm going to give a little overview of the analysis that we did to sort of further define the issues. I'm going to talk a little bit about some policy documents that we have issued, some policy documents that we have in draft, and some policy documents that we want to revise to address this issue. And then we'll talk about the questions that we'd like your input on over the course of the next day and a half.

So on Slide 3, as doing our normal analysis of FSIS verification sampling results, we had come to the conclusion that our test results for Shiga toxin-producing *E. coli*, which include our *E. coli* O157:H7 and not our non-O157:H7, sampling programs for veal products appear to have a higher percent positive rate than other larger cattle slaughter classes.

And what's on the slide, we have begun to sort of report out those results, separating out the larger beef cattle classes from veal, according to label designation. So that is the spot on our

website where that information is now being shown.

And then on Slide 4, this is just sort of a broader view. There is more information on the website, and which you were provided the link to sort of look deeper. But this is sort of like a snapshot and you can see the differences in percentages between the larger -- our verification results, sampling results of larger beef cattle classes and the veal, which sort of was a red flag for us.

And so when we saw -- when we looked at that data, of course we wanted to investigate as to what could be leading to that, to those differences in sample results. And so we looked at some reviews of FSA, food safety assessments, and we did some on-site visits in various veal slaughter establishments to sort of investigate more of the problem. And during the course of that analysis and those visits, we found that sanitary dressing and antimicrobial intervention implementation were common themes that we saw.

Sort of going a little deeper into that,

some of our key findings were that there was inadequate sanitary dressing procedures to prevent carcass contamination and creation of insanitary conditions; contamination with inadequate sanitary dressing procedures that then overwhelmed the antimicrobial interventions; and we also saw some ineffective implementation of antimicrobial interventions, mainly in issues with identifying the critical operating parameters and ensuring that they were translated into their process.

Some additional key findings for us, that veal industry may not consistently implement sanitary dressing procedures; inspection personnel may not consistently be enforcing existing sanitary dressing procedures at veal establishments.

And so some of those issues included identifying and implementing sanitary dressing procedures; identifying critical operating parameters and implementing them associated with their interventions; and then also an additional one of being able to relate their microbial data from both FSIS and their establishment testing, and then

analyzing that and then looking as to what does that tell them about their day-to-day process with respect to sanitary dressing.

And this is one example. There was a particular veal slaughter establishment. They had had multiple FSIS-positive STEC results in trim. The establishment's generic *E. coli* carcass results indicated also increasing contamination. And the findings of our investigation were that the establishment had a failure to relate microbial data to their slaughter operations. There was a disconnect. Sampling was being done, results were being filed away, but there wasn't that sort of carryover into what does that mean for my process.

And then there were also significant sanitary dressing deficiencies and ineffective implementation of their antimicrobial interventions. So this is just one example of establishment.

Going a little deeper into sanitary dressing deficiencies, some of the things that we observed were cutting through the esophagus during sticking or head removal without closing it first,

leading to a contamination with ingesta; failing to bag and tie off the bone, leading to carcass contamination; failing to adequately remove the hide so that carcasses are free of visible contamination prior to carcass washes.

Some additional things: failure to prevent the hide from contacting carcasses during hide removal, basically hides flapping and contacting exposed carcasses; failure to clean and sanitize hands, gloves, knives, and equipment as frequently as necessary; and routinely puncturing the GI tract during evisceration.

So those were some of the more sort of in-depth examples of sanitary dressing deficiencies. And then there were also some ineffective implementation of interventions.

In some cases we had carcass coverage was not achieved because carcasses were suspended from a single hook. So therefore you have both hind legs suspended from a single hook, which are not exposing the inner parts, so therefore antimicrobial intervention is not gaining complete coverage

because all areas were not exposed.

In other cases we had establishments were not implementing antimicrobial intervention so they achieved full coverage, in the fact that we had potential antimicrobial interventions for primals and sub-primals or trim, where product is stacked on top of each other, interventions where the top was exposed but the bottom that's on the belt was not exposed. We had situations where the sort of breadth of the spray was not wide enough to sort of cover the product that's coming along the conveyer. So various things like that.

And then also there's always an issue, when you're applying an intervention to an already visibly contaminated carcass, that you're just going to spread it around. So those were some observations.

And then looking at the critical operating parameters of some of their support documents, we had some establishments that the scientific technical support looked at -- showed the concentration, temperature, and pressure of the

antimicrobial intervention was important. However, we had some establishments where they were only implementing concentration as a critical operating parameter, leaving this sort of coverage issue and other aspects of the intervention unmonitored or unverified and unvalidated.

So that's sort of the overview of the observations that we found once we started looking at FSA reports, once we started going out into the field and doing observations, talking with our inspection personnel and gathering information.

So now we're moving into the part where, well, what are we going to do about this? So when we also looked at existing guidance and verification procedures, generally most of these documents, whether they're FSIS documents or whether they're industry documents, they focus heavily on the larger cattle classes. There's a heavy sort of -- you know, which over the years, I mean, that's what a lot of those documents focus on.

So when we looked at those documents, we potentially saw that there may be some gaps here

that need to be filled in, in any unique circumstances or unique situations, you know, for veal that we need to share and we need to get into the public domain.

So that's one of the concerns we had when we -- one of the existing verification procedure documents that we have as an agency is FSIS Directive 6410.1, which I believe you were provided a link. And this is the document that FSIS personnel use to verify sanitary dressing and other process control procedures. And when we looked at that, you know, we potentially have a concern that there may be some data gaps with respect to veal and we want to sort of make sure that we cover that.

And then one of the things that we did issue this year in response to the veal issues that we identified and I believe you also have, this one is FSIS Notice 1712, where we began providing some additional verification of antimicrobial intervention coverage of carcasses at veal slaughter establishments. And so this was an initial document that we put out.

And then we're also developing -- as we gain information and we're moving forward and gathering information, we also have in draft a sanitary dressing verification FSIS notice for inspection personnel, which we provided in draft form, where we are providing additional clarification to our inspection personnel, in addition to the 6410 directive, on specific things with veal, some common deficiencies, relating microbial data to slaughter operations, assess associating noncompliance reports to strengthen enforcement. And you'll see in there we've used a number of photos to aid understanding best practices and deficiencies.

And then also we're in the process of revising the 2002 beef slaughter guidance, and we have provided discussion points of where we're going, where we see we want to go with that document. And so we want to make sure that this revision has what it needs to have in there with respect to veal.

And that takes us to where we want you to

help. And so we are requesting feedback on these various documents that we have either issued or are in the process of developing. And we want to make sure that we incorporate any additional aspects unique to veal that have not been covered in the past, since we realize that most documents out there have focused greatly on the larger slaughter classes. We're requesting your innovative ideas on how we get this information out once we put the documents together. And we have some questions to pose for you and they sort of follow along with what I've said.

So the first question for the Committee is, What improvements can be made to the existing sanitary dressing verification procedures (FSIS PHIS Directive 6410.1) to address unique aspects of veal slaughter and processing?

And so breaking that down:

Are there instructions that do not apply to veal slaughter establishments?

Are there instructions that need to be added to address unique aspects of veal slaughter

and processing?

Should the frequency of sanitary dressing verification be different for veal as compared with beef?

You know, those sorts of questions we'd like input on.

And then Question 2 is, What improvements can be made to the draft notice on verifying veal slaughter sanitary dressing to address any additional unique aspects of veal slaughter and processing not currently in the document?

You know, members of my staff and others have been gathering information and we believe that we've made a good -- we have a good draft that's working, but we would like to have additional input from the Committee, if there are additional things that we need to add.

And then Question 3 is, What improvements can be made to the 2002 beef slaughter compliance guidance document to address unique aspects of veal slaughter?

Again, you know, what guidance, you know,

may apply to larger cattle, but may not apply to veal? What needs to be added that's unique to veal?

And we have provided -- I think we provided a one-pager that sort of, you know, outlines what our general outline of what this document is going to look like to provide to the Committee with a little bit more context. But we're in the beginning stages of this one, so we don't really have a draft yet that we could share.

And then Question 4. And this will probably permeate through Questions 1, 2, and 3. But we wanted to make sure that we put this on your radar screen, that, are there differences in the classes of veal between, you know, bob veal all the way up to heavy calf, that impact slaughter and should be pointed out in the FSIS policy documents?

You know, in these cases, sometimes size does matter with respect to especially sanitary dressing and the antimicrobial interventions.

And then Question 5: What innovative strategies can the Agency use to help industry and FSIS inspection personnel better understand the

needs for slaughtering animals used to produce veal products?

And so this is more of a communication question.

And with that, that sort of concludes what I'm bringing -- what we're bringing to the table. And so I think we can offer any questions.

MR. PAYNE: Thank you, Dr. Shaw.

And I see a number of tent cards have gone up immediately, so questions, comments from the Committee. And I missed whoever was first over here, Dr. Reinhard or Mr. Waldrop.

Dr. Reinhard?

DR. REINHARD: Thank you, Dr. Shaw. I have like five questions, so I'm going to try to go through them pretty quick.

Can you explain what specifically is unique in the slaughtering and harvesting of veal compared to beef?

DR. SHAW: I think those are some of the things we're asking the Committee to share with us. But from our point of view with what we have seen so

far, it's a lot about size of the animal and how that affects movement through the slaughter process and sanitary dressing and difficulties that kind of come from that.

And then sometimes, with the antimicrobial interventions, we have potentially seen some establishments that, you know, most of the interventions, most of the guidances that are out there are for bigger, larger beef cattle. And some of the veal slaughter establishments are trying to retrofit certain types into their specific situation.

And so we do believe, you know, there are some potential unique -- and then there are also some things about, you know, what they're coming in with their diets or the different types of diet, withdrawing situations, you know, how the rearing -- well, the short rearing process can then potentially add some challenges at the slaughter site. Those are the kind of things I think --

DR. REINHARD: Okay. And then I'll ask one more question and I'll save the rest because they

may get asked by someone else.

The data showed veal, traditionally small and very small -- you talked to that specifically -- versus beef plants or, you know, all beef, I guess. But that would include very large manufacturers that certainly do have a lot of guidance and a lot of food safety intervention in place.

Was the beef small and very small compared to veal? Did you guys look at that as a comparison and take out the large beef manufacturers? Because the number of samples and the rates would skew the data and it's not really a direct comparison if you look at what's there. So I wondered if you saw that data.

DR. SHAW: We do look at that data. And if you look at the percentages, even if we take out the large beef slaughter establishments, the percentages for small and very small, larger beef cattle, they're not going to be anywhere near the veal. So if you're thinking about a small versus large, that was not a correlation we saw.

MR. PAYNE: Mr. Waldrop?

MR. WALDROP: I have a couple questions about just the industry itself, just to give us some perspective, and then a question about enforcement and kind of what you're asking.

So first, can you just give a little bit of information about the industry itself? How many veal plants are in FSIS's catalog? And then, do veal plants only slaughter veal or do the slaughter plants do both veal and beef?

And then my last one is, does veal go into other products? So like, do trimmings from veal, does that go into ground beef or is it only just veal is veal is veal?

DR. SHAW: Okay. So I'll start with the third one and work my way back.

So as far as various products, I think there's no one answer to that. For the most part veal, there's an economic incentive for veal to be veal, because of the differences in price per pound that come along with veal.

And so, for the most part, if establishment is -- if there are mixed establishment of producing

veal and products from larger cattle, you know, they're going to use their veal products for products labeled as veal because of the economic incentive.

I would not, you know, discount the fact that an establishment may have a small amount of veal trimmings left over of an insignificant amount and it may get put into traditional ground beef production because there isn't enough to really do anything with it. I mean, that's possible.

And so then your second question was establishments, do they do just veal or do they do -- the largest veal slaughter establishments in the country, they are for the most part veal and all veal all the time. They do various age ranges of veal, but they're typically veal all the time.

Now there are some very small establishments across the country that will do a mix. But they're not only doing a mix of larger cattle and veal. They may have some pork in there. You know, they may have some swine in there and they may have some various other things. So they've got

a lot going on.

And so then your first question was just sort of the veal industry as a whole. We have for the most part the heavy veal slaughter establishments technically under our house of terminology. They're considered small establishments just because -- and that's number of employees. Generally, none of them have over 500 employees, so they're not going to be in that large establishment category.

So the largest of the veal slaughter establishments are technically in that small category of 10 to 500 employees, and we do have some that are in the very small category.

For the most part, we have 32 establishments that produce like 99-point-something percent of all the veal produced in the United States. And I don't have that point in my mind right now, but it's 99-point-something. And so those are 32 establishments.

And just for the Committee to also know, in looking at our sampling results, those 32

establishments also do a combination of slaughtering animals and fabricating those animals on site and there are also a large percentage of those establishments that are slaughtering and sending out whole carcasses for further processing at another establishment or even a retail establishment.

And that's a verification sampling challenge that we're working through right now to make sure we sort of cover that aspect of sending out whole carcasses, because our MT60 sampling program is, you know, sort of pointed at trim produced at a slaughter establishment. So we have some situations where trim isn't produced at a slaughter establishment. But we're working through that.

But -- so does that sort of help --

MR. WALDROP: Yes.

DR. SHAW: -- give like a sort of overview?

MR. WALDROP: Yeah. And then I had an enforcement question also.

DR. SHAW: Okay.

MR. WALDROP: In terms of these deficiencies that you're finding, that you kind of laid out, is -- are inspectors writing NRs for those deficiencies now, or are you finding that your directives and notices aren't sufficient to be able to write the NRs you need to right to be able to hold these plants accountable for --

DR. SHAW: We have a mixture and I think that's what -- when, you know, being honest, when we went out and we did our sort of discussions and we did our sort of investigations, we had a mixture. I think, to be honest with you, we had some issues going on within the Agency, of people realizing that veal equals beef and that all of the expectations that we've traditionally considered with larger cattle, that we call the term beef, also apply to young cattle, often called veal, but still beef. And so we have a little bit of that issue, which has led us to the notices that we have issued to this date.

You know, with these additional policy documents, we want to strengthen that knowledge

that, you know, veal equals beef and sort of strengthen that enforcement so we are getting the NRs consistently written that we need written.

MR. PAYNE: Ms. Donley?

MS. DONLEY: Thank you.

First of all, I'd like to thank FSIS for looking into this particular problem. And I guess my rhetorical question is what took you so long? HACCP has been around for decades now, going on decades. And some of these things you point out, when I was reading this on the plane, I just was absolutely flabbergasted because they're so basic. This stuff is just so, so, so basic to HACCP and sanitary procedures and all the other things.

Chris actually, because great minds think alike, had asked a lot of the questions that I was going to ask. But two that I still do have is to his point of understanding the industry a little bit.

Is this a scattered industry? Is it concentrated more in one geographical area of the country or is it kind of scattered geographically?

DR. SHAW: Okay. So looking geographically, it's a water -- what's really funny, and it's a water-related industry and a dairy-related industry. So if you look at the two coasts and you know, the Great Lakes area, where you have dairy production, you'll find -- with some exceptions, you'll find most of the veal slaughter establishments because of the bob veal issue, you know, being gotten from the dairy industry and sort of moving to slaughter. So most of them are on the coasts and in the Great Lakes area, where you have high dairy production. So that's generally where you'll find veal slaughter establishments.

MS. DONLEY: Okay. And then my second question is, do you have a timeline for when these materials that you're talking about will be going out?

And then just as a suggestion, since I'm not on the Subcommittee, is that as far as communicating to these, when you're communicating, and the fact that these are very small plants and establishments that you're working with, I think

sometimes a picture says a thousand words. And like, you're incorporating them in your materials, which is great. You might want to think about doing something that just about everybody has and that is they can play a DVR. Make a DVR and use that as a visual, again, visuals where you can educate --

DR. SHAW: Yes.

MS. DONLEY: -- in a very simple way.

DR. SHAW: Yeah.

MS. DONLEY: Do you have a timeline?

DR. SHAW: Oh, timeline. So we have the notice that has draft written all over it. That one is fairly far through clearance. So you know, with the input of this Committee, we can expedite and get that first one out and then follow up with sort of then incorporating it into the larger guidance document that we want to revise this calendar year and moving on with the other issues. But yeah, that notice is something we really want to act on.

MR. PAYNE: Next, Dr. Shultz?

DR. SHULTZ: I'll go back to Bob Reinhard's comments just a bit to point out that I think that

comparing sanitary dressing procedure and pathogen reduction intervention methodologies between veal slaughter and beef slaughter, I think that there is -- it would be very useful to compare how sanitary dressing procedures and pathogen reduction interventions are applied in small veal slaughter plants, or veal slaughter plants in general, compared to small beef slaughter plants. Because I think there is not that attentiveness in the small slaughter operation, especially with pathogen reduction interventions, for all of those specific parameters.

I mean, you go into a large beef slaughter plant and they are adjusting and they're monitoring every inch of that carcass to see whether or not the PRI gets there and how much of it gets there and at what pressure it gets there and at what temperature it arrives there. That just doesn't happen in small slaughter facilities, whether they're beef or whether they're veal.

So I think it would be useful to really have some data to say this is a small plant issue

versus a beef versus veal issue, to make sure that the comparisons are useful.

The other comment I would have is that I think, in terms of the beef and veal industry as a whole, there's no greater case for pre-harvest intervention and pre-harvest considerations than there is with veal. Bob veal calves are immunosuppressed if they didn't get colostrum, and that is a significant problem in dairy calves that come to slaughter.

If you look at calf environments on farms, the level of STEC contamination in those areas on the farm is going be much higher with the calves than it is with the mature cattle because of immunity.

So I think you're starting out with a much higher risk, much more pathogen-exposed individual, when you deal with a bob veal calf.

And I think there again, across the various types of veal, I think there are -- if you compare the level of sophistication in slaughter processes and sanitary dressing procedures in, say, the

formula-fed veal versus the bob veal industry, I think you'd see some significant differences, again, because of the organization of the industry and the tools that they have available to them.

MR. PAYNE: Ms. Buck?

MS. BUCK: This is Patricia Buck.

And I would absolutely agree with Craig because I think you have an opportunity here, with your interest in why veal is more a high-risk product, to do some really creative research into the pre-harvest conditions of these animals in particular. And I think that FSIS should become creative and find ways to do that type of research so that we have a better understanding of what's going on with these animals.

Just like children are not the same, they're not little adults, calves are not just little calves, and they have particular problems. One of their problems might be something as simple, that when slaughtering does take place, you may have during evisceration, a much higher level of episodes where cross-contamination from the intestines

occurs. And I think that would be something that the industry needs to investigate very thoroughly, because this is unacceptable numbers, as Nancy said. They're just way too high.

Thank you.

MR. PAYNE: Next, Ms. Gapud.

MS. GAPUD: I agree with what Nancy said, but I think it's really about time for us to do -- for FSIS to really do work in the veal.

What I can think of here is, historically, I think the focus is mostly on beef. So maybe, and again I say maybe, the veal industry is not paying as much attention because the Agency is focusing more on the beef.

And also, how many establishments did you study where there is a mixture of veal and beef processing? Do you know?

DR. SHAW: Off the top of my head, I don't know the exact number. But the larger veal slaughter establishments that we were in and investigating, they stopped at heavy calf. It's like the very small establishments that you'll see

some larger cattle being slaughtered in the same facility.

And you also have some situations where establishments will, on different days, like you'll have some small and very small establishments where on certain days they'll do veal and then on other days they'll do different species or larger cattle. So it may be a separation by days, not necessarily days of the week, where they're doing different types of species and classes.

MS. GAPUD: Yeah, because in my previous experience in my previous career in the slaughtering plants, when there are animals like -- of course, it's hard to really come up with just uniform size all the time.

Let's talk about chicken. It's hard, okay, and some companies, some establishments, maybe they have higher counts because -- especially for the smaller birds. And so that can be what's happening in the veal. Okay, sometimes their machine, they won't bother to readjust it in order to really clean the inside of it. So that's one thing that you have

to look at.

And then the field with the rollout, again it's very, very important because that's where you can have all the contamination coming out, especially, of course, there's lots of things, lots of factors in the design of the machine, in order to clean the whole thing inside, that can cause contamination.

But I'm just trying to share with you the experience I had in my previous career, where there's that smuggling issue again with the sizing of the animals, because there's no way you can always have the same size, that that machine will really work 100 percent. Okay, there's no 100 percent. There's always a change. So that's when you -- that's why I asked you, especially those establishments where there's more of like mixture --

DR. SHAW: Um-hum. Yeah.

MS. GAPUD: -- I think you can see that a lot. But I encourage you to also look at the farm, on how they are doing it, and I think that will help a lot.

Thank you.

MR. PAYNE: Next, Mr. Winchester.

MR. WINCHESTER: Leonard Winchester, King County Health.

You did answer most of my questions already. I just had one regarding the actual data collection for the veal. There's like 32, 30-some.

Do you know how many plants that actually came from? Was that from just like 5 or 10, or was it actually just from one, in comparison with the number of beef plants?

DR. SHAW: Oh, the 32 establishments that I talked about, they are slaughter establishments.

MR. WINCHESTER: Yeah, the actual number of the on-site core, you have like 3 positive out of 38 samples and 3 out of 23 samples. Do you know how many plants where that data came from? Was that from one facility or from multiple facilities?

DR. SHAW: Oh, are you on Slide 4?

MR. WINCHESTER: Yeah.

DR. SHAW: Okay. So when we look at veal, for the most part, not all -- and what I said

before, with our sort of trim versus shipping out whole carcasses --

MR. WINCHESTER: Sure.

DR. SHAW: -- we have our MT60 sampling program. I mean, establishments are in a frame and then the sample allocation happens.

And so I think in the Committee we can get like all of the fine-tooth data on what -- but it does not represent every veal slaughter establishment because we have some issues where some of them are not fully being sampled the way we would like them to be sampled at the moment.

So I guess I'm trying to understand what you're really trying to get at, so I can give you what --

MR. WINCHESTER: In getting from out of 38 samples, did those 38, where three positives came out, was that from a random sampling of 38 inputs or from just five plants or seven plants?

DR. SHAW: No, it's not from five plants.

MR. WINCHESTER: Okay.

DR. SHAW: It's 38 samples from our

universal MT60 sampling frame --

MR. WINCHESTER: Okay.

DR. SHAW: -- of, you know, all of these slaughter establishments, including beef and veal, the larger beef classes and veal in our MT60 frame, sampling frame, and how they're allocated according to risk. And then what those 38 represent are 38 samples where veal was indicated that that product was labeled as veal.

MR. WINCHESTER: Okay, thanks. Most of the other questions I had are already answered.

I did want to acknowledge that when I read through the stuff regarding cattle of any age, many times there's a reference to beef and I can see that somebody reading that might think, well, you're not really representing veal. And I can see where you guys have already identified that. So just reading it myself it's hard --

DR. SHAW: Yeah, there's a semantics challenge going on in that.

MR. WINCHESTER: Right, right. And I'm glad you already acknowledged that that's a

potential problem.

MR. PAYNE: Next, Ms. Klein.

MS. KLEIN: Thanks.

As an outsider to the cattle industry, I find it amazing that there is a semantics problem here. Like, to me, it's the same animal and so I'm just kind of surprised that this is happening.

Okay. So I have a question for USDA and also a question for Art from CDC. And I don't know if either of you have this kind off the top of your head.

But the question for USDA is whether you all have a sense of the consumption data around veal as compared to beef, you know, segregated out from beef, whether we know what the universe is on consumption in terms of veal.

DR. SHAW: Off the top of my head I do not know, but it is much less than, you know, beef from larger cattle. And I think probably during the course of the sessions, we can get some more information.

And I don't know if Art, off the top of his

head -- but we can get some to give you an idea.

MS. KLEIN: Okay. So my question for Art is slightly different and that is, do you know off the top of your head, whether veal is appearing as a separate category in the outbreak data?

You know, CSPI has -- I was just texting with my office and they were providing me some outbreak data, but it doesn't mesh with these sampling results.

And so I am concerned that there are a number of veal illnesses or outbreaks. And if they're sporadic, then of course that's why they're not getting counted. But if there are outbreaks that are being categorized as beef, because we have in our database -- I think they just told me -- you know, our database, just for those of you who don't know, is a subset of CDC's data. We take only those outbreaks that have a fully identified food and pathogen combination. So we're just a tiny subset of CDC's full data.

But we have 12 outbreaks, less than 500 illnesses, and none of those outbreaks have happened

after the late 1990s. And so that doesn't mesh with the rates of contamination. And so I'm wondering whether we're seeing -- whether it's all being lumped together as beef.

DR. LIANG: I don't know and I can find out. But my experience with that is that I wouldn't be surprised if veal problems, if any, are not -- are buried in this larger category. And without taking a lot of the advisory's time, that's a continual issue.

Previously, there was a question about -- a legitimate question, meaning years ago, about blade tenderized beef and we had the same situation where we looked at it and there was a lot of beef being mentioned, but blade tenderized wasn't -- we weren't getting that level of granularity through our reporting system.

MS. KLEIN: Right. I mean, just to try to -- yeah, just to build on that, you know, CSPI has been looking at the granularity of data. Right now, we're in an ongoing project and there are -- within beef there are several discreet

subcategories. Blade tenderized, of course, is not one of them, but you can separate out steak, for example. Ground beef, of course. And there are some others that we've been able to tease out from the data. But I don't think veal is being captured in that granularity.

MR. PAYNE: Okay, next, we have Dr. Rybolt. And then after Dr. Rybolt, just to round out our comments so we don't get too far behind on schedule, I have Ms. Harvey, Dr. Shultz, and then Dr. Vetter.

Dr. Rybolt?

DR. RYBOLT: To follow up on Leonard's question, he asked a question about the data that's represented here, how many plants were there, and I think it'd be good to have the fine-toothed data when we get in the Subcommittees, to understand how many plants that represents.

But also on the survey itself that you guys did and looked at the FSAs, how many plants was that? How many surveys or FSAs? I mean, you said earlier 32 plants.

DR. SHAW: Yeah. We're probably over 10.

I know it was a combination of visits and looking at FSA reports and also participating in food safety assessments. I know we're over 10 establishments and we may be even higher than that. And when we get into the Subcommittee, we can give you even more fine-tuned exact numbers.

DR. RYBOLT: Thank you.

DR. SHAW: But I know we're over 10 establishments, and we may be closer to 15, with respect that we were sort of looking at.

MR. PAYNE: Okay, next, Ms. Harvey?

MS. HARVEY: Sherika Harvey.

I would first like to point out that I agree with everyone's comments thus far, somewhat. But to say that it's basic, I understand that from an exterior point of view. But from an inside point of view, it's actually quite complicated.

But bottom line, I think where the problem lies is there needs to be more room for enforcement of these regulations and such.

MR. PAYNE: Next, Dr. Shultz.

DR. SHULTZ: A very quick comment. Just in

comparison of beef to veal, I think it's important to remember that we never see clinical colibacillosis in mature cattle, or hardly ever, but we constantly see it in young calves. It's a well-established syndrome. So you certainly have a different breed of cattle in terms of a slaughter class.

And in terms of the products that are produced and the way they are consumed and the way that they are prepared are entirely different. Ground veal is a very frequently produced product, but I don't think it's consumed in a rare presentation very often, because it's kind of a white meat and it doesn't look so great compared to a nice pink hamburger.

And in terms of the way veal products are produced and consumed, I think it's much different and I think that does have an effect on what we seen in terms of disease data.

DR. SHAW: Are we done?

MR. PAYNE: We're a little bit over.

DR. SHAW: Well, I just want to say that

when the Subcommittee gets into their discussions, you know, for the most part, I'll be there.

And then I just want to point out to key members of my staff, we've been working on this subject for now, you know, months and months. Dr. Jan McGinn and Dr. Selena Kremer will be with you also throughout the day and we can sort of get some of those more fine-tuned information and sort of provide even additional context as you're talking and discussing and provide whatever help we can.

MR. PAYNE: And the next final comment or question is coming from Dr. Vetter.

Dr. Vetter, if you'd like to come up to the table here.

DR. VETTER: I think I'm loud enough.

MR. PAYNE: Or use the microphone.

DR. VETTER: I just have a quick question about the data itself and then what you found, if you found any higher risk than the veal categories themselves, because you talk about size being a big factor -- with our positives.

DR. SHAW: I would say that, for the most

part, what I'm going to say right now is not statistically significant because we don't really have -- if you look at the end of the sample, I'm not going to have -- what I'm going to say is not going to be statistically, you know, supported.

What we did see were some trends because of this fact of shipping out whole carcasses that really aren't represented in our sampling right now. So some of the larger -- it's a little hard to say one way or the other, but the bob veal and like -- yeah, that's the trend one from what we can ascertain from the data that we have so far.

MR. PAYNE: Thank you, Dr. Shaw and the Committee, for your questions and comments on the first issue.

Moving on to our next issue is the Review of Criteria for Categorizing Public Health Related Regulations. And we have Mr. Christopher Alvares at the podium again.

MR. ALVARES: Okay. Thanks everyone for having me back again. I'll move through this fairly quickly. I know we're a little bit behind time and

I do want to make sure we've got time for questions. So I'll try and move through it as quickly as I can and then leave some time before we break.

So just as kind of a background. This isn't an entirely new activity for FSIS. In fact, we've been using data about our noncompliances and the regulations cited before, for scheduling and prioritizing some of our activities, like FSAs. And part of some of the material that was given to the Committee was our public health decision criteria report, which was put out -- posted on our website in 2010, which really characterized our first implementation of this approach.

And one thing that we did was -- and I'll talk a little bit just to give everyone some context, a little bit about that process as well, to put everyone into -- to give everyone that context.

So we've been doing this for a little while, but we're here today because we're really making some advances in our approach and making some updates to our process and we're really looking for the Committee to help guide that. We really got

some good feedback the original time or the first time with engaging stakeholders, getting some public comment, and we really are looking for that as we go forward here.

So just to start out. These are the questions we have posed to the Committee and I mention them here so that we can keep them in mind as we go through the talk and go through the questions and answers.

We have an approach that I'm going to lay out in the presentation. We're really looking for input from the Committee, comments on the approach that we're using. We've kind of moved to more of a multi-step process. We're taking a little bit more of a data-driven approach in terms of selecting the regulations, and I feel like that's giving us a more robust process. But we'd like the Committee to provide comments on that.

We're sort of starting this process by defining four broad criteria that we're using for selecting regulations. And so I've described them here, but we also would appreciate the Committee's

input on whether we've encompassed what we think are the major public health areas or themes for noncompliance to focus on.

And then, finally, we're trying to link some of these reg citations and noncompliances with outcomes. We focused on pathogen results because they're really fairly directly linked to the establishments and to the products that we're doing the inspections on. Obviously less so, ultimately we'd like to be able to link public health outcomes, illnesses, but that's a much more difficult connection. So we've defined our outcomes as our testing data, but certainly we'd appreciate comments on that, as well.

So I mentioned the public decision criteria report. This was published in 2010, but really informed by an NACMPI meeting in 2008 and NAS input in 2009.

For context, this decision criteria is actually a set of seven criteria that we use, and those are laid out in the report. I'm on Slide 6. This W3NR rate that we're going to be talking about,

or the revision to it that we're going to be talking about today, is one of those seven decision criteria.

So there are a number of others, including enforcement actions, recalls, human illness outbreaks that are linked back, and pathogen testing as well, our other criteria that we use for the same sort of decision-making approach.

The W3NRs are a little bit unique in the sense that they're focused on noncompliances. They're using cut points that are based on sort of industry trends or industry averages and then looking for establishments that are well above that. That's a little bit different than the others, which are more event based and a single event would drive that.

In the W3NR, what I'm calling here the W3NR approach, a single NR is not a criteria for scheduling an FSA, but at least at this approach.

This W3NR criterion that I'm talking about, that we were using in 2010, 2011, had a set of 62 regs that were selected. These were chosen by FSIS

staff, but based on a number of inputs from program areas and based on their experience and understanding of noncompliances. But certainly there was a call at the time for some broader input on this process. And that's something we had committed to do in the decision criteria report.

So that's sort of how we got to the original W3NRs. Some examples of the regulations that got included or selected through that process are on Slide 8. Things like failure to maintain HACCP plans, keep CCPs under control, failure to take appropriate corrective actions, those are the kinds of regs cited that were included in those 62.

And for reference, the report, there's a report that was given to the Committee prior to today and in there -- I think it's Appendix 1 or Appendix A -- it has the originals, these W3NRs that I'm talking about, that we've been using historically.

We do have a need for updating these regs, and that's part of why we're here today and part of why we're making some of the changes that we are

now. Certainly, the implementation of PHIS changed in some ways the data that we have. The inspection fundamentally hasn't changed, but some of the data that we capture in our systems has changed, and that's allowed us to -- really allowed us in one way, and maybe forced us in another way, to take another look at how we're calculating W3NRs. Are we taking the right approach or do we need to make some adjustments based on the data we're capturing now?

And we did determine that we need to reevaluate. So that's what we've been doing over the course of the past year or so. We've been analyzing the data we've been gathering from PHIS. We've been doing a variety of analyses on inspections. And that's really informed where we're at today.

So we do have an update to the W3NRs and I'll walk through that process. It's outlined in much more detail in the report that was given to the Committee.

One thing I do want to highlight in particular is that we'd like to -- we are changing

sort of the name. So we've often referred to it as W3NRs, and almost, you know, in every conversation I've had, everyone asks, what does W3 mean? It becomes sort of a distraction almost. So what we'd like to do is kind of rename it. It's not because we really are changing the purpose or the mission of this activity or this criterion, but just because we think it would be clearer to describe it as the public health regulations that we're using.

The other reason is that NR isn't really the way that we're thinking of it now. In the past, in our prior system, we really were looking at noncompliant NRs, as we call them, because that's essentially how they were recorded in the system. With PHIS we now know what regs are being verified when a test is being performed. We've always known regs cited when there's a noncompliance. But really we're down now at the reg level. And so it's not NRs per se. It's really public health regulations that we're looking at.

Our approach is also here on Slide 10: to define a set of evaluation criteria; to develop a

list of candidate regulations by applying those criteria to the regulations and our understanding of noncompliances and their impact on -- the potential impact on public health; and then, finally, to use data to inform and select really a subset of those.

So in the second bullet, to develop a list of candidate regs, that's really sort of a first pass based on our subject matter expertise and our understanding of the regulations. We think that these are ones that we should analyze and are candidates for using. But ultimately we're trying to use data to really select what we think are the informative regs. And we also have a process where we'd like to continue to evaluate that on an ongoing basis and update it as the data informs that.

So here's sort of our process schematically: define a set of selection criteria; select the candidate regulations; narrow down our list using data, including noncompliance rates and our pathogen outcomes, and then apply that final list to an ongoing process of evaluating establishments and scheduling or prioritizing for-

cause FSAs.

For comparative purposes, I think really the earlier approach didn't go through quite as many steps or maybe didn't outline them in the procedural way that we're trying to do now. We really originally focused on kind of the second box here, select a candidate set of regs, really analyze that set as a whole and apply it. Now we're trying to add more data to inform that and kind of weed out the ones where we just don't have enough data to support it at this time and move forward from there.

But in a lot of ways, it's very similar to the approach that we had been using and we think that that's been working well. But as I've said, we want to be able to advance it and also update it with the data that we have now.

So I've talked about the four criteria. They're outlined here on Slide 12: regulations concerning establishing and maintaining HACCP plans and critical control points; maintaining sanitary conditions; preventing adulteration; implementing effective corrective actions. Those are really the

broad categories that we're looking at.

And the failure to do those is what we're thinking about as we look at the regs and we say, is a noncompliance in this reg likely to kind of fall under one of these four criteria? And if they are, then that's a basis for including it in our candidate list, assuming we recognize that not every noncompliance has the same level of, maybe, significance or severity.

And so to that extent, we're trying to looking at this in a more holistic sense, look at a set of regulations, look at a set of noncompliances, and use that to inform it.

But at the same time, if the noncompliances associated with a certain reg are so, maybe, variable in their nature that they're just not informative, we're going to take that information also and use that to try and help evolve our process and gather the right kinds of information that we need to make those kind of distinctions. I'll talk a little bit more about that further on.

I mentioned Step 2. Selection of the

candidate regs is really applying these criteria to the regulations. We've gone through and done that already. That's part of what's in the report sent to the Committee. And as I mentioned, we're looking for comments on that. But we do think that it helps the Committee to kind of assess how the Agency is moving forward by seeing how we would apply these criteria. So you can see there, there's kind of the set of regulations that we would apply using the criteria. Or identify it, I should say.

So there was a set of 143 regs that we defined as candidate regs because of kind of a number of complexities with implementing the C.F.R. in the information system that actually maps to about 118 regulations.

What do I mean by complexities? Things like we don't map down to every paragraph level to our information system. So some of them might be -- a number of paragraphs in the C.F.R. might be encompassed in just a higher order regulation in there.

So for example, in the example on the slide

here, there are a number of paragraphs, 381.1 Part I through IV, that relate to pathogen testing. But in PHIS, they all fall under 381.1. So that's where we kind of had to map what we identified in going through the C.F.R.'s to what we have in our PHIS system.

And then, finally, the third step is to take that list and, through data analysis, try to identify the ones that are the most informative, that are supported by data, that are supported by outcomes such as pathogen positives, and use those in our decision-making approach going forward.

So of those 118 candidate regs, PHR regs, 28 of them were identified as being higher in the 3 months before *Salmonella* positive, six for *E. coli*, and at the moment we're only looking at O157. I think we're going to -- we need to gather some more data before we start including non-O157. But that's fully the intention of the Agency. And four for *Listeria*.

Some of these regs, there is some overlap in these regs, so they aren't purely distinct. When

you combine them, you get 33 regulations that we've identified as being important, based on the regulations and being supported by data that we have in our systems.

A fair number of those overlap with our earlier list. Sixty-four percent really map, in terms of one-to-one exact matches of regulations. But the overlap is even higher when you start to talk about sort of broad themes. And I think I have some examples coming up.

These are some examples of regs or, I guess, sort of the categories of regs that were selected for the public health PHR approach, that are in common with our prior set of W3NRs. One example here -- and like I mentioned, this is sort of more at the higher level theme. For example, the last one on the list is specify risk materials.

There were regs in the original W3NR list. There are also regs related to that in the PHR list, but they aren't the exact same regs. They're all related to SRNs and from that perspective, we feel we've captured noncompliances related to SRNs. But

the more data-driven approach, I think, selected a different set of regs than what we had earlier.

And we have some that are a little bit different. The specific regs are mapped in one of the appendices to the report that we sent. But there are some regs that were selected in this current approach, that were not in our earlier list. And there are some broad theme examples here. Protecting products from adulteration at all times. That sort of means even including transport and some of the other, maybe, points in the process that we don't normally consider; evaluate the effectiveness of SSOPs, et cetera.

So where are we at today? As the Committee, we've gone through and we've applied this process. We've gone and we've identified a set of candidate regs. We've done some analysis to show you sort of where these candidate regs would result in a final set of public health regs. And you can get some context as to what a PHR list would look like if we were to go ahead and implement today. We do think that that's a fairly good overlap with our

past approach.

So we do have kind of a set, as we move forward, that we feel is pretty consistent with before and better informed by data analysis. We do have plans that we would like to start using this approach this year. I think we feel that we're pretty close to being ready to go. And we do plan to reevaluate. And I'll talk a little bit about that.

In terms of using the public health regs, the PHRs, as I mentioned, are one criteria. So this would be added into the overall decision criteria approach, one of the seven that I mentioned at the beginning of the talk.

And I want to reiterate that the intention isn't to have a single noncompliance trigger an FSA. So there are situations where a finding at the plant is egregious enough that we would want to act based on one observation. And there are procedures within the Agency to be able to act upon that. This decision criteria isn't that approach. This is much more of a data analysis prioritization process. But

if there's a really discreet event, that would be handled separately from a PHR decision criteria approach.

Okay. And then, similar to the approach we used before, we would evaluate the 3-month period prior to an establishment and use that and compare it to what we call cut points or levels that we think either would warrant prioritizing that plant on an FSA schedule or maybe prioritize other activities.

So how does this apply to an ongoing process? Right now, what we would do for our decision criteria is, on monthly cycle, we would evaluate and make recommendations. Each month we select establishments for doing FSAs, and this would be incorporated into that monthly cycle.

So what we would do is compute noncompliance rates for establishments based on this set of public health regulations. We would compare that establishment's rate to cut points for similar establishments and, if selected, they would go on to a schedule for FSAs. That would then go out to the

districts. And ultimately they sort of make the decisions about where to do them and what time to do them, but it's very much informed by this.

And certainly for-cause FSAs take a higher priority over routine FSAs. But even if we had just done one the month before, that might also inform their decision making about when to do an FSA and where to do it.

So some related topics, because I know that there are a number of activities that this may inform or may raise questions about. What about the candidate list, this larger set of list, that don't get selected through the data-driven process? So they're in the larger set of 118, but they're not in the smaller set of 33.

One thing that we plan to do is to continue to reanalyze the data, as I'd mentioned, and we want to develop a process, probably on an annual cycle, to make any updates that the data informs us we should make.

But we also recognize that there's a need to understand why we may feel that these are public

health important, you know, significant regulations, but are not necessarily supported by data. Is that just because we have insufficient data? Is it because we need to provide more guidance to the field about when to cite certain regs? Is it because of a number of things that maybe we just don't -- you know, a number of things that we could use to kind of improve our process and provide a feedback loop?

So we are going to look at those regs that aren't selected and try to identify whether there are things we can do to improve how we cite those regs, how we evaluate them in the context of inspection, and use that going forward.

And I'm sure I'll get a question about changes to regulations, including the proposed poultry slaughter rule. Certainly we don't see any -- I think that the way that the proposed rule is written will certainly be supported by this approach. Although new regs would come out as part of that proposal, assuming it moves forward, those could be incorporated into this process.

And as I mentioned, by having an annual update cycle or a continuous evaluation process, we would be able to integrate any changes to our inspection into this process.

Future updates. I've talked about this a couple times. We've put forth a plan here, so we would welcome comments. We'd like to be able to analyze this data as we go forward. With PHIS data, there's a lot that we could still learn from that. There are a lot of questions that we're working through. But we also think that, over time, policies and regulations that are put forward can inform how inspection is being done in the field, and we want to be able to respond to those changes in terms of data.

So if we're making -- you know, adding non-O157 STECs or *Campylobacter*, we want to be able to add those, and if there are regs that haven't been selected, that are informed by those, we want to be able to add that in a process that we think is timely and informative.

We also recognize that that has to be a

transparent process. Everyone has to understand when that's happening. And I think, to be fair to all parties, people have to be able to react to that. They have to be able to adjust to things that we're seeing in the data. And so we've defined an update cycle that we think meets a lot of those needs.

Roughly speaking, you know, just to kind of put something out there that we've discussed internally, is that we would analyze these regs on -- you know, probably late spring, early summertime, come up with our -- what we would think is any updates we need to make to the PHR list. We would communicate those probably no later than June. That gives really a full quarter of time for people to understand what updates are coming forward from the Agency and how we're going to apply them, and really probably in the October timeframe, implement those.

That gives about 90-day period for everyone to understand if there are any changes to the regs and what those changes might be. And 90 days is the 3-month period that we're looking back in time for.

So I think it sort of -- the timing of that cycle just works well for the entire process.

It also allows us to get any materials out that we would have for stakeholders, for within the Agency, those sorts of things as well.

Stakeholders, as I mentioned, is another area where we need to be able to share information about this process on an ongoing basis. With the original W3NR approach, there were a lot of questions and a lot of interest.

Establishments want to know, where do I stand? How do I figure out if I'm likely to be above this cut point? You know, how can I -- if I'm seeing that information, that gives me some context to maybe act upon that and take some corrective actions to try and address those before they get beyond the 30-day window and become a bigger issue and just really move quickly. So that's one area that we see is important. Establishments need to know where they are in this process.

They also need to know what the cut points are and what they're being measured against. And I

think there's a broad interest in that process as well. So what do want to do is make those cut points broadly available.

So an establishment may know, okay, my rate is X. It might be 1 percent. But the cut point, I think all of the industry is going to want to know what their cut point is. We can either tell everyone individually or we can just post that broadly. I think that the easiest way is to just make that broadly available.

And certainly the original 2010 decision criteria report, which really looked at, as I mentioned, all seven criteria, that certainly needs to be updated. There were a number of analyses about how does this work if you do this every month for a period of a year? It gives you some context about are establishments getting selected multiple times, how many are getting selected, you know, what's the number of FSAs that might be scheduled as a result of this process? So those are things that we want to be able to update and also make available.

So in conclusion, and I know that this has been a very high-level presentation, but I think we have a more transparent and data-driven process. We really are trying to analyze each reg and make decisions about those regs. We are trying to evaluate each reg in the context of these criteria. And I think that that gives everyone a better understanding of why we selected what we selected, you know, what that basis is. And I think, based on input from the Committee and some guidance and discussions going forward, we hope to be able to incorporate a lot of that and improve this process, as I mentioned, as we go forward.

So just to bring everyone back to the questions that we posed to the Committee. I talked a bit about our overall approach, defining a set of criteria, selecting regs based on our understanding of the regs and our understanding of noncompliance with those regs, and then to analyze those informed and changed regulations against testing data to try to identify the ones that really can be used in a data-driven selection process.

So we're looking for comments on that approach, feedback on how to improve that as we go forward. Does the Committee have comments on the four criteria? And are there comments particularly on the outcomes as well? Are there other outcomes that we should think about as we go forward? You know, I mentioned some other pathogen ones. But certainly I think there are some other ideas where, with more data or maybe we just don't have the right kind of data right now, that we might be able to eventually incorporate some other outcomes as well. And we certainly would be interested in feedback on that that might help drive future efforts in this area.

So I know I moved through that fairly quickly. If there are questions, I'm happy to entertain them, and then I know we'll have a lot more time for Q and A in the Subcommittee group.

MR. PAYNE: Thank you, Mr. Alvares.

We're at 11:51. On the Agenda we should be at lunch, so I'll put this before the designated Committee Chair, Mr. Derfler. In terms of the time,

do you want to allow for questions, so we don't move too far behind our schedule?

MR. DERFLER: We should take questions.

MR. PAYNE: Okay, we're going to take a few questions and the first tent card I saw go up was Ms. Donley's.

MS. DONLEY: Thank you. Mike takes care of my mike.

Chris, I have two -- and I'm on the Subcommittee, but two overarching things that just kind of jump out at me and maybe you can talk them off the cliff.

I think the whole group -- what I looked at, when I looked at this table of the current W3NR lists, they all looked critically important to me for public health.

MR. ALVARES: Um-hum.

MS. DONLEY: I mean very, very, very important. And obviously, you know, a group had put a lot of input into this one, developing this list to begin with.

To go from that, how many is it down to?

Was it 118 to 32 or 64 to 32?

MR. ALVARES: Um-hum.

MS. DONLEY: Roughly cutting it in half. I'm very concerned of the impact that it can have on public health and safety.

MR. ALVARES: Um-hum.

MS. DONLEY: For instance, what's -- I'm going to give you just to for instances. 311.16 is not going to be on PHR, which is carcasses so infected that consumption of meat may cause food poisoning.

And then the second one I'll bring up is 417.6, which is inadequate HACCP systems due to plant and operation not meeting requirements, personnel not performing the specific HACCP plan tests, failing to take corrective action with records not maintained or adulterated product shipped.

And maybe there are components in them, in some of these other ones, to understand that. Because I'm not an expert in these, I don't know what's falling out during this process.

MR. ALVARES: Right.

MS. DONLEY: So that's concern number one. And then concern number two is how -- and I wish Stan was here, Stan Painter -- is how is this going to make the inspectors' jobs out in the field -- I'm very concerned that this could get very complicated if they keep shifting. They're used to dealing with all of these now. So if we keep changing the rules of the game as you reevaluate -- and I love the fact that FSIS is reevaluating. So anyway, those are the two things that really jump out at me.

MR. ALVARES: Okay. So I'll try to address them, but we can probably talk in more detail in the Subcommittee.

You're right. I think that the larger set, the candidate regs, you know, I think there are certainly ones in there, and I think probably all of them, that when you read them you can say yes, these kind of make sense if there's a noncompliance that could be a significant public issue, potentially.

The reason that they didn't get into the 33 that we selected from this analysis we've done

already, is that we didn't see them linked to pathogen test results, which is really, I think, one of the outcomes that we see as supporting evidence, you know, that product might have a pathogen on it, that there's an increased risk. We didn't see that in the data analysis.

Now does that mean that next year or with more data, that it couldn't get included in the future? It certainly could and that's why I think the reevaluation process will help to inform that.

But I also think we have to take those kinds of observations and try to understand why they didn't get -- why they aren't supported by data. Is it because we need better understanding of when to cite those regs? Is there just something about how we're implementing those regs in our inspection process that is not informative enough?

So that's where I think, internally, we should do a reevaluation to try and assess why are these regs that seem so important not being linked to outcomes like the pathogen test results?

So I'm hoping that what we'll be able to do

is eventually refine our process. You know, in some ways, you know, getting down to the reg level is a bit more detailed than what we've done in the past. I mean, we've always needed to have an understanding of the regs and we've always needed to do tasks. Right now, with PHIS, they're going through and actually checking off which regulations they verify when they do a task. And I think that's providing some more prompting as to what regs they really need to be verifying when they do an inspection, and I think it's kind of a reminder. And that may evolve over -- you know, as they get more comfortable with those regs.

The other part of your comments were about sort of the impact to the inspectors in the field. The way that we're implementing the decision criteria is to prioritize FSA scheduling. And FSAs are really conducted by the EIAOs. So it's sort of in some ways, you know, we're not directing tasks to inspectors based on these PHR outcomes.

I do think that inspectors may have an interest in their establishments getting selected in

this process. I think it's important to understand that certain regs can inform this process. But we aren't directing tasks to inspectors based on the public health regs. They're really tasks that are going to the EIAOs for more in-depth analysis or assessment.

I think that kind of addresses the question about inspectors, but if not, we can certainly talk about that more.

MR. PAYNE: Next, we have Dr. Chen.

MR. ALVARES: I can repeat questions if we need to.

DR. CHEN: Fur-Chi Chen.

My question is related to the criteria you use for the public health outcome, the pathogen test result.

And the three pathogen lists there, are they all applied to the all the species, like beef versus poultry, or do they have any different focus on particular product, like a ground product or cold cuts?

MR. ALVARES: Yes, that's a good point. We

don't test every establishment and product from every establishment for every pathogen that we've listed there. But I do think that by analyzing those pathogens, we've covered a pretty broad range of establishments.

So for example, *E. coli* is most commonly tested in raw beef products. So that covers a lot of our beef establishments. *Salmonella* covers a lot of our poultry establishments, raw poultry products. *Listeria* covers a lot of our ready-to-eat and processing establishments.

So I think that we've covered some really broad categories there. But you're right, it may not -- not every pathogen is in every establishment or tested in every establishment and we don't have pathogen outcome or positive data in every establishment.

MR. PAYNE: Okay, next, we have Dr. Tilden.

DR. TILDEN: Chris, just a quick question. Are you going to be with us today? Do you have the inspections from your staff?

MR. ALVARES: Yes, yes, I'll be here.

DR. TILDEN: Okay. And the way you calculate noncompliance rates under the existing one, it's not weighted towards any one of the regulations?

MR. ALVARES: No, it's not. You know, all the regulations in the PHR list are treated equally.

DR. TILDEN: Okay.

MR. ALVARES: We do recognize that there is a lot of variability in the frequency of verification of regs and some regs can be cited or are part of multiple tasks. So it's not necessarily a one-to-one relationship between regulations and tasks performed. They could do five different tasks and the same regulation could be verified under any of those five.

That's something that we've identified as maybe a future need. I don't think we quite have the data that we need to get to that level. But we'd like to understand more about, when regs are being cited, which tasks are they performing when they cite that.

And we've talked a little bit about the

nature of the noncompliances. If we can elucidate that some more, that might also help inform. Eventually, that could evolve into some weighted approach, but I think that's going take a good bit more work and it's going to be -- you know, if we were to go in that direction, it's a much more complex thing to describe and characterize.

DR. TILDEN: Also I just wanted to commend you guys for getting us out the information ahead of time. An inch of documents is a bit stiff to review in a day or two over the weekend. But I really do appreciate it, because it's good quality information.

MR. ALVARES: Thank you.

MR. PAYNE: Next, we have Ms. Buck.

MS. BUCK: Basically what I'm interested in is the data. I do strongly believe the data will lead us out of a lot of situations.

Is there any plan, as we are compiling this data, to bring it into some kind of way of looking at the high-risk products or those plants that have extremely poor histories?

MR. ALVARES: Um-hum.

MS. BUCK: I mean, just collecting the data is not going to be enough to solve some of the problems we're facing.

So is there an FSIS plan to correlate or bring together these other factors?

MR. ALVARES: Well, I think certainly the Agency looks at how their approaches are effective or working, and one of our measures that we keep an eye on is -- that we're trying to evaluate is how often are establishments being selected by these criteria. Are we getting similar to or maybe analogous to residue repeat violators? Are we getting plants being selected multiple times? And certainly if there are, you know, what's going on in those situations? Are we doing FSAs? Are they effective or are we resolving the issues? So that's one level, I think, of feedback in this process. How is the process working in terms of operationally?

I do think we need to try to identify ways to improve how we document an inspection and use

that for informing our process. But I also think that, you know, if there's input from the Committee on how they think we should try to evaluate this as we implement, you know, we certainly would like to hear that.

MS. BUCK: Well, I'm not on that Subcommittee, but I certainly hope that the people who are on that Subcommittee will ask that very specific question.

Thank you.

MR. PAYNE: Next, I had on my list Dr. Reinhard. I noticed you put your tent up and then you put it down.

DR. REINHARD: It was answered.

MR. PAYNE: Okay, his question was answered.

And next is Mr. Waldrop.

MR. WALDROP: Thanks.

So the second cut of PHRs that you're doing is looking at whether or not an NR occurred in a 3-month period before a positive for pathogen, is that correct?

MR. ALVARES: Yes.

MR. WALDROP: Okay.

MR. ALVARES: Well, I guess maybe just to clarify a little bit, not so much that they occurred, but are the rates of those PHRs higher in those establishments than in ones that didn't have a positive?

MR. WALDROP: And for that data analysis you used a period from January through July of 2012 --

MR. ALVARES: Yes, yes.

MR. WALDROP: Is there any impact on what the data showed? For example, you have, I would say, a couple months high-prevalent season, but not the entire high-prevalent season, captured in that data, when you're looking at pathogens.

And then second, would you use that same time period, or whatever your time period you decide to use, that same time period with the analysis year after year after year?

MR. ALVARES: Um-hum. So the time period that we used was based on some timing of our

process. So January of 2012 was really when we had completed our implementation of PHIS. All of our establishments were using the same system and documenting inspection tasks and noncompliances the same way. And so that was really kind of our starting point. That was how far we wanted to go back, as far as analysis.

July was really when we started kind of updating this information. Although January was really when we had full nationwide data, we've really been implementing this over the 8 months or so prior to that.

So we had some other data to also kind of get some basic level understanding of how tasks were being performed. But when we did the analysis for this, it was really just focused on those 7 months because that was the data that was available for this project.

But I think, going forward, that will be expanded to 12-month cycles. So we'll always, I think, try to look at 12-month periods of time, assuming we do like an annual update, which I think

is our intention.

If for some reason we were doing like a biannual update, we'd probably be looking at 2 year's worth of data. I think we'd want to use all of the data that we've gathered since our last update. Okay, thank you, everyone.

MR. PAYNE: Thank you, Mr. Alvares.

And now it's time for lunch. Just be sure to check in your binders. There is a listing of who is on which Subcommittee. Just verify that you're in the right place, and if there are any last-minute changes or requests, they need to be approved and run by Mr. Derfler here.

Since we're a little bit behind schedule, I might suggest that we reconvene promptly and get started at 1:00. Everybody congregate here and then we'll break out into our two Subcommittees for deliberations.

Thank you very much. And please ask staff here on recommendations, places to eat, anything you need.

(Whereupon, a lunch recess was taken.)

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

(1:05 p.m.)

MR. PAYNE: Take our seats to resume the final portion of today's meeting. Okay, I think we've got everybody back from the Committee. The full Committee is here.

Question to both Subcommittees. Do you need more time for deliberation? We do have options, if you need more time, in the morning. We can open up. This is opened up earlier.

So Chris, I spoke to you a little while ago. The Veal Subcommittee, how are we doing?

MR. WALDROP: I'll defer to my chair --

DR. SHULTZ: I think we're doing well.

MR. PAYNE: Okay. You have your recommendations?

DR. SHULTZ: Yes.

MR. PAYNE: We have it saved on --

DR. SHULTZ: Yes.

MR. PAYNE: -- a flash drive. So that is your final Subcommittee's recommendations?

DR. SHULTZ: Natasha told me she saved it

on the flash drive.

MR. PAYNE: We saved it on the hard drive here, too.

DR. SHULTZ: Okay.

MR. PAYNE: But we had a backup flash drive. So you're good?

DR. SHULTZ: Yeah.

MR. PAYNE: Okay. What about the other Subcommittee?

MS. KLEIN: So we made significant progress. I don't think we need to meet unless my Committee suggests otherwise. I don't think we need to meet before 9:00 a.m. to finish anything up. We have our recommendations on the flash drive and I would love for you to put them on there so that nothing happens to them.

MR. PAYNE: Great, great.

MS. KLEIN: And then just for clarification, tomorrow during the session, we will have time to do wordsmithing, whatever, as a full Committee?

MR. PAYNE: Yes. Each Subcommittee will

report out your recommendations and then it comes before the full Committee. We can get into the wordsmithing, but come to a consensus as a full Committee on your recommendation.

MS. KLEIN: Great. And then somehow it will be streamlined into a document that's --

MR. PAYNE: Streamlined into the final draft document and then we'll -- if I remember correctly from the last meeting, what we did, we sent them back out to the Subcommittee chairs for final proofing and any minor modifications and then produce the final, which would be posted on our website.

MS. KLEIN: Okay, great. Thanks.

MR. PAYNE: Okay, any final questions or comments before we move into the public comment session?

And while you're thinking of any possible questions or comments, I do want to let you know the ethics training that is required, by law, for the Committee, we were going to have that this morning before the meeting started but unfortunately, the

person who was due to deliver it wasn't here, but she will be here at 5:00 to give the 20-minute ethics training for the whole Committee. So that will start promptly at 5:00, after we conclude. It's just 20 minutes.

All right, shall we move into the public comment session? Okay, I'm getting an affirmative there from Mr. Derfler, so we will start the public comment session.

And the last time I checked, we had two individuals who signed up to make public comments, Mr. Tony Corbo and Mr. Scott Goltry. Okay, Mr. Goltry has indicated he is not going to make a comment, so Mr. Corbo.

MR. CORBO: Tony Corbo from Water Watch again.

I participated in the Subcommittee that was on data analysis and for the first hour and 45 minutes, I was thinking back to the good old days. I see the former administrator here, Dr. Masters, who, whenever she chaired this Committee, allowed participation from the audience and it didn't occur

until about an hour and 45 minutes into our meeting upstairs, that the audience was allowed to participate. And I understand that a similar discussion happened here during the Veal Subcommittee. And I think we need to make it consistent as to what role the audience is going to play in the Subcommittees.

So I think there was some input. I got up a couple of times, and others from the audience made valuable contributions to the deliberations upstairs, so I would recommend that we be consistent in terms of allowing audience participation.

Second thing that I remember was Dr. Masters involved all of the employee organizations to participate, as least as ex-officio members. I contacted Stan Painter. He was never invited to participate in your -- group. Same thing happened when you all picked your teleconference call on the poultry slaughter ruling. And he just remembered you called out the names of employee representatives twice and there was no response because none of them were allowed to participate.

So I don't know what's going on, if there's miscommunication, but Stan said that he would have been here had he known that he was invited. So that's Number 2.

As far as the deliberations upstairs with the Data Subcommittee, I think that the Agency -- in terms of the direction that it wants to go, but I want to echo both concerns that Nancy Donley and Pat Buck registered earlier about the lack of data, the lack of quality data.

And I've said this to the Agency before, every time you say that PHIS is fully implemented, it's like fingernails scratching across the blackboard. It's not fully implemented. Yes, you had stopped using PBIS. I'm glad that PBIS is gone. But PHIS is not fully implemented because it's still not working properly. Inspectors have problems using it; you're not collecting quality data of the access issues. And so I would really appreciate, you know, that you stop using the term it's fully implemented.

And one of the things that would have been

useful in terms of the discussion upstairs was where we're at with the implementation of the hazard analysis verification procedure that we were promised was going to go into existence in 2010 and it got bumped into 2011, then it got bumped into 2012, and here we are, 2013, with no end in sight in terms of when that procedure is going to be implemented.

Because the discussion that was going on upstairs focused on food safety assessments, but eventually the public health regulations that were being discussed in terms of FSAs is also going to apply to HAVs. And it would have been interesting to have Stan Painter's input in that discussion as Nancy had asked earlier. So that's my comment about today's proceeding.

I want to get back a little bit to the discussion of the international program here at FSIS because one thing, I wasn't prepared to get up when I did and Sarah was very kind to have me do the presentation, but one thing I want to point out is that the budget for the international programs has

taken a hit. It took a hit in 2010. And I just hope that the *Federal Register* notice that you put out is not designed to put a square peg in a round hole because of the fact that they have a lower budget.

Consistently during the Bush administration, you were spending between $18-20 million a year on international programs; it's down to $15 million. That's the real reason you're not visiting all of these countries as frequently as you are.

The other thing I want to point out is that Mr. Almanza never answered Put Buck's question about why you are using a pilot program involving five swine plants to determine equivalency of inspection systems of entire countries that are exporting to the United States, and that question needs to be addressed because how in the world are you using a pilot program, confined to only five swine plants and allowing Australia, New Zealand, to ship beef and mutton products to the United States for all of their plants?

Thank you very much for your time.

MR. PAYNE: Thank you, Mr. Corbo.

Any other comments? Dr. Shultz?

DR. SHULTZ: Only one with regard to PHIS. I spent 17 years in FSIS and I came from an era where we did everything with paper. I came from an era where we submitted all of our data to a data processing center in Des Moines, Iowa, on paper. And the ability to get that data entered, hand-entered, was simply -- even though we were well-funded at the time, it couldn't be accomplished. And tremendous amounts of data just fell through the cracks.

And I had the opportunity, with Dr. Basu this morning, to look at residue data because of having an interest in residues for a long time and he had some questions about the national residue program. And the opportunity to look at PHIS data and to see the way it was organized and the kinds of comparisons, plant-to-plant comparisons, that we could make, the kinds of various filtering mechanisms that are available with that data are

truly extraordinary compared to my days with paper data.

And so even though I fully recognize that there's probably still only about two-thirds to three-quarters of the data getting in, because it's simply an overwhelming task, and having gone through ESample, EAVRS, and all of the formative phases of electronic data processing in FSIS back in the nineties and the early part of -- turn of the century, I just see extraordinary improvement. So I'm sure we have a long way to go, but I think we -- I must give FSIS credit for its accomplishments with PHIS.

MR. PAYNE: Thank you, Dr. Shultz.

Ms. Donley?

MS. DONLEY: Thanks. This is kind of not relating to what we were all working on today, but I think it would be very helpful. And I don't know if anyone here from FSIS is equipped and ready to answer this type of question, but it would be nice to start these meetings with kind of a recap of what's happened with all of the information we've

given from the prior meeting, where is it in the system, what's been done with it.

You kind of like, you feel like you give all this input and then it just kind of gets, you know, shoved into a drawer and nothing gets done with it. So if you have any information to share, I, for one, would welcome it.

MR. PAYNE: Mr. Derfler?

MR. DERFLER: What I would say, in response to that, is that was the point of the first two presentations today. I mean, when we have something to report that we think is significant, we are trying to show that we're absolutely committed to feed it back to the Committee because we appreciate the Committee's input, we want the Committee's input. And so we want to show you what we're doing.

I'm not sure, you know, like if you're asking for all of the things, all the recommendations that you've made, we could look into that. But what we wanted to do was to show you that we are taking the input that we get from the Committee seriously and we're trying to feed it back

to you, which was how we started today.

MS. DONLEY: And that was just -- yes, it was helpful. Just though, that was from 2008, and but even just the things that we talked about, you know, a year ago is -- you know, what's been done with the information, our recommendations, that type of a thing, just would be helpful.

MR. PAYNE: Thank you. Dr. Tilden?

Ms. Buck? Sorry.

MS. BUCK: I would concur that we need to have better communication with the NACMPI Committee from FSIS. Not to belabor a point, but we certainly -- many of us remember the telephone conference call that we had on the poultry slaughter inspection rule and while that was an effort on the part of the Agency to keep the Committee involved, I think it might be a very good idea to have some way of communicating major key topics to NACMPI on a more regular basis. And it might even be helpful to have something like a suggestion box, that when Committee members are gathered, they might be able to give you some time for some suggestions that

might improve our effectiveness.

MR. DERFLER: And all I would say is we value the time with the Committee. We had the presentations today and then we had the two major topics and we have the -- so we'll try and find a way to strike a reasonable balance. Okay.

MR. PAYNE: Thank you, Ms. Buck.

And next, Ms. Gapud.

MS. GAPUD: Well, the question I want to ask, also, is like what Pat and Nancy said. We had our conference last, I think, March or April, that proposed whether the slaughter -- modernization process and since then, we really never heard anything else from you guys on what happened, what was the plan on that one.

I know that there were some meetings, but -- you know, I know there are some union workers doing this, doing that, and so on. But we never heard any more from the Agency on what is our next step, are we going to post group proposal, what is next? I think we need to know, too. You know, this is the Committee that helps the Agency, so -- but we

never heard anything from you guys. I don't know what's your next step in that.

MR. DERFLER: I'm not going to comment on that. I mean, obviously, there's a rulemaking going on and the comments of the Committee have been taken and included as part of the rulemaking record and we're reviewing it. And when the process is over, we'll announce it. We can then -- you know, we'll announce and we'll show the Committee's input, you know, as part of the rulemaking process.

MS. GAPUD: Do you have any ongoing --

MR. DERFLER: No. It's very difficult to predict the rulemaking process.

MR. PAYNE: Thank you, Ms. Gapud.

Mr. Warshawer?

MR. WARSHAWER: This is maybe just a personal comment to these series of comments, because I share the Committee members' desire to be in the loop more. And I'm stuck with this mental frame of kind of project management and progress measurement and outcome orientation, and I want to know what's happening. And I'm getting the message

that that's just not our function. We are on deck; we're called on when we're needed. We're to be rested, ready, and raring to go and when they want something, they'll tell us. The rest of the time, we're just like the public.

And maybe that's okay. And if I'm wrong about that, I'd love to hear it clarified. But, you know, like when I'm trying to manage something for an outcome, I keep track of what was done last, what's done next, and I think that's what we're hearing is that's not our part of the job. So I would love to just know for sure so I can chill out, relax, and be ready when you call on me.

MR. PAYNE: Mr. Derfler.

MR. DERFLER: All I would say is thank you for the comment and we'll take it under advisement, all the stuff that we're hearing.

MR. PAYNE: Thank you, Mr. Warshawer.

Ms. Klein?

MS. KLEIN: Could I ask a historical question? I don't know if it's something that either Phil or somebody else would have the answer

to, and it's kind of a point of order about the way the Committee works, not about a specific issue.

And that is, has -- we have, over the last several sessions of this Committee, expressed varying degrees of what Steve just said, this kind of dissatisfaction with the way that the Committee is being run, and so we're being called upon.

And so the question, from a historical perspective is, has the Committee ever, to your knowledge, captured that complaint in one of the Committee documents that gets put forth to the Agency and to the Secretary? Has that ever been captured in one of these Committee reports?

MR. DERFLER: I don't have an encyclopedic knowledge of the recommendations, but to my recollection, we've never gotten that, per se. We've heard the complaint before, which is part of the reason why we're making the presentations that we made, to start off the presentation. We do want to keep you in the loop as to what's going on and all I can say is there's a balance between the issues that we presented to the Committee and our

progress on those issues so that the presentation we make back to the Committee is something that's reasonably well developed and worthwhile. And this is the balance we've struck.

I mean, we're open to -- obviously, this is an advisory committee. We're open to suggestions and we'll take it under advisement and we'll try and do the best job we can. But it is a balance of your time and our time and trying to make your time as worthwhile as possible because we appreciate it.

MS. KLEIN: So maybe, as a question for the Committee members, if anyone is interested in working up some language that could be deliberated tomorrow during the session that would reflect, maybe, some recommendations for the Agency about how to handle this Committee and information sharing with this Committee and even where the Committee is -- I know that's been an issue, where, within the Agency the Committee is overseen.

I don't know if it would be the will of the Committee to have that kind of language included in our final report, but it seems that that would be a

way to memorialize the struggle that we're all having, or some of us are having, with the way that the Committee is run, in a more formal way.

So I don't know whether anyone else is interested in doing that, but I would offer it as an opportunity or an option.

MR. PAYNE: Ms. Buck?

MS. BUCK: In response, Sarah, I would say that I would be interested and I'm willing to work with you on that. Are there other members that might be interested?

MR. PAYNE: Mr. Warshawer?

MR. WARSHAWER: Interested to a point, but resource-limited.

MR. DERFLER: I'll just say we hear you, what you're saying, and we'll -- I mean, I'll commit to you that we'll take it back and we'll talk about it, whether we get something formal or not. I mean, you know, like I said, we appreciate your time, we appreciate your input. We're not here to make you feel like you're being dissed or anything like that.

We're here because we want your advice and

we want to get back to you and let you know what we're doing because -- I mean, as the first presentations today showed, we really do take it seriously. Our process might not move as quickly as some or all of us would like, but that's where we are.

MR. PAYNE: Ms. Buck?

MS. BUCK: Thank you for those comments, because I really believe you are interested and you want to help NACMPI to become more productive. But sometimes it has to be taken to the higher level so that they understand the problems that are simmering, okay?

And I think that this might be helpful to you for us to take some action as a formal recommendation. And I hope other members would join us. Doesn't have to be long, just something short.

MR. PAYNE: Thank you, Ms. Buck.

Mr. Warshawer?

MR. WARSHAWER: I'm maybe not saying that much different. I don't view this as crippling and don't feel like we're being dissed. We're just, to

the extent that you do call on us and do value us, we want to do all we can.

And so there is this critical striving quality that almost everybody that would volunteer for this kind of work brings to it, so we're probably not going to just sit back and wait and see what happens next; we're going to reach out and try to engage the process as much as we can. And that is totally in support of you that we do that, not to criticize and be negative and be destructive.

MR. PAYNE: Thank you, Mr. Warshawer.

Next, Ms. Donley.

MS. DONLEY: Question. It would have been really helpful, maybe for next time you could do this, is even as you're formulating within the Agency of what topics of discussion you're thinking of bringing to the Committee, that you're saying hey, we're heads up, you know, Veal Slaughter and Data, that even if you haven't zoned in on it that we have a bit of a heads up and could do a little bit of additional research before the meetings.

Appreciate getting the information ahead of

time. Unfortunately, for me, it wasn't enough ahead of time to really be able to dive into it. But even if it's just a broad, general hey, we're going to continue on this topic or go to this topic, I would find it helpful. I don't know if the rest of the Committee would, but it would be for me.

MR. DERFLER: You know, it sort of -- I mean, we've heard -- because I've been involved in the Advisory Committee off and on for a long time.

You know, we hear -- we've heard different things about providing materials and stuff like that, to prepare people. Some people have said, you know, we want it and then other people say it's just a waste of your time because I'm only going to read it on the plane going out there, anyway, so there's no reason to get it to me before that.

So, I mean, that's -- we're open -- you know, we're going to put together the information. We spend a fair amount of time, as I think is evidenced from the materials that you have for this meeting, putting it together. We just have been responding to some of the things that we've heard.

MR. PAYNE: Any further comments in the time remaining?

(No response.)

MR. PAYNE: Mr. Derfler, I don't see any tent cards raised or anyone coming up to the microphone, so do we adjourn today's session?

MR. DERFLER: Sure.

MR. PAYNE: Okay, you heard it from the chair, designated chair. Today's session is adjourned.

And as I mentioned just a while ago, we have that ethics training that starts at 5:00; only 20 minutes. Perhaps we can get started sooner, if the person comes earlier than 5:00. We have about -- it's 14 before 5:00, 14 minutes before 5:00.

And the question I'm going to ask, the question about leaving binders in this room -- Ms. Fernandez. Can we? Okay, hear the answer that we can leave them in the room.

(Whereupon, at 4:50 p.m., the meeting was concluded.)

C-E-R-T-I-F-I-C-A-T-E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION
PLENARY SESSION
Washington, D.C.
January 16, 2013

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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CATHY BELKA, Reporter
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