

## UNITED STATES DEPARTMENT OF AGRICULTURE

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## NATIONAL ADVISORY COMMITTEE ON

## MEAT AND POULTRY INSPECTION

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## PLENARY SESSION

+ + + + +

September 29, 2010

1:00 p.m.

USDA South Building Cafeteria  
Washington, D.C.

CHAIR: MR. ALFRED V. ALMANZA  
Administrator  
Food Safety and Inspection Service

MODERATOR: MR. ROBERT TYNAN  
Deputy Assistant Administrator  
Office of Public Affairs and Consumer  
Education  
Food Safety and Inspection Service

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MS. SARAH A. KLEIN

**Free State Reporting, Inc.**  
1378 Cape St. Claire Road  
Annapolis, MD 21409  
(410) 974-0947

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DR. J. BYRON WILLIAMS  
MR. LEONARD W. WINCHESTER

## FSIS:

DR. ELISABETH HAGEN  
UNDER SECRETARY FOR FOOD SAFETY  
MR. JEROLD MANDE  
DEPUTY UNDER SECRETARY FOR FOOD SAFETY

MR. CHRISTOPHER ALVARES  
MR. ANTHONY ANDREASSI  
DR. PAT BASU  
DR. PATTY BENNETT  
MR. JOHN LINVILLE  
MR. JEREMY "TODD" REED  
MR. WILLIAM C. SMITH  
DR. DANAH VETTER  
MR. STANLEY PAINTER

## ALSO PARTICIPATING:

MR. TONY CORBO  
MR. CHRIS WALDROP

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(1:00 p.m.)

MR. TYNAN: We're going to be starting in just a moment. So if you could take your seats please. And I guess the other question is can you all hear me in the back? Yes. Okay.

Good afternoon. Welcome to our meeting of the National Advisory Committee on Meat and Poultry Inspection. This is the first meeting of our new Chartered Committee, and I want to welcome you all here today.

I'm Robert Tynan. I'm with the Office of Public Affairs and Consumer Education, and I'll be moderating the meeting today.

We realize that you all have busy schedules, and we sincerely appreciate you coming and spending your time with us today to share your thoughts, your recommendations with us, and it's very important we take your concerns seriously, and we're looking forward to a good meeting.

Before we get into some of the things, the logistical things like the agenda, I want to

1 introduce our Administrator, Mr. Al Almanza for some  
2 welcoming remarks.

3 MR. ALMANZA: Can I do it from here?

4 MR. TYNAN: Yes.

5 MR. ALMANZA: Perfect.

6 MR. TYNAN: You're the boss.

7 MR. ALMANZA: She's the boss. I just want  
8 to welcome everyone and certainly the new members,  
9 and I'll say the remaining members, not the old  
10 members, as well as the employee groups and the  
11 affinity groups we have here as well and certainly  
12 the consumer groups, because what we do here will  
13 really impact what we do in the future, and so I  
14 hope that everybody recognizes the importance that  
15 we put on this.

16 I do apologize, it has been two years since  
17 we've had a meeting, but that being said, we're  
18 looking forward to working with this Committee and  
19 thank you all for coming in on somewhat of a short  
20 notice, and I appreciate what you all are doing for  
21 FSIS. Thank you.

22 MR. TYNAN: Okay. Thank you, Al. I'd like

1 to introduce Elisabeth Hagen. Dr. Hagen is our  
2 Under Secretary for Food Safety, and she has some  
3 opening remarks. So she's sitting way down at the  
4 end. If you'd like to come up here, that would be  
5 fine. Again, you're the boss.

6 DR. HAGEN: Hi, everybody. Can you hear me  
7 okay in the back? Yeah. Okay. Great.

8 Thanks, Robert. Thanks all of you for  
9 coming. I'm really happy to join you today as you  
10 kick off your work on this Committee and to start  
11 what I know is going to be a very good and  
12 thoughtful discussion on two topics that are very  
13 important to FSIS in our mission to become a more  
14 preventative public health agency. The first is  
15 better, more transparent use of data, and the second  
16 is collaboration and opportunities on pre-harvest  
17 food safety.

18 Both of these areas have the potential to  
19 improve the way that we do meat and poultry  
20 inspection. Both can help this Agency meet some of  
21 the very real challenges of today's complex food  
22 system, and ultimately we can use these approaches

1 to help protect consumers from harm. That's why  
2 we're here, right? Protecting consumers. That's  
3 all of our top priority. Scientists, industry  
4 leaders, consumer advocates, regulators, we're all  
5 trying to figure out how do we get the safety  
6 products to American tables and tables around the  
7 world.

8 So the question that my office and FSIS is  
9 asking that we continually have to ask is, are we  
10 doing the best job that we can to protect the public  
11 through food safety? Are we too often reacting to  
12 food safety problems, or are we preventing more of  
13 them in the first place? Are we reducing and  
14 working to eliminate the risk of pathogens and other  
15 contaminants before they reach our consumers?

16 Prevention has to be and will be the  
17 foundation of everything that we do.

18 Do we have the right tools to do the job?  
19 The tools actually in the hands of our inspectors on  
20 the lines, the data in the hands of our analysts,  
21 the authority in the hands of our policymakers. Are  
22 they current? Do they help us get the job done?

1           So starting today and for the next two  
2 years of your membership on this Committee, we're  
3 going to be asking for your help to answer these and  
4 other questions. We need your perspective and your  
5 insight and your ideas to make our system work the  
6 best it can for consumers.

7           So as I said to the small group this  
8 morning, your work here really matters. It matters  
9 to the Secretary who uses your advice and  
10 recommendations. It matters to me, as my team works  
11 to make USDA's food safety program stronger, and  
12 most of all, it matters to the people that we serve.

13           This Committee is a forum for sharing  
14 ideas, for getting input from everyone with a stake  
15 in food safety, and for thinking about ways to  
16 tackle the challenges, not by agency, by  
17 jurisdiction, and in any kind of silos, but together  
18 across the entire farm to fork continuum.

19           That's why we added members this year from  
20 FDA and CDC to the membership of this Committee, and  
21 that's why we have such a diversity on our Committee  
22 in the first place. And that's how and why we're

1 really going to make some improvements, by looking  
2 at the big picture, by getting the best ideas on the  
3 table, and by putting our heads together to solve  
4 them. So that's what you all are going to be doing  
5 for the next couple of days. You're going to be  
6 solving everything. Isn't that good to know?

7           So a little bit about data, our first  
8 topic. To effectively prevent foodborne illness at  
9 the production level, we need the best technological  
10 and scientific tools. I think we all know that.  
11 Everybody from our inspectors to our food safety  
12 policymakers need the right tools to effectively  
13 protect public health, and data is really one of the  
14 most powerful tools that we have. So we'll be  
15 looking for your ideas and feedback on some ways  
16 that FSIS can better collect, analyze, and use data  
17 and share data.

18           The second topic is pre-harvest controls.  
19 So we also know that pathogens and other food safety  
20 threats don't begin at the slaughterhouse door. We  
21 know that what comes through that door then needs to  
22 be managed and really combated throughout the entire

1 system all the way to the consumer. So we also want  
2 your thoughts and recommendations on how we use this  
3 crucial stage before poultry and livestock reach the  
4 slaughter plant. This is where the first line of  
5 defense occurs against foodborne illness. How do we  
6 invite the right people into the discussion to  
7 actually move forward on this?

8           So during the past months, I've been  
9 talking to a lot of groups, both inside and outside  
10 the Agency, and I've told people that I feel very,  
11 very hopeful about what this Agency can accomplish  
12 during this Administration, and that we have to do  
13 it by utilizing the input of everybody. So I feel  
14 that same kind of hopefulness when I look at this,  
15 you know, variety and skill level and different  
16 perspectives that have gathered here in the room  
17 today.

18           So I can't thank you enough for accepting  
19 the challenge, accepting the nomination to be on  
20 this Committee. You've taken on a really important  
21 role to the Secretary, to me, to our entire Agency,  
22 and you each have a really, really key role of

1 protecting public health.

2           So we're just really looking forward to the  
3 work that we're doing in the next couple of days  
4 together. We take it seriously. We look forward to  
5 your membership on this Committee for the next  
6 couple of years. We have a lot to do, and I think  
7 we've got a lot to accomplish.

8           So thank you so much for coming. That's  
9 all I'm going to say, and have a great meeting. I'm  
10 going to be around, listening in on everything and  
11 happy to take questions from you throughout the  
12 afternoon. Thank you.

13           (Applause.)

14           MR. TYNAN: Thank you, Dr. Hagen. I  
15 appreciate your remarks.

16           I just wanted to mention that the Committee  
17 actually is supplemented a little bit today. We  
18 have two ex-officio members that have been added to  
19 the Committee, Dr. Jeff Farrar from the Food and  
20 Drug Administration and Dr. Art Liang from the  
21 Centers for Disease Control. They'll be with us  
22 today, and I also have to my right, we have

1 representatives from our employee organizations,  
2 Mr. Stan Painter from the National Joint Council of  
3 Food Inspection Locals, Dr. Danah Vetter who is with  
4 the National Association of Federal Veterinarians,  
5 and Dr. Pat Basu who is with the APANA, and you'll  
6 have to help me out on the --

7 DR. BASU: Asian Pacific American Network  
8 in Agriculture.

9 MR. TYNAN: Thank you. And so in that  
10 regard, why don't we just go around the table very  
11 quickly, introduce ourselves, maybe give our name  
12 and our affiliation, and we'll go from there.

13 Again, I'm Robert Tynan. I'm with the  
14 Office of Public Affairs and Consumer Education.

15 MR. MANDE: I'm Jerry Mande, Deputy Under  
16 Secretary, USDA Food Safety.

17 MR. ALMANZA: Al Almanza, Administrator,  
18 FSIS.

19 MS. TUCKER-FOREMAN: Carol Tucker-Foreman,  
20 Consumer Federation of America.

21 DR. LIANG: Art Liang, CDC Food Safety  
22 Office.

1 DR. FARRAR: Jeff Farrar, FDA.

2 MR. WARSHAWER: Steve Warshawer, Mesa Top  
3 Farm in New Mexico.

4 DR. KASSENBERG: Dr. Heidi Kassenborg,  
5 Minnesota Department of Agriculture.

6 DR. CUTTER: Dr. Cathy Cutter, Penn State  
7 University.

8 DR. JONES: Dr. Cheryl Jones, Morehouse  
9 School of Medicine.

10 MS. GAPUD: Veneranda Gapud, Fieldale Farms  
11 Corporation.

12 DR. TILDEN: John Tilden, Michigan  
13 Department of Agriculture.

14 DR. WILLIAMS: Dr. Byron Williams,  
15 Mississippi State University.

16 MS. DONLEY: Nancy Donley, STOP, Safe  
17 Tables Our Priority.

18 MR. COVINGTON: Brian Covington, Keystone  
19 Foods.

20 DR. SHULTZ: Craig Shultz, Pennsylvania  
21 Department of Agriculture.

22 DR. NEGRON-BRAVO: Dr. Edna Negron-Bravo,

1 from the University of Puerto Rico at Mayaguez.

2 MS. KLEIN: Sarah Klein, Center for Science  
3 in the Public Interest.

4 DR. HENRY: Craig Henry, Deloitte and  
5 Touche.

6 MR. WINCHESTER: Leonard Winchester,  
7 Seattle, King County Public Health.

8 DR. MURINDA: Shelton Murinda, Cal Poly  
9 Pomona.

10 MS. BUCK: Patricia Buck, Center for  
11 Foodborne Illness Research and Prevention.

12 MR. REINHARD: Bob Reinhard, Sara Lee  
13 Corporation.

14 MR. STROMBERG: Stan Stromberg, Oklahoma  
15 Department of Agriculture, Food and Forestry.

16 DR. CHEN: Fur-Chi Chen, Tennessee State  
17 University.

18 MR. TYNAN: Okay. Thank you very much. At  
19 this point in the agenda, we normally go over some  
20 of the rules of order that we conduct the meetings  
21 by. It's the same thing we've done for the six or  
22 seven years that I've been working with the

1 Committee. It is a good idea, though, to take just  
2 a moment to go through those.

3 At Tab 6, I believe, in your manual, and  
4 we'll go over those right now.

5 The Chair, the FSIS Administrator, this is  
6 the Secretary's Committee, and that responsibility  
7 is delegated to Mr. Almanza as the Administrator of  
8 the program, and he is, in fact, the Chair of the  
9 Committee. So the Chair is the person that opens  
10 the meeting and, as you know, I'm the one that's  
11 really opening it. That also has been delegated  
12 down to me to moderate the meeting and sort of  
13 manage it so that Mr. Almanza can sort of devote  
14 some time to concentrating on what you're saying as  
15 opposed to managing the comings and goings.

16 All the questions and requests to speak are  
17 to be addressed to the Chair. People must be  
18 recognized by the Chair before speaking.

19 The normal routine that we use during the  
20 meeting is if during the discussion you have a  
21 question, we take the tent card that you have in  
22 front of you with your name on it, stand it up on

1 its side, and then I'll know you have some question  
2 or comment that you want to make about a  
3 presentation that's occurred, and then we'll find  
4 some orderly way of going around the room and  
5 responding to the questions.

6 Presentations of issues and briefing  
7 papers, all of them are going to be followed by a  
8 short question and answer period. In the interest  
9 of time, we will put some limit to the length of the  
10 questions and the comments that you make. The Chair  
11 will exercise some discretion depending on where we  
12 are in the meeting.

13 Speeches or statements of opinion, long  
14 comments, things of that nature, if they're coming  
15 from the members or even from the public, we need to  
16 hold those until the public comment period.

17 The Chair will approve any materials in  
18 advance. We have, at some of our previous meetings,  
19 when people come to the meeting, they have materials  
20 that they want to share with the public that comes  
21 to the Advisory Committee meeting as well as the  
22 members. If someone has that kind of an issue,

1 please let me know and we'll have to consider how  
2 we'll proceed with that or whether we'll put that  
3 material out at all.

4           The Committee members are expected to  
5 attend the plenary sessions and the Subcommittee  
6 meetings to which they're assigned. The Committee  
7 members who do not attend the presentation or don't  
8 participate in a Subcommittee, if you come at the  
9 end when the report's out, I think in fairness to  
10 the members who participated in all the discussions,  
11 if you haven't participated, we're going to not have  
12 you part of that voting activity.

13           The Subcommittee Chair, and this is an  
14 important point to make, the Subcommittee Chairs  
15 will be responsible for managing the Subcommittee  
16 meetings. So they have a lot of latitude as far as  
17 I'm concerned in terms of how they want to manage  
18 that meeting. The public is invited to attend  
19 whichever issue is most important to you. You can  
20 sit in that meeting and participate to the extent  
21 the Chair allows you to do that.

22           This is an Advisory Committee meeting. We

1 are seeking recommendations from the Advisory  
2 Committee. So at the end of the day, whatever comes  
3 out of that Subcommittee represents the work of that  
4 group. So if there's a public comment that's  
5 incorporated into that report, we're perfectly happy  
6 to accept that if the Chair thinks that's a  
7 recommendation that the Subcommittee wants to make.

8 And then these rules of order, if there's  
9 some problem with them, we've had them as I say for  
10 probably a good six or seven years. They're  
11 reviewable. If there's some other things we need to  
12 add or modify, we're perfectly happy to do that.

13 For anybody in the public, when we talk  
14 about the agenda, anybody in the public that wants  
15 to make a comment during the public comment period,  
16 if I could ask you at some point during the break or  
17 sometime during the meeting to register at the desk  
18 so we have a sense of how many people are going to  
19 be making comments, and how much time we need to  
20 allot for those comments. That would help us out  
21 quite a bit. So I would appreciate it if you would  
22 do that.

1           Also just a couple of quick logistical  
2 issues. Cell phones, if you can put them on  
3 vibrate, that would be very much appreciated. And  
4 then for those of the public that just came,  
5 restroom facilities, if you need them, you're going  
6 out this doorway here, passing down the hallway into  
7 the corridor, the second wing, the men's room is to  
8 the left, ladies' room is to the right. Did I do  
9 that correctly? I don't want to send anybody in the  
10 wrong place. Thank you.

11           Okay. And with that, let me take you  
12 quickly through the agenda, and then we'll get into  
13 the substance of the meeting.

14           The first two topics we have on the agenda  
15 are what we call briefing topics. They are just  
16 short presentations that we're going to do today,  
17 and we'll have a question and answer period. They  
18 are not the focal point of the meeting or where we  
19 need your advice and comments, but they are some  
20 preliminary issues that we thought would be helpful  
21 to you to discuss those before we get into the  
22 actual issues themselves.

1           So we'll have one that will be talking  
2 about the strategic data analysis plan, and the  
3 second will be the Public Health Information System,  
4 PHIS, which the Agency has been working on  
5 diligently for quite some time. So we want to be  
6 sure that we get those briefings out for you and  
7 that will give you some background information to  
8 work during your Subcommittees. So those will be  
9 two briefings. As I say, there'll be no discussion  
10 in the Subcommittees about those. We're not seeking  
11 recommendations on those. We're simply attempting  
12 to inform you of what those two areas are about.

13           Can you not hear me? Okay. I'm sorry. I  
14 apologize. If there's anything I need to repeat,  
15 let me know.

16           I think at one of our preliminary agenda,  
17 we had a follow-up issue from a previous meeting  
18 which had to do with international equivalence, and  
19 so in the interest of time, we've taken that issue  
20 off as a briefing. We have a briefing paper in your  
21 book, and I believe it's under Tab 7. So it  
22 addresses the topic that was our meeting in August

1 2008, and all of that had to do with international  
2 equivalence. So if there's some questions after you  
3 read that paper, if there's some questions that are  
4 burning for you and you want to have answered, I  
5 will try and get somebody here, an expert on it, to  
6 talk with you a little bit about it later.

7           After we get through the two briefing  
8 topics, then we are into the real substance of the  
9 meeting. We have two issues that we want to talk  
10 about today, and as Dr. Hagen mentioned, the first  
11 topic has to do with data collection, analysis,  
12 response and transparency, and we have Todd Reed  
13 here to present that. I think on your agenda,  
14 Mr. Andreassi, I don't know if I pronounced his name  
15 correctly, was not able to come today. He had an  
16 emergency. So Todd will be the person that will be  
17 doing that presentation. That presentation will be  
18 followed by some questions and answers again.  
19 Depending on where we are in terms of time, we may  
20 have to limit the number of questions at that  
21 particular point, but we'll try and entertain as  
22 many questions as we can at that point.

1           We'll take a break, and after the break,  
2 the second issue of the day will be strengthening  
3 policy and collaboration in pre-harvest food safety,  
4 and again Dr. Hagen mentioned that in her opening  
5 remarks. It's a very important topic for us and one  
6 that we have a very good presentation by John  
7 Linville. John is out in our Omaha office, and with  
8 the Office of Policy and Program Development. So  
9 he'll be doing a presentation, and there will be an  
10 opportunity for you to ask some questions and  
11 answers after that.

12           Then we'll have a public comment phase;  
13 hopefully it'll be earlier than 4:15, but  
14 approximately 4:15. We'll have a public comment  
15 phase, and again if anybody in the public wants to  
16 make a more substantive or lengthy remarks, if you  
17 could register at the table outside, I would  
18 appreciate it very much, and then at the end of the  
19 public comment, I'll do a summary here to get us set  
20 up for tomorrow, and we'll adjourn about 5:00. So  
21 that will be Day 1.

22           Day 2, tomorrow morning, we're going to ask

1 the Committee to come back here, no later than 9:00,  
2 so that we can get you to your different Committee  
3 meetings, and essentially the Committees will be  
4 working on a specific issue they're assigned. There  
5 is an issue paper I think for Subcommittee Number 1,  
6 it's at Tab 15, and for Subcommittee Number 2, it's  
7 Tab 16. So both of those, we have the issue paper.  
8 It's just a brief summary of the presentations  
9 you'll hear today and four or five questions and  
10 sub-questions we need the Subcommittee to deal with.

11           So, basically, in the morning we're going  
12 to be asking the Subcommittee Chairs again to manage  
13 the meeting so that all of those questions get  
14 answered. I realize there are a number of questions  
15 that have to be dealt with. So it's going to be a  
16 challenge for the Subcommittee Chairs to work  
17 through those questions. If time becomes an issue,  
18 I think they're in a priority order. I'll check  
19 with the presenters to make sure that that's the  
20 case, and so get as far as you possibly can on those  
21 questions if you can't finish them all.

22           Sometime after lunch, we'll have Committee

1 report outs. So what essentially will happen is the  
2 Subcommittees will come back here. We'll ask the  
3 Chair of each Subcommittee to do a report out. What  
4 was the essence of the discussion, how did you  
5 respond to the four or five questions that were  
6 assigned to your Subcommittee, and at that  
7 particular point, it becomes an open discussion  
8 among all of the Advisory Committee to weigh in, to  
9 modify, to add to, whatever, and at that point,  
10 we'll see if we have consensus on that report. If  
11 we do, it becomes a report for the Advisory  
12 Committee, and that's the official report that will  
13 be sent to the Secretary after the meeting. The  
14 same thing will happen with Subcommittee Number 2.  
15 We'll have a presentation on what the deliberations  
16 were in the Subcommittee meeting, and then we'll go  
17 from there, make it a plenary discussion and  
18 finalize that report as well.

19           Again, we'll have a public comment at the  
20 end of that day and give you an opportunity to make  
21 any comments on the topics that we've presented.

22           We'll probably be wrapping up around 3:30

1 tomorrow. I know some of you may have made flight  
2 arrangements. If you can have them after 3:30, that  
3 would be great. I know it's a little bit of a  
4 challenge sometimes to get back to Cal Poly from  
5 Washington, but if you could do your best on that.

6 Last, but not least, I want to mention the  
7 topics that we have here, including the strategic  
8 plan, are noted in our Federal Register, and we are  
9 providing for comments after the meeting on those  
10 topics. So if there's something on the plane flight  
11 back you thought about and want to make a comment,  
12 there is a formal way of doing that in the Federal  
13 Register Notice. So we will provide opportunities,  
14 not only for the Committee members but for the  
15 public as well to comment on any of the topics that  
16 were presented today.

17 Are there any questions on the meeting or  
18 the management of the meeting?

19 Okay. And with that, let's get into the  
20 substance of the meeting and talk a little bit about  
21 the two briefings, and I will introduce Mr. Chris  
22 Alvares, and Chris is going to talk about the

1 strategic data analysis plan. Chris.

2 MR. ALVARES: Thanks, Robert. Thanks for  
3 having me today. As Robert said, I'm here to give  
4 you a briefing on the strategic data analysis plan  
5 and the public health decision criteria reports.

6 These are two reports the Agency has just  
7 recently made public, about two weeks ago. They are  
8 intended to really lay out the Agency's plans and  
9 current approaches to data collection, some of the  
10 improvements that we're planning with PHIS and other  
11 systems, but also with putting a lot more detail  
12 around some of the things such as the decision  
13 criteria that we've gotten a lot of public input on,  
14 and really this briefing is intended to give some  
15 background, some of the drivers, some of the context  
16 for which these reports were produced.

17 So I think the place to really start is  
18 with the FSIS strategic goals, and I have four of  
19 them up here. I really put them up here to  
20 highlight that there are quite a few, well, at a  
21 very high level, the Agency is focused on enhancing  
22 our systems, become more data driven, improving the

1 approaches that we have to using data for inspection  
2 tasks, for informing our policy, really for  
3 improving our decision-making process.

4           So even at the very high level, it's  
5 important I think to recognize that FSIS is looking  
6 to become more data driven, to improve the way that  
7 data informs the activities that we're doing, and so  
8 as a starting point, we see these goals as the  
9 background and the support that we need to really  
10 develop the kinds of proposals and ideas that we've  
11 put forth in these reports.

12           We've also, over the course of really  
13 years, received a lot of external feedback. This  
14 Advisory Committee, in particular, has provided FSIS  
15 input on use of data for certain inspection  
16 activities. We've asked the National Academy of  
17 Sciences to review several approaches, and we've  
18 recently, in 2008, asked them to look at our  
19 approach to inspection, a proposal that we had back  
20 then. We've also asked them to look at attribution  
21 and provide comments to us on the use of attribution  
22 data in the work that we're doing. That's resulted

1 in letter reports that we've used to really help  
2 form what we're doing and make improvements to our  
3 approaches.

4           The Office of Inspector General has also  
5 done some reviews of some of our data-driven  
6 approaches to inspection, provided a lot of feedback  
7 there and made recommendations really on how we can  
8 improve that process.

9           All of those recommendations have been  
10 taken very seriously by the Agency. We've taken a  
11 lot of steps to try to adopt those recommendations,  
12 incorporate what's been proposed or suggested by  
13 these groups, and really try to improve the  
14 approaches.

15           So the reports again are intended to really  
16 lay out where we're at and where we'd like to go as  
17 we move forward.

18           I do also want to acknowledge, we have  
19 stakeholder input from a variety of sources.  
20 Certainly consumer groups, industry groups provide  
21 us with their recommendations as to how we can do  
22 better. We certainly appreciate that, and we take

1 that very seriously. We've had other external  
2 groups, you know, subject matter experts, the NARMS  
3 Committee has provided some input on sampling  
4 programs. The Advisory Committee we have has also  
5 reviewed some of our sampling programs and provided  
6 recommendations. So stakeholder input has also  
7 really been taken into context with these reports,  
8 and I think we've tried in a lot of ways to adopt  
9 those recommendations and to reflect that in these  
10 reports.

11 There's also been a great deal of internal  
12 feedback, and I think this is important to  
13 acknowledge as well, and has really driven a lot of  
14 our approaches to data analysis. It's driven a lot  
15 of our requirements for PHIS, and so I think it's  
16 important to acknowledge that this was also an  
17 important driver.

18 Current systems, and some of our legacy  
19 systems, are not well integrated, and we need to  
20 come up with a solution that improves the  
21 communication within the Agency in terms of data,  
22 our response times, and that's really an important

1 part of us being able to be more effective and more  
2 productive.

3           We've also, in a variety of analyses and  
4 activities that we do, we've identified things such  
5 as data gaps, such as the need to standardize our  
6 production volume data that we collect, the need to  
7 gather some additional profile, establish some  
8 profile information to help us build effective  
9 sampling programs, to direct inspection tasks where  
10 we need them to be.

11           We've also identified areas where we can  
12 collect more granular data or better data about the  
13 inspections that we're doing, the findings that  
14 we're finding at establishments, and to really help  
15 us make more informed decisions.

16           So the result of all this input, the result  
17 of the goals, the drivers that have been helping us  
18 move forward has been these reports, and I think  
19 they really have been an attempt to move beyond  
20 briefings and presentations and discussions on very  
21 focused matters and to really give, particularly  
22 with the strategic data analysis plan, a high level

1 view of where the Agency's at, where we're looking  
2 to go, and how we are trying to get there.

3           At the same time, the public health  
4 decision criteria report is focused on these  
5 decision criteria. They are an important part of  
6 what we're planning as far as prioritizing FSAs,  
7 scheduling some of our new inspection tasks, and  
8 what we've heard from a variety of feedback is that  
9 there's a lot of detail that people want to see  
10 about that, and so particularly the public health  
11 decision criteria report lays out, I think in pretty  
12 significant detail, how those criteria have come to  
13 be, how they're being applied, and I'll talk a  
14 little bit more about that in a second.

15           So again these reports are really meant to  
16 lay out in a lot more detail than we've done in the  
17 past, or in recent past, our plans for data, how  
18 we're planning to use that particularly with PHIS  
19 and how to move forward. And so that's where I  
20 think we really can improve the communication that  
21 we've had, some of the transparency that we need to  
22 improve upon, and I think lays some good groundwork

1 for us to get some additional feedback and input  
2 from this Committee, from stakeholders, and from  
3 everyone really.

4           So the public health decision criteria  
5 report, really just to give you a high level outline  
6 of the report, the report, as I mentioned, is  
7 available publicly. I think the Committee has  
8 received links to these reports. The report itself  
9 is intended to be a very detailed explanation of the  
10 public health decision criteria. These decision  
11 criteria have developed as a result of again the  
12 feedback that we have received from this Committee,  
13 from the National Academy of Sciences in particular,  
14 and so they really have evolved over time and  
15 reflect what we think is a good approach to  
16 addressing public health concerns.

17           So the report itself talks about what are  
18 these decision criteria? We discuss and we detail,  
19 itemize what each of the criteria are. We put  
20 forth what the scientific basis is for those  
21 criteria. For example, one of the criteria is an  
22 establishment having an O157 positive test result,

1 and so we put in that report, the scientific basis.  
2 We know that it's a pathogen that's likely to cause  
3 illness. We have risk assessments that are  
4 referenced. We have outbreak data from CDC about  
5 the affect of O157 on consumers. So all of that is  
6 put forth in these reports to really lay out why  
7 each of these criteria has been selected as public  
8 health decision criteria and why they're being used  
9 in this decision tree or decision-making approach.

10 We also talk about how these criteria are  
11 going to be used and applied. So in particular, the  
12 vision is to have these decision criteria used to  
13 schedule FSAs, both for cause FSAs and routine FSAs.  
14 We have a new task coming with PHIS, the hazard  
15 analysis verification. The decision criteria that  
16 will be applied will to some extent adjust or  
17 determine the frequency of those activities.

18 There are also other activities that the  
19 Agency does in response to like E. coli positives  
20 and other events, and so I think the decision  
21 criteria have a broader scope, but in particular  
22 they're intended to inform these two tasks.

1           We've also had a lot of questions about how  
2 the decision criteria may apply to establishments,  
3 how many establishments might be identified by the  
4 tier 1 criteria, how many might be affected by the  
5 tier 2 criteria, and so in the reports themselves,  
6 we've taken some historical data. We've applied the  
7 criteria. We've provided some breakdowns of what  
8 the landscape of the industry might look like with  
9 these criteria applied, and I think that that will  
10 give people some context about what the impacts of  
11 these criteria will be in terms of tasks and  
12 activities.

13           We've also tried to break down the types of  
14 establishments in terms of the differences between  
15 slaughter establishments and processing  
16 establishments, meat establishments versus poultry  
17 establishments, whether we see differences according  
18 to geographic location, and so we have presented in  
19 these reports some analyses where we've applied the  
20 criteria, we've looked at the outcomes, and we're  
21 putting that forth to really try to give everyone an  
22 idea of how these might fit when they're applied

1 fully with PHIS and, as I mentioned, differences  
2 related to the establishments as well.

3           Now, this didn't come out too well on the  
4 presentation here, but the figure at the bottom  
5 really is a schematic. This is in the report  
6 itself, and we do walk through this decision tree  
7 approach in that report. Really what we're talking  
8 about with decision criteria are two tiers of  
9 criteria. The first criteria or the first set of  
10 criteria, these tier 1 criteria, are really applied  
11 to establishments, and establishments that are  
12 identified by these would be scheduled for, for  
13 cause FSAs monthly, HAVs, until the issues  
14 identified by this criteria are resolved.

15           If establishments are not identified or not  
16 flagged by any of those tier 1 criteria, then we  
17 evaluate them on these tier 2 criteria, and those  
18 really are intended to prioritize our routine FSAs  
19 and also to determine the frequency of HAV tasks.  
20 Again, the report itself has a lot more details  
21 about that.

22           I think it's important to acknowledge also

1 that the criteria themselves are really, in addition  
2 to the scientific basis, intended to really identify  
3 establishments that have produced product that have  
4 tested positive for pathogens or that are not in  
5 compliance with federal laws or regulations or that  
6 may be performing worse than their peers with  
7 respect to FSIS inspection findings.

8           So we are trying to take into consideration  
9 inspection results, sampling testing results, data  
10 from recalls, from outbreaks, from enforcement  
11 actions, really a variety of data and a variety of  
12 activities that the Agency collects and really to  
13 get an overall picture of what's going on in  
14 establishments and make decisions based on that.

15           The other report that we put out is the  
16 strategic data analysis plan. This plan is, in a  
17 lot of ways, a bigger, more sort of umbrella style  
18 approach or overview of data at the Agency. It's  
19 intended to address how FSIS intends to improve data  
20 collection and data analysis. Many of the data  
21 collection needs that we've identified over the  
22 years through our feedback, through our analyses

1 internally have driven the needs and the  
2 requirements for PHIS, and so we really are looking  
3 forward to PHIS being able to move us forward as far  
4 as the data that we're collecting, the information  
5 that we have, the ability to make decisions on that  
6 data, and the ability to respond and react to data  
7 that we see that may be of concern and that may  
8 warrant further attention.

9           So, again, the strategic data analysis plan  
10 identifies different stages, data gaps that we've  
11 identified. We've cited examples of analyses that  
12 we've done in the Agency, efforts we've done where  
13 we've identified the need for better data. We've  
14 laid out some of the specific data collection  
15 improvements that we see as needed. And so we've  
16 talked about improvements to production volume,  
17 establishing profiles, recording of inspection  
18 tasks, generally the desire to move to more  
19 quantifiable data and take some of the free text  
20 information that we're getting now and put it in a  
21 format that would improve our ability to analyze it.  
22 And we also are really, as I mentioned, using that

1 information, that knowledge and those plans to drive  
2 the development of PHIS, and so those business  
3 needs, those needs that we've identified to help us  
4 make better decisions have really been instrumental  
5 in defining the requirements for PHIS and defining  
6 what we need that system to do for us.

7           We've also put in that report some  
8 discussion about future plans. So really looking  
9 beyond the immediate data needs, the immediate data  
10 collection needs. Once we put systems in place,  
11 once we gather the kind of data that we've  
12 identified as needs, what we intend to do with  
13 those, and how that data's going to be used, how to  
14 make decisions based on that, and how do we take  
15 further steps when we identify new data gaps. So  
16 the strategic data analysis plan itself is also  
17 intended to really kind of lay out a groundwork for  
18 making even the next steps beyond some of more  
19 immediate needs.

20           I think it's important to acknowledge that  
21 as we move forward with some of those next steps,  
22 those further plans, the Agency is committed to

1 making that a public process, and we'll continue to  
2 try to communicate what we're thinking and what our  
3 approaches are, request and receive feedback and  
4 really work with our stakeholders to drive those  
5 improvements as we go forward.

6 I think another sort of aspect of that that  
7 I want to mention is the use of external data and  
8 the integration of that with our process. The  
9 strategic data analysis plan talks about several  
10 areas of external data that we've identified that we  
11 feel will be instrumental in terms of our ability to  
12 make decisions, to take actions on a day-to-day  
13 basis. So we've identified in there several  
14 sources. We're working with CDC. We're working  
15 with FDA to collect that kind of data. We're  
16 working with some of our partners, with ARS, with  
17 AMS, to collect data from the activities they're  
18 doing, and that's all going to be integrated into  
19 our process, and inform inspection tasks, inform  
20 outcomes. To some extent, also to inform our  
21 agencies that may have access to PHIS, our  
22 establishments that will have access, and that may

1 be receiving data based on activities we're doing.  
2 And so the integration of external data is an  
3 important part of the data gaps we've identified as  
4 needs and the improvements that we look forward with  
5 PHIS.

6 I won't go too much into detail about  
7 automated reports and alerts, but the overall  
8 message here is that we really see these  
9 improvements to data collection, these improvements  
10 through PHIS to integrating data from our different  
11 activities, as a way to improve our responsiveness,  
12 to improve the communication throughout the Agency  
13 from Headquarters all the way down to the inspectors  
14 and those on the line, to really give them the kind  
15 of feedback that they need and put more data in  
16 their hands so that they can understand what's going  
17 on and take the actions that they need to take.

18 So just to kind of wrap things up, these  
19 reports have really been intended to present  
20 detailed plans of the continued improvement that the  
21 Agency's working on in terms of the collection of  
22 data, the use of data, the analyses that we intend

1 to do and have done that have driven where we're at  
2 right now.

3 I think it's important to acknowledge that  
4 these reports in some ways are living documents.  
5 They aren't meant to be static and sort of gather  
6 cobwebs over time. We do intend to revise them. We  
7 do intend to enhance them. There are some aspects  
8 or activities within the Agency that we haven't  
9 fully addressed in these reports, and I think as we  
10 continue to revise them and develop them, we'll add  
11 that content in there. We're also looking for  
12 feedback from this committee, from the public  
13 through the Federal Register Notice, and we're going  
14 to use that information to drive the content of  
15 those reports, to really drive the next steps in  
16 terms of our data needs and really I think  
17 ultimately to improve the communication and the  
18 transparency that the Agency's had.

19 So with that, I think I'll stop there, and  
20 if there's any questions, I'll be happy to try and  
21 answer them. Yes.

22 MS. BUCK: Patricia Buck from the Center

1 for Foodborne Illness Research and Prevention. I'm  
2 just a little nervous. Excuse me.

3 I have a question about, in the very first  
4 part of the slide, under background, you talk about  
5 recommendations have been considered. Can we have a  
6 copy of the recommendations that FSIS sent to NAS  
7 and OIG in response. I've been looking for them,  
8 and I have not been able to find them.

9 MR. ALVARES: Well, the recommendations  
10 came from the Committees to us, and so --

11 MS. BUCK: But have you responded to those  
12 Committees or to those bodies?

13 MR. ALVARES: Well, we have in a couple of  
14 ways. One is earlier this year, particularly with  
15 the NAS recommendations, I think that's what you're  
16 referring to in particular.

17 MS. BUCK: Yes.

18 MR. ALVARES: We have received letter  
19 reports from NAS, and those included the  
20 recommendations that the Committees made. We've  
21 taken those, we've adjusted the approaches that  
22 we've made. Earlier this year, we gave I think a

1 rather high level, sort of 10,000 foot briefing to  
2 NAS on the improvements that we made, and really the  
3 two reports here are intended to be much more  
4 detailed and formal responses to the NAS  
5 recommendations.

6           So in these reports themselves, we've  
7 included as an appendix the recommendations that OIG  
8 made, the recommendations that NAS made. We've  
9 referenced in the reports, for example, when we talk  
10 about integrating external data, or in the public  
11 health decision criteria report, our specific  
12 approaches. We've referenced the recommendations  
13 there.

14           I think Mr. Almanza has also submitted  
15 those reports to NAS, both the strategic data  
16 analysis plan and the public health decision  
17 criteria report. So we do see these reports as  
18 formal responses to those recommendations.

19           MS. BUCK: So these are the responses to  
20 NAS and -- okay. I thought maybe there was  
21 something else I was missing. Okay. Thank you.

22           MS. TUCKER-FOREMAN: Carol Tucker-Foreman

1 with Consumer Federation. Did you request that the  
2 NAS review the documents and get back to you as to  
3 whether or not they think that you have responded  
4 appropriately and adequately to their  
5 recommendations? Do you expect to hear back from  
6 them?

7 MR. ALVARES: I guess maybe I'm not the  
8 right person to ask that, but we certainly would  
9 appreciate any feedback.

10 MS. TUCKER-FOREMAN: I think he's next to  
11 me here.

12 MR. ALMANZA: We might just wind up sharing  
13 this microphone. What we did in the form of the  
14 letter, as Chris said, when we responded to them, we  
15 suspect that if they have any issues with our  
16 response, we'll be getting a response back from  
17 them, and are we anticipating that? Yes.

18 MS. TUCKER-FOREMAN: But did you  
19 specifically ask them to?

20 MR. ALMANZA: I don't recall that we  
21 specifically asked them, but that's typically how  
22 that works. I can double check though.

1 MS. TUCKER-FOREMAN: Well, I think it would  
2 be a useful thing to do. Just for the record, the  
3 NAS reports were undertaken because the Congress  
4 directed the Agency to do that. This exercise in  
5 transparency was driven by the Congress.

6 Did you send it to OIG with a similar  
7 request as to whether or not you had responded to  
8 the issues that they raised?

9 MR. ALMANZA: Yes.

10 MS. TUCKER-FOREMAN: And you expect to hear  
11 back from them?

12 MR. ALMANZA: We always hear back from them.

13 MS. TUCKER-FOREMAN: Is there any intention  
14 to put these documents out for public comment before  
15 you move ahead?

16 MR. ALMANZA: I don't have a problem with  
17 that. I mean I think that once we get a final  
18 product from the back and forth, that then at the  
19 end, we would post that, yes, ma'am.

20 MS. TUCKER-FOREMAN: I think it would be  
21 useful because as I tried to prepare for today's  
22 meeting and certainly in this very, very, very brief

1 Q&A after the presentation, there's very little  
2 opportunity to actually raise the multitude of  
3 questions that we have. Thanks.

4 MR. ALMANZA: Understood. Yes, ma'am.

5 MR. ALVARES: Well, I think just to follow  
6 up on that a little bit more, the Federal Register  
7 Notice that's part of this Committee announcement  
8 does have a mechanism for submitting formal  
9 comments. So certainly if we don't have time today  
10 to answer all the questions, we would recommend  
11 using that to submit comments. We do want to  
12 receive those, and that way will be one way I think  
13 to address some of those. And certainly there will  
14 be other opportunities. We are looking for some  
15 opportunities to brief consumers and industry and  
16 other groups on these reports and have sort of a  
17 dedicated time to respond to questions as well, but  
18 as far as a formal response, the Federal Register is  
19 the most immediate mechanism.

20 MS. TUCKER-FOREMAN: Yeah, maybe you ought  
21 to have a public meeting on it.

22 MR. ALVARES: Okay. I'm not sure who was

1 next.

2 MR. TYNAN: We'll take two more questions.  
3 We'll have Mr. Painter maybe first, Dr. Henry, and  
4 then if we can close out through the briefing, and  
5 if there are some questions, we'll try and respond  
6 to those during the rest of the meeting.

7 MR. PAINTER: Stan Painter with the  
8 National Joint Council.

9 In looking at the presentation, more  
10 specifically slide 6, 8, pretty much is full of  
11 questions, but where are the answers? Where can I  
12 find the answers to number 6 at the bottom of page 2  
13 and number 8 in the center of page 3?

14 MR. ALVARES: So the questions that I've  
15 posed in these slides were really the questions that  
16 we believe that the reports are answering. So the  
17 reports I believe are answering these questions.

18 MR. PAINTER: What reports are you  
19 referring to?

20 MR. ALVARES: So there are the strategic  
21 data analysis plan. About two weeks ago we posted  
22 on the Agency's website the strategic data analysis

1 plan and the public health decision criteria report.

2 Are they in the briefing books?

3 MR. TYNAN: Yes.

4 MR. ALVARES: They're in the briefing books  
5 as well.

6 MR. TYNAN: Tab 8.

7 MR. PAINTER: Tab 8?

8 MR. TYNAN: Yes.

9 MR. PAINTER: Thank you.

10 DR. HENRY: Chris, this is Craig Henry with  
11 Deloitte and Touche. Two quick questions. What  
12 percent increase in data do you expect once you  
13 implement the data collection plan over what you  
14 have now?

15 MR. ALVARES: Percent increase in data. I  
16 guess that's a hard question to answer specifically.  
17 I can tell you that we are looking to gather more  
18 information about establishment profiles. I think  
19 as far as the number of data points on an  
20 establishment, I don't have that kind of data or  
21 that kind of measurement in front of me. A lot of  
22 it is really additional information about existing

1 activities, for example, with inspection tasks.  
2 Right now we record compliance or noncompliance with  
3 an inspection task, and when a task is compliant,  
4 it's really just recorded as compliant. What we're  
5 trying to do with some of the data collection  
6 improvements is really gather, you know, we want  
7 them to check off which regulations were verified  
8 when that task was performed. So there is going to  
9 be more data, but to be honest, I don't have  
10 quantitative number of what we think the number of  
11 additional data points will be.

12 DR. HENRY: Yeah, because in reading  
13 through all of the background material, granularity  
14 is increasing. There's a large scope now as to the  
15 amount of data plus the plan, if I read it  
16 correctly, is an ongoing baseline assessment or  
17 continuous collection at random that raises just my  
18 second question and we'll move on. With that type  
19 of a sliding rule or ruler, if you will, you're  
20 continuing to change that, how does the Agency  
21 expect to measure the impact of changing technology  
22 or applied processes for any given plant or across

1 the inspection amenability at this point? I mean if  
2 you continue to change, you know, your point in  
3 time, the amount of data, how you're collecting it,  
4 how you're applying it, and somebody comes in and  
5 applies a process at some point on the calendar --

6 MR. ALVARES: Uh-huh.

7 DR. HENRY: -- how are you going to reflect  
8 back if the ruler changes?

9 MR. ALVARES: Well, in terms of applying a  
10 process, you're talking about maybe a policy change  
11 or a new technology or something?

12 DR. HENRY: Well, the ultimate goal is to  
13 reduce the number of pathogens on outbound product.

14 MR. ALVARES: Yes.

15 DR. HENRY: I mean at the end of the day,  
16 regardless of anything else, that is the goal.

17 MR. ALVARES: Right.

18 DR. HENRY: So the question is how is the  
19 Agency going to effectively measure that if your  
20 data plan continues to change over time?

21 MR. ALVARES: Well, the data plan itself is  
22 really intended to identify data improvements, and I

1 think that a major driver of these data improvements  
2 is our inability to in some cases effectively  
3 measure the impact of changes to industry or maybe  
4 changes to what we're doing, and so we do feel that  
5 this data is going to help us get a better picture  
6 of what's going on when we're doing a task, where  
7 that task is being done at, better characteristics  
8 about the plants where those tasks are done, and I  
9 think that's going to inform some of the decisions  
10 that we can't make right now.

11           So, for example, and this is purely a  
12 theoretical example, but if a certain activity is  
13 more effective at plants that have a certain type of  
14 intervention or that are during a certain activity,  
15 if we don't know what those interventions are now,  
16 we can't make any decisions on that. So we believe  
17 that with these improvements we'll be able to  
18 collect the kind of data to measure those kinds of  
19 changes.

20           As far as the question about sliding  
21 timeframes, I'm not sure if it was about timeframes  
22 or data.

1 DR. HENRY: Well, your terminology in the  
2 briefing book says it's an ongoing baseline  
3 assessment and that you will continue to change your  
4 standards and your collection policies as you get  
5 more data. So, in other words, the more we'll  
6 learn, the more we'll enhance the program.  
7 Therefore, the stake in the ground no longer  
8 exists --

9 MR. ALVARES: Yeah.

10 DR. HENRY: -- you know, because you can't  
11 say I'm going to measure one way, apply a  
12 technology, and measure after that technology has  
13 been applied. You've got apples and oranges right  
14 out of the box because it's kind of like chasing  
15 zero, you know, the more you look, the more you  
16 find.

17 MR. ALVARES: Yeah.

18 DR. HENRY: So I'm not seeing that  
19 correlation because at the end of the day, if the  
20 dataset or the data process is more driven at  
21 evaluating current processes and the way your  
22 inspectors execute, that's one thing, but I think

1 the ultimate goal is to improve public health.

2 MR. ALVARES: Certainly.

3 DR. HENRY: And so therefore, you know, we  
4 need to look at the technology or the process  
5 application within the plant and see what that  
6 output is on finished product at least based on the  
7 attribution data that's already been described.

8 MR. ALVARES: Well, certainly evaluating  
9 current processes is just one of the outcomes of one  
10 of the benefits that we see of improving the data  
11 collection analysis that we do. I'd be happy to  
12 talk some more about that question, but I think  
13 there's maybe some clarification.

14 The ongoing baselines, in the strategic  
15 data analysis plan, there's some discussion of  
16 ongoing baselines, and that's really intended to  
17 address some concerns about the current designs of  
18 our sampling programs in particular and not so much  
19 about inspection tasks or establishment profile. To  
20 that extent, I think, you know, from the design  
21 point of view, the approaches that we're considering  
22 for those sampling programs will improve our ability

1 to measure changes when technologies are applied and  
2 address some of the biases and some of the gaps that  
3 we have with our current program. So I do think  
4 that we're going to see improvements in our ability  
5 to analyze changes in the industry with new  
6 technologies or approaches with some of these  
7 improvements to sampling programs, but we can talk  
8 in more detail if you have specific questions.

9 DR. HENRY: Thank you.

10 MR. ALVARES: Certainly.

11 MS. TUCKER-FOREMAN: Can I just ask one  
12 more question?

13 MR. TYNAN: Yes.

14 MS. TUCKER-FOREMAN: This is Carol Tucker-  
15 Foreman with CFA again. I really think that the  
16 Agency has done a good job with putting together  
17 this data analysis plan.

18 MR. ALVARES: Thank you.

19 MS. TUCKER-FOREMAN: I have lots of  
20 questions about it, but it is a real step forward.  
21 One big issue for me is the predictive analytics.  
22 Is the purpose of this to move to a system that uses

1 predictive analytics to make risk management  
2 decisions, or is it just a way to organize your data  
3 to determine which establishments meet public health  
4 decision criteria?

5 MR. ALVARES: Well, the predictive  
6 analytics component of PHIS, I think you may hear a  
7 little bit more detail in the next presentation, but  
8 that module, that component of PHIS is really  
9 intended to be sort of the groundwork for us to  
10 apply the decision criteria that we have now, and  
11 those are really, as you mentioned, intended to  
12 identify events or issues of public health concern  
13 and direct our resources there where we need them.  
14 But I think it's fair to say that we would in the  
15 long term want to be able to identify potential  
16 public health risks before they occur, to really  
17 stop those before, you know, ultimately we wanted to  
18 have no outbreaks, no illnesses in the public, and  
19 so we do want to be able to continue to advance that  
20 and move forward. As far as exactly how that's  
21 going to be done, I think to some extent, we're  
22 going to have to let the data tell us what the best

1 approaches are and work with our stakeholders and  
2 everyone to really apply that appropriately, but I  
3 guess it's hard to say right now, you know, where  
4 the goal is. The goal is to develop a system  
5 ultimately, that the big picture is develop a system  
6 that prevents those illnesses and those deaths. And  
7 so how we get there I think, predictive analytics is  
8 going to help us, but the form itself, whether it's  
9 some predictive model, years in the future, it's  
10 hard to say right now.

11 MS. TUCKER-FOREMAN: Thank you.

12 MR. ALVARES: Sure.

13 MR. TYNAN: Thanks again, Chris. I  
14 misspoke. It's Tab 10, so rather than Tab 8. So  
15 that's where the plan is located.

16 The next briefing that we'll have for you  
17 has to do with the Public Health Information System.  
18 We have Mr. Bill Smith. He is the Assistant  
19 Administrator in the Office of Program Evaluation  
20 and Enforcement and Review. Bill.

21 MR. SMITH: Thank you, and I get the  
22 opportunity here to present our Public Health

1 Information System overview to you.

2           What this system, we are planning to have  
3 it do, is automate and replace many of FSIS'  
4 existing systems such as PBS, our AIS which is our  
5 import, and the RS which is our resource information  
6 system.       These are all systems that act  
7 independently to drive our inspection today. They  
8 are separate systems, and what we're trying to do is  
9 get them integrated in this process so there's one  
10 system where all information is contained so we can  
11 do data analysis.

12           We also see this as a system that will  
13 facilitate data sharing among our inspection  
14 personnel, at field level, at the district, at the  
15 import supervisor level, Headquarters, our labs, and  
16 so everybody can have information to make decisions  
17 on. Therefore, by having all our systems integrated  
18 as opposed to isolated systems, or separate systems,  
19 we can have a more effective decision-making tool to  
20 make public health determinations.

21           The system really operates through  
22 interaction of four components, and I just want to

1 go through those. There's a domestic inspection  
2 component. There's an import activities component,  
3 an export activities component, and then the last  
4 piece is the predictive analytics.

5           Just a brief description here of each. In  
6 the domestic inspection piece, we are enhancing our  
7 ability, as Chris was talking about, of collecting  
8 information in the establishment profile. So we  
9 will be able to get more information, volume types  
10 of equipment, processes, those kinds of things that  
11 we're not able to get today. Another thing we'll be  
12 able to do is this system will allow us to automate  
13 our food safety assessments. So today those  
14 systems, the EIAO comes in, they create a report,  
15 that's largely a text report. It's very hard to do  
16 any kind of analysis and assimilation in that kind  
17 of format. By automating, a lot of the food safety  
18 assessment now we'll be able to download. We'll be  
19 able to standardize our analysis of our food safety  
20 assessments, and we think that will be much more  
21 helpful.

22           In our import facility, we have data-driven

1 foreign country audits. So essentially what those  
2 foreign audits are telling us about the countries  
3 exporting product to this country will drive then  
4 our re-inspection point of entry inspections in  
5 real-time, and we see that as a major improvement  
6 than what we're doing today. We'll also be able to  
7 automate fully the import application process and  
8 receive electronic foreign health certificates for  
9 advanced notice of incoming shipments. Essentially,  
10 we'll know what's on the water before it gets here.  
11 We don't have that capability today.

12 In the export arena, we're looking to  
13 automate the entire application and export  
14 certification process, and so we see that as a big  
15 plus because we will be able to ensure that all  
16 requirements are met before the product leaves the  
17 country. We'll be able to ensure correct statements  
18 are on the export certificates, and we'll be able to  
19 also electronically transfer these, and we'll get  
20 into that further in the presentation.

21 And then the predictive analytics piece, we  
22 just see a major improvement in the ability to

1 generate alerts, reports, and do data mining.  
2 Today, the people that do the work in the field, our  
3 inspectors and our veterinarians, in order to do any  
4 kind of analysis or trend assessment of what's going  
5 on in that establishment, literally have to go back  
6 through reams of inspection schedules or NRs in  
7 order to pick up a trend. It takes a lot of time to  
8 do that. With this system, as Chris has pointed  
9 out, we'll have the capability where the system will  
10 do an analysis and look for trends and then report  
11 those to the inspectors and the frontline  
12 supervisors and the import inspectors, so they can  
13 spend their time on what they need to be doing which  
14 is reacting to that information.

15           So first to walk through the domestic piece  
16 a little bit, basically we have the same inspection  
17 procedures that we've had in PBIS. There is some  
18 changes. One is we are now doing separate zero  
19 tolerance procedures. We're scheduling those  
20 separate. We are combining today in PBIS, we have  
21 what we call a HACCP 01 and 02 procedure. 01 looks  
22 at specific features of a HACCP system. The other

1 looks at all the features applied to one specific  
2 production. What we're doing is changing to have a  
3 HACCP procedure that is more like the 02 where it  
4 will look at all features being applied at one time.  
5 And we're also adding the hazard analysis  
6 verification procedures, and we will be asking our  
7 inspectors to help verify that the establishment  
8 meets our regulatory requirements for a hazard  
9 analysis by performing this procedure.

10 This system does not create any new  
11 requirements or regulations on establishments for  
12 domestic inspection.

13 Our documentation also changes in this  
14 system. We'll be documenting specific findings  
15 verified by inspection program personnel via a  
16 dropdown menu and documenting findings. What is  
17 different here in PBIS is PBIS is pretty much a  
18 negative reporting system. We only document when we  
19 perform something or we document a noncompliance.  
20 In this system, we will be documenting what we  
21 verify that was in compliance as well as documenting  
22 noncompliance. So we'll have a lot more information

1 again to analyze for data analysis.

2           We will also in this system be able to  
3 document our memorandums of interview or notes with  
4 plant management so that we have weekly meetings  
5 with plant management. The inspection personnel  
6 will be able to be provide now what the substance of  
7 those meetings were. When we have policy that goes  
8 out, we've been asked to verify that the industry is  
9 aware of them and understanding them. We document a  
10 memorandum of understanding. Now they will be able  
11 to do that in the system.

12           So that's pretty much the changes,  
13 similarities, and differences that we're seeing in  
14 the domestic component.

15           In the import component, again we have  
16 moved to electronic certification from foreign  
17 countries. We have electronic application by the  
18 importer of record, and again all this information  
19 is coming to us before the shipment gets here. We  
20 are working very closely with Customs and Border  
21 Patrol. There is a system they are developing.  
22 It's called the automated commercial environment,

1 ACE system. That's running a little slower at this  
2 point in the development of PHIS, and so we have an  
3 interface that we're working with Customs and Border  
4 Patrol. So we'll have that functionality, but we  
5 won't be able to do it immediately through the ACE  
6 system.

7 We will get alerts also when shipments are  
8 failed, failure to present. Sometimes it takes us a  
9 while to catch up to it. By having this  
10 notification come to us while it's on the water,  
11 then we can start tracking, well, why hasn't  
12 something been presented to us. And it will also  
13 automate our refused entry disposition decisions and  
14 tracking system. Again, that is mainly a paper-  
15 based system. A lot of conversation goes back and  
16 forth between Headquarters, the Region, and the  
17 actual import facility. We'll have a lot better  
18 handle on tracking those kinds of shipments.

19 In addition, this system, AAIS does not  
20 currently incorporate the shell egg and egg product  
21 import inspections. All that now will be integrated  
22 into this system, and it will give us an ability to

1 target again specific products that are coming in  
2 based on either sample information that we're  
3 getting from our labs or previous shipments or  
4 findings we're finding from our auditing function in  
5 the foreign country audits. So that really will  
6 give us an ability to drive very quickly and adjust  
7 our reinspection process.

8 Another thing it will do is it will allow  
9 us to align our import and domestic program. What  
10 we mean by that, that the sanitation performance  
11 standards and the SSOPs that are required at import  
12 reinspection facilities will not be documented the  
13 same in this system as they do in our domestic  
14 plants, and we've harmonized our product  
15 classification system of HACCP so the designations  
16 for HACCP categories in domestic and import  
17 inspection are the same. They will be using NRs and  
18 the appeal process and the memorandum of interview  
19 process that I talked about before, and the  
20 establishment profile. Everything that's available  
21 from that aspect in the domestic will now be able to  
22 be used in imports.

1           We'll also be able to reach out and  
2 communicate with direct notification of rejected  
3 products to other agencies. That becomes pretty  
4 important when we're dealing with APHIS and Customs  
5 and Border Patrol, again if a product is being sent  
6 back out of the country.

7           We have a direct notification now and  
8 communication with foreign governments and  
9 authorities, and importers of record and brokers,  
10 they will be able to track again shipments through  
11 the system and their status, and again this  
12 automates our foreign country audit process. So,  
13 again, when our auditors are over there reviewing  
14 plants, reviewing other countries, that information  
15 immediately goes into the system, and then that  
16 drives again our reinspection here at the import  
17 facility.

18           On the export activities, today our  
19 existing export certification system is manual.  
20 It's paper-based. FSIS inspection personnel play a  
21 critical role in verifying requirements and will in  
22 the new process, but the data is sometimes not

1 readily available. So this automates our entire  
2 process. The establishment will be making  
3 application for an export in the system, and then  
4 once an export application is entered into the  
5 system, then the system will be able to determine  
6 what requirements need to be met, what statements  
7 need to be added, what products are or are not  
8 allowed into the country, and so that greatly  
9 improves our use of resources. That burden then is  
10 not on inspectors to make those determinations.  
11 That's on the system, and they can avert their  
12 attention to performing inspection, public health  
13 inspection.

14 So the system automates the establishment  
15 and product eligibility library, and that's what we  
16 call the export library validation service. So what  
17 that means is that all the product specifications,  
18 requirements for products going overseas are in this  
19 system, and so that application will be  
20 electronically put against this system, and it will  
21 say whether that product's able to go overseas, that  
22 particular product or not. It automates statements.

1 Some countries require certain statements to be on  
2 the export cert. That will automatically automate  
3 that process, so inspectors will not have to again  
4 dig through the library or notices and directives to  
5 find out which statements go where, and again when  
6 each export certification does require reinspection  
7 of that, we will then now be able to provide a  
8 checklist to help the inspector determine what  
9 requirements need to be verified in order to certify  
10 that export.

11           So we'll have export product lists. We'll  
12 be able to detail what products require what  
13 requirements. The industry will be able to get into  
14 this system and verify what products are approved,  
15 category. Again, we're linked with our sister  
16 agency, AMS. They do the EV program verification.  
17 This will automatically be done again at the process  
18 of application.

19           Processors will be able to see what  
20 products of their company is in the system, and  
21 again they will be able to apply for export  
22 application through this web-based system through

1 PHIS. They will also be able to batch export  
2 applications if they want and will be able to batch  
3 the applications and certificates.

4           There's going to be three ways that export  
5 certificates will be issued, and it depends on the  
6 countries. We have approximately I believe 110 or  
7 more countries that we export product to. Some will  
8 accept paper. Some will accept electronic transfer.  
9 We're getting out of the export "certificate"  
10 business, and so all the information will be in the  
11 system. If a paper export is required, we will be  
12 providing inspection program personnel with security  
13 paper that then the export cert will be printed onto  
14 that security paper, and that will have the same  
15 security and acceptance by the foreign governments  
16 as our present export cert, and then we provide two  
17 possibilities for electronically moving export  
18 certificates. One is the electronic trade document  
19 exchange process, and the other is eCert developed  
20 by UN/CEFACT, and again that provides a secure  
21 Internet exchange to move exports to other foreign  
22 governments.

1           On the predictive analytics piece, there's  
2 three schematics here. This one just gives pretty  
3 much an overview of what Chris was talking about.  
4 The inspectors will perform procedures. They will  
5 take lab samples. Those results will go into the  
6 data warehouse. That information then will flow  
7 back to frontline supervisors, back to the  
8 inspectors. It'll allow us to do data analysis. It  
9 will allow us to share data with other agencies,  
10 CDC, FDA, DHS, as Chris was saying earlier. It  
11 allows us to partner and exchange data between  
12 APHIS, ARS, AMS. It'll allow us to generate reports  
13 to the Congress, and it will also allow us to share  
14 information with the public.

15           This is a schematic diagram of how the  
16 predictive analytics piece will support inspection.  
17 The most important part I always start with is the  
18 inspector on the ground. The inspector gets  
19 establishment procedures. We'll be able to  
20 determine what procedures and schedule those  
21 procedures for inspection. Those reports, those  
22 results, both compliance and noncompliance, will

1 then be reported back to the system data warehouse.  
2 They will be sent to the predictive analytics piece  
3 of that data warehouse, and then decisions can be  
4 made as Chris was saying, tier decisions. Do we  
5 need to sample more? Do we see a trend in  
6 sanitation? What's the HACCP verification  
7 procedures telling us? What is the HAV procedure on  
8 the hazard analysis telling us? Does that mean then  
9 that we need to drive either more sampling or do we  
10 need to drive a food safety assessment? That's the  
11 for cause based on criteria that's in the paper that  
12 Chris referenced, will drive a food safety  
13 assessment. The results of the food safety  
14 assessment are then partnered with and combined with  
15 the inspection results, and it's a continuous loop  
16 back to the data warehouse to inform and drive  
17 inspection procedures in the plant or samples in the  
18 plant.

19 It also will allow for again analysts and  
20 management to receive this information, to perform  
21 risk assessments as David was talking about earlier  
22 with you, to do analysis. How well is our policy

1 doing? Do we need to make adjustments in our policy  
2 to help our inspection force be more effective? So,  
3 again, there's a continuous loop there of  
4 assessment, policy development, execution, what is  
5 the execution of those inspection findings telling  
6 us in a risk assessment, and then will that drive  
7 changes to policy.

8           This is a schematic of the same type system  
9 in the import arena. It's similar in the task list,  
10 what we saw for sanitation, that we saw in the  
11 domestic. The inspector again gets an assignment.  
12 They determine whether there's compliance or  
13 noncompliance. The results of that inspection,  
14 reinspection go back to the data warehouse. That  
15 informs what we do for sampling. That informs maybe  
16 what we need to focus on in a foreign audit in a  
17 foreign country, and again what you see here also is  
18 the foreign audit system driving the frequency and  
19 what we do at reinspection at the ihouse. So again  
20 you see this continuum of information generated in a  
21 foreign country or as the result of reinspection or  
22 result of sampling, and that drives then what we do

1 at the next point.

2           Again, all this information gets applied  
3 and goes to analysts for their analysis. What is  
4 this telling us about product coming into the  
5 country? What do we need to do with our import  
6 rules? And, again drives our reinspection  
7 frequencies.

8           And so as Chris was talking to you, by  
9 integrating our data streams, by putting this all  
10 together, we are able to do data reporting, and I  
11 think what's really important alerts down to the  
12 inspector level today. We don't have that  
13 capability to get it to our frontline inspectors,  
14 veterinarians, and frontline supervisors who are the  
15 ones that need the information the most and who have  
16 to do the most work to get it. With this system, we  
17 hope to put it in their hands so they can react to  
18 that information instead of having to do the data  
19 mining themselves. That's done for them, and then  
20 they react to the information.

21           We will have public health-based prompts.  
22 Again, that's the decision criteria that Chris

1 talked about, and again that will drive the  
2 frequency of performing hazard analysis  
3 verifications and for cause FSAs.

4           The training right now, what we feel is  
5 that there are many critical components to the PHIS  
6 training. So we are training. Our inspection  
7 personnel and supervisors will be trained together.  
8 We see that we need to bring people on site, have  
9 them working in workshops and exercises, going into  
10 detail about the policy, why we're doing what we're  
11 doing, what is the requirements and statutory basis,  
12 and then how the system, which is a web-based  
13 system, what we call a click-by-click or how the  
14 web-based system addresses that, how they will  
15 complete information, download information, and that  
16 kind of thing.

17           Again, I think it's very important for us  
18 to continue to reiterate the reasons we are moving  
19 to this system. It is to improve the public health  
20 benefit by getting information, being able to be  
21 analyzed across many streams. It's very important  
22 for inspection personnel in order to understand that

1 what they're doing and the information they're  
2 gathering from performing an inspection is a  
3 critical component of the overall Agency process for  
4 addressing public health.

5           And as you can see here again, these are  
6 the major pieces that we'll be covering, domestic  
7 export/import, predictive analytics. We're going to  
8 try, as a familiarization thing, do a comparison,  
9 what is in PBIS, what's carried over, what's  
10 different. Again, we will be going through the  
11 various directives that drive the policy. They will  
12 be verifying, and we'll be spending a lot of time on  
13 the hazard analysis verification process, and that's  
14 really going to get in depth into verifying a  
15 plant's flowchart, a plant's support of hazard  
16 analysis, how plants are using prerequisite programs  
17 and how they inform their decisions. Are they  
18 carrying them out? If a prerequisite program  
19 standard is not met, what happens? We will again  
20 review basic micro principles, and then we will  
21 review again how the things we're doing with humane  
22 handling, eADRS, animal disease reporting, how

1 that's handled in PHIS as well as today if we get an  
2 O157:H7 positive in a plant, then we input that  
3 information into our STEPS database, and then that  
4 generates sampling at the supplying establishments.  
5 That will all be automated through PHIS, and so that  
6 will decrease the amount of time from the finding of  
7 a positive in a grinding establishment to when we  
8 start testing in a slaughter establishment.

9           Right now we're looking at this training to  
10 take about two weeks, and we will again want to be  
11 doing evaluations on how effective the training is  
12 prior to people getting there and when they leave,  
13 so that if there's adjustments that need made in the  
14 training, we can do that on an ongoing basis.

15           As far as the industry, we've already done  
16 some webinars. We have some more scheduled in  
17 October on the domestic component, the import  
18 component, the export component. We're putting a  
19 lot of information on our website, a lot of  
20 informational mailings. We will be reaching out  
21 very soon to the industry with a letter on how to  
22 obtain e-authentication because in order to interact

1 with this system, the domestic industry will be able  
2 to interact from the standpoint of responding to NRs  
3 should they want to use that option, making appeals,  
4 those kinds of things, getting reports on what the  
5 system's saying about their plant. In order to get  
6 into our system, you will have to have  
7 e-authentication level 2. That's a USDA standard.  
8 Right now there is 14,000 centers across the  
9 country, pretty much our Farm Service Agency is  
10 where we would be telling folks to go to get their  
11 e-authentication.

12           And then when we get closer to starting up  
13 this system, we will be sending out what we call a  
14 licensing to each establishment, and they can  
15 determine who in that establishment will be  
16 authorized to make decisions or do appeals or do  
17 exports in their particular establishment. So they  
18 will set the roles for people.

19           Export applications, again we are moving to  
20 a full automated process. So we would encourage  
21 those that are in the export business to get into  
22 e-authentication, really look at this. The Agency

1 will provide an alternative to the automated  
2 process, but essentially that would be faxing  
3 information or mailing information to one contact  
4 point. We believe right now we're looking possibly  
5 at our Omaha Office, and then that will be entered  
6 electronically there.

7           So that's a status and an overview of what  
8 we're looking at, the four components of the  
9 systems, what changes, what's the same, and so I'll  
10 be glad to take questions. I believe Nancy was  
11 first. I'm sorry. I wasn't watching.

12           MS. KLEIN: I'll take it. I'll be first.

13           MR. SMITH: Okay.

14           MS. KLEIN: Are there specific public  
15 health objectives for PHIS? And if so, where are  
16 those articulated?

17           MR. SMITH: Well, I think our data, our  
18 strategic analysis plan lays out our objects as far  
19 as the expectations for tier 1 plants, and then, you  
20 know, if we have plants that are having issues with  
21 positive pathogens or number, we're seeing a trend  
22 in NRs that is way out there from all their other

1 peers, that that would be a trigger to take a look  
2 at that facility. So essentially what the target  
3 is, is to verify the document that plants are  
4 meeting our requirements, that's basic, what the  
5 inspection procedures will do, and by documenting  
6 what was compliant, we'll be able to document, which  
7 we can't do today, what was looked at in that  
8 particular plant, or was verified as being compliant  
9 and the same thing if something's noncompliant, what  
10 specifically, what requirement was noncompliant.

11           So, for startup, I think that's a goal.  
12 When our samples are taken, it will give the  
13 inspectors ability today, if a plant's not making a  
14 product, then their options are limited, you know,  
15 to send the sample form back. With this system,  
16 we'll be able to pick alternative days and  
17 reschedule that with the lab so the sample is taken,  
18 so we'll get more samples take. So our food safety  
19 assessments, again by automating those, we will now  
20 have the ability not only to know what's going on in  
21 one facility, but what we're seeing across a region  
22 or across a country of similar operations, and so

1 that's a goal to tell us what are the production  
2 controls and practices to meet our requirements. So  
3 those would be our goals.

4 MR. COVINGTON: Bill, Brian Covington,  
5 Keystone Foods. It's evident that the Agency's put  
6 a lot of time and effort into this system, and I  
7 commend them for that because the ability to capture  
8 all of the data easily to evaluate it is going to be  
9 very much a positive going forward, and I also  
10 commend the Agency for going toward documentation of  
11 regulatory compliance as well as noncompliance  
12 specific to the regs.

13 With that, we're going to have a lot of  
14 data collected. What's the transparency and the  
15 visibility of all of the information collected in  
16 the system both to the particular establishment in  
17 which the data is collected and to the Agency say at  
18 the frontline level or above? For example, will a  
19 FLS be able to see establishments not within their  
20 circuit or how will that work in terms of the  
21 visibility?

22 MR. SMITH: The web-based system has to be

1 based on a role basis. So, one is, we have reached  
2 out to industry and will continue to work with the  
3 industry about kinds of reports they would like to  
4 see. We can't give them ad hoc capability at least  
5 at startup. So we do need to get some kind of  
6 agreement on what are the things they would like to  
7 see reported on, what's going on in their  
8 establishment, and then be able to provide that in  
9 some kind of a reporting format that they can go in  
10 then and access it. Because it is a role-based  
11 system, then inspectors see the plants and their  
12 assignments. Frontline supervisors see plants in  
13 their circuits or in the form of an OIA supervisor  
14 of the plants and under their responsibility, and  
15 then it goes up region for OIA, district seen by  
16 district, and then Headquarters, of course, has  
17 access to everything.

18 MR. TYNAN: Brian, some of that's going to  
19 be discussed in the Subcommittee session. I know  
20 you're in the other one, but if there's some issues  
21 I know, some of your colleagues are going to be  
22 there, so they can talk a little bit about some of

1 the concerns you may have.

2 Ms. Donley, why don't you go ahead next.

3 MS. DONLEY: Thank you very much. This  
4 really sounds terrific as far as being able to get  
5 additional data communicated more quickly to the  
6 frontline personnel, and hopefully make big  
7 differences. Does the Agency have any idea of  
8 perhaps how this might, that it's going to save time  
9 on certain things, that it's going to free up  
10 resources in a sense, that will this be able to  
11 translate into additional resource dollars to go  
12 down into the inspection level where more food  
13 safety inspection tasks can be performed?

14 MR. SMITH: I think it's a little early. I  
15 mean I can't really answer that today. What we're  
16 saying is that the inspector workforce is there  
17 today and maybe some additional ones, just to carry  
18 out what I presented here, and we know that by  
19 automating the export process, that we feel that we  
20 can save some time that they're doing now in looking  
21 through documents or going to the export library now  
22 and looking up information and having to do that.

1           But I think what we really need to do is  
2 work the system six months, a year, to make that  
3 determination, and then, yes, I would think that  
4 this Agency, I know this Agency will want, if  
5 there's more time to devote and focus on food  
6 safety, that that will be the goal in the  
7 establishment.

8           MS. DONLEY: Because I guess, too, on the  
9 flip side of that, do you see the Agency having to  
10 spend additional resources to hire additional  
11 analysts to do and perhaps, you know, undermine a  
12 little bit of some of the other tasks that they're  
13 currently doing?

14           MR. SMITH: Well, I mean I can't really  
15 talk about -- I don't see big changes in the number  
16 of analysts because at the end of the day you want  
17 this system doing the analysis. You want this  
18 system doing the algorithms. Now, certainly complex  
19 analysis and risk assessment, that needs to be done  
20 by trained analysts. I don't see us growing in any  
21 great numbers at this point.

22           So what I do see is information being

1 analyzed a whole lot sooner and then like I said,  
2 the data mining and all that has been automated,  
3 that information goes back down to the levels where  
4 people can use it. So I'm not seeing a big increase  
5 in the number of analysts. I am seeing a big  
6 increase in our ability to analyze data, said  
7 algorithms, and then get information going back to  
8 the field as well as to Headquarters. So that's  
9 where I see the changes.

10 MS. DONLEY: And just my final comment on  
11 this. I really do believe that, you know, this is  
12 the age of technology, and last century was the age  
13 of technology. So I think this is very important.  
14 You're making a tremendous investment to be able to  
15 put this system into place, and what does the Agency  
16 see as a success, that they've spent this money  
17 well, and I guess that kind of circles back to  
18 Sarah's question. At the end of the day, what does  
19 success look like for this system?

20 MR. SMITH: And that's a very good  
21 question. I think a number of things. One is just  
22 your basic, in order to develop a system like this,

1 you have to follow certain criteria, a design,  
2 functional requirements, user testing, certification  
3 accreditation which includes security and all those  
4 things. So from just a pure application piece, it  
5 has to meet all that. So that's a given.

6 I think from an inspection standpoint, I  
7 think by again providing more information to our  
8 inspectors and having them be able to use the  
9 information alerts and use the capability to  
10 document findings, do surveys that we'll be doing,  
11 perform HAVs and those kinds of things, all those  
12 things we just have to evaluate after we implement,  
13 that that's making a better inspection process. We  
14 believe it is because we've never had this  
15 documentation. We've never had these findings  
16 before. So by having this data and knowing what  
17 plant processes are doing as well as just saying  
18 something's acceptable or not, that's what we're  
19 seeing as a success here. Once we get the entire  
20 country, once implementation would start, getting  
21 the whole country involved, having again in the  
22 import arena, having what your findings are and

1 foreign audits drive almost in real-time what your  
2 reinspection is at the port of entry, knowing what's  
3 on the water, of products coming in before they get  
4 here, all that we just see as an improvement, and we  
5 will have to set up criteria and evaluation to  
6 demonstrate that that is working to everybody's  
7 advantage.

8 MS. DONLEY: Okay. So you have planned a  
9 feedback loop and evaluation of it to see --

10 MR. SMITH: Absolutely. We will be  
11 evaluating it. Management controls will be put in  
12 place, and I'm sure other government agencies will  
13 be looking at us on some kind of audit basis, all  
14 those.

15 MR. TYNAN: Ms. Donley, I know you probably  
16 have 12 more questions but, Dr. Shultz, did you want  
17 to? If we could shorten up the questions just a  
18 little bit to help with time.

19 DR. SHULTZ: Okay. This is a very short  
20 one. In terms of documenting compliance, will that  
21 be a narrative documentation similar to the  
22 narrative that we put into a NR when there is a

1 noncompliance, or will it simply be like a checkbox  
2 that says the requirements of 9 C.F.R. yada, yada,  
3 were assessed and determined compliant?

4 MR. SMITH: The latter.

5 DR. SHULTZ: The latter.

6 MR. SMITH: Or closer. So it will say we  
7 verify 417.2, 417.3, 417.4, so each one of those  
8 will be checked, yes.

9 MR. TYNAN: Ms. Buck.

10 MS. BUCK: Yes. First of all, I guess the  
11 last time I spoke, I didn't say, I thought this is a  
12 very good plan and starts moving us forward. I  
13 think as usual, the devil is in the details. So I  
14 think we're here to try and fether out, you know,  
15 some of those problems.

16 In this presentation, in slide 3, page 1,  
17 you talked about the four components of PHIS, and  
18 then in the report on page 8, it makes reference to  
19 a project charter, okay. And the project charter it  
20 says here was written at the beginning of this  
21 project and included an overview of the PHIS  
22 initiative, defines the scope of the project and

1 name, project primary stakeholder for each FSIS  
2 program area, and it goes on. I'd like to see a  
3 copy of that project charters, and I think the rest  
4 of the Committee would benefit from it. Is that  
5 going to be possible to provide us with that project  
6 charter?

7 MR. SMITH: Certainly.

8 MR. TYNAN: Well, we certainly can and, in  
9 fact, I think the charter that you're referring to,  
10 we passed out just before you came in. I know there  
11 were several members, and Ms. Foreman in particular  
12 had commented that she wanted to see that. So we've  
13 gotten that for you.

14 MS. BUCK: Thank you.

15 MR. TYNAN: It's available, and we respond  
16 very quickly. You ask, and it's there.

17 MS. BUCK: Okay. The second question, and  
18 again it might be just very brief but when you're  
19 talking, and I believe it's, I have to get back to  
20 my slide, where those beautiful charts that you  
21 developed, and it's the predictive analysis block.  
22 That is a very important block. Who is going to be

1 in charge of that within the Agency? Has that been  
2 specified as to how you are going to administer what  
3 the input is?

4 MR. SMITH: Well, I think there's several  
5 owners in the Agency. I would say the owner of who  
6 does the analysis and sets the parameters for that  
7 will be worked with our Office of Public Health  
8 Science and our Office of Data Integration and  
9 Assessments. So Chris' group he oversees and David  
10 Goldman through his risk assessment component, they  
11 will own that, but the algorithms and types of  
12 analysis need to be done. Certainly OPPD, our  
13 policy, will be the recipient, and so they will be  
14 getting that information so they can develop policy,  
15 and then certainly it'll be available to all our  
16 regulatory operational programs, field operations  
17 and imports, and they will have that.

18 The data itself will reside at the USDA  
19 Data Center in Kansas City. So our entire  
20 infrastructure will reside there where it has 24/7  
21 maintenance and security and protection, and then  
22 should some kind of unforeseen disaster happen

1 there, we have a backup facility in another USDA  
2 Data Center, and so our standard right now is we go  
3 back online within four hours if there's some kind  
4 of a disaster that would take our systems down at  
5 the primary location.

6 MS. BUCK: So if I had a question about the  
7 data, I would look to Chris, about the quality of  
8 the data.

9 MR. SMITH: You would always come in the  
10 way as you're doing now, and I think there is a  
11 presentation later today on data.gov, and I think  
12 Todd will be able to answer that question better for  
13 you.

14 MS. BUCK: Okay. Thank you.

15 MR. SMITH: Yes.

16 MR. TYNAN: Mr. Stromberg?

17 MR. STROMBERG: Yes, my question has to do  
18 with your PHIS training. One of your bullet points  
19 there listed the basic steps of HAV. Can you  
20 describe those real briefly for me?

21 MR. SMITH: Well, I think the next slide  
22 did that, if we can go back to this slide here,

1 proposed training content continued. The HAV, it's  
2 hazard analysis verification, the training, the  
3 exercise, looks at the plant, all components of the  
4 hazard analysis, and so it looks at the flowchart,  
5 it looks at the support, the documentation for the  
6 analysis, how prerequisite programs factor into  
7 whether a CCP's determined or not, those kinds of  
8 things. What kind of microbiological or chemical  
9 sampling programs are going on, all of that. So for  
10 each HACCP category then, you know, we do today,  
11 they have to have a hazard analysis flowchart and  
12 that addresses all the components of the HACCP  
13 requirements, and that's really, we're not asking  
14 them to make scientific determinations and  
15 assessments about the validity. What you are asking  
16 is are those things there, and are they being  
17 monitored, and if something's not right, is it being  
18 corrected?

19 MR. TYNAN: Ms. Foreman.

20 MS. TUCKER-FOREMAN: Thank you. Carol  
21 Tucker-Foreman with Consumer Federation. I just  
22 have so many questions about the predictive models

1 and how that measures with what the NAS said and  
2 about attribution, and I would just love it if we  
3 had more time to explore this. Let me ask a couple  
4 of short practical questions in deference to the  
5 schedule that hasn't really given us enough time on  
6 this subject.

7 How do you know that the data are entered  
8 correctly?

9 MR. SMITH: I'm sorry. I didn't hear you.

10 MS. TUCKER-FOREMAN: How will you know that  
11 the data have been entered properly and then  
12 integrated appropriately?

13 MR. SMITH: There's been a lot of work put  
14 into automated data edits into the system that if  
15 this occurs, it can only go in this way. If I'm  
16 verifying something that's compliant, then all the  
17 requirements have to be verified with that, have to  
18 be documented. If I'm documenting a noncompliance,  
19 it's going to specifically ask which requirements  
20 are not being met. And there's edit checks with  
21 each and every one of those. If a procedure, a  
22 HACCP process, let's say a fermented sausage because

1 sometimes that can take 60 days from the start of  
2 the process, the grinding, through the fermentation,  
3 drying process, this system will track the  
4 procedures not done until all the requirements are  
5 met, and it will report an alert to the inspector so  
6 they know that it hasn't been completed yet, and  
7 they'll be able to follow up on that.

8 As always, we'll have our frontline  
9 supervision, and there will be management controls  
10 independent of the system to see that things are  
11 being entered like they are today. So it will be  
12 that combination of the automated edits plus the  
13 supervision plus the management controls.

14 MS. TUCKER-FOREMAN: What are the  
15 management controls?

16 MR. SMITH: We will have certain tasks  
17 scheduled, how many performed. I don't have that  
18 complete list with me, but you set a performance,  
19 that 80 percent of something needs to be done or 90  
20 percent of something or if it's food safety, like  
21 retain product, properly retain at 100 percent.  
22 Then you'd put in your system some kind of reporting

1 mechanism to track that, you know, that it was  
2 rejected product, that it was determined to be  
3 adulterated, was it destroyed, and hopefully we can  
4 build through our dropdowns and from our inspection  
5 procedures are telling us, we can make those kinds  
6 of determinations. Time spent on humane slaughter  
7 verification, just like we do with HATS today, we'll  
8 be able to track how much time is actually spent  
9 performing humane handling, those kinds of things.

10 MS. TUCKER-FOREMAN: And where does the  
11 company have a chance to challenge something that's  
12 been entered in the database?

13 MR. SMITH: They will be able to appeal  
14 individual noncompliance determinations. They can  
15 appeal if they don't agree what's in the memorandum  
16 of interview. They will be able to view again these  
17 reports that I was talking about. If they don't  
18 agree that the math adds up, they will be able to  
19 appeal that.

20 MS. TUCKER-FOREMAN: So the inspector will  
21 still inform a plant that there's a noncompliance?

22 MR. SMITH: Absolutely, absolutely.

1 MS. TUCKER-FOREMAN: Okay. You've been  
2 doing user testing. How's that been going? Have  
3 the users been able to apply this so that it works  
4 well?

5 MR. SMITH: User testing, a very good  
6 question. User testing from what we started and  
7 where we are today, I believe right now have  
8 approximately 4400 issues that we documented, what  
9 we call bugs, and we've corrected to this point  
10 approximately 3650, 3700 which gives us about 800 to  
11 go.

12 As you can see from what I put up there, at  
13 the end of the day, what is a bug? A bug is that  
14 every command, every interaction has to be at some  
15 point coded with, you know, a binary system, 01s,  
16 and so what a bug is, is that one code is not  
17 interacting, is not either representing something  
18 correct or it's not allowing something else to  
19 interact, and so we're going through those and we  
20 feel that, well, we know that we will have to have  
21 those things corrected before we have any idea of  
22 entertaining any kind of implementation. But right

1 now we feel very good about what we're seeing.

2           When we first started user testing, we were  
3 getting, I don't know, 70 to 150 a week, and from  
4 different users that was building up those numbers.  
5 The last user testing that we had, we received  
6 numbers that were less than what we had seen before,  
7 but also these were repeats of things we already  
8 knew we had to fix. So we didn't get very many new  
9 from the user testing that we did in the field. We  
10 didn't get any new issues, and so that's good. So  
11 what that's telling us is the things we're fixing  
12 are not creating other problems, and that we're  
13 catching up with the backlog of U18.

14           So the next step, after you get a handle on  
15 that, of course, then you have to do performance.  
16 Will it talk to other systems correctly? Will it  
17 send data to the data center correctly, and so  
18 that's the next step after we get through these, and  
19 then, of course, the certification and accreditation  
20 process.

21           MS. TUCKER-FOREMAN: Just one more short  
22 question.

1 MR. SMITH: Sure.

2 MS. TUCKER-FORMAN: PBIS has been in effect  
3 for what? Twenty-five years.

4 MR. SMITH: It went into effect I believe  
5 1989.

6 MS. TUCKER-FOREMAN: Okay. How are you  
7 going to integrate the information that you get from  
8 PHIS with the information that you have from PBIS?  
9 Are all these companies going to get a clean slate?  
10 Are they going to have the day they wake up and  
11 there's no data there?

12 MR. SMITH: No, thankfully we have Chris  
13 and Todd over here that are developing the  
14 algorithms and the process to extract from PBIS into  
15 PHIS.

16 MS. TUCKER-FOREMAN: And who's going to  
17 review that from outside the Agency to be sure that  
18 it works appropriately?

19 MR. SMITH: Well, what I can say is when we  
20 transfer data, there's specifications and things  
21 that have to be met in order to determine if we've  
22 had a successful transfer of data, and so to the

1 extent that our systems document that we can  
2 accredit and certify, that our systems do these  
3 things including our processes to transfer data,  
4 that is looked at that department, that would be the  
5 outside look that I know of right now.

6 MS. TUCKER-FOREMAN: I didn't hear anybody  
7 from outside the department.

8 MR. SMITH: And, again, we're following our  
9 procedures of data management, and so our reporting  
10 is up through the department.

11 MS. TUCKER-FOREMAN: Well, it seems to me  
12 that that's something that ought to be subject to  
13 some outside scrutiny, that you can't afford to lose  
14 the data you have.

15 MR. SMITH: Sure.

16 MS. TUCKER-FOREMAN: You've got to be sure  
17 that these work together, and that you don't lose  
18 the historical accuracy that you have. Thank you.

19 MR. SMITH: Yes.

20 MR. TYNAN: Can I impose on Dr. Henry and  
21 Dr. Negron, could we hold your questions? We've  
22 been sitting for a good long time, and I know that

1 myself, that it's a challenge to do that for this  
2 length of time. We were going to take a break at  
3 2:30, but then we got into some other questions.  
4 Could we take a 15-minute break now, to 3:15? We're  
5 going to go ahead and take a break until 3:15, back  
6 as quickly as you can. I think the cafeteria still  
7 has drinks and things that are available.

8 (Off the record.)

9 (On the record.)

10 MR. TYNAN: Could I ask everybody to take  
11 their seats please?

12 Veny, Byron, I see your cards are up. I  
13 didn't see them from where I was sitting, but if we  
14 can hold those questions on PHIS, I would appreciate  
15 it. I'm assuming that's what it was. Okay. And  
16 we'll try and address them sometime during the  
17 session.

18 We're actually at the point of really the  
19 meat of the meeting, even though we've spent quite a  
20 bit of time on the two briefing issues. They are  
21 important because they are background information  
22 for you to prepare to have this discussion on data

1 and perhaps the discussion on pre-harvest activities  
2 as well.

3           So with that, I'm going to introduce Jeremy  
4 "Todd" Reed, and he's going to talk about data  
5 collection, analysis, and transparency.

6           MR. REED: Thank you. So let's see if I  
7 can get the timing right. Does that sound right?

8           MR. TYNAN: That sounds good.

9           MR. REED: Okay. So first of all, I just  
10 wanted to say, I'm Todd Reed. I'm with the Office  
11 of Data Integration and Food Protection, and  
12 specifically the Data Analysis and Integration  
13 Group. And so our responsibility is to look at data  
14 and to analyze data. And really we're changing  
15 gears now from the previous presentation to where  
16 Chris and Bill did a great job of kind of showing  
17 where we're at in the Agency. The next few  
18 presentations, we're going to be showing, kind of  
19 asking questions of you, of the Committee about  
20 where we want to go, which is really the heart and  
21 soul of why we're here. So we're really changing  
22 gears.

1           So the topic is data collection, analysis,  
2 and transparency, and briefly this slide is just the  
3 agenda that we're going to go over in the next few  
4 slides here. We're going to look at the background,  
5 some data sharing issues, briefly FSIS data that  
6 we're sharing now, and then I'm going to go into the  
7 heart of the slides, the broad issues, the criteria  
8 to choose data and sampling data and results.

9           So really on the background, what I want to  
10 get to and what we actually want to talk about is  
11 that transparency is an Administration priority.  
12 It's a FSIS priority. We want to increase  
13 transparency. We want to share data with the  
14 public. We want to decrease FOIA requests, and what  
15 we mean by that is we want the data to be there up  
16 front. We don't want you to have to ask for it. We  
17 don't mean we don't want to share the data, just to  
18 avoid any confusion.

19           We want to meet stakeholders' needs, and  
20 really what we're trying to do here is we want to  
21 understand how to evaluate the usefulness of data.  
22 So really what I'm going to be talking about, and

1 what we're looking for, for the Committee tomorrow,  
2 is really criteria, criteria for us to evaluate  
3 data, criteria to choose types of data and criteria  
4 to share data because over time, as we all know,  
5 we're going to get new data, different types of  
6 data, different things are available now as will be  
7 in the future, and we're really looking for the  
8 Committee to give us direction on how we should be  
9 making those evaluations, to help determine how data  
10 should be shared and what data should be shared.

11           So before we get going, there are some data  
12 sharing issues that we just need to acknowledge and  
13 really should be involved in the Committee's  
14 discussion.

15           One is confidentiality of individual  
16 establishments. Some data, as we know, is trade  
17 secret. Some data comes in with recipes on labels.  
18 Sometimes there's means of production that  
19 establishments don't want us to share and that we  
20 shouldn't share, and there's other data that just by  
21 law we cannot. So that is an issue and that we  
22 should consider and the Committee should consider

1 when you're talking about data.

2           And the second issue which is really  
3 something that we actually have a bit more of a  
4 touch with is data stability. Really what I want to  
5 explain here is what we mean by that because I know  
6 we could be confusing. When we say timing,  
7 completeness, fluctuations, really what we mean data  
8 has natural lags. So when we schedule a sample, it  
9 takes a while for that sample to actually get on the  
10 inspector's calendar. It takes some time for the  
11 sample to be taken. It gets shipped to the lab. It  
12 has to get analyzed. The results get processed. So  
13 even though in PHIS, that process is going to get  
14 faster, there's still natural lags in the system,  
15 and that's one example and that happens on many  
16 types of data.

17           So when we publish data, or we make data,  
18 we share with the public, we really have a tradeoff.  
19 On the one hand, we could share today data up  
20 through current through yesterday. But what's the  
21 loss? If we do that, the data is not going to be  
22 complete. It's not going to have a lot of finalized

1 results. It's going to be misleading for all  
2 interpretations on either side.

3 On the other hand, we can wait forever and  
4 ever for the data to get completely stable, but if  
5 we do that, then there's some risk that the data's  
6 no longer useful or it's less useful or it's out of  
7 date.

8 So really what we're looking for is  
9 criteria from the Committee for us to be able to  
10 evaluate what that middle group is. Where's the  
11 right tradeoff between timeliness and completeness  
12 in the fluctuations in that data.

13 All right. So the next slide is on FSIS  
14 data. As I mentioned before, you know, we have two  
15 main goals that we're talking about here today. One  
16 is we want to share data publicly but, two, we don't  
17 want to just share data if it's not going to be  
18 useful or meaningful to anyone. So we want to make  
19 the data easy to use. We want to make it meaningful  
20 to the stakeholders. Right now we share data in two  
21 locations, and I'll show you some examples of that  
22 just briefly before we go on, but when we share

1 data, obviously we want the data to be clean, we  
2 want it to be consistent, we want it to be defined  
3 properly with definition so people know what they're  
4 getting. It needs to have descriptions when  
5 necessary, and any assumptions or limitations that  
6 go with that data need to be made clear.

7 So when the Committee is considering  
8 proposing criteria to FSIS and how we evaluate data,  
9 please consider that in your criteria that you  
10 propose to us. What are the limitations? What are  
11 the items that we need to do when we share that data  
12 so that it is useful to end stakeholder?

13 So the two main places that we share data  
14 right now are data.gov, and this is just a  
15 screenshot of the website, and there are links in  
16 the presentation which you all have, and the FSIS  
17 website. Right now there's a lot more data on the  
18 FSIS website, a lot more explanation, and there's a  
19 lot of other material there as well. So not  
20 inclusive but, you know, there's data, analysis,  
21 stuff on education, there's reports that we've done,  
22 there's policy documents and many more things, but

1 right now those are our two means to get data to  
2 you.

3 And so when you're having your deliberations,  
4 consider that, take that into account, and think  
5 about what way we can get data to you through these  
6 mechanisms that meets all of our goals and meets all  
7 of your goals more importantly.

8 All right. So let's get into the heart of the  
9 talk here. Broad issues. Okay. Who are the likely  
10 audiences and customers that FSIS should consider?  
11 Okay. I can think of many audiences right now by  
12 myself. People in this room, industry, consumers,  
13 academia, other government organizations, employee  
14 groups. I can think of other possible groups, but  
15 maybe you, the Committee, know of other stakeholders  
16 that we should be considering, and that would be  
17 helpful if you can tell us, who are our audiences  
18 and customers.

19

20 Secondly, which types of datasets are  
21 most important? Sampling results, list of  
22 establishments, something else. We can't release

1 everything, but if we had some type of ranking, some  
2 type of criteria that the Committee could agree to  
3 that said these are our priorities that if you could  
4 release data, that would be the best. That would  
5 help FSIS in our ability to make data available and  
6 to share that.

7           When should FSIS consider sharing  
8 establishment-specific data? This is a big question  
9 that we really would like the Committee to get  
10 involved in and to tackle. What is that data that  
11 identifies an individual establishment? On the one  
12 hand, I can see times where that would be very  
13 important to release publicly. On the other time, I  
14 could see where that could be misleading. And one  
15 observation taken out of context without information  
16 that relates that establishment to the rest of the  
17 industry could be misused. It could affect trade.  
18 It could affect the establishment. I don't know  
19 what other second order effect, well, I don't know  
20 what they would all be, but we would really hope  
21 that the Committee could help propose that and to  
22 weigh those into their considerations.

1           Okay.     Criteria to choose data.     What  
2 criteria should FSIS use to evaluate our potential  
3 datasets?   Again, at the beginning, as I mentioned,  
4 this is really what we're hoping to get from the  
5 Committee.   What criteria should we use all across  
6 the board?   Which types of datasets are top  
7 priority?   I mean I could assume sampling results,  
8 but we would really like the Committee to help tell  
9 us what the priorities are.   What types of data  
10 should we consider sharing that we don't currently  
11 share?   Are there things that different groups feel  
12 that we really should?   Can the Committee come to  
13 some type of consensus or some kind of ranking that  
14 would be like this is wish list, this would be our  
15 best thing that we would really prefer?

16           What time intervals should FSIS use to  
17 share data?   We really think of time intervals in  
18 two ways.   When we say which intervals are most  
19 useful and which intervals provide the best  
20 information, think of it as timing of releasing the  
21 data.   How much of a lag should there be as I talked  
22 about earlier?   But also aggregation time intervals.

1 Should we release daily data or weekly or monthly or  
2 quarterly? What level of aggregation is most  
3 useful, is most appropriate? And so we would ask  
4 the Committee to take that into consideration when  
5 you make recommendations on data and to help guide  
6 us in that area.

7 Okay. Sampling data and results. So we  
8 know that one type of data that everyone's  
9 interested in is sampling data. We publish a lot of  
10 that right now on our website as we've already  
11 talked about, but which types of sampling result is  
12 most useful? Microbiological, *E. coli*, *Salmonella*,  
13 *Listeria monocytogenes*, or chemical, you know,  
14 pesticides, antibiotics, other type of data, or  
15 maybe something else. We're really looking for the  
16 Committee to tell us what would be useful to make  
17 recommendations so that we can consider that among  
18 all the other considerations that we have.

19 Which variables are highest priority? Now,  
20 I know this is a little bit in the weeds for some  
21 people, but it really does matter because when you  
22 say data, and you start releasing it, different

1 variables have different implications on what can be  
2 done with that data, how someone could do a second  
3 order analysis of the data, how the data could be  
4 interpreted or even misinterpreted, and really how  
5 fine a grain can you get with that in understanding  
6 from the public. So we're looking at that, you  
7 know, what is appropriate? What makes sense? What  
8 is useful? What does the Committee recommend? What  
9 intervals provide the best information?

10 So really as I started in the beginning and  
11 kind of where I'm going is, what are the possible  
12 criteria to evaluate the criteria, to share it  
13 publicly, to identify establishments? I bring that  
14 up again because that's an important question that  
15 we could really use criteria on.

16 What criteria can FSIS use to determine our  
17 priority in the future, because priorities will  
18 change. Your priorities will change. Our  
19 priorities will change. The Administration  
20 priorities will change. So what criteria can we use  
21 to help identify those priorities and their changes?

22 So this slide provides a couple of sample

1 data locations, all that are available to you now.  
2 There are many more. On the website, if you went  
3 and look, but here are some specific examples that's  
4 in your packet.

5 Finally, what are we missing? This is  
6 really us asking you, looking forward, not looking  
7 back, looking forward, what kind of criteria should  
8 we use to help evaluate data to help release data?  
9 And so really we've asked the Committee to help us  
10 do that. That being said, I know that was kind of  
11 short and sweet, but we wanted to get to the heart  
12 of the matter. Any questions? Yes, sir.

13 DR. CHEN: Before we look at the data, what  
14 we should put into the system, but can you briefly  
15 describe what's the current type of data you have on  
16 the data.gov and the FSIS website?

17 MR. REED: Yes, I can, although I think  
18 Anthony Andreassi, the co-port here is the better  
19 one to describe. He's from our Office of the Chief  
20 Information Officer, and so he would have more  
21 direct knowledge on that.

22 MR. TYNAN: And could I ask, as we go

1 along, if everybody could, when they ask their  
2 question, identify themselves for purposes of our  
3 transcript so that we make sure we get you credited  
4 with the question and as well as the answer.

5 MR. ANDREASSI: Good afternoon. What we  
6 have released currently on the data.gov website is  
7 the same that we have on our FSIS website. The two  
8 websites are linked. So the document that we have  
9 out there is meat and poultry directory. That's the  
10 only document that we have that has gone through  
11 governance process and been released to data.gov.  
12 That is also on our FSIS website. That's all that  
13 we have. So part of our question to you is how can  
14 we get more out there, and what is the process to  
15 think about the data that's going out.

16 As Todd mentioned earlier, we have many  
17 studies that we've done internally as a result of  
18 our business processes that we put on our website,  
19 FSIS.gov, and those are available to you publicly  
20 right now. So there's many, many different issues  
21 regarding analyses as well as education processes  
22 that we're going through and things of that nature.

1 It's very broad, and we encourage you to take a look  
2 at that as you deliberate on what the criteria will  
3 be. Is that sufficient for you?

4 MR. TYNAN: Dr. Chen, does that help you?  
5 Do you need a little bit more detail to go with  
6 that?

7 DR. CHEN: Yes, any sampling data on the  
8 website already?

9 MR. ANDREASSI: On our website right now.

10 DR. CHEN: Yeah.

11 MR. ANDREASSI: We do have on the FSIS  
12 website, nothing yet on the data.gov.

13 MR. TYNAN: I just had a little birdy over  
14 my shoulder, John Linville, who is going to be  
15 coming up in a few minutes, talking about pre-  
16 harvest activities, but he mentioned that he would  
17 touch on some of the data points that might respond  
18 to your question.

19 DR. CHEN: Thank you.

20 MR. ANDREASSI: As we go through our  
21 business processes, we create analytics and we  
22 release it to the FSIS website. So there's just

1 many different types of subject matter out there,  
2 and pretty much as you look at subject areas that  
3 were listed from the PHIS slides, we carry those  
4 same import, export, domestic and other analytics  
5 although we're couching it as predictive analytics  
6 for PHIS.

7 MR. TYNAN: Dr. Chen, one last point. I  
8 think we had some ideas on some other things that we  
9 wanted to post, and we'll have that for you tomorrow  
10 because I think we were talking about somehow  
11 prioritizing those as well. So I'll check and be  
12 sure that I'm still correct, and if that's the case,  
13 then we'll have that as part of the discussion  
14 tomorrow.

15 MR. REED: But just briefly, on our  
16 website, there's sampling results from *Salmonella*,  
17 *E. coli*, *Listeria monocytogenes*, RTE, and I believe  
18 we also published some of the residue sampling  
19 results. Yes, ma'am.

20 MS. GAPUD: How about establishments? Do  
21 we have those published, and who are the good ones  
22 and the bad ones?

1           MR. REED:     Okay.     So the establishment  
2 lists are published in both the data.gov website as  
3 well as the FSIS website.     Chris, do you know more  
4 about the actual --

5           MR. ALVARES:   So there are some types of  
6 data that we post on the website that address things  
7 such as recalls that are associated with  
8 establishments, and those may be indications of  
9 plants that have had public health issues.     We have  
10 postings of broiler establishments that are in  
11 what's called *Salmonella* category 3.     This is a  
12 category where through our *Salmonella* testing  
13 program, the testing results of that establishment  
14 have not met a certain level of performance standard  
15 that we've set for the industry, and so in this  
16 category 3, these are the ones that really represent  
17 establishments that have higher *Salmonella* positive  
18 rates than others.

19           So there are some examples of that, but in  
20 the *Salmonella* category 3, we do list specifically  
21 establishments, but in a lot of our other sampling  
22 results that we post, it's very much aggregated

1 data, and at a very high level. And so one of the  
2 issues that we've been dealing with in the Agency  
3 and in terms of evaluating what we could post on  
4 data.gov is do we present individual testing results  
5 for all of our testing programs and what sort of  
6 problems does that present as far as just putting  
7 that data out there publicly? And so there could  
8 be, you know, issues such as what is a good plant  
9 and what is a bad plant, may affect the kinds of  
10 data that we need to post out there, and maybe some  
11 of the, as Todd mentioned, the variables which is  
12 information about those plants and those testing  
13 results.

14           So there is some data about plant  
15 performance particularly around *Salmonella*, around  
16 some other things like residue violators or  
17 establishments that have had recalls, but we don't  
18 have sort of out of the 6, 7, 8 thousand  
19 establishments, we don't have any information at  
20 that level.

21           MS. GAPUD: Yes, because sometimes again I  
22 was looking at all these papers about even the

1 category 1, category 2 and 3, and so on, and again  
2 there are lots of questions about, you know, about  
3 the *Salmonella* issue in my mind that, well, you  
4 know, if they are setting a new standard which is  
5 very, very good, we know before that, you know, the  
6 standard was 20 percent and the industry did so well  
7 and worked hard, and so we achieve around 7.3  
8 percent, and then here we are, we are increasing it  
9 to 7.5 which is great, okay. However, the issue  
10 there is like, it's like you are also punishing some  
11 of the small processors. The bigger or larger  
12 processors will be benefiting from that because if  
13 there's some issue in one plant, they could easily  
14 move to another plant. So the small processor who  
15 is doing great job, doing everything they can and  
16 also contributed to that lower percentage from 20  
17 percent to 7.3 percent, they're losing some  
18 business, too, because some of these people, the  
19 consumers, they're thinking, oh, I want to just work  
20 category 1 establishments.

21 So, anyway, those are the things in my mind  
22 that I'm sure we will be discussing tomorrow and so

1 on, and this will be very, very helpful to have  
2 that discussed.

3 MR. REED: We appreciate that comment, and  
4 that's exactly the type of discussion we're hoping  
5 the Committee takes up tomorrow.

6 MS. GAPUD: Yeah, I'm thinking, you know,  
7 we have fail, pass, maybe it will be better because  
8 some people they just think, oh, category 1, even,  
9 you know, it's just like you're out if you are  
10 category 2. You know, there are all these things  
11 like I came from food service before. Now, I am the  
12 supplier. I am seeing both sides, and again, there  
13 can be an economic impact on that particular issue.  
14 So anyway. Thank you.

15 MR. TYNAN: Ms. Gapud, I think you're on  
16 that Subcommittee tomorrow. So if you can hold some  
17 of those comments and sort of fuel the discussion  
18 tomorrow.

19 MS. GAPUD: Thank you.

20 MR. TYNAN: Ms. Buck, if you would.

21 MS. BUCK: Patricia Buck, and I do have a  
22 question. This is a big task to look at

1 establishing criteria, and I quite frankly would  
2 like some help from various people in this room to  
3 let us figure this out in a timely fashion. We only  
4 have one day to come up with our plan or  
5 recommendations for you.

6 In your presentation, you talked about data  
7 sharing. We have CDC and FDA present here. I'd  
8 sort of like to have some feedback from them about  
9 how the high priority performance goals are working  
10 with *Salmonella* because that might give us some  
11 indication as to what criteria we should actually be  
12 thinking about. Will they have the opportunity to  
13 brief us?

14 MR. REED: I don't believe we have any  
15 scheduled briefings with CDC or FDA.

16 MS. BUCK: Well, I would like it in the  
17 record that I think we need that kind of input for  
18 the future when you have qualified guests visiting.  
19 Thank you.

20 MR. TYNAN: Thank you. Ms. Foreman.

21 MS. TUCKER-FOREMAN: Carol Tucker-Foreman  
22 with Consumer Federation. This kind of puts you on

1 notice about my intentions for tomorrow. I'd like  
2 the Agency to think a little more broadly about  
3 transparency as a synonym for openness, for example,  
4 and that means not just putting out the data that  
5 you have but being more open and encouraging input  
6 from the public and the stakeholders about what you  
7 decide, and I want to use one particular example  
8 from the PHIS presentation where it talks about on  
9 page 30, the 3.2, the predictive models, and it says  
10 that the models were run extensively to assess their  
11 predictive power. The data was divided into two  
12 sets, one for training models and a second for  
13 testing predictive power. Subject matter experts  
14 were polled to identify the points in the data  
15 likely to provide some predictive power. These  
16 subject matter experts were chosen from the FSIS  
17 senior staff. No statisticians. No people from  
18 outside the Agency. This is absolutely key to the  
19 process that you're getting into here, and you very  
20 carefully did not get any input from anybody who  
21 didn't get a paycheck from the U.S. Department of  
22 Agriculture, and I can extend that to using guidance

1 instead of rulemaking. If you go to rulemaking, you  
2 have to have more opportunity for the public to come  
3 in and say this is what we think about what you're  
4 doing, and you have to provide a formal risk  
5 assessment before you go through the process.

6           And then finally on a really simple basis,  
7 and FSIS has gotten much better about this in recent  
8 years, FDA, who I almost always criticize, has  
9 generally been very good through the years in using  
10 advanced notice of proposed rulemaking to get out to  
11 the public from the very beginning, this is  
12 something that we're thinking about doing at  
13 sometime in the future, and they usually put it out  
14 when their views are not only not locked in stone,  
15 they're not fully formed, and they're saying to the  
16 public, send information into us and at this early  
17 point in the process, not after we have narrowed it  
18 down to three options.

19           So I'm going to suggest that if you can  
20 think of transparency as being more open in  
21 interacting with the public in a variety of ways,  
22 you'll get a lot more benefit out of this activity.

1 Thank you.

2 MR. REED: We appreciate your comments, and  
3 we've definitely taken note of them. I guess what I  
4 would say is that this Committee we've specifically  
5 brought in on the two questions, both the pre-  
6 harvest question that will be following me and on  
7 the data question that we're getting to, and no way  
8 am I suggesting that your comments on transparency  
9 in general are not important because we all feel  
10 that they are.

11 I do know that we're trying to tackle one  
12 issue at a time, and the data issue of sharing data  
13 is a part of transparency, and that we really hope  
14 from the Committee we can get input on those  
15 criteria to drive that forward.

16 The only other thing I would say is that on  
17 predictive analytics in PHIS, that includes a suite  
18 of tools that will enable many types of predictive  
19 analysis, but which predictive analysis is not set  
20 in stone. It will be using the data, using input  
21 from outside stakeholders to help us determine which  
22 models will be used and which will be appropriate in

1 the future. And so if that was not clear in the  
2 report, I'm sure that I'll work with Chris to make  
3 sure that future versions of the report are clear,  
4 but that is not a set-in-stone thing where there is  
5 a predictive analytics model and that is it.  
6 Instead, PHIS contains a module which has a generic  
7 academic based framework developed by Carnegie  
8 Mellon to allow us to do analysis, but the analysis  
9 is not set. Thank you.

10 MR. TYNAN: Ms. Buck, do you still have a  
11 question or --

12 MS. BUCK: Oh, I'm sorry.

13 MR. TYNAN: No, that's okay. I just wanted  
14 to be sure. If there's no other questions for Todd,  
15 I'm going to let him sit down, and we're going to  
16 start with our next discussion, which has to do with  
17 strengthening policy and collaboration around pre-  
18 harvest food safety, and I have Mr. John Linville  
19 from the Office of Policy and Program Development.

20 MR. LINVILLE: Good afternoon, everyone. I  
21 was asked a couple of weeks ago to put together this  
22 particular presentation around strengthening policy

1 and collaboration in pre-harvest food safety, and by  
2 the way, can you do it in 30 minutes? So I'm going  
3 to move quickly through this because it is a very  
4 large topic. We do think, however, that it is a  
5 very important topic. So the brevity of my  
6 presentation has nothing to do with importance.

7           What we would like to get out of this  
8 particular presentation and out of this particular  
9 meeting today and tomorrow, in our efforts to  
10 develop effective policies and collaborative steps  
11 to promote public health, we really would like to  
12 receive input from this Committee on the following  
13 pre-harvest subtopics. Because it is such a large  
14 arena, we're trying to narrow it down to some more  
15 manageable chunks, (1) *Salmonella* Enteritidis, (2)  
16 *E. coli* O157:H7, (3) chemical residues, and (4)  
17 antimicrobial resistance.

18           I would like to make one note about *E. coli*  
19 O157:H7. This particular presentation really is  
20 going to focus O157:H7. That being said, the Agency  
21 and the Department is really looking into STECS in  
22 general, and so as we move forward in our pathogen

1 reduction strategies, we really do anticipate more  
2 policies around STECS, but this particular  
3 presentation does not take those into account.  
4 However, you can keep those in mind as you  
5 deliberate.

6           So let's look at *Salmonella* Enteritidis or  
7 SE. If we look at the CDC case rates in the FoodNet  
8 data over the past 10 years or so, we can actually  
9 see that *Salmonella* in general, these aren't  
10 specific to SE, these are *Salmonella* case rates in  
11 general, have been fairly flat-lined somewhere  
12 between 14 and 16 per 100,000, and that is  
13 unfortunately woefully well above the dotted blue  
14 line which represents the Healthy People 2010 goal  
15 of 6.8 cases per 100,000. So I think everyone can  
16 agree that we have a lot of work to do when it comes  
17 to *Salmonella* in general.

18           So why are we thinking about focusing on  
19 SE, or why are we wanting to focus this particular  
20 subgroup on SE? Well, SE has consistently been  
21 identified by the CDC as a top 10 *Salmonella*  
22 serotype of human health concern, and we know that

1 it does account for approximately 17 percent of all  
2 *Salmonella* cases in humans. So it does sort of  
3 contribute a significant chunk to human  
4 Salmonellosis.

5 The etiology has been reasonably well  
6 defined, and we do know that prevention is possible  
7 through interventions and strategies that are known  
8 to be effective on the farm.

9 If we look at FSIS data, and this is from  
10 our verification sets in broiler establishments, we  
11 can show that from 2005 to 2009, we have a really  
12 nice decline in the overall percent positives in  
13 *Salmonella*. That's the entire bar. If you look at  
14 the blue portion of that bar, that represents the  
15 proportion of SE within the total percent positives.

16 So, in other words, if we look at it in a  
17 different type of graph, in a line graph, in 2005 of  
18 the entire positives, about 8 percent were SE. In  
19 2009, while we've had overall a reduction in the  
20 total percent positives, the proportion of SE has  
21 more than doubled to slightly above 18 percent.

22 So in the universe of *Salmonella* percent

1 positives in our verification testing, SE is on the  
2 rise.

3           So you might wonder how that compares to  
4 other serotypes within our verification positives.  
5 Looking again at 2005 through 2009, the lion share  
6 of the positives have actually been *Salmonella*  
7 Kentucky. In 2005-2006, they represented about 50  
8 percent of our positives.

9           The next three serotypes that fall in at  
10 the verification testing positives are *Salmonella*  
11 Enteritidis, Heidelberg, and Typhimurium. If you  
12 look at the 2009 data, *Salmonella* Kentucky now only  
13 represents about a third of the positives. SE,  
14 Heidelberg, and Typhimurium together represent about  
15 another third, and SE is on the top with slightly  
16 above 18 percent.

17           So by effecting change in the number of SE  
18 positives, we believe that we can effect a  
19 significant change in human salmonellosis in  
20 general.

21           So much so, and this goes back to some of  
22 the questions that were received a little bit

1 earlier, our FSIS high priority performance goal for  
2 *Salmonella* is to prevent approximately 50,000  
3 foodborne *Salmonella* illnesses by the end of fiscal  
4 year 2011, and in order to do that, we really are  
5 collaborating very strongly with the FDA around  
6 their SE prevention policies as they were put in  
7 place for the shell/egg rule. So the FSIS and the  
8 FDA goals really are interdependent and really are  
9 dependent on our collaboration and working together,  
10 but more than just FSIS and FDA working together,  
11 everyone in this room really needs to come together  
12 and collaborate on some strategies to move this  
13 forward because we really do need that input.

14           The lion's share of the presentations today  
15 have been about data, and obviously I can't let data  
16 drop. Data and data sharing strategies are really  
17 important as far as moving for FSIS. I hope that by  
18 now that has become clear, and we do have a number  
19 of strategies that we're looking at specifically  
20 around *Salmonella* and SE, for sharing the FSIS  
21 internal data, not only with the public but also  
22 with the regulated industry. We have a number of

1 data points from verification data that we have  
2 historically not shared for a number of reasons, and  
3 we fully intend to share more specific serotyping  
4 data with the industry and also PFGE pattern data,  
5 pulsed field gel electrophoresis pattern  
6 information, not the actual patterns themselves, but  
7 trend data back in our what are called end of set  
8 letters that are provided back to the individual  
9 establishments at the end of a set. So we really do  
10 have an intention to be more transparent with that  
11 data, and what we really need from the Committee is  
12 at what level that makes sense and how we best  
13 explain that in a manner that's useful for industry.

14 Industry, on the other hand, we think could  
15 also do a better job at collecting data and using  
16 more complete data in their decision making  
17 processes. So it's not just a matter of FSIS  
18 sharing the data that we have. We really think that  
19 industry as a whole is going to have to do a better  
20 job at collecting data and making use of that. And  
21 some of that is actually already happening through  
22 the *Salmonella* Initiative Program or SIP, a

1 voluntary program that a number of establishments  
2 are participating in. They're already collecting  
3 more *Salmonella* data and making use of that.

4           So the data types that we think that would  
5 be important to consider would be the *Salmonella*  
6 subtyping data. So serotype, PFGE patterns or any  
7 other subtyping data, molecular subtyping data as  
8 science moves forward, but more importantly  
9 something that we've really not focused on much in  
10 the broiler industry, and it's really kind of  
11 baffling why not because we do have such a vertical  
12 integration in the broiler industry, is the producer  
13 information. So if we take the *Salmonella* data, the  
14 subtyping data and tie that back to better collected  
15 producer information, we think that really strong  
16 inroads can be made in the pre-HACCP environment.

17           Another type of approach that can be looked  
18 at is a poultry improvement plan type approach.  
19 Now, there is the National Poultry Improvement Plan,  
20 and there are other poultry improvement plans that  
21 are similar in scope to the National Plan. The  
22 basic premises that there's some sort of a

1 vaccination program that goes on in this particular  
2 instance would be for SE, that there are biosecurity  
3 and sanitation procedures that are put in place,  
4 that there's some sort of a process to assess the SE  
5 status and certify that back, that can be done  
6 through on-farm testing, drag swabs, BUTO swabs, I  
7 mean there are a number of different ways that that  
8 can be done. And then more importantly a decision  
9 must be made on those particular flocks that are  
10 positive. So it's not just a matter of finding out  
11 which flocks are positive and which aren't.  
12 Obviously if they're not, that's good, but if they  
13 are, what do we do with them?

14           The FDA rule has a number of things that  
15 were put in place to deal with that particular  
16 product. The EU has a number of things that they  
17 have in place that we can look at as potential  
18 sources of strategies, and things to think about  
19 would be only allowing SE positive flocks to be  
20 slaughtered under very strict sanitation controls,  
21 and that the product only be processed as ready-to-  
22 eat if indeed it is processed.

1           That being said, we do acknowledge that  
2 there are some barriers at achieving some of these  
3 things. Currently, there is no U.S. licensed SE  
4 specific live vaccine for broilers. There's just  
5 none available. That being said, in the EU, there  
6 are some, and the historical barriers that we've had  
7 in place that would prevent licensing these vaccines  
8 in the U.S. are no longer there. So at least in  
9 theory they could be licensed in the U.S.

10           Historically poultry improvement plans have  
11 not been designed for broilers. They've been  
12 designed for other flocks and other populations. I  
13 believe it was the week before last the U.S. Poultry  
14 and Egg Association announced that the National  
15 Poultry Improvement Plan has voted to adopt  
16 voluntary measures to assess the relative SE burden  
17 within the breeder flocks. So that's really a  
18 positive step and moving forward in these arenas and  
19 moving these types of plans into the broiler arena.

20           And, again, around the data issue, Todd  
21 talked about it a little bit ago, we made really  
22 strong inroads in moving data forward and across

1 lines and sharing it once we have the data  
2 available, but there just are some currently  
3 laboratory methodology issues that are there.  
4 Science is only able to do so much, and it takes  
5 time to get some of the results, and we acknowledge  
6 that that can be an issue if you really want to use  
7 the data on the spot. That being said, we think  
8 that the data can be very useful and can be used for  
9 trend analysis, especially if it's tied together  
10 with the producer information.

11           So let's shift gears a little bit and move  
12 over into *E. coli* O157:H7. Here the data, at least  
13 from a public health perspective looks much, much  
14 better. In 2009, we actually met our Healthy People  
15 2010 goal, and that is an awesome achievement that  
16 everyone needs to be applauded on. That being said,  
17 we should not and we cannot rest on our laurels.  
18 One case per 100,000 is 1 case per 100,000 too many.  
19 So we really think that we can move forward on this,  
20 and obviously a lot of things have been tried in  
21 plant. So it's pretty obvious that it makes sense  
22 to move into the pre-harvest arena.

1           Some of the goals that FSIS is looking at  
2 in the pre-harvest arena for cattle is reducing the  
3 prevalence of O157:H7 in the fecal excretion and/or  
4 reducing the magnitude of *E. coli* O157:H7 in the  
5 fecal load. And there are sort of three main  
6 strategies that you can look at to achieve these  
7 goals. The first set are exposure reduction  
8 strategies. These are management practices such as  
9 basic sanitation biosecurity features again, just  
10 providing clean feed and water, minimizing or  
11 preventing cross-contamination in transportation,  
12 and then as sort of a piece of the management  
13 practice, particular water treatments that can be  
14 done with chlorine, electrolyzed water, ozonation.  
15 So there are a number of things that are being  
16 looked at that would basically reduce or prevent the  
17 animal from being exposed to the organism in the  
18 first place.

19           The second set of strategies or exclusion  
20 strategies, and these are strategies that basically  
21 in vitro, in the animal development and environment  
22 that is more helpful for particular good organisms

1 and is more hostile for the organisms we don't want,  
2 in this particular instance, O157:H7.

3           Some of the things that have been looked at  
4 are different feed types and feeding strategies,  
5 grain based versus high forage diet, feeding  
6 probiotics, feeding prebiotics. So, again, there  
7 are a number of things that are being looked at with  
8 a lot of promise. At this point in time though,  
9 unfortunately still somewhat inconsistent results.  
10 So still very promising.

11           Then the third set of strategies would be  
12 the anti-*E. coli* O157:H7 therapies which would be by  
13 providing bacteria phage and vaccination. Again, a  
14 lot of work being done with somewhat different  
15 results, which brings us to the current barriers.

16           In contrast to the poultry industry  
17 obviously, in the cattle industry there's not a  
18 hugely vertically integrated system of production  
19 and supply. So there is a lack of direct control by  
20 the beef slaughter operators over the pre-harvest  
21 management strategies that are employed by the beef  
22 producers and suppliers. So that's something that

1 we would be interested in finding ways that we can  
2 incentivize that.

3           There's a lack of incentive for beef  
4 slaughter operators to incorporate pre-harvest  
5 practices into the HACCP plans. Again, something  
6 that we really need to find ways that we can  
7 incentivize that particular process, and then as  
8 already said, many of these interventions are still  
9 in the research phase and are ongoing, and many of  
10 the products are not commercially available yet. We  
11 obviously hope that they will in the future be so.

12           I'm going to shift away a little bit now  
13 from particular pathogens, and the next two  
14 subtopics, chemical residues and antimicrobial  
15 resistance, are going to tie together somewhat. So  
16 some of the pieces that I talk about the chemical  
17 residue piece will follow through on the  
18 antimicrobial resistance piece.

19           If we look at the National Residue Program,  
20 it's a program that requires the cooperation of  
21 FSIS, FDA, and EPA and is really meant to ensure  
22 that chemical residues in meat, poultry, and egg

1 products are at or below the tolerances that are set  
2 by the FDA and the EPA. And it's made up of a  
3 couple of different components. There's the  
4 scheduled sampling which is sort of the randomized  
5 component. There's targeted sampling which is also  
6 called inspector generated sampling, which is done  
7 at the discretion of the inspector in charge in the  
8 plant, if they have cause to believe that the animal  
9 needs to be tested, and then there are exploratory  
10 assessments that are done at particular frequencies.

11 The goal is obviously to maintain consumer  
12 confidence and discourage establishments against  
13 slaughtering animals that have violated residue  
14 levels, and also to provide verification of residue  
15 controls in the HACCP systems.

16 So if we take a look at some of the data,  
17 this is 2008 scheduled sampling. So again this is  
18 the randomized component, by production class and  
19 not all production classes are depicted here. A  
20 couple of things I'd like to point out. The number  
21 of violations is fairly low, and the percent of  
22 violations is fairly low. I mean if we just take a

1 look at the data in whole, these are fairly low  
2 numbers. Keep in mind, however, that we do have  
3 numbers in the third column, the non-violative  
4 positive columns. These levels, these results are  
5 not violative. That means that they followed the  
6 withdrawal periods, they followed the withdrawal  
7 times, everything is fine as far as violations are  
8 concerned, but just keep in mind that we do have  
9 these positive results. We'll come back to those.

10           Looking at the 2008 scheduled sampling  
11 violations and just the way they're broken down by  
12 class, you'll notice that the red and sort of the  
13 yellowish pieces make up about half of that pie.  
14 Those are the sulfonamides in the antibiotics. So  
15 half of those violations are from those particular  
16 populations.

17           Looking at the data a little bit  
18 differently, again by compound class, what I'd like  
19 to again point out, the numbers of violations aren't  
20 tremendously high. The percent violations are  
21 tremendously high, but look at the number of non-  
22 violative positives for antibiotics. That's a

1 fairly significant number there, again just pointing  
2 out that there is the use of antibiotics out there.  
3 It may have been used appropriately following the  
4 rules, but the use is there, and as we move forward  
5 in looking at issues of antimicrobial resistance,  
6 this type of data may prove very useful.

7           This is a pie chart of the inspector-  
8 generated sampling violations. So, again, this is  
9 the for cause sampling, if you will. Here we have  
10 completely different results from the randomized  
11 sampling as far as the results that we get back.  
12 Number one, we have a larger number of violations  
13 obviously because hopefully our people are doing a  
14 good job at picking out the animals that need to be  
15 sampled, but also the particular results are  
16 different as far as the compounds. If you look  
17 here, antibiotics and sulfas make up about three-  
18 quarters of the positives. The result of the  
19 results are non-steroidal anti-inflammatory drugs or  
20 NSAIDs, so flunixin and phenylbutazone. These  
21 aren't really picked up very well in our scheduled  
22 samplings. So the targeted sampling here is really

1 an important piece to pick those violations up.

2           This particular slide, what I really would  
3 like for you to focus on is the line for bob veal  
4 and the line for dairy cows. Those two production  
5 classes together make up over the targeted sampling  
6 and the scheduled sampling, 90 percent of our  
7 violations. The dairy cows themselves make up 44  
8 percent, and again, I'd like for you to keep that  
9 thought in mind for a little bit later.

10           So what is FSIS doing? And this gets back  
11 a little bit to some of the information that's  
12 provided on the website. What do we do with this  
13 information? We have basically two lists that are  
14 provided on the FSIS website. One is the residue  
15 violator alert list. It's updated monthly, and it  
16 contains the names and addresses of parties that are  
17 responsible for repeat violations and responsible  
18 means that there has been an FDA investigation  
19 performed. There has been a FDA investigation  
20 performed and that takes time.

21           Repeat violators meaning that the  
22 individuals or firms have repeatedly sold the

1 animals with violative levels, and that means on  
2 more than 1 occasion with 12 months.

3           So this information goes out monthly, but  
4 again because that investigation piece is in there,  
5 it takes time, and industry came to us and asked us  
6 if there wasn't a way that we could provide data  
7 that's a little closer to real-time. And so we  
8 started putting the same source supplier, residue  
9 violator list on the website. It's updated weekly,  
10 in a PDF and Excel spreadsheet format, and the  
11 difference here is again, between this one and the  
12 last one, is we are again putting repeat violators  
13 on this list. However, in this particular instance,  
14 it's not FDA investigated. It's when we have two  
15 laboratory confirmed positives that are violative,  
16 and obviously that means we're really, really  
17 heavily dependent on the information that we receive  
18 from industry on who the supplier is. So we work  
19 very hard to fix any issues that are identified to  
20 us, but because we're really dependent on that, you  
21 can see how the quality of the data here is really  
22 important because a lot of people are making

1 decisions off of this type of data.

2           So that brings us to sort of the issue that  
3 we need to struggle with around is, you know, how  
4 can we determine collaborative incentives for  
5 establishments to provide the most accurate data,  
6 but not only for them to provide us with that data,  
7 for them to go after that data. So they obviously  
8 have to have accurate data before they can provide  
9 it. So we really need to figure out ways that we  
10 can provide incentives for the establishments to get  
11 the accurate data and then to provide it to us.

12           On antimicrobial resistance, I'd just like  
13 you to think back to 2009. You may be aware that  
14 there were three outbreaks of human illness that  
15 were tied back to ground beef, and the pathogens in  
16 these percent cases were *Salmonella* Newport, and  
17 *Salmonella* Typhimurium definitive, type 104, and the  
18 sort of twisting factor here was the fact that they  
19 were multidrug resistant, and so this did result in  
20 three fairly large recalls.

21           This is NARMS data. Chris talked about  
22 NARMS a little bit ago. That's the National

1 Antimicrobial Resistance Monitoring System that's  
2 administered by FDA in collaboration with the CDC  
3 and with USDA, and this particular data is from our  
4 verification testing data. NARMS has several  
5 different definitions for multidrug resistance, and  
6 just so that the graphs don't get completely  
7 cluttered up, I've just focused on three here.  
8 Those strains that are resistant to three or more,  
9 those strains that are resistant to four or more,  
10 and those strains that are resistant to five or more  
11 antimicrobials. And if you just take a descriptive  
12 look at this without, you know, really getting into  
13 the numbers, I think it's really fairly striking if  
14 you look at cattle in the upper left quadrant there,  
15 how those all kind of nicely follow one another and  
16 have a fairly striking upward trend. In chickens  
17 and turkeys, we can also see upward trends. So it's  
18 very apparent here that we're having an increase in  
19 the number of our positives that have multidrug  
20 resistance.

21           So in sort of the vein of trying to figure  
22 out how we can provide and share useful data again,

1 FSIS has looked at different ways of how we could  
2 report this in a useful manner back. Luckily  
3 sometimes you don't have to reinvent the wheel. FDA  
4 already has a classification system in place that  
5 classifies antimicrobials according to their  
6 importance for treating human illness, and that  
7 there's a critical classification, a highly  
8 important classification and an important  
9 classification, and in case you're wondering why I  
10 have critical in two different colors, that's not a  
11 FDA thing. That's something that FSIS was looking  
12 at to make the data more useful as we report it back  
13 potentially. The third generation cephalosporins  
14 and the fluoroquinolones are those that are most  
15 important in treating invasive human salmonellosis.  
16 So we thought it might be important to kind of  
17 highlight that in some manner if and when we do  
18 report it back.

19 So let's tie all this together really  
20 quickly. If we think about cull dairy cattle again  
21 and what we've seen, we know that it's a common  
22 practice to use therapeutic and subtherapeutic

1 levels of antimicrobials in the production of food  
2 animals. I mean that's a given. I think everyone  
3 understands that, but this is where those columns  
4 that I highlighted a little bit ago, where we have  
5 those positives but non-violative levels that we're  
6 finding. So there's some data there that we could  
7 be looking at.

8           We know that the cull dairy cattle together  
9 with bob veal have the highest rate of chemical  
10 residue violations. Remember, cull cattle, cull  
11 dairy cattle, 44 percent. We know that they come in  
12 at an older age at slaughter, and as such, they have  
13 a higher probability of medical issues over their  
14 lifetime. I mean dairy cattle are plagued with  
15 mastitis, with laminitis, with a number of different  
16 illnesses that have to be treated. And if you take  
17 into account that upward trend just in the NARMS  
18 data, it really does kind of give you pause to  
19 think.

20           If we tease that data out a little bit  
21 more, here, just using as an example of some data,  
22 again we couldn't show all of the drugs on the

1 chart, you couldn't see anything anymore, but here  
2 we have what would be considered by the FDA to be  
3 critical, and then aminoglycosides as an example of  
4 highly important, and again you can see at least on  
5 a couple of them that there is that upward trend in  
6 resistance.

7           So what does all that mean? That's the  
8 good question. That's the one we really want you to  
9 focus on. It obviously would be great if we could  
10 determine if there is a causal association between  
11 animal production practices and antimicrobial  
12 resistance. We're not going to settle that here.  
13 That's been a debate that's been around for a while  
14 and obviously will probably be debated for a while.  
15 If that is determined, it obviously will give us  
16 some opportunities for strategies in the pre-harvest  
17 arena that we won't have if that association is not  
18 found. Either way, I think we've been able to show  
19 that antimicrobial resistance is on the rise in the  
20 animals that are coming into slaughter, and  
21 something is going to have to be done because we  
22 can't allow that to go out in our products.

1           So, again, FSIS is looking at ways that we  
2 can share more complete data. Again, we have data,  
3 we have the antimicrobial resistance data from our  
4 verification positives, and we can share that back  
5 with industry, again to what level, to what detail  
6 and what manner makes the most sense for industry to  
7 make the best use of that data.

8           And, again, we acknowledge that that  
9 procedure, that laboratory procedure to determine  
10 that resistance, takes some time, but again the same  
11 is with the serotyping data and with the subtyping  
12 data. If you tie that back with other datasets that  
13 we have, we really think that positive inroads can  
14 be made.

15           And that was going through it as quickly as  
16 I could. So --

17           MR. TYNAN: John said to me before we  
18 started the presentation, I don't think I'll have  
19 many questions. Okay. We shot that one right off  
20 the bat. I'm going to start to my left, and I'll  
21 work my way around the table, so, if that's okay.  
22 Dr. Kassenborg.

1 DR. KASSENBERG: Dr. Heidi Kassenborg. My  
2 question is has an attempt been made to reach out to  
3 dairy processors to help solve the cull dairy cow  
4 antibiotic residue issue?

5 MR. LINVILLE: There are some things that  
6 we're looking at currently. There's some surveys  
7 that we're looking at within FSIS that we want to do  
8 to get some better data where we can do that.  
9 There's some collaborations that we're currently  
10 doing with FDA on some of that within the National  
11 Residue Program. So the answer is yes. I honestly  
12 couldn't tell you at what level, however. That's  
13 outside of what I currently do. But, yes, we are  
14 actively looking at that, and what has not been done  
15 is absolutely on the table.

16 MR. TYNAN: Dr. Cutter.

17 DR. CUTTER: Cathy Cutter from Penn State.  
18 Building on Heidi's question, the residue violator  
19 list, is it effective? Are processors going to that  
20 information? Are they using it? Are they turning  
21 people away?

22 MR. LINVILLE: It is very effective. I

1 mean the slaughter establishments use that data. I  
2 mean they really have to. From the beginning of  
3 HACCP, we've had the pre-HACCP components sort of  
4 there. It's just not really been emphasized in that  
5 manner and, yes, if residue violations come in, then  
6 that's a noncompliance that will be documented. So  
7 they do make use of that particular data. The issue  
8 again is the fact that around the original residue  
9 violator list, the monthly list, that FDA component  
10 is in there to really make sure that whoever is  
11 identified really is the source of the problem, if  
12 you will, and that takes time. I think the best  
13 indication that industry uses is the fact that they  
14 came to us and said can you provide us, you know,  
15 data more quickly realizing that it may not be quite  
16 as accurate.

17 DR. CUTTER: And I have one other question.  
18 When it comes to subtyping for the *Salmonella*  
19 *Enteritidis*, what is the current thinking on who's  
20 going to do that?

21 MR. LINVILLE: It's already being done.

22 DR. CUTTER: By industry. But I'm talking

1 like smaller --

2 MR. LINVILLE: Well, that's obviously, I  
3 mean that's the thing that we're struggling with. I  
4 mean obviously right now from the beginning of time,  
5 as far as HACCP information testing has been done,  
6 they have the subtyping information on all of the  
7 positive isolates. The *Salmonella* Initiative  
8 Program is a voluntary program that a lot of  
9 establishments are coming in. It has certain  
10 requirements around *Salmonella* testing and the data  
11 that's being done there. Again, it's sort of  
12 striking that balance between, you know, what makes  
13 sense and what is not going to provide strong  
14 results. So, yeah, I mean that's sort of kind of  
15 giving out what you would report back on.

16 DR. CUTTER: Okay.

17 MR. TYNAN: Ms. Gapud.

18 MS. GAPUD: Veny Gapud, Fieldale Farms.  
19 I'm just curious about that slide that you showed, I  
20 think it was the second slide, where you were  
21 showing that the *Salmonella* remains flat, the  
22 salmonellosis remains flat, despite the fact that we

1 are, the processors did their best to lower or, you  
2 know, to work so hard in order to control the  
3 *Salmonella* in the products, and still it remains  
4 flat. And, again, it's just like --

5 MR. LINVILLE: Okay.

6 MS. GAPUD: -- we put all this stuff in  
7 category 1 and everything, category 2, and it's just  
8 like looking at them that way. You can do good job.  
9 It's like they are being -- they work so hard and  
10 we -- the, you know, the requirements, the  
11 standards, but still I don't think it's just the  
12 chicken that causes salmonellosis.

13 MR. LINVILLE: No, absolutely not. And I  
14 guess I have two comments to that. The first is,  
15 yeah, absolutely, there are other products out there  
16 that are ultimately resulting in the entire caseload  
17 of human salmonellosis. So it's not just broilers.  
18 But the point of this slide is, yes, the broiler  
19 industry has done good at increasing their process  
20 control and remember, the *Salmonella* verification  
21 testing is a measure of process control. It really  
22 is only looking at plus or minus on *Salmonella*. Is

1 it positive or not. So the first thing is, yes, we  
2 have other products that have sort of, if you will,  
3 made up for the inroads that the broiler industry  
4 has made. They've made up for that by increasing  
5 their attribution to human illness. So that's one  
6 reason it's remaining flat, and the other that I was  
7 trying to maybe show a little bit as a possibility  
8 is the fact that even though the process control is  
9 there, that we've gotten the overall numbers down,  
10 maybe the numbers that we have now from a public  
11 health perspective are more important in that we're  
12 now increasing the numbers of serotypes of human  
13 health concern.

14 MS. GAPUD: Also a follow-up question is  
15 again on your other slide, I think the sixth slide,  
16 where you were showing something about *Salmonella*  
17 Kentucky which is never I think, it's not even in  
18 the top 20 --

19 MR. LINVILLE: That's correct.

20 MS. GAPUD: -- of CDC --

21 MR. LINVILLE: And that's again what I was  
22 trying to show is the trend that while the process

1 control is there, the overall numbers have gone  
2 down. Within those overall numbers, those that  
3 aren't really of that much concern, any *Salmonella*  
4 can cause human illness, any under the correct  
5 circumstances. *Salmonella* Kentucky under normal  
6 circumstances is not one that I would consider to be  
7 a high threat, but those numbers are shrinking as an  
8 overall proportion in the positives, and those that  
9 really are in the top 20 are increasing.

10 MS. GAPUD: Yeah, but at least one-third of  
11 I think the *Salmonella* Kentucky is the one that I  
12 believe they found in the chicken carcass, right?

13 MR. LINVILLE: In some.

14 MS. GAPUD: About one-third of --

15 MR. LINVILLE: About one-third -- in 2009,  
16 about one-third of the positives were Kentucky,  
17 that's correct. But about one-third were *Salmonella*  
18 Enteritidis, Heidelberg, and Typhimurium.

19 MS. GAPUD: I'm just trying to point here  
20 that again if one-third of *Salmonella* Kentucky has  
21 been found in most of the chicken carcass and, you  
22 know, and it's not even considered in the top 20

1 cause of human illness by the CDC although, of  
2 course, it's still there, but it's not the high  
3 priority, and then we're talking about all this  
4 category 1, category 2, and so on. It's just like  
5 we are missing some of those who are good  
6 processors. It's just my, you know, I'm curious  
7 about what's going on here, along those lines.  
8 Thank you.

9 MR. TYNAN: Well, if I could just interrupt  
10 for a second. I know you're not on that  
11 Subcommittee, but there will be another opportunity  
12 tomorrow afternoon when that Subcommittee does its  
13 report out for you to see what kind of  
14 recommendations. There may be other folks in the  
15 group that share some of your concerns, and you'll  
16 see the recommendations, and maybe that will be a  
17 better point to make some of the comments you're  
18 making.

19 MS. GAPUD: Thank you.

20 MR. TYNAN: Not to cut you off. Your --

21 MS. GAPUD: No, you're fine. Thank you.

22 MR. TYNAN: -- comments are important to

1 us. Mr. Covington.

2 MR. COVINGTON: Brian Covington, Keystone  
3 Foods. I am on that Subcommittee, and I'm sure we  
4 will have good discussions about that subject.

5 Two quick questions. In the very beginning  
6 when you asked the question why should we focus on  
7 SE --

8 MR. LINVILLE: Uh-huh.

9 MR. COVINGTON: -- one of the things was  
10 prevention's possible through interventions and  
11 other strategies known to be effective on the farm.

12 MR. LINVILLE: Uh-huh.

13 MR. COVINGTON: Can you discuss the  
14 Agency's definition of prevention?

15 MR. LINVILLE: Well, I would think that any  
16 vaccination program in the largest arena would be a  
17 prevention. Obviously it's not going to eradicate  
18 it under normal circumstances by itself, but it  
19 would greatly reduce it. So that is a prevention  
20 strategy. The biosecurity and sanitation programs  
21 that can be put in place obviously will reduce it  
22 greatly. There are obviously methods that you could

1 completely prevent it and eradicate it. I'm not  
2 saying those are off the table, but that's not  
3 necessarily what we're saying would be the best  
4 response. Those again are the things that we're  
5 trying to get from you. What can we effectively put  
6 in place under current conditions, and what do we  
7 need to be looking at to remove some of the barriers  
8 to get some of these other things in place that we  
9 know could be effective?

10 MR. COVINGTON: And then my second question  
11 is, there's a lot of reference in the discussion  
12 paper to the NPIP program which I understand is  
13 under the purview of your sister agency.

14 MR. LINVILLE: APHIS, yes.

15 MR. COVINGTON: Has FSIS looked at the data  
16 generated in particular, the PFGE patterns on  
17 positives, SE positives found under that program and  
18 correlated that to CDC data?

19 MR. LINVILLE: I honestly couldn't tell  
20 you. Chris, do you know? Do you have any idea?

21 MR. ALVARES: I'm sorry. Can you repeat  
22 the question?

1           MR. COVINGTON: Has FSIS evaluated the data  
2 from the NPIP program because as we're getting to  
3 specific PFGE patterns, to see if there's any  
4 association with CDC illness data?

5           MR. ALVARES: I'll take a shot, and then  
6 maybe Dr. Basu can add some content. We are  
7 certainly interested in the serotype information  
8 that we're getting through our testing programs and  
9 how that might be linked to outbreak data from CDC.  
10 So there is certainly analyses and work going on  
11 within the Agency, definitely within the data  
12 analysis integration group. I'm sure it's occurring  
13 within OPHS as well and other areas.

14           Part of what we're trying to do in some of  
15 PHIS is integrate some of that data to get us some  
16 better tools to evaluate those links and  
17 associations, and we are looking at those kinds of  
18 links. We're looking at approaches for attribution,  
19 taking into account serotypes. So that kind of work  
20 is going on. I don't have anything that I can point  
21 to as far as a report. A lot of it is very much  
22 ongoing work, and I think as we learn things, we'll

1 try to communicate those. Do you want to add  
2 anything more?

3 MR. TYNAN: Does that help, Brian?

4 MR. COVINGTON: Yes.

5 MR. TYNAN: Maybe if you don't mind, just  
6 in the interest of full disclosure here, Dr. Basu  
7 sounded like he had something to add to that  
8 discussion.

9 DR. BASU: I might cover everything. This  
10 is Pat Basu. I wear different hats. So I'm going  
11 to answer different things, bring up different  
12 things from different hats I wear. I've been in  
13 charge of the residue program for about 10, 15 years  
14 in the past. Based on that, I'm just going to  
15 mention the rest of the stuff you talked about. I  
16 think Todd brought up, when do we publish the data?  
17 We don't publish the residue data until one year  
18 after the fact. Sometimes it's two years after the  
19 fact. You presented 2008 data. We already have  
20 2009 data but it's not published yet. So that's  
21 something, you know, we need to look at as to how  
22 late do we hold the data. We have the blue book,

1 the plan published but not the data published, and  
2 we can really push up the date of publication  
3 depending on quality control. I think Ms. Foreman  
4 brought up that question about data quality, and  
5 that's the only reason we hold the data publication  
6 before. Now, things are improving. So we can push  
7 that forward in the future.

8           The other question was we need to remember  
9 our new in-plant test kit does not identify all  
10 antibiotics used commonly in the animals  
11 unfortunately. So we're missing a big segment of  
12 the antibiotics unless they go the lab which can  
13 confirm everything. So that's something we are  
14 looking into now. I think Patty is standing back  
15 there. She can talk about more of that.

16           The other thing that's missing is animal  
17 ID. We don't have animal ID requirements, which  
18 fails to give us the traceback we need sometimes to  
19 find the animals which are causing the violations  
20 again and again. That's all I'm going to talk  
21 about.

22           Changing HACCP pre-harvest, and Mr. Mande

1 is over here. I'm sorry Dr. Hagen left. The other  
2 thing is in March of this year, Secretary Vilsack  
3 signed a new format for us, one health program,  
4 which Dr. Hagen knows about from CDC. We have  
5 started a newborn health program under the direction  
6 of the Secretary with powers given to the Under  
7 Secretary for Food Safety, Dr. Hagen, and  
8 Mr. Avalos, the Under Secretary for Marketing,  
9 Regulation and Standards, right?

10 MR. TYNAN: Marketing and Regulatory  
11 Programs.

12 DR. BASU: Programs, okay, RMP. They're  
13 the heads of all of USDA. Under that, there's also  
14 a joint team for all of USDA to have one health  
15 looked at with partnership with CDC, FDA, we have  
16 partners with HHS, State Department, USAID, and the  
17 National Security Council, and we're looking at  
18 different things about the things you brought up.  
19 We have a program now, I helped coordinate both  
20 groups, the group under the political appointees,  
21 Dr. Hagen and Mr. Avalos, and also the USDA group  
22 which is led by Dr. Bill James from FSIS and

1 Dr. John Clifford from APHIS as the USDA heads.

2           Anyway, the three projects we're looking at  
3 directly right now, one is the MDR *Salmonella*  
4 Program, and the other thing is *E. coli* O157:H7 and  
5 the other is non-STEC *E. coli*. For those projects  
6 that are going on right now, we will work with  
7 APHIS, but we've already started working with APHIS  
8 and with NAS, National Agricultural Service, and  
9 with AMS, to do some of the testing for STEC for us.  
10 So work has already started and we have the money  
11 that's been put in from 2012 budget that will help  
12 get us there. So we will get the data. We have  
13 started the work. We have had a couple of meetings  
14 so far. So we have good partners, FDA and CDC. So  
15 it's a joint program with all the Federal Government  
16 involved. Hopefully we'll get you more information  
17 in the next year or so, much before that hopefully.

18           MR. TYNAN: Well, Dr. Basu, we're going to  
19 invite you to participate in that subgroup tomorrow.  
20 So you'll be --

21           DR. BASU: Okay. Sure. I'm interested in  
22 both groups. You decide which one.

1 MR. TYNAN: Well, we can't clone you.

2 DR. BASU: No, that's fine. Thank you.

3 MR. TYNAN: Dr. Shultz.

4 DR. SHULTZ: Craig Shultz, Pennsylvania  
5 Department of Agriculture. A little historical  
6 information on repeat violators and the road that  
7 we've been down with repeat violators. In 2000 and  
8 2001, I served on a national working group on  
9 residue violations in cattle, and at that time when  
10 a violation occurred, it was the responsibility of  
11 the owner to then present five additional cattle  
12 that were identified as his for residue screening at  
13 slaughter to basically demonstrate that the  
14 corrective action had been taken, and this was a  
15 real problem because an individual could bring a  
16 high-risk dairy cow in violation, and then do  
17 follow-ups on four lower-risk fed cattle or any  
18 other animals, and particularly with cattle dealers,  
19 they could bring, you know, low violation risk  
20 animals in and basically satisfy the requirement.  
21 That was why we went to a repeat violator, a  
22 published repeat violator list, to respond to this.

1           The problem there is timeliness and getting  
2 the information in a timely manner and tracing the  
3 animals back in a timely manner. I think our  
4 thoughts at the time were that we would eventually  
5 have our RFID technology that we'd be tracing  
6 animals back with, and we'd have timely tracebacks,  
7 and so the time required to get back to the violator  
8 would get shorter and shorter, and then eventually  
9 we wouldn't have the problem with verifying that  
10 violator in a reasonable amount of time. That  
11 hasn't occurred, and as a result, sometimes it takes  
12 longer than a year to get an individual listed as a  
13 repeat violator, even though they might have  
14 presented three or four repeat violations during a  
15 short period of time because of the verification  
16 process of making sure FDA or the state contractor's  
17 verifying that that animal traces to that producer  
18 actually. And it's very unfair if we just take  
19 preliminary data provided by the industry that we  
20 think this animal came from Farmer X and then say  
21 that Farmer X is a repeat violator. That causes a  
22 problem. So traceability is an extremely important

1 component of this process, animal traceability.

2           And one other question.       During that  
3 working group activity, one of the problems we  
4 determined was our inability to look at screening  
5 activities across plants and screening activities in  
6 plants with similar slaughter classes and similar  
7 risk slaughter classes and whether or not, you know,  
8 screening was proportionate based on the risk of the  
9 animals, and the problem was that we couldn't really  
10 get the screen activity data because of the way the  
11 data was reported.   So we couldn't really look at  
12 that at that time, and I was wondering if anything's  
13 been done to get more accurate reporting of  
14 screening test activity in the plants.

15           MR. LINVILLE:   I'm going to let Dr. Patty  
16 Bennett take that in just a second.   However, I will  
17 say, and again, I don't want this to sound too  
18 clique, but PHIS really is going to take care of a  
19 lot of the sampling issues that we've had over the  
20 past as far as being able to look at things across  
21 the data.   So I'm in hopes that that will satisfy  
22 some of that, but Patty may be able to give you

1 some --

2 MR. TYNAN: Patty, before you weigh in, I'm  
3 going to ask you to hold it to a minimum, and then  
4 if you want to participate in the discussion in the  
5 morning, to elaborate a little bit more, I'll let  
6 you do that, but we're getting pretty late on the  
7 agenda.

8 DR. BENNETT: Okay. I'll speak very  
9 quickly.

10 MR. TYNAN: You need to identify yourself.

11 DR. BENNETT: My name is Patty Bennett.  
12 I'm with FSIS, and I'm the current Branch Chief of  
13 the Chemical Residue Risk Branch.

14 So to address Dr. Shultz's questions and  
15 comments, I think there's two things. One is back  
16 to what John had said earlier, NMI especially came  
17 to us a little more than a year ago and said, look,  
18 we need more timely data, and we will act on it,  
19 which is really what the same source supplier list  
20 has become, and then later they said to us, look,  
21 the PDF file really isn't useful. We need to see an  
22 Excel sheet that we can manipulate, and we said

1 fine. So since August of 2009, we've had the weekly  
2 list, and I don't remember when the Excel sheet came  
3 out, but it was probably maybe four or five months  
4 into it that we provided an Excel sheet where they  
5 can actually start scanning and seeing what plants  
6 are associated with what suppliers and what  
7 suppliers are they seeing repeatedly.

8 Now, the thing that we said at the very  
9 beginning was, this list is only as good as the  
10 people providing us the information, and what we  
11 have found since instituting that list is that we  
12 actually get haulers call us, we get auction houses  
13 call us, and they're going, hey, I shouldn't be on  
14 the list, and we're like, you go back to the plant  
15 and you figure out who the culpable member is and we  
16 will change that data when you give us another name,  
17 and that seems to be working. And so the  
18 negotiation seems to be happening at the pre-harvest  
19 level where they're working it out and saying, okay,  
20 so who really was responsible for giving this animal  
21 these chemicals and then again, when they reported  
22 back to us, we changed the information immediately,

1 and that's something our IT folks had said from the  
2 very beginning that they would do.

3 In terms of -- I forgot the second part.

4 MR. LINVILLE: The screening tests.

5 DR. BENNETT: The screening tests, right.

6 Thanks, John. So now with the screening tests,  
7 right now we have implemented that. We implemented  
8 that in May of 2009. We started something called  
9 eSample. So with the in-plant tests, the inspectors  
10 are asked to put in an electronic form, they  
11 actually record that they did the implant test, and  
12 we have just started creating in-house reports where  
13 we're starting to track this kind of information.  
14 So I really don't have any data for you right now,  
15 but we are beginning to look at it, and exactly what  
16 you're saying, to be able to say, okay, across all  
17 the dairy cows, the large dairy cows versus the  
18 medium versus the small, how is everybody doing it,  
19 and are we seeing that they are relatively testing  
20 at the same rate or not? And then that's something  
21 when we have that information, we can go back to  
22 Bill James or the field in general and say, you know

1 what? Perhaps we need to work on additional  
2 policies or additional implementation to see if we  
3 can't make this more equitable testing if that's  
4 what we're finding is happening, and right now I  
5 don't think we have enough information to track  
6 that.

7 MR. TYNAN: Okay. Patty, you're invited  
8 back in the morning, too.

9 DR. BENNETT: I'm actually going to be in  
10 Chicago, going to see a taping of "Wait Wait...  
11 Don't Tell Me." So don't wait for me.

12 MR. LINVILLE: That's why I really wanted  
13 her up here today.

14 MR. TYNAN: Okay. Dr. Murinda, I think --  
15 did I see a couple of others over here? No.  
16 Dr. Murinda, you had a question, comment?

17 DR. MURINDA: On page 9, the third diagram,  
18 the pie chart, I was just curious, on those --

19 MR. TYNAN: Page 9 and you're referring to  
20 the --

21 DR. MURINDA: The pie chart.

22 MR. TYNAN: -- discussion paper.

1 DR. MURINDA: Yeah, on the chemical  
2 residues.

3 MR. TYNAN: Or the slides, the PowerPoint.

4 DR. MURINDA: PowerPoint.

5 MR. TYNAN: Okay. I'm sorry.

6 DR. MURINDA: I was just curious why the  
7 sulfonamides were separated from the antibiotics.

8 MR. LINVILLE: That's the way they reported  
9 out on it, I think, Patty.

10 DR. BENNETT: I'm sorry.

11 MR. LINVILLE: Sulfonamides, why are  
12 sulfonamides separated from antibiotics?

13 MR. TYNAN: Patty, you have to come up to  
14 the microphone for the purposes of the transcript.

15 MR. LINVILLE: In the reporting of the red  
16 book, why are antibiotics reported separately from  
17 sulfonamides?

18 DR. BASU: Because they're measured  
19 separately by different tests.

20 MR. LINVILLE: Okay.

21 DR. BASU: There's different test used for  
22 antibiotic than used for sulfonamides. So they

1 identify differently and are written differently.

2 DR. BENNETT: So simply the test methods?

3 DR. BASU: Right.

4 DR. BENNETT: Historical.

5 DR. BASU: The antibodies are tested with  
6 -- bioassay. The sulfonamides are measured by  
7 chemical means.

8 MR. LINVILLE: Does that help?

9 MR. TYNAN: Did that help, Dr. Murinda?

10 DR. MURINDA: Just a bit. Sulfonamides are  
11 generally, they're all chemically synthesized,  
12 whereas antibiotics in general, they come from  
13 nature, although some of them are synthesized.

14 MR. TYNAN: Are you okay, or do you have  
15 follow up?

16 DR. MURINDA: No.

17 MR. TYNAN: You're done. Okay. Ms. Buck,  
18 we're going to have one other question down here,  
19 and then we're going to have to close out for this  
20 portion of the discussion.

21 MS. BUCK: Yes. I have a question on the  
22 third slide on page 12 of the PowerPoint, and it's

1 pretty much directed to CDC. I'm concerned about  
2 this rise in the multidrug resistance because it  
3 looks to me it is clear.

4 MR. LINVILLE: I'm sorry. Which slide is  
5 that? I'll pull it up. They're numbered  
6 differently on here. So what's --

7 MS. BUCK: I'm sorry. It's on page 12 of  
8 the PowerPoint. It's the graph about the  
9 antimicrobial resistance. And you show at the top  
10 bar those two critical antibiotics, and I would like  
11 clarification from CDC, one of them.

12 MR. TYNAN: Dr. Liang has already pointed  
13 out to me, this is not CDC data. So he's not --

14 MR. LINVILLE: No, it's not CDC data. It's  
15 NARMS data.

16 MS. BUCK: Do you know then, one of those  
17 two antibiotics cannot be used with children, in  
18 treating children.

19 MR. LINVILLE: Okay. We must be on a  
20 different, on this one.

21 MS. BUCK: No. That one. That one there.

22 MR. LINVILLE: Okay.

1 MS. BUCK: One of the top two antibiotics  
2 there in the critical phase cannot be used in  
3 treating children.

4 MR. LINVILLE: Right.

5 MS. BUCK: Do you know which one of those  
6 it is?

7 MR. LINVILLE: The fluoroquinolones.

8 MS. BUCK: Fluoroquinolones.

9 DR. SHULTZ: Craig Shultz, Pennsylvania  
10 Department of Agriculture. Fluoroquinolones can't  
11 be used to treat pediatric salmonellosis because of  
12 the toxicity in small children.

13 MS. BUCK: Yes.

14 DR. SHULTZ: So as a result, ceftriaxone is  
15 the drug of choice for small children, and third  
16 generation cephalosporins, then, that are used in  
17 animals are a concern if we're generating third  
18 generation cephalosporins resistance.

19 MS. BUCK: Yes. Well, I would like the  
20 Subcommittee considering this tomorrow to remember  
21 that the incident rate for salmonellosis is highest  
22 in children, in particular children under I think

1 four years of age, the bar is very, very high. So  
2 when they're talking about the multidrug resistance  
3 tomorrow, I hope they take that into consideration,  
4 and I have one final thing and then I'm done.

5           What you've presented this afternoon is  
6 just really I think a lot of material for all of us  
7 to take in. This is all science related material,  
8 and we are being given one afternoon to put a final  
9 report together. I am lodging a request that the  
10 NACMPI Committee be given the time to come back  
11 either through a webinar or through a mini-meeting  
12 to finish up their final comments. I just think  
13 that this is an awful lot to try and digest in the  
14 time period that we have been given, and if you want  
15 our best recommendation, you will become creative  
16 and try something else. Thank you.

17           MR. TYNAN: Ms. Buck, it's a very good  
18 recommendation. Why don't we see where we are  
19 tomorrow, and if you're able to come up with some  
20 good recommendations and you're satisfied, if for  
21 whatever reason, we're falling short, we certainly  
22 will entertain the possibility of doing some kind of

1 a conference call. I would have to say just from  
2 trying to organize that, it would require a public  
3 meeting. So we'd have to have Federal Register  
4 Notice. So it would be considerably down the road  
5 before we'd be able to do that. So while it's a  
6 good idea, it will take a little doing to get it  
7 done.

8 MS. BUCK: We always need to keep reaching  
9 to improve communications and a way of getting the  
10 best out of your resources, and this is a wonderful  
11 resource that you have here, and you really want the  
12 best from all of us.

13 MR. TYNAN: I'm totally with it.

14 MS. BUCK: Thank you.

15 MR. TYNAN: Thank you. Mr. Painter, we're  
16 going to let you have the last word on this portion,  
17 and if I could impose on you and ask you to be  
18 concise.

19 MR. PAINTER: Stan Painter with the  
20 National Joint Council. My question is concerning  
21 the *Salmonella* consent waivers, and what I would  
22 like to know is when and what criteria is used in

1 granting a SIP waiver and can plants get a waiver of  
2 the *Salmonella* testing if they're failing the test  
3 results, and in receiving a waiver of the *Salmonella*  
4 testing, is that fair to the other plants who have  
5 to continue testing for *Salmonella*?

6 MR. LINVILLE: I'm not sure I'm  
7 understanding where you're saying they wouldn't have  
8 to test for *Salmonella*.

9 MR. PAINTER: Stan with the National Joint  
10 Council again. The Agency can and does grant  
11 waivers to companies for these *Salmonella* testing,  
12 and --

13 MR. LINVILLE: No. The waivers are for  
14 regulatory requirements in a broader base. We  
15 currently have regulations in place -- I mean we  
16 come from a command and control background. We've  
17 loosened those up through HACCP, but there are still  
18 a number of regulations out there that are black and  
19 white that have to be met. Some of those  
20 regulations aren't necessarily conducive to new  
21 technologies, and then through, for example, in  
22 poultry, through 381.3(b), a request for a waiver

1 from a particular regulation can be lodged, and the  
2 Administrator or designee then decides whether that  
3 regulation can be waived or not. So that could be  
4 in theory any regulation.

5           The SIP program is being looked at, being  
6 put in place and again that's not finalized. So all  
7 the criteria aren't all there yet, but the SIP  
8 program is being looked at as a process to say, we  
9 will allow you to be waived for a certain regulation  
10 but in response to that, you have to do extra  
11 *Salmonella* testing, not no *Salmonella*. They have to  
12 increase their *Salmonella* testing and share that  
13 data with the Agency. So if anything, the plants  
14 that volunteer for SIP are providing more data than  
15 those that don't. That's the tradeoff for receiving  
16 the waiver so that we can ensure that if we waive a  
17 regulatory requirement, we are not creating  
18 inadvertently an atmosphere that would have a  
19 potential negative impact on public health.

20           MR. PAINTER: So you're telling me that a  
21 plant cannot get a waiver for testing of *Salmonella*?

22           MR. LINVILLE: Currently if an

1 establishment is sending all of their product to  
2 ready-to-eat, we don't do verification testing if  
3 they can show that, and in theory, again as I  
4 stated, they can get a waiver from any regulation.  
5 So in theory they could get a waiver, but there's no  
6 regulation for an establishment to test *Salmonella*.

7 MR. PAINTER: Okay. Well, you know, I  
8 actually dealt with this this past spring, and with  
9 *Salmonella* coming up for this process, the Agency  
10 had granted a company a waiver regarding the testing  
11 of *Salmonella* and meeting of the standards. So, you  
12 know, you still didn't answer my question. Let's  
13 say that they did grant the waiver for this, which  
14 that was the case in this particular situation, you  
15 know. Is that fair to other plants that are meeting  
16 the requirements, and if a plant is failing the  
17 *Salmonella* program, can they get a SIP waiver then?  
18 Can they get a waiver from testing for *Salmonella* if  
19 they're failing the standards?

20 MR. LINVILLE: The current thought process,  
21 and again, this is not all finalized yet, as you  
22 know, we haven't got the final rule out on SIP yet.

1 Yes, they could if they are not meeting the  
2 standard. But that being said, they still are  
3 required, they, the industry is required to do  
4 additional testing above and beyond what FSIS is  
5 doing and provide that information to FSIS. So,  
6 again, the burden is higher on those particular  
7 establishments to provide additional data above and  
8 beyond what FSIS is collecting in their verification  
9 testing.

10 MR. TYNAN: Stanley, I don't want to cut  
11 you off. I know you have an important point to  
12 make.

13 MR. PAINTER: I do.

14 MR. TYNAN: But if we can, if could invite  
15 you to do this in the morning, so I'll give you  
16 about 30 seconds to sort of --

17 MR. PAINTER: Yeah, I want to know if  
18 you're giving a waiver, what are you testing for?  
19 If you're giving a waiver, what are you testing for  
20 with additional testing?

21 MR. LINVILLE: Again, the establishment  
22 does not have a requirement to test for *Salmonella*.

1 There's no regulatory -- *Salmonella* testing is done  
2 by the Agency. The waiver is for something else  
3 which requires them actually to test, which is  
4 something that they're not doing without the waiver.

5 MR. TYNAN: Well, Stanley, again, not to  
6 cut you off, but you can have this discussion in the  
7 morning as part of this Subcommittee group.

8 MR. PAINTER: I'm getting used to that,  
9 Robert. It happens about every time. That's the  
10 reason when you see my name on the list. Thank you.

11 MR. TYNAN: Okay. We want to get to those  
12 comments as well. So we're at that point. So I'm  
13 going to cut off the conversation as far as this is  
14 concerned for this evening. Tomorrow morning the  
15 Subcommittee will deal with it, and if there are  
16 some additional comments, questions, concerns, we  
17 can bring them up as part of that and discuss them  
18 further as part of the plenary session.

19 We are at the point on our agenda where we  
20 have to allow for some public comments. So some of  
21 the folks at the back of the room who have been  
22 amazingly patient to stay there, I have only two

1 folks that have signed up for comment, so I'm going  
2 to invite them to come up first, and then I will  
3 allow anybody that had a second thought and wanted  
4 to make a comment but didn't sign up to do it after  
5 that, and the first name I have on the list is  
6 Mr. Chris Waldrop. Chris, could you come up to the  
7 microphone and identify yourself and your  
8 affiliation?

9 MR. WALDROP: I'm Chris Waldrop, Consumer  
10 Federation of America.

11 I wanted to go back to the original, the  
12 first two reports that the Committee was talking  
13 about, the strategic data analysis plan and the  
14 decision criteria documents. I just wanted to say  
15 that I appreciate that the Agency has finally been  
16 able to get those documents out. I think they're a  
17 good attempt to let the public and the Committee  
18 know sort of where the Agency is heading and have a  
19 better understanding of its intentions with regards  
20 to data and with regards to PHIS.

21 It is, I think, important since the NAS was  
22 sort of the institution that provided the initial

1 comments on the Agency's efforts, to send those  
2 reports back to the NAS and get some sort of formal  
3 response from the NAS so that you really do have a  
4 sense of if the NAS agrees that you are headed in  
5 the right direction. I think that's going to be  
6 something very important.

7 I mentioned that this is going to help this  
8 Committee and the stakeholders have a better  
9 understanding of the Agency's intentions, and I  
10 think I use the word better because there's a lot,  
11 as I was reading through this report, there's a lot  
12 of plans to and the Agency is intending to and is  
13 working on and are exploring, and I think those  
14 elements are still sort of out there in this phase 1  
15 that the Agency highlights. So I think it's  
16 unclear, and it will be useful for the Committee and  
17 for the Agency to know where the Agency is in terms  
18 of that phase 1 and how far along it is and how many  
19 of these things are actually going to be done prior  
20 to implementation, so the Committee has a better  
21 understanding of how this data will be used, when  
22 PHIS goes live.

1 I think there are a number of other  
2 elements that are important in terms of the data  
3 quality and the data changes to the data system such  
4 as the sampling program, redesign that's  
5 anticipated, identifying the type 1 and type 2  
6 errors, the predictive analytics. A lot of that is  
7 some real heavy data stuff that I'm not sure this  
8 Committee necessarily has the time to or is able to  
9 delve into, that you have another committee that's  
10 focused more on the data issues and looks really at  
11 the scientific justification for a lot of the  
12 Agency's background. That's the NACMCF, and I think  
13 that committee could be very well suited to look at  
14 some of these more technical issues and really dig  
15 down into some of these data approaches. So I'd  
16 recommend that the Agency consider bringing some of  
17 those issues to the NACMCF and having them look at  
18 this before the Agency moves forward in addition to  
19 what this Committee is going to be doing. Thanks.

20 MR. TYNAN: Thank you, Chris.

21 Mr. Painter is the next person on our sign-  
22 up sheet. So, Stanley, you're right there at a

1 microphone. We'll let you talk from there.

2 MR. PAINTER: Stan Painter with the  
3 National Joint Council.

4 I need to clear up some misconceptions and  
5 some concerns that I have with the presentation that  
6 was given earlier today by Mr. Bill Smith.  
7 Mr. Smith made the statement that there were over  
8 4,000 comments regarding PHIS and all were corrected  
9 but some 800. This is the situation. Inspectors  
10 are commenting, I can't log onto the system, I can't  
11 move, I can't go anywhere, I can't do anything. Two  
12 days later, they fixed the problem, and then you're  
13 able to move forward. So the Agency is considering  
14 that fixed. So that is not fixed. Two days later  
15 then I have the same issue.

16 So that is a misconception, and if the  
17 Agency's going to be open and transparent, the  
18 Agency needs to tell it like it is. The Agency  
19 don't need to gloss over the situation, and glossing  
20 over the situation, the Agency's only allowing eight  
21 minutes in order for an inspector to do a NR. The  
22 biggest part of the time of an inspector's day is

1 going to be sitting behind a computer. At this  
2 point in time, an inspector is going to be doing HAV  
3 studies. They're going to be programming their own  
4 work into the system. They're going to be doing  
5 their timesheet through webTA and they're going to  
6 be sending behind a computer doing GovTrip. So my  
7 question was to the Agency, when are we going to be  
8 doing inspections? What are we going to program  
9 into the system? That has not been open. That has  
10 not been transparent.

11 We're giving awards in the tune of \$25,000  
12 to managers for PHIS, and I ask what for? Where is  
13 the openness and where is the transparency for that?  
14 That's like saying I'm going to give a lifeguard a  
15 big award for saving a life, yet no one has drowned  
16 yet. No one is in distress. I can't understand in  
17 the budget constraints and with what President Obama  
18 has put forth to the Agency that we should cut 5  
19 percent how that is even possible. Folks, PHIS is  
20 nothing but risk-based inspection. The Agency has  
21 said it is an information system. It has changed  
22 jobs. It has changed classifications. It has

1 changed position description. What inspectors enter  
2 into data is going to determine how much inspection  
3 they get which is risk-based inspection.

4 That being the case, you know, that creates  
5 an inspection system versus an information system,  
6 connectivity. If we were open and transparent, the  
7 Agency would have told people that an inspector is  
8 going to be guaranteed one connectivity at one  
9 plant. They may have five plants, but yet they only  
10 have connectivity at one. So when the Agency says  
11 we have real-time data, that's not the case because  
12 if you go to the first plant and you have that  
13 connectivity, you log into the system. Then you go  
14 to four of the facilities, you're working off of the  
15 data. If the data changes, which it can in exports,  
16 you're working off of data. It is not real-time.  
17 They're not being transparent when the Agency says  
18 that they're being provided with connectivity at all  
19 assignments, and I'm going to close by saying this.  
20 If there was openness and a transparency, why am I  
21 continuing to have to file through this PHIS process  
22 FOIA requests and requests under the statute, under

1 71.14(b) to get information from these people? It  
2 shouldn't be a fight. I will say this. I've said  
3 this a number of times. I pay more attention to  
4 what you do than what you say, and I judge you by  
5 the fruits you bear. Thank you.

6 MR. TYNAN: Okay. Thank you, Mr. Painter.  
7 I'm going to ask if there's anybody in the audience  
8 that didn't sign up that would like to make a  
9 comment. I'll give you an opportunity. Please,  
10 Tony, but --

11 MR. CORBO: It'll be short.

12 MR. TYNAN: Thank you.

13 MR. CORBO: Tony Corbo from Food and Water  
14 Watch. The only blessing of the U.S. Senate not  
15 taking up the FDA Food Safety Legislation has been  
16 my ability to focus on what FSIS is doing with PHIS.

17 I made the treks over to George Mason  
18 University back in 2006, 2007, when risk-based  
19 inspection was being discussed, and most of the  
20 consumer groups were saying that the Agency was  
21 moving too fast. I think the same can be said here,  
22 that in theory, PHIS is a promising system, but

1 there are some issues that were raised earlier today  
2 that I still at least sitting back here haven't  
3 gotten answers to.

4 Sarah Klein asked the question what are the  
5 public health goals of PHIS. I really didn't hear  
6 clear-cut answers.

7 Chris Waldrop reiterated a point that was  
8 made by Carol Tucker-Foreman about you have these  
9 two papers, on the date. Did you submit it to the  
10 National Academy of Sciences? Didn't get a clear-  
11 cut answer as to whether the Agency is going to wait  
12 for the NAS evaluation of those papers before  
13 they're going to proceed.

14 An issue was raised about linking PHIS to  
15 your legacy system, to the PBIS data, whether the  
16 establishment history from PBIS is going to be  
17 translated somehow into PHIS so that there is  
18 continuity in terms of establishments. I still  
19 haven't gotten an answer to that.

20 Whether there are other interface problems  
21 with other IT systems that the Agency has in place  
22 right now, between PHIS and those other IT systems.

1 Haven't gotten a response to that.

2           Even if you reduce the number of problems  
3 through the user testing to 800, that is still a  
4 significant number, and the fact that some of these  
5 issues are recurring raises an issue as to whether  
6 the software is really capable of dealing with the  
7 actual inspection responsibilities.

8           MR. TYNAN: Tony, you said brief. So you  
9 have to wrap up for me.

10           MR. CORBO: Yeah. The HAV procedure is  
11 great. Fourteen years after the HACCP rule went  
12 into effect, now we're going to do verification of  
13 HACCP plans. That means that other inspection  
14 duties are going to be diminished in terms of  
15 importance. There has to be a discussion of that.

16           And then there are representatives from  
17 state inspection programs here. How is this all  
18 going to impact those state inspection programs?

19           And last but not least, as much as this  
20 Agency tries, you're not going to put me out of the  
21 FOIA business. Thank you.

22           MR. TYNAN: Okay. Thank you. I'm not

1 going to invite anybody else up. There will be  
2 another opportunity tomorrow for the public to  
3 comment, and there is always the opportunity to send  
4 written comments in under the Federal Register  
5 Notice that we have for this public meeting.

6 Let me mention a couple of things briefly  
7 because we're supposed to be out of here at 5:00.  
8 If the members can come back tomorrow morning, be  
9 here no later than 9:00 so we can get you to your  
10 rooms and get you started with your deliberations  
11 because there are, as Ms. Buck points out, there's a  
12 lot to go over in a short period of time.

13 Dr. Jones is going to be chairing Committee  
14 Number 1. Dr. Cutter will be doing the one related  
15 to pre-harvest. There's issue papers, and the  
16 member lists are under Tab 14, so to make sure that  
17 you know which committee you're on. The issue  
18 papers and the questions you'll be dealing with for  
19 tomorrow are under Tabs 15 and 16 in your notebook,  
20 and we're going to invite John Linville to come to  
21 the Committee Number 2. We'll have Chris Alvares  
22 and Todd come to the data meeting. So you'll have

1 resources to talk to and ask questions of. They're  
2 not there to direct the conversation, but simply to  
3 be a resource if you have some concerns or some  
4 issues that you want to try and clarify.

5           And last but not least, under Tab 16, we  
6 have the paper, the discussion paper that relates  
7 again to pre-harvest, and that's a little bit more  
8 detailed, and we gave you an opportunity, we sent  
9 that to you late, but I just wanted to call that to  
10 your attention so you have it, and that will sort of  
11 be the framework for tomorrow.

12           I appreciate all of your efforts, your  
13 patience. Yes, Ms. Donley.

14           MS. DONLEY: Just a real brief question.  
15 I'm on Subcommittee 2, which are you suggesting we  
16 all meet here tomorrow and then go to Whitten or --

17           MR. TYNAN: No, if you meet here, then  
18 Committee 2, you'll be in Room 1160. So we'll make  
19 sure that you find your way to 1160 so that the  
20 Chairperson isn't the only one that's sitting there.

21           MS. DONLEY: So come here.

22           MR. TYNAN: Yes, please. So come here

1 first, and then we'll take Committee 2 around to  
2 Room 1160, and with that, I'm going to move we  
3 adjourn for tonight, and I will see you first thing  
4 in the morning. Thank you very much for your  
5 patience and attention.

6 (Whereupon, at 5:09 p.m., the meeting was  
7 concluded.)

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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.

September 29, 2010

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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TIMOTHY J. ATKINSON, JR., Reporter  
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