

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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PLENARY SESSION

+ + + + +

THURSDAY
SEPTEMBER 22, 2011

+ + + + +

The Advisory Committee met in the Ballroom Room in the Savoy Suites, 2505 Wisconsin Avenue, N.W., Washington, D.C., at 9:00 a.m., Philip Derfler, Deputy Administrator, Food Safety and Inspection Service, presiding.

PRESENT:

PHILIP DERFLER, FSIS
PATRICIA K. BUCK, Center for Foodborne
Illness Research and Prevention
FUR-CHI CHEN, Tennessee State University
CATHERINE N. CUTTER, Pennsylvania State
University
NANCY J. DONLEY, STOP Foodborne Illness
VENERANDA GAPUD, Fieldale Farms
CHERYL JONES, Morehouse School of Medicine
HEIDI KASSENBOG, Minnesota Department of
Agriculture
SARAH A. KLEIN, Center for Science in the
Public Interest
SHELTON E. MURINDA, California State
Polytechnic University
ROBERT G. REINHARD, Sara Lee Corporation
CRAIG E. SHULTZ, Pennsylvania Department
of Agriculture

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STANLEY A. STROMBERG, Oklahoma Department
of Agriculture, Food, and Forestry
JOHN D. TILDEN, Michigan Department of
Agriculture
CAROL TUCKER-FOREMAN, Consumer Federation
of America
STEVEN E. WARSHAWER, Mesa Top Farm
J. BYRON WILLIAMS, Mississippi State
University
LEONARD W. WINCHESTER, Public Health -
Seattle & King County

FDA LIAISON:

JOSHUA HAYES, Center for Veterinary
Medicine

CDC LIAISON:

ARTHUR LIANG

USDA STAFF:

BRIAN RONHOLM, Deputy Undersecretary for
Food Safety
CHRISTOPHER ASTON, ODIFP-DAIG
CATHERINE COCHRAN, FSIS
DAN ENGELJOHN, FSIS

SALLY FERNANDEZ

ALLAN HEPNER, Office of the Chief Financial
Officer

JOANNA LOBLOTSKY KUTEL, ODIFP-DAIG
JOHN LINVILLE, Office of Policy and
Program Development
RICH McINTIRE, FSIS
LAURA McKEE, FSIS
LEO O'DRUDY, FSIS

KEITH PAYNE, Outreach and Partnership
Staff

JANICE SCHECHTER, FSIS
WILLIAM SHAW, Risk, Innovations, and
Management Division
WILLIAM SMITH, Office of Program Evaluation,
Enforcement & Review

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ALSO PRESENT:

BETSY BOOREN, American Meat Institute
SAVONNE CAUGHEY, Elanco
TONY CORBO, Food & Water Watch
ASHLEY COOK, Food Directions
CARL CUSTER, Self
MARTY EWING, Sanderson Farms
H. PETIT EWING, Koch Foods
SCOTT GOLTRY, American Meat Institute
AMBER HEALY, Food Chemical News
MELISSA HERBERT, NEOGEN
BRYNN KEPLER, American Association of Meat
Processors
KATE LEVY, HSUS
KRISTIN LINDAHL, Smithfield
BARB MASTERS, OFW
ANNE MURPHY, Cargill, Inc.
ASHLEY PETERSON, National Chicken Council
BETH ROBERTSON, Smithfield
DANIEL SPELLACY, Arrowsight
SCOTT STILLWELL, Tysons Foods, Inc.
JAY B, WENTHER, American Association of Meat
Processors
ALLIMY YOUNG, U.S. Poultry & Egg Association

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

2 9:00 a.m.

3 MR. PAYNE: Well, good morning,
4 everyone. I'm Keith Payne, and we'll go ahead
5 and get started. I'll be the moderator for
6 today and tomorrow at this meeting. I'm with
7 the Office of Outreach, Employee Education and
8 Training. And before we get into the nuts and
9 bolts of the meeting, the logistics and all
10 that, I would like to turn it over to Mr. Phil
11 Derfler, who is our Deputy Administrator for
12 FSIS, and Mr. Brian Ronholm over here, who is
13 our Deputy Undersecretary for Food Safety for
14 the opening and welcoming remarks for the
15 Committee.

16 MR. DERFLER: Good morning,
17 everyone. We're going to deviate a little bit
18 from the agenda. I'm just going to say a
19 couple of things, and then Mr. Ronholm is
20 going to do some welcoming remarks, and then
21 I'm just going to fill in behind him. But
22 there are a couple of things I want to say

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1 before I turn it over.

2 So first of all, I want to welcome
3 everybody on behalf of our Administrator, Al
4 Almanza. He's really sorry that he could not
5 make it today, but he sends his greetings and
6 his appreciation to you all for participating
7 in today's meeting.

8 I can't emphasize enough how
9 important this committee and this meeting is
10 to us. I know that there were some questions
11 raised when we didn't have the spring meeting
12 and then when we switched the management of
13 the committee from one part of the agency to
14 another as to whether or not we were still
15 taking this committee seriously and whether we
16 were still valuing it. And I can't tell you,
17 I have to tell you that none of that is right,
18 and we really do value this committee and
19 we're really looking forward to what we're
20 going to get from this meeting. And, I mean,
21 in the spring, there were just a number of
22 other things going on that made it impossible

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1 for us to come up with a worthwhile agenda.
2 And in the absence of a worthwhile agenda, it
3 just wasn't appropriate for us to take your
4 valuable time to do this.

5 As far as switching the management
6 of the committee, we did that because there
7 were some people who left the agency who had
8 been in management positions for this
9 committee. And we tried to put in place the
10 people with the most experience in organizing
11 meetings of this type, and that's why we're
12 here.

13 I understand that the last meeting
14 of the committee was really productive and
15 really worthwhile, and we're really hopeful
16 that we'll have the same sort of meeting
17 today. There's a lot of people here both on
18 the committee and in the audience with a great
19 deal of expertise and information, and we're
20 really looking forward to hearing from you.

21 So with that, I'm going to ask Mr.
22 Ronholm to make some statement. He's the

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1 Deputy Undersecretary. He's been with the
2 Office of Food Safety for about four months,
3 and he comes to us from Congresswoman Rosa
4 DeLauro's staff, and he's just been really
5 invaluable to the agency since he's been
6 working with us. So Brian?

7 MR. RONHOLM: Thank you, Phil.
8 Thank you for lying and saying that I'm
9 invaluable. Time will tell about that. But
10 good morning, everyone. Thank you very much
11 for being here and for participating in this
12 very important meeting. What's great about
13 this advisory committee is, despite the high
14 pay that you all get for participating, I know
15 that you all would be here regardless of what
16 we are paying you because of the personal
17 passion that you all have for safety issues,
18 and we know that it plays an important role in
19 your personal and professional lives.

20 I recently finished the book
21 "Poisoned" by Jeff Benedict, and I think
22 you're all familiar with it. I understand now

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1 why Bill Marler was so eager to hand it out to
2 everyone he would see. I mean, with all the
3 details that were revealed about his life, I
4 think the only details that were missing was,
5 you know, what kind of cape that he would
6 change into whenever he entered the phone
7 booth.

8 But the book tells a very
9 compelling story, and it's difficult to
10 ignore. Lauren Rudolph was a six-year-old
11 girl when she became sick from the E. coli
12 outbreak in 1993, and she became ill during
13 the holiday season and sent a letter to Santa
14 in which she simply wrote, "Dear Santa, I
15 don't feel so good. Please make me feel
16 better for Christmas. Lauren."
17 Unfortunately, she didn't get better and
18 became the first child to die in that
19 outbreak, and that's a big reason why we're
20 all here today and that's why your work is so
21 important: to make sure that another letter
22 like that one Lauren wrote doesn't get sent to

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1 Santa again.

2 We have a lot of notable items on
3 the agenda for this meeting, and the
4 importance of this group getting together
5 really can't be overstated. As most of you
6 probably know, I'm still somewhat new to the
7 agency, as Phil mentioned. I came onboard in
8 April. But it's great to see familiar faces,
9 like Pat Buck and Nancy Donley, Bob Reinhard,
10 Barb Masters out in the audience. I got to
11 know you all really well when I worked for
12 Congresswoman Rosa DeLauro. And I was proud
13 to become a member of the food safety team at
14 USDA, especially when you consider the immense
15 talent that's already there, including Mr.
16 Derfler.

17 One thing that was clear from the
18 start is that the team at the Office of Food
19 Safety and at FSIS really placed a great
20 amount of importance on stakeholder outreach
21 and on developing policy with considerable
22 stakeholder input. We have a mandate to make

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1 sure food is safe, and meeting that mandate is
2 not an easy task. These are complex problems
3 that we are dealing with; and, while we have
4 many intelligent, bright, hardworking people
5 here at USDA, we're not able to do it alone.
6 That is why your work is important. So thank
7 you again for being here.

8 Let me just touch on a couple of
9 the agenda items. As I said, we have a lot of
10 important topics. Last year, I understand the
11 agency was starting to discuss pre-harvest
12 food safety, and I understand there were
13 discussions here on that topic that really got
14 the ball rolling. As Dr. Hagen frequently
15 says, we need to look at protecting public
16 health in every possible way we can, so pre-
17 harvest has been something we continue to
18 think about at the department because we think
19 it's a real opportunity to make important
20 strides in reducing foodborne illness.

21 We know that the conditions of
22 animals when they come to the slaughter is

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1 going to impact risk that has to be addressed
2 from processing to food preparation. Knowing
3 this, it makes sense to examine the condition
4 of animals as they come to slaughter. At
5 FSIS, we're doing everything we can do within
6 our authority, but the fact remains that there
7 are other things that can be done to make
8 food safer. That is what pre-harvest food
9 safety is all about.

10 So given that reality, what can be
11 done? What can we do to help improve food
12 safety in the pre-harvest environment while
13 respecting the boundaries of our current
14 authority? That is something that we want you
15 to consider.

16 A couple of things on HACCP
17 validation, which is also on the agenda. As
18 you know, this is not something new that we're
19 trying to implement. Validation is a critical
20 part of HACCP. If establishments are not
21 validating HACCP plans, then they really do
22 run the risk of producing adulterated product.

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1 In fact, we've seen that happen. During the
2 course of our inspection and verification
3 activities, we found that some plants were not
4 validating or were not correctly validating
5 their HACCP plans. And in some cases, this
6 resulted in adulterated product. So in a
7 sense, yes, we are trying to do something new
8 with validation. We're simply trying to help
9 everyone comply with the requirements as they
10 currently exist.

11 So the document before you today is
12 the revised draft. It represents the agency's
13 current thinking, but it doesn't necessarily
14 represent the final thinking. We obviously
15 are interested in your input and questions
16 and, ultimately, it will be posted for public
17 comment and will likely be revised yet again
18 after that.

19 That brings me to PHIS. Bill Smith
20 is going to provide you with a status update
21 later, but we are moving forward with PHIS
22 because it really will help us become a more

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1 prevention-based food safety agency. It will
2 allow us to maximize the use of our data and
3 identify problems as they develop, rather than
4 after the fact. It is a significant
5 undertaking, and it is not without difficulty.

6 However, we're headed in the right direction,
7 and it is something we are very excited about
8 and I hope that you also recognize the value
9 of PHIS.

10 So you've got a busy two days ahead
11 of you, so I appreciate the fact that you're
12 all here willingly. And we're here seeking
13 the same thing, and that is to secure the
14 safety of the meat and poultry supply.

15 So on behalf of Dr. Hagen, thank
16 you very much to our committee members and for
17 your commitment to public health and have a
18 great meeting. Thanks a lot.

19 MR. DERFLER: Thank you, Mr.
20 Ronholm. Thank you. I'm just going to go
21 back over the agenda that Mr. Ronholm just
22 laid out and put in a little bit more detail.

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1 And then we'll just start with the meeting.
2 I'll turn it over to Mr. Payne to start the
3 meeting going.

4 We have two sort of update
5 presentations that are part of the agenda, and
6 then we'll be presenting two issues that we're
7 going to ask you to address in your
8 subcommittees. The first presentation is
9 going to be made by Mr. Allen Hepner of our
10 Office of the Chief Financial Officer. And
11 what he's going to do is make a presentation
12 about our new strategic plan. We adopted this
13 plan about two weeks ago. As an agency, we're
14 really, really excited about it, which is the
15 reason why we're presenting it to you. All
16 too often in the past, strategic plans have
17 been established and then forgotten and put in
18 a drawer. This we have a real commitment to,
19 and we tried to make it measurable and
20 concrete, and Mr. Hepner will provide more
21 details about that for you.

22 The second update is by Bill Smith

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1 from our Office of Program Evaluation,
2 Enforcement, and Review. And he's going to go
3 over the PHIS, where we are with the Public
4 Health Information System, where we are with
5 it now. As some of you know, we had some
6 difficulties when we initially rolled out
7 PHIS, and Mr. Almanza asked Mr. Smith to take
8 the leadership of the rollout. And since he's
9 taken over, we've made great, great strides
10 and great improvements, and the system is
11 working a whole lot better.

12 One of the reasons why we wanted to
13 have a presentation on PHIS for you today is
14 that I know that last time you met there was a
15 discussion about data, and one of the key ways
16 that we're going to handle data is PHIS. I
17 know that a longstanding complaint by members,
18 various generations of members of this
19 committee is that we present you with issues,
20 you get an opportunity to discuss them, you
21 make recommendations to the agency, and then
22 you never really hear anything about what the

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1 agency does with the information. And so Mr.
2 Smith's presentation is, in part, an effort to
3 respond to that, as is the presentation that's
4 going to be made by Dr. John Linville from the
5 Office of Policy and Program Development. He
6 talked to you last time about pre-harvest, and
7 he's going to be making the presentation about
8 pre-harvest. I think Mr. Ronholm has laid
9 that out pretty well for you as to what to
10 expect from that presentation. I don't really
11 need to deal with it anymore, except we really
12 do think the pre-harvest is really key. On
13 the basis of what we heard from you last time,
14 I think Dr. Linville has narrowed down the
15 questions and is trying to give you a more
16 focused presentation. And that's as a result
17 of what we heard from you last time, and we
18 hope to continue and use the information that
19 we're getting to help make food safer.

20 Then the last presentation will be
21 by Dr. Bill Shaw, also with the Office of
22 Policy and Program Development, about

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1 validation. We informally put out a version
2 of the guidance document last year. We got a
3 lot of comments. We had a public meeting. By
4 doing it informally, we got a lot of comments
5 on it. We significantly revised it, and we're
6 presenting it today because we intend to put
7 it out for public comment, as Mr. Ronholm
8 said, but we really want to make sure that the
9 document that we put out is as good as
10 possible so the comments that we get are as
11 valuable as possible. So Dr. Shaw will be
12 making a presentation about that today.

13 So, again, I want to thank you all
14 for being here. Thank you for your
15 participation, and thank you for your
16 guidance. And now I'm going to turn it over
17 to Mr. Payne.

18 MR. PAYNE: Thank you, Mr. Derfler.

19 And for now, what I'd like to do is cover
20 some housekeeping measures. And we have a
21 staff here. Sally Fernandez is either in the
22 room here or outside. Sally Fernandez will

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1 have Commander Jeff Tarrant and Lieutenant
2 Kazuhiro Okumura. They are helpful staff. If
3 you have any questions, please refer to them
4 and me, as well.

5 Before we go around and introduce
6 the members of the committee who are here
7 today, I'd like to point out and recognize we
8 have officials representing other
9 organizations for this committee, and we have
10 Dr. Danah Vetter representing the National
11 Association of Federal Veterinarians there in
12 the front row in the back there. We have
13 Justin Reed here representing the Asian
14 Pacific American Network in Agriculture. Is
15 Justin Reed here? Maybe he hasn't shown up
16 yet.

17 We had extended an invitation to
18 Stan Painter of the National Joint Council of
19 Food Inspection Locals and Robert McKee of the
20 Association of Technical and Supervisory
21 Professionals and, unfortunately, they were
22 not able to make it to this meeting. We do

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1 have two other representatives. These are
2 liaisons to the committee, and they are
3 actually sitting here at the table. We have
4 over here Dr. Joshua Hayes who is filling in
5 for Dr. Jeff Farrar from the U.S. Food and
6 Drug Administration, and we have Dr. Arthur
7 Liang here from the U.S. Centers for Disease
8 Control and Prevention representing the CDC on
9 our committee. And each one will respectively
10 be in a different subcommittee.

11 So with that said, let's, for the
12 record, just go around the table here, I guess
13 starting with Mr. Derfler, just to identify
14 who you are, your affiliation, and we'll go
15 around the table to introduce ourselves.

16 MR. DERFLER: Phil Derfler from the
17 Food Safety Inspection Service. I almost said
18 the Food and Drug Administration.

19 MR. HAYES: I'm Josh Hayes from the
20 Food and Drug Administration, Center for
21 Veterinary Medicine.

22 DR. CUTTER: Cathy Cutter, Penn

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1 State University.

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

4 DR. WILLIAMS: Byron Williams,
5 Mississippi State University.

6 MS. DONLEY: Nancy Donley, Stop
7 Foodborne Illness, formerly Safe Tables Our
8 Priority.

9 DR. SHULTZ: Craig Shultz,
10 Pennsylvania Department of Agriculture.

11 MR. WINCHESTER: Leonard
12 Winchester, Public Health - Seattle and King
13 County.

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

17 MR. REINHARD: Bob Reinhard, Sara
18 Lee Corporation.

19 DR. JONES: Cheryl Jones, Morehouse
20 School of Medicine.

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

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1 MS. BUCK: Pat Buck, Center for
2 Foodborne Illness Research and Prevention.

3 MS. GAPUD: Veneranda Gapud,
4 Fieldale Farms Corporation in Baldwin,
5 Georgia.

6 DR. CHEN: Fur-Chi Chen, Tennessee
7 State University.

8 DR. KASSENBERG: Heidi Kassenborg,
9 Minnesota Department of Agriculture.

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

12 MR. WARSHAWER: Steve Warshawer,
13 Mesa Top Farm and Beef Industry Improvement
14 Initiative of New Mexico.

15 MR. MURINDA: Shelton Murinda,
16 California State Polytechnic University.

17 MR. RONHOLM: Brian Ronholm with
18 USDA.

19 MR. PAYNE: Thank you. And, again,
20 I'm Keith Payne with FSIS, the Office of
21 Outreach, Employee Education and Training.
22 Thank you. And you all figured out, the

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1 committee members figured out how to use the
2 microphones, as I see. But just a reminder,
3 when you're not talking, just press the button
4 so the red light is not on so we don't have
5 any other noise showing up.

6 Okay. When it comes to the
7 comments, as Mr. Ronholm and Mr. Derfler
8 referenced in their remarks, we have a couple
9 of briefing papers. We do have short question
10 and answer periods after each one, and what
11 we're trying to do is keep things moving along
12 according to our agenda so we don't get far
13 behind. We may limit the comment, and don't
14 take it the wrong way. We're just trying to
15 be fair to everybody who wants to make a
16 comment or question, so we may have someone
17 keeping track of the time. Especially when we
18 get to the end of the day where we have the
19 public comment period, we may have about three
20 minutes. But we'll see where we stand on that
21 just to make sure that everybody gets a fair
22 chance to make a comment.

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1 All questions should be directed to
2 the chair of the committee, and the chair of
3 the committee is the FSIS administrator. And
4 today and tomorrow, this is delegated to Mr.
5 Derfler over here, so any questions should be
6 addressed to Mr. Derfler, as well as if
7 there's any requests to make announcements or
8 put anything out on the tables, please, that
9 needs to be run by Mr. Derfler, as well.

10 Okay. One more thing, a couple
11 more things. In terms of restrooms, there's
12 men's and women's restrooms past the elevator
13 here on this floor. That seems to be the only
14 public restrooms here in the hotel. Where the
15 other subcommittee will meet, one of the
16 subcommittees will meet downstairs in the
17 Georgetown Room. I checked down there, and
18 there's no restroom facility down there. So
19 there only seems to be restrooms up here.

20 For the lunch, each one of the
21 committee members has a form in front of them.

22 If you opt to order lunch through the hotel,

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1 they need that order by 10:00, just as a way
2 to make sure you get it in time. And we need
3 to reconvene at 12:45 promptly after lunch.

4 For the committee members, again,
5 going back to the comments, if you have a
6 comment, like it is customary in the past, if
7 you want to make a comment, please set your
8 tent card up vertically, and we will get to
9 you when we can, okay?

10 All right. Without further ado,
11 we'll go ahead and turn it over to our first
12 presenter on the agenda, and that is Mr. Allen
13 Hepner, who is the Senior Planning and
14 Performance Manager with the Office of Chief
15 Financial Officer, who will be talking about
16 our strategic plan.

17 MR. HEPNER: Thank you, Keith.
18 Greetings, everyone. Good morning. As Keith
19 mentioned, my name is Allen Hepner. I'm the
20 Senior Planning and Performance Manager at
21 FSIS, and I was actually quite fortunate to
22 work on the strategic planning effort. It was

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1 a very interesting and, hopefully you'll
2 agree, productive exercise that we undertook.

3 It was just actually released last week. I
4 know that Keith sent out to the members a link
5 to it. It's on the FSIS website,
6 fsis.usda.gov. If you haven't looked at it, I
7 strongly encourage you to do so.

8 I was, again, very fortunate to
9 shepherd the project through from really soup
10 to nuts while all of the other people at FSIS
11 did all of the hard work. So it was quite an
12 interesting endeavor as I'm sure, if anyone
13 has been involved in a strategic planning
14 exercise, you can attest.

15 As Brian and Phil mentioned, I
16 think that, and hopefully you'll agree, it's
17 an important document that we wanted to
18 present today, and it's important for a number
19 of reasons. The first is that it serves as
20 the agency roadmap to ensure that goods
21 produced under the FSIS authority are safe for
22 the American people. There's really nothing

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1 that can be more important than that. Second,
2 it serves really as a foundation or touchstone
3 document for the day-to-day operations of the
4 agency and also for our long-range planning,
5 as a strategic plan should. And, third, it
6 provides you all, it provides the public, it
7 provides the stakeholder, and, importantly, it
8 provides FSIS employees with clear goals,
9 discrete actions, and targets to protect the
10 public.

11 I'll speak very briefly as I go on
12 about the process. A lot of people are
13 interested in process, some people not at all
14 and are just interested in consequence. I'll
15 speak about that in a minute, but I did want
16 to mention a conversation I had with someone
17 the other day. They were asking me about the
18 strategic plan since it was just released, and
19 they asked what I thought were two really core
20 or pivotal questions, and I just wanted to
21 relay them. One was now that the plan is
22 released and you went through this process,

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1 what's changed, what's changed in the agency?

2 And, second, how will it be used? As Phil
3 mentioned, oftentimes, people produce
4 voluminous plans. They're put on a shelf.
5 They look nice. They're handed out. People
6 move on. I thought those were two critical
7 questions, and I'll answer those in a second.

8 The other thing that I wanted to
9 mention was what I thought was a very good
10 Alan Lincoln quote. He's the guru on time
11 management. And I thought that it really
12 summarized our process, crystalized our
13 process. It said, "Planning is bringing the
14 future into the present so that you can do
15 something about it now." It's very unusual
16 for people to focus on three to five years
17 out. Most people focus on today or the end of
18 next week or, if you're making appointments
19 and thinking about your calendar, you're
20 focusing maybe on next month. So this
21 exercise, this was really a long-term exercise
22 that took the agency over eight months and

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1 really forced us all to focus on where the
2 agency wanted to be to protect public health
3 five years from now. And for that reason, I
4 think it's critically important.

5 So I'll talk very briefly now just
6 about the process and consequence. The most
7 important thing here for people to see is
8 really what's in the box. It's how can the
9 strategic plan be developed and then utilized
10 to protect public health? The key
11 requirements here on the right side is what we
12 were really looking for as a textbook
13 strategic plan, something that would be
14 extremely accessible, easy to read, clear,
15 provide all the groups that I mentioned with a
16 clear line of site from vision, mission,
17 goals, strategies, tactics, and discrete
18 performance measures, and something that was
19 measurable over time. Also something that
20 incorporates the leadership and management
21 vision and expertise. Very, very important
22 things, something that was very outcome and

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1 results oriented. So we looked at a lot of
2 plans. We spent a lot of time thinking about
3 what we wanted it to be.

4 We were also very fortunate that,
5 at the time when we were starting the
6 exercise, as you'll see under the second
7 circle under key drivers, Dr. Hagen was just
8 confirmed. Our administrator, Al Almanza, who
9 had been in the position for a long time, was
10 also confirmed. The President and the
11 secretary, our Secretary of Agriculture, has
12 very, very strong commitments to food safety.
13 We are undertaking a cultural transformation
14 exercise in the department and the agency, as
15 well, and also, and a number of you may have
16 heard, OMB and the President very interested
17 on results and high performance goals.

18 We were also able to use the
19 building blocks from the previous strategic
20 plan, most notably a risk-based approach
21 focused on metrics and longstanding goals, to
22 really jumpstart our exercise at the beginning

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1 with a focus on prevention, as I mentioned,
2 public health, things that are extraordinarily
3 important to both Brian and Dr. Hagen.

4 Now, I won't go through this. I
5 just wanted to provide it. This is, again, I
6 think a textbook example of the process
7 itself, very heavy in research, consultation,
8 analysis. As I've said to other people and
9 I'm sure, again, people that have worked on
10 this can attest it's very easy to write a
11 strategic plan if you do it by yourself in a
12 room with the door closed, extremely difficult
13 to do it when you're consulting with a wide
14 range of interests, oftentimes divergent
15 interests. And that was, shall we say, some
16 of the fun, but we produced I think and were
17 able to distill a lot of these visions and
18 input into extraordinarily crystal clear
19 targets and measures.

20 Now, the framework also was a very
21 topdown approach. We started with vision,
22 mission. We were able to spend quite a bit of

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1 time on the actual wording because the words
2 matter on those things before we went down the
3 chain into developing strategic themes and
4 then specific discrete goals, objectives,
5 strategies. All of this was really done in a
6 very logical, ordinal, rational, sequential
7 process.

8 And it all started with Dr. Hagen's
9 vision, and I think that the plan adheres to
10 it and is a testament to that very strong
11 commitment to public health and one team, one
12 purpose. What we did was spend quite a bit of
13 time interviewing senior leadership and
14 management to ensure that we got the vision
15 and mission right before we started down the
16 path to develop the goals and the strategies
17 and the tactics.

18 The next slide I just wanted to
19 include in terms of process because it really
20 shows, this was an embryonic schematic that we
21 developed to develop the groupings, the themes
22 A, B, C of prevention, operational learning,

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1 and efficiency and efficacy. This was a
2 development process after we interviewed Dr.
3 Hagen, so it shows you all and hopefully the
4 reader how we went from conversation to
5 action, from conversation to discrete tactics.

6 And this is where we ended up. This was how
7 we consolidated and congealed, for want of a
8 better term, the conversations. This was the
9 actual strategic framework that's in the plan
10 which has the vision mission and now eight
11 discrete goals that focus on the core critical
12 activities of the agency that we see ourselves
13 doing over the next five years, focusing on
14 things that you're all very familiar with:
15 inspection, enforcement, international
16 compliance, public education and outreach as a
17 new specific goal, collaboration, education,
18 science, working with people, developing our
19 people, policy development, and a special new
20 goal on A which focuses on the importance of
21 innovation and especially things like PHIS.

22 This is, again, just an example of

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1 the level of detail that we went down to, and
2 you can read about it in the plan. This is an
3 example of a discrete goal, our goal seven, on
4 people, empowering people and strengthening
5 infrastructure, how we worked actually down to
6 the level of developing discrete outcome
7 strategies and specific performance measures.

8 And this is extremely impossible
9 for you to read but just illustrative. It's
10 in the strategic plan where it is very
11 readable. It's a two-page roadmap, so it's
12 really the executive summary, if you will. If
13 you're just going to look at two pages, these
14 are the two pages. It provides the reader
15 with an extraordinarily clear line of sight
16 from the vision to the mission to the goals to
17 the outcomes to the corporate performance
18 measures and the targets. All of the 30
19 performance measures in here are quantifiable,
20 which is something that is extraordinarily
21 unusual for a public strategic plan.

22 Now, these are some of the

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1 benefits. Again, it's been released for a
2 week. It's difficult after a week to say what
3 are the results, but these are some of the
4 things that we are already seeing. It
5 provided and provides leadership, Dr. Hagen,
6 Brian, Phil, Al, and the managers, with a
7 touchstone document to chart a new course. It
8 links strategy and tactics, as I mentioned,
9 and a variety of other things.

10 As I mentioned, roadmap, line of
11 sight, clarity, flexibility, and detailed
12 measurable strategies. I guess that's another
13 key thing to just continually reenforce with
14 the 30 performance measures that are provided.

15 So I'll go back. This is the end
16 of the presentation, which you can read. It's
17 not an end really but a beginning. But to
18 answer the two questions because I really
19 thought that it was critically important to
20 talk about it a little. What's changed,
21 already what's changed in the organization
22 just by the process of planning is that we now

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1 have a greater focus on prevention, public
2 health, and the importance of activities like
3 PHIS. We have a reemphasis on the one team,
4 one purpose. It's more than a mantra. It's
5 renewed focus on teamwork collaboration with
6 field and headquarters staff.

7 The document reinforces the
8 importance of the FSIS role in inspections and
9 enforcement as really bedrocks of what we do.

10 It has a much more explicit emphasis on
11 cutting edge science and technology, effective
12 policy development, public education and
13 outreach, and, importantly, collaboration with
14 our food safety partners. Also, it affords
15 the reader, all readers, with a tremendous
16 amount of transparency and, I think really for
17 the first time, measures and measurement. And
18 also special attention, as I mentioned
19 earlier, on this notion of innovative methods
20 and priorities and practices, something that,
21 prior, is really not listed or included.

22 So how will it be used, the second

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1 question. I think some of these, which I'll
2 touch on in a second, answer it, but I also
3 wanted to mention the Peter Drucker quote
4 about planning, which I thought was very
5 opportune. His quote was, "Plans are only
6 good intentions unless they immediately
7 degenerate into hard work." And our plan has
8 immediately degenerated into hard work, I can
9 attest. It's already being used in almost
10 every senior management enterprise governance
11 meeting. We have used it over the last 60 or
12 80 days for the fiscal year 13 budget process.
13 It's really helped re-engineer our budget
14 process. We went through an expansive and
15 exhaustive activity mapping, ranking,
16 prioritizing, and costing of all of the
17 activities aligned to the goals, which was
18 really the first time that we had done that.
19 And it informs all of the annual performance
20 plans all the way down to the individual
21 performance standards for SES and staff. In
22 addition to those things, we're also at the

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1 present time working on a dashboard which
2 would actually provide senior managers and
3 leaders with a very quick easy access so we
4 all know how we're doing over time.

5 So the most important thing to
6 convey here is that it is a living document,
7 and I, again, encourage you all to read it
8 thoroughly. I've provided an email address
9 here. I'm happy to take some questions now,
10 but if you think of questions after this
11 presentation, after you've read the document,
12 please don't hesitate to get in touch.

13 MR. PAYNE: Thank you, Mr. Hepner.

14 Are there any questions? We have about five
15 minutes for questions. Comments? Okay. I
16 take that as a no. Thank you very much.

17 MR. HEPNER: Thank you.

18 MR. PAYNE: Okay. We'll move along
19 here to our next briefing. It's from Mr.
20 William Smith, Assistant Administrator from
21 the Office of Program Evaluation, Enforcement
22 and Review, who will give us an update on the

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1 Public Health Information System.

2 MR. SMITH: Thank you. I
3 appreciate the opportunity to give you all an
4 update on where we are with PHIS.

5 I've had the opportunity throughout
6 my career with a lot of food safety inspection
7 system information systems done way back in
8 the late 70s and early 80s with our quality
9 control, and then we moved into our inspection
10 system planning in the late 80s. In the 90s,
11 we moved into PBIS, which was our first
12 automation of inspection system information
13 and data. In the mid-90s, we incorporated
14 HACCP into the PBIS system, and today we have
15 the Public Health Information System, which is
16 logarithmically more complicated and more
17 encompassing than any system we ever had in
18 the past. So we are very excited about its
19 possibilities. It's different from the
20 staying point that it integrates our
21 laboratory, our inspection findings, our data
22 analysis all under one system, not only

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1 domestic inspection but import and export, and
2 it allows us to reach out and bring in other
3 pieces of information from sister agencies
4 AMS, our salmonella testing serotypes and
5 those things that we're getting in cooperation
6 with ARS and AMS. And so it really is an all-
7 encompassing system, so we are very excited
8 about it.

9 You know that we implemented in
10 April, April 11th in fact, of 2011. And
11 turning all those pieces on at that time, it
12 was sort of like, you know, you have your
13 circuit breaker in your house, and we flipped
14 the switch to everything at one time and some
15 circuit breakers started going off. And so we
16 needed to take a look at what was going on
17 with that, and we determined that we couldn't
18 do everything all at one time and we needed to
19 bring things on incrementally. And so we
20 stood back and started bringing pieces on, and
21 so I just want to give you an update of where
22 we are with PHIS now. And so I'm going to

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1 talk about it in three major categories:
2 domestic, import, and export.

3 So one of the first things that we
4 looked at when we were evaluating why some of
5 the circuit breakers were going off is that
6 the initial load to PHIS, as I said, is very,
7 very important. There's a lot more
8 information now than there's ever been in our
9 system to drive what PHIS does. Our total
10 grant of inspection process is now part of
11 this system. No other system where you had
12 before relied so much on the grant of
13 inspection and then the slaughter
14 configurations and process information and the
15 types of information we're doing.

16 We're also including in this system
17 the hazard analysis process and the critical
18 control points and the process interventions
19 are all being loaded into the system. And so
20 what we learned early on was that that drove a
21 lot of the other functions of PHIS and just
22 electronically loading that did not, on the

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1 initial load, bring everything over that we
2 needed to make it function properly. So we
3 went back and looked at our data upload
4 process and we put a system in place now that
5 is a very methodical process where inspection
6 granted information data is entered at the
7 district level and then product information is
8 loaded at the district level and all verified.

9 That gets PHIS working, and then the other
10 information about the hazard analyses, the
11 process interventions, and all those steps
12 will be added as we go along. So that was a
13 major, major change to our data upload process
14 that's making PHIS run a lot smoother.

15 Another thing, when you do have
16 circuit breakers sometimes going off,
17 everybody wants to fix everything at once.
18 And what we learned, what we put in place was
19 that, yes, everything is important, but when
20 you're relying on your field to implement this
21 first, their priorities need to take
22 precedence over everybody else's in order to

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1 get it fixed. And so we did put that in
2 place. The field inspection program issues
3 received top priority for immediate changes or
4 fixes to the system.

5 We also had a process in place, and
6 we still have that process in place today, for
7 people to identify problems they were having
8 with PHIS, they came into our help desk
9 center. That is staffed by mostly IT folks,
10 and so there was some issues with the IT
11 people at the service desk understanding what
12 inspectors were doing. There was issues, on
13 the other hand, when questions IT people were
14 asking of the inspection personnel that if you
15 don't have a very deep background in IT
16 sometimes you're not communicating well.

17 And so we decided what we'll do is
18 put a triage process in place. And so what
19 happens is now the inspectors or the
20 veterinarians or anybody in the field, if they
21 have any question of PHIS, they bring it into
22 this help desk, but it is quickly determined,

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1 if it's not an IT problem, then it's sent to
2 what we call an incident management response
3 team. These are made up of agency experts,
4 and this is a full-time duty right now. And
5 they're spread across the country and time
6 zones. And so as soon as an issue comes in,
7 we may triage it and determine, one, whether
8 it is a user error, and then what we put in
9 place, field operations, has put a cadre of
10 experts across the country. Then that issue
11 will be handed over, and that person will be
12 contacted. And then that person will walk
13 through what their user's particular problem
14 is because sometimes it's not the system
15 that's wrong, it's that the user didn't
16 understand how to do something. And so that's
17 worked very well.

18 The other thing is, sometimes, as
19 we go along, we see question and answers that
20 would benefit everybody on how to do
21 something. And so immediately then an issue
22 of that nature is sent to our policy people in

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1 Omaha and they put out and post on *InsideFSIS*
2 questions and answers that will help people
3 work through a particular situation when
4 they're seeing something, and we're finding
5 that very effective.

6 Then the last thing is sometimes
7 the application does need an upgrade and needs
8 to do something differently. So then that is
9 handed off to an application team, and they
10 then prioritize again any issues that come in
11 that need a change in the system. They
12 prioritize it specifically to field people.
13 Changes to the application that makes things
14 work better in the field are prioritized as
15 top priority, and everything else then falls
16 in line after that. We put this in place mid
17 to late July. Since that time, we've issued
18 six updates to the national software. Another
19 thing we wanted to do for our people in the
20 field is we wanted to communicate to them why
21 we're changing something, what they're going
22 to see, what it's going to change, and how

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1 it's going to work for them. And so we're
2 seeing that that's being received very well in
3 the field.

4 Another major part to the PHIS
5 system is what we call a disconnected state.
6 I don't need to tell you that many plants are
7 in rural parts of the country or are spread
8 throughout the country that connectivity works
9 well in some places, and we still have
10 challenge with connectivity in other places of
11 the country. And so you don't always have the
12 best high speed in order to transmit data and
13 work your systems. PHIS is a web-based
14 system, so it requires a high-speed
15 connectivity that telephone lines cannot
16 deliver, and so we need to move to, we're
17 using DSL, we're using cable just like
18 everybody else, we're using EVDO, cards, and
19 in some places we're actually running UTN
20 lines, T3 lines, T1 lines, just in order to
21 provide a means for people to exchange their
22 data.

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1 Presently, the agency can only
2 afford that for at least one headquarters
3 plant where every inspector is assigned, one
4 location. So we do have some places in the
5 country where an inspector may have, let's
6 say, four plants on their assignment. They
7 will have one high-speed connectivity at one
8 assignment and the other three they won't have
9 that type connectivity. So that means that
10 the system needs to work in a disconnected
11 state, which means offline. So the inspector
12 has to have the ability to schedule their
13 tasks, write their reports, document
14 noncompliances, take their laboratory samples
15 and those kinds of things out without being
16 connected to the system. And, again, PHIS
17 really contains billions and billions of bytes
18 of information, and a system of this
19 complexity, at the end of the day, comes down
20 to zeros and ones in how you configure and
21 program and code a system, and so there's
22 literally billions of those. And so not only

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1 then do we have to have it working online, we
2 have to make sure those same bytes all line up
3 offline and synchronize properly. And so
4 there's just not been a whole lot of
5 experience with that out there at this point,
6 and so we're one of the leading agencies
7 really to get in and heavily use this kind of
8 application in an offline state.

9 And so what we found was, when we
10 first implemented this system, we wanted to
11 send all this out over our network, just like
12 we do our security patches and those kinds of
13 things that we do on an everyday basis. And
14 all of you are familiar with with your
15 systems, too, if you have people out from a
16 location, you always have to transmit your
17 data then through the network.

18 The initial data load for this
19 disconnected state was probably too large to
20 be transferred over a network in a timely
21 manner, and so it was causing long, long
22 times, hours, for the initial download. And

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1 then, as you all know, any time you get an
2 interruption in the system, it stops and has
3 to start all over again, so that was causing a
4 lot of frustration. And, again, synchronizing
5 between on and offline was taking a lot of
6 time.

7 And so we knew we needed to deal
8 with that, and we have. We're moving the
9 initial download process now to a CD. On our
10 initial process, again, not only did they have
11 to bring it down over the network, there was a
12 rather complicated set of instructions for
13 inspectors to follow on the first time they
14 hooked up to this system in the disconnected
15 state. So what we've done is automate all
16 that or most all of that for them. We've put
17 it all on a CD, so just like when you get a
18 new computer or a new application at your
19 home, you put the disk in, the thing auto
20 runs, and it loads itself. And so we're
21 finding that is working much better for the
22 inspectors.

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1 We also have retained some
2 configuration settings in our system, so what
3 used to take hours is now down to minutes.
4 And so that is making that system work a whole
5 lot better in the disconnected state. And we
6 have, in fact, five circuits in the United
7 States right now where this is working on an
8 everyday basis and working well. And so what
9 we learn from that then we're going to send
10 out to the rest of the country.

11 So our implementation process then.

12 So as I said, on opening day, April 11th, we
13 implemented 42 circuits. One of the things,
14 again, we learned with networks and traffic
15 and, again, moving a lot of data over the
16 system that probably 42 circuits is way too
17 much for one to turn on at one time. And so
18 what we're doing now is moving to a smaller
19 number of circuits per week. The changes that
20 I just talked about with the data upload, the
21 issue of prioritization, and the DCU, we spent
22 a lot of time testing and making sure that we

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1 would not have the problems that we had
2 earlier in April. In August, we brought 14
3 circuits on in August doing that process, five
4 of those, again, were with our disconnected
5 state. So we have validation that things that
6 were put in place now is making for a much
7 smoother implementation.

8 So beginning on the first week of
9 September, we started bringing six circuits a
10 week on in PHIS. So the first week, the
11 second week, so we now have an additional 12
12 circuits. By the end of September, we'll have
13 75 circuits on.

14 One other key part of August trials
15 was making sure that our sampling component
16 worked. And so, again, we wanted to make sure
17 that what worked in four circuits first and,
18 again, any issues that we were seeing would be
19 dealt with then. We're pleased also that our
20 sampling process is working.

21 So beginning in October, we will be
22 bringing nine circuits a week on in the PHIS

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1 with full functionality of the disconnected
2 state, sampling, full implementation. And
3 then what we will have to do is go back and
4 catch up on those 42 circuits that originally
5 we implemented in April to put things in place
6 so they have all the most up-to-date software.

7
8 So we feel pretty good that we've
9 identified the issues by prioritizing the
10 field as the main focus for starting this
11 system up because no data goes in without the
12 people in the field putting it in. That's
13 been our first emphasis, and that's what we
14 put in place. And we expect a full and
15 national domestic inspection implemented by
16 January 2012. The reason it is January 2012
17 is because of our training schedule. We do it
18 in the month of November. Our training is a
19 two-week training, and we have Veteran's Day
20 and we had Thanksgiving. We have two holidays
21 in there that we could not work around, so we
22 lose the whole month of November as far as

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1 training. And so our last training class ends
2 in December, I believe, and so that means we
3 can't implement PHIS until the people are
4 trained, so there will be a little catching up
5 there. But this is a very aggressive
6 schedule, and we feel confident we're going to
7 be able to meet that and notify folks. You're
8 the first ones outside the agency that we've
9 laid out this schedule.

10 And so that's a little planning for
11 domestic. We do know we will be piloting an
12 industry interface later in October. Again,
13 our focus, first and foremost, is on the
14 domestic and the field application. We've
15 gotten through those issues, and now we can
16 start looking at other things. And so we had
17 said we would be piloting an industry
18 interface in October it looks like, late
19 October. It looks like a good time to start
20 that. We'll need to, again, run that for
21 about 30 days or so and then determine how to
22 go forward with that.

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1 As far as import, we had been
2 talking about early winter for imports. One
3 thing that just came about literally in the
4 last 60 days, 30 to 60 days, we had been
5 working with Customs and Border Patrol and
6 they have a major system where they're putting
7 in place now with not just our agency but 42
8 agencies throughout the country to transmit
9 data in and out through one process for
10 importers and exporters.

11 Back in 2009, when we engineered
12 this piece of PHIS, it did not look like they
13 were going to be able to meet our
14 implementation dates, so we went another
15 route. Just recently, the Customs and Border
16 Patrol people have come to us and said they
17 can do the interface now through ITDS and
18 they're asking that we take advantage of that.

19 The agency has decided that that will benefit
20 both the importers, the brokers, and the
21 inspection system, as well, by taking an extra
22 60 days to make this interface work. And so

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1 right now we're looking at a March
2 implementation for import inspection.

3 Now, the import piece has a lot
4 more industry interaction because, pretty
5 much, the importer puts all the information in
6 the system to schedule that drives the
7 reinspection process. So we're expecting a
8 lot more traffic once this system import
9 starts coming in from the import folks.

10 All the lessons we learned doing
11 the domestic we want to carry over to imports,
12 so we will be putting a triage process back in
13 place for imports. The issue management
14 process for imports, everything, will be just
15 like domestic. Again, lessons learned, and
16 we're going to apply those so it's a much
17 smoother implementation for the import folks.

18 And then our last piece is the
19 export. Exports are a dynamic, we're finding
20 it a very dynamic process. There's 110
21 countries that we export to. Requirements
22 change, sometimes on a weekly, if not daily,

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1 basis. When you have a system, you have to
2 have a system that's able to program and
3 adjust to those on the fly. And so we're
4 learning how to do that.

5 When we built a system two years
6 ago with the requirements, three years ago
7 with requirements, I need a species in there,
8 I needed this in there, I needed certificates
9 to do certain things. Countries change. Some
10 countries will let you bundle certificates,
11 some countries want single certifies. Some
12 countries want species, some countries want
13 subspecies. With 110 of them, you can see
14 it's an evolving process. So we decided that
15 we need to put an infrastructure in place that
16 will deal with that evolving process so that
17 we can deliver the full expectations for the
18 export. And so it's going to take us a little
19 longer to do that, but I think, at the end,
20 it's going to be much more beneficial because
21 the system will be able to operate in a
22 realtime scenario as requirements change. So

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1 that's putting us probably into summer of 2012
2 to get all that infrastructure and programming
3 and ability to do that with implementation,
4 sometime into 2012, maybe beginning 2013.

5 So that's an update. We're already
6 starting to get a lot of data coming into
7 PHIS. Our analysts are able to now look at
8 that information and see what's coming in.
9 That will start when our ability to do our
10 alerts and our tracking for field supervisors,
11 inspectors, because, again, one of the
12 benefits always has been for inspectors,
13 inspection program personnel, they can get the
14 information back in order to make decisions
15 and it will be in the system and available for
16 them to start doing that. And so that's why
17 we're really looking forward to having this
18 all implemented domestically this December so
19 folks in the field, as well as the analysts,
20 can start really using this data as this
21 system was designed.

22 So that's an update. I'll be glad

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1 to take any questions.

2 MR. PAYNE: Okay. We have a
3 question from Nancy Donley.

4 MS. DONLEY: Thank you. I have
5 two, and I think they're going to be real
6 softballs to you, Bill. Number one is what
7 are the total number of circuits?

8 MR. SMITH: The total number of
9 circuits, 173 FSIS circuits and 8 Talmudge-
10 Akin of a similar type, we'll call them
11 circuits but similar.

12 MS. DONLEY: And then for those of
13 us that are really acronymally, if that's a
14 word, challenged with some of this, what is
15 OCIO?

16 MR. SMITH: Okay. It's the Office
17 of the Chief Information Officer. So it's our
18 IT structure.

19 MS. DONLEY: Office of --

20 MR. SMITH: Chief Information
21 Officer is the acronym, but that's the person
22 who's in charge of all the IT functionality.

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1 MS. DONLEY: Okay. And then I
2 assume OFO Field Tier 3, is that Office of
3 Field Ops --

4 MR. SMITH: Yes, that's --

5 MS. DONLEY: -- in Omaha?

6 MR. SMITH: No. Actually, it's the
7 Office of Field Operations, and there's Tier
8 3 team, which is levels of support. Tier 1 is
9 if you can't fix it then you go to Tier 2. So
10 the Tier 3 is really presently 45 field
11 operations people spread throughout 15
12 districts there to help folks. And what
13 happens is, just like the information system,
14 all of the requests go in to queue, and then
15 they're immediately sent out to one of these
16 43 to follow up with the person.

17 MS. DONLEY: Okay. And then DCU,
18 I'm assuming it's disconnected something?

19 MR. SMITH: Disconnected unit. We
20 call it disconnected state, but it's the
21 disconnected unit module part of PHIS, which
22 means the offline piece.

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1 MS. DONLEY: Right, okay. And then
2 just last is the ACE/ITDS.

3 MR. SMITH: That's the
4 International Trade System, and I forget what
5 the ACE part means. But that is the system
6 that Customs and Border Patrol is using for
7 all entry of products coming into the country.

8 So FDA will use it, USDA uses it, APHIS, and
9 our agency, so they know what's coming into
10 the country, where it's going. So even when
11 the ships are on the water, they will know
12 what's coming into the country and what port
13 it's going to before it gets here, and then
14 what kind of requirements it's going to need
15 for reinspection, whether it's FDA, USDA. So
16 it's all information, all that information
17 comes in about every shipment coming into the
18 country now.

19 MS. DONLEY: Thank you.

20 MR. PAYNE: Thank you, Ms. Donley.
21 We have a question from Ms. Buck, Patricia
22 Buck, and then one from Steven Warshawer. Ms.

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1 Buck?

2 MS. BUCK: Yes. Thank you for your
3 very good presentation. The question I kind
4 of have, this is included in your strategic
5 plan under the --

6 MR. SMITH: Yes.

7 MS. BUCK: -- area.

8 MR. SMITH: I would say heavily,
9 heavily included under goals one, two, five,
10 and six.

11 MS. BUCK: Yes. I just, I haven't
12 read the entirety of the plan, but I saw it's
13 been sort of incorporated.

14 MR. SMITH: Right.

15 MS. BUCK: As such, do you have a
16 document that actually shows the goals and
17 objectives of PHIS so that I would more
18 clearly understand what we're trying to do
19 with this rather large, I don't know what to
20 call it, IT system, you know --

21 MR. SMITH: Information, IT. I
22 think right now our best document is, I'll

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1 refer you back to our September 2010
2 documents. The one document went in-depth
3 about how PHIS was to work, and that is still
4 the functionality provided in that document --

5 MS. BUCK: So that's still the
6 same.

7 MR. SMITH: -- and then the data
8 analysis plan also. So everything is still
9 the same. It's making the system meet those
10 two papers.

11 MS. BUCK: Okay, okay. The one
12 thing I guess I am concerned about is that we
13 might end up with having put too much into one
14 IT system, and I don't know, I'm not an IT
15 person, so I don't know that for a fact. But
16 I would, that's one thing I want to
17 investigate because we really need to have
18 collaboration of all types of data, and I'm
19 encouraged that you brought in Customs and
20 Borders, and I see the advantage of bringing
21 in some of these other, but I think we need to
22 have it highly integrated. And I don't

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1 understand IT enough to make a statement on
2 it.

3 MR. SMITH: And I would agree with
4 you, and that is this system, I can tell you
5 our previous systems would never put the
6 agency in a position to do that. But by
7 moving to this web-based technology, yes, you
8 can interface a lot better with FDA, CDC, AMS,
9 ARS, because now you're talking about web
10 interfaces and they're more modular.

11 MS. BUCK: Well, I think, as your
12 training people and moving forward, a simple
13 document outlining what we're trying to do
14 would go a long way to helping all of us
15 understand the goals that are trying to be met
16 by implementing this rather large system.
17 Thank you.

18 MR. SMITH: A lot of this
19 information is on our FSIS website, and if you
20 just click on PHIS a lot of this will come up.

21 MR. PAYNE: Thank you, Ms. Buck.
22 Mr. Warshawer.

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1 MR. WARSHAWER: Two questions. I
2 think I'm going straight off into the weeds on
3 this, and you may not want me to go there.
4 But first one is a lot of conversation in our
5 last meeting had to do with levels of access
6 for public and for non-agency. How will that
7 part be, where will the final decisions be
8 made and how will those be vetted and rolled
9 out through pilot and test processes?

10 MR. SMITH: And, again, I'll rely
11 on Greg a little bit to give me a start,
12 jumping up and down if I say something wrong
13 here. But we do plan to put a lot of our data
14 out through data.gov interface one. We will
15 put a lot of our information on, again, the
16 web and make that available. As far as actual
17 access, because of security considerations and
18 accreditation, only FSIS personnel that use e-
19 Authorization are able to access the
20 information inside our firewall. Now,
21 industry interface and foreign government
22 interface will sit on a server and will

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1 require that same type e-Authorization, but it
2 will be a web outside our firewall. And so it
3 won't have the same security as inside our
4 firewall. There will be means for people to
5 interact. We will be able to secure industry
6 information that only goes to end users, as
7 done through our e-Authorization and licensing
8 process. But for actual data that's going to
9 be out to the public, our plans that we've
10 already published in the data.gov initiative
11 would be the best source to go to to see how
12 we plan to use it and publish it.

13 MR. WARSHAWER: Okay. And the
14 other one is sort of along the same line.
15 Let's say, walk me through this one, I'm a
16 very small plant and I'm out in the middle of
17 God knows where with dial-up, and I've got a
18 negative report that I want to review and do
19 something about. I don't have the kind of
20 access, I don't have the opportunity to go to
21 a nearby facility with high speed. How are we
22 going to have equitable access for the kind of

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1 dynamic follow-up that I think the system is
2 designed to offer if we have such a disparity
3 of access means and we have a system that
4 depends on high speed?

5 MR. SMITH: Very good question.
6 We're not moving away from one inspector in
7 the plant on a daily basis, and so you'll
8 still get visited.

9 MR. WARSHAWER: I understand that.

10 MR. SMITH: And we still expect
11 them to be able to share with you information
12 as inspections are performed. Inspectors will
13 document their interviews, and we can
14 certainly print and share those with you. So
15 those things will be made available to you on
16 the spot. There will be reporting that will
17 be made available, and we will have to work
18 out, if you don't have high-speed
19 connectivity, if you want to access those
20 outside the inspector, how we can get those to
21 you. Right now, we have not tested the system
22 with dial-up.

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1 MR. WARSHAWER: One of the
2 strengths of this system, as I see it, is the
3 ability to respond in the event of a
4 disagreement. And I would suggest that it's
5 crucial that that ability to respond and
6 intervene quickly not be limited based on
7 technology. That would be a disappointment if
8 the technological requirement of the system
9 was so designed that we disenfranchise a
10 portion of the client base that then can't
11 take advantage of this kind of response time
12 simply because of technology. As much thought
13 as you're putting into the disconnect state
14 and so on, this is an example of something
15 like that disconnect state being looked at
16 from a plant perspective.

17 MR. SMITH: Absolutely. And we are
18 working a lot with our sister agencies in the
19 department still on the role of broadband
20 initiatives because that's one way to get it
21 really out there to everybody.

22 MR. WARSHAWER: Understood. And if

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1 you want to test any of these out somewhere
2 where there's no service, we've got plenty in
3 New Mexico that would be happy to join in.

4 MR. SMITH: I understand that.
5 Thank you. Just so you know, there is some
6 inventive ways of working. Los Alamos was a
7 particular problem for us in the standpoint
8 that there was no easy connectivity from an
9 EVO or DSL. There just wasn't any. And
10 running an UTN line through Los Alamos was not
11 an option either. But they were able to come
12 up with, I'll call it a gadget, a wireless
13 that could pull signals from a wi-fi type
14 thing. And so whenever there's a new
15 technology, we're trying to grab it and then,
16 again, we'll try and share it, one through the
17 department so it's available to everybody.
18 But, yes, I am aware of that New Mexico is a
19 challenge in some places, yes.

20 MR. PAYNE: Thank you. Before we
21 move into the break, are there any questions
22 and comments from those in the audience?

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1 MR. CORBO: Tony Corbo, Food and
2 Water Watch. First, I want to thank Bill
3 Smith for spearheading correcting the issues
4 with PHIS. I've gotten involved with this
5 more than I ever dreamed of, and the fact that
6 the agency has listened to the complaints from
7 the inspectors. This system was rolled out
8 too fast, and I think the agency learned the
9 hard way that it was. But I think the
10 systematic approach that is being used to
11 correct the issues I think is going to make
12 the system work the way it was designed to,
13 the way it was promised to all of us.

14 I love working with IT. I
15 oftentimes complained to our own IT folks at
16 Food and Water Watch that if they don't fix
17 the problem that I'm encountering I'm sending
18 them over to FSIS to work on PHIS. But the
19 thing is that the inspectors were telling you
20 during user acceptance training last year that
21 the system was not ready for prime time. You
22 rolled it out too fast, and I'm still

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1 concerned about those 42 circuits. I don't
2 know what they're doing out there. I don't
3 know what information they're collecting, how
4 good that information is. And so the fact
5 that you're going to run it through all these
6 other circuits and then go back to the
7 original 42 still concerns me.

8 The thing that was sold to the
9 inspectors was the fact that this was going to
10 operate in a disconnected state. They all
11 complained that PBIS was a big problem in
12 terms of getting access to the system, getting
13 knocked off the system, and it seems that that
14 is still a big problem.

15 But, again, I want to commend Bill.

16 Bill took a lot of time. He took time out of
17 his own schedule to explain various issues to
18 me in detail, but it sounds like there's
19 progress being made. It's not as fast as it
20 should be, but I still have concerns.

21 MR. SMITH: Thank you. And just
22 two things. Yes, we agree that the catchup on

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1 the 42 is very important because, yes, we
2 don't want folks out there not being able to
3 work in the disconnected state. The 42, if
4 they're online, they have full function with
5 the system, so, you're right, it's the
6 offline. And we do have plans, I probably
7 didn't cover that well in my presentation.
8 When we go to nine per week starting in
9 October, we also, depending on how things are
10 working with the system and the network and
11 all, but mid October we do plan to start doing
12 the catchup, both the sampling and the DCU, so
13 they're not waiting until the very end to get
14 caught up. And we've already asked the
15 district manager for a schedule for which
16 circuits they would like to be brought, of the
17 original 42, brought into the DCU first based
18 on their ability not to be able to connect.

19 MR. PAYNE: Thank you. Thank you,
20 Mr. Corbo. And what we'll do now is go to
21 break so we don't get too far behind on our
22 schedule. So if we could take a quick break

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1 and reconvene at 10:30, and that's when we
2 will explore the issues for the current
3 meeting.

4 (Whereupon, the foregoing matter
5 went off the record at 10:21 a.m. and went
6 back on the record at 10:35 a.m.)

7 MR. PAYNE: Okay, folks. Well,
8 let's go ahead and get started, resume our
9 agenda here. And if I may have your
10 attention, we have Dr. John Linville, who will
11 present the first issue before the Committee,
12 and that's on pre-harvest food safety. Dr.
13 Linville?

14 DR. LINVILLE: Good morning,
15 everyone. And to the Committee, welcome back.
16 It's been a year. It doesn't really seem
17 like it has been. As Mr. Derfler said, last
18 year I presented sort of a plethora of
19 subtopics on pre-harvest to you, sort of a
20 broad-spectrum approach. And as you
21 mentioned, this year we really would like to
22 sort of hone it down and focus it in a little

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1 bit and build on the good work that was done
2 last year.

3 But before I do that, I just wanted
4 to sort of give a really brief recap of what
5 we talked about last year. If you'll recall,
6 our goals last year were, number one, to
7 develop effective policies and collaborative
8 steps to promote public health. And in order
9 to do that, we requested input from you, as a
10 committee, on the following pre-harvest
11 topics: Salmonella Enteritidis, E. coli
12 0157:H7, chemical residues, and antimicrobial
13 resistance. And I'm going to drop salmonella
14 down to the bottom of the list for now because
15 it will sort of be a segue into this year.

16 But if you'll recall, you gave us
17 sort of a preamble in your response to us last
18 year, and it set the tone for your response
19 and it set the tone for a lot of the actions
20 that we have undergone as an agency. So I
21 would just kind of like to read that preamble
22 back to you, just bringing you back into the

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1 picture.

2 So what you said was, "Questions
3 regarding pre-harvest are incredibly complex
4 and amply recognized is the great need for and
5 importance of pre-harvest controls among the
6 industry. The Committee appreciates the
7 opportunity to begin tackling the necessary
8 and complicated issue of pre-harvest controls.

9 The Committee supports FSIS and its partner
10 agencies on the federal and state level in
11 their pursuit of the development of policies,
12 verification activities, and the efficacies of
13 practical and applicable technologies that
14 could be employed by producers to better
15 protect public health." So that was your
16 overarching statement that you gave back to
17 us. And just as a reminder back to you, that
18 was the framework in which you were working
19 last year.

20 Then you gave us sort of an
21 overarching recommendation back that
22 encompassed all four of the subtopics, and

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1 that was that you recognized that the approach
2 would require multiple public meetings,
3 possibly a series, with all stakeholder groups
4 and many areas of expertise represented, and
5 that those meetings should focus on the
6 various market classes. And to that end, the
7 agency is currently planning such a series of
8 meetings that will start this fall, starting
9 with cattle, so we are going to have a series.

10 We are going to do it by market class.

11 And so the first one is going to
12 have sort of the charge to explore practical
13 pre-harvest interventions designed to reduce
14 the likelihood that FSIS-regulated products
15 will be contaminated with pathogens of public
16 health concern. So we did hear you, and we
17 are moving forward with that recommendation.

18 And like I said, I'm going to drop
19 salmonella down to the bottom of the list
20 because that will be a good segue into this
21 year. So let's take a look at 0157:H7. We
22 had some discussions around that. If you'll

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1 recall, we sort of went through the compliance
2 guidelines that had just come out last year.
3 And, you know, if a picture can say a thousand
4 words, I think this slide does. If you look
5 at the overall U.S. 0157-related illnesses in
6 the country, we have made significant progress
7 as a country in driving those numbers down.
8 The red dashed line is the Healthy People 2010
9 goal, and we met that goal and we have
10 exceeded that goal, and the trend continues
11 down. The green dot is our new Healthy People
12 2020 goal, so we can't sit back and rest on
13 our laurels. We have every intention of
14 meeting that goal, and we need to move towards
15 that goal, hence the public meeting and
16 starting out with cattle.

17 Chemical residues. We also had a
18 lot of discussion around that last year. And
19 the recommendation or one of the
20 recommendations that the Committee came back
21 with was that FSIS relay information to
22 industry as quickly as possible and that FSIS

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1 gather input from industry about what
2 information would be useful. To that end, the
3 agency has recently developed new compliance
4 guidelines for residue prevention and agency
5 testing for residues, and that compliance
6 guideline will be announced in an upcoming
7 Federal Register notice. And, obviously, by
8 that, the agency will be requesting and
9 accepting comments on those compliance
10 guidelines and also on the utility and ease of
11 use of the Repeat Violator List. So we are in
12 the process of gathering that particular
13 input.

14 Which brings us to Salmonella
15 Enteritidis. And for the recap, I'm also
16 including sort of the antimicrobial piece into
17 that because it fits together. If we look at
18 where we're at within our FSIS verification
19 testing on broiler carcasses, overall,
20 industry has done a really good job at driving
21 down the overall percent positives within the
22 verification testing realm. However, if you

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1 look at the blue section of these bars, that
2 represents the proportion of Salmonella
3 Enteritidis positives; and, as the other
4 serotypes go down, Salmonella Enteritidis
5 continues to rise.

6 So that is of concern to us that
7 this trend is remaining. And for those of you
8 that are interested in the numbers, our data
9 integration folks did run those numbers for me
10 very recently. And there is a statistical
11 significance in that rise, so it's not just
12 sort of a qualitative trend. It is a real
13 trend. And this is just looking at that in a
14 slightly different manner, so you can see the
15 obvious upward trend in the percent of SE
16 positives within the overall positive samples.

17 So the Committee provided us with
18 several recommendations around salmonella last
19 year. One is that we work with other federal
20 agencies and public health partners to
21 identify best practices. And the agency
22 continues to collaborate. I mean, we have,

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1 obviously, always done that, but we continue
2 to collaborate with the Food and Drug
3 Administration, with the Centers for Disease
4 Control and Prevention, and the Animal and
5 Plant Health Inspection Service, our sister
6 agency, to develop and expand on effective
7 strategies to reduce the human disease burden
8 associated with SE.

9 And on top of that, we're in
10 continued discussion with the Agricultural
11 Research Service on potential associated
12 research projects. And along that vein, we're
13 also in the process of figuring out a way, as
14 an agency, that we can sort of better market
15 our research needs and get those out there for
16 other research entities to also focus on those
17 and hopefully provide us with good
18 information.

19 The Committee also recommended that
20 FSIS relay information to industry as quickly
21 as possible and also gather input from them on
22 what information would be useful. And to that

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1 end, we, as an agency, have collaborated with
2 an industry coalition to provide blinded
3 verification data specific to SE in poultry,
4 starting with chickens, on a frequent basis
5 that's still yet to be determined to
6 supplement industry data and augment industry-
7 wide analysis of trends. And then that same
8 information will then be also made publically
9 available on the agency's website at a
10 somewhat reduced frequency. So we will get
11 the data to the industry coalition first and
12 then provide it in a somewhat different
13 package, a more processed package to the
14 public.

15 We have always provided, well, I
16 can't say always, but over the past several
17 years we have provided any serotyping
18 information on verification sample positives
19 back to the establishment, but that has been
20 on a sample-by-sample basis. So in the very
21 near future, we're going to make a change to
22 our End of Set letters that we provide at the

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1 end of a verification set back to the
2 establishment to provide a compilation of all
3 those serotypes in one spot. And so we hope
4 that that will provide useful information back
5 to the establishment at the end of the set.

6 And then also we are ultimately
7 planning to include PFGE-based and drug
8 resistance information on a sample-by-sample
9 basis back to the establishments through the
10 End of Set letters, as well. Similar to some
11 of the issues that have come up with PHIS,
12 we've had some sort of data issues that go
13 along with that. Currently, it takes us quite
14 some time to manually pull that data and
15 collate it. And also that's just on top of
16 the fact that it takes quite some time to get
17 the PFGE and drug resistance results back. So
18 we have to keep that in mind as we move
19 forward with this, but that is our ultimate
20 goal is to provide all of that information
21 back in as timely a manner as we can.

22 And then, finally, we intend to

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1 provide complete available historical
2 salmonella verification result data to every
3 active federally-inspected facility in the
4 country. It's one of the lessons that we've
5 recently learned and think it would provide
6 valuable input. We have lots of data in our
7 data warehouse going back several years. And
8 in an effort to sort of, as a one-time
9 service, catch that up, we plan to provide
10 that data back to every active facility. Now,
11 obviously, that's a large undertaking.
12 There's a lot of data there, and so we're
13 prioritizing how that will happen. But that
14 is a goal that we have started and intend to
15 meet.

16 So with that, let's transition over
17 to this year's meeting. Obviously, we still
18 have sort of the same overarching goal, which
19 is to develop effective policies and
20 collaborative steps to promote public health,
21 this year with a slightly different and more
22 focused goal in mind. And so we'd like to

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1 receive input from you, as a committee, this
2 year on the follow pre-harvest topics: food
3 safety hazards that can occur before entry
4 into the official establishment and then with
5 a focus on salmonella.

6 So why salmonella? We talked about
7 a lot of different things last year, so why
8 are we focusing on salmonella or why do we
9 continue to focus on salmonella? Well,
10 according to the CDC, salmonella is the
11 leading cause of the most serious foodborne
12 illnesses. For illnesses related to known
13 foodborne pathogens, it is responsible for
14 about 28 percent of deaths and 35 percent of
15 hospitalizations. So, I mean, it does have a
16 large impact on our public's health.

17 And while salmonella can be
18 contracted from a number of foodborne sources,
19 FSIS-regulated products, especially poultry,
20 contribute to the overall disease burden. We
21 estimate that 472,859 people became ill with
22 salmonella from consuming FSIS-regulated

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1 products in the third quarter of 2011, FY
2 2011.

3 The agency does take salmonella
4 very seriously to the extent that we have, as
5 one of our corporate performance measures, the
6 so-called all-illness measure. And within
7 that measure, we track illnesses that are
8 caused by three major foodborne pathogens:
9 salmonella, *Listeria monocytogenes*, and *E.*
10 *coli* 0157:H7.

11 As part of the slide that I showed
12 you on 0157 a little bit ago demonstrates, we
13 have made significant progress towards
14 reducing illnesses caused by LM and *E. coli*
15 0157:H7, so we're really on track there to
16 meet our mission. The salmonella illness
17 numbers, however, remain relatively flat,
18 maybe even with a slight upward tick over the
19 last year. And those estimated to be caused
20 by FSIS-regulated products are significantly
21 higher than are conducive to meeting our
22 Healthy People 2020 goals.

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1 So if we look at that on the graph,
2 the blue line that's well above the red dashed
3 line which is the 2010 goals and the green dot
4 which is the 2020 goal, that blue line
5 represents the overall salmonella illnesses.
6 So we have some work to do here.

7 On top of that, since 2009, over 37
8 million pounds of raw ground beef and ground
9 turkey products have been recalled over five
10 separate recalls because they were implicated
11 in salmonella outbreaks. The impetus of those
12 recalls was human illness, which triggered a
13 resource-intensive investigation after the
14 products had been consumed, resource intensive
15 in the sense that it takes a lot of people,
16 resource intensive in the sense that it takes
17 a lot of time. And as that investigation was
18 moving forward, obviously there's the
19 opportunity, at least, that others could
20 become ill.

21 So if we look at ground products,
22 which has seemed to have been our major

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1 problem of late around salmonella, the blue
2 line below shows you the volume-weighted
3 percent positives for SE. And the red line
4 above shows you the same for ground chicken.
5 So, I mean, at first blush, it's fairly
6 obvious to see that the ground is more of an
7 issue than the carcasses in the sense of
8 percent positives, but it's a little less
9 obvious in this particular graph. However, if
10 you run the numbers in the background, there
11 is a fairly strong correlation between these
12 two lines. So as the percent positives for SE
13 goes up in carcasses, it also goes up for the
14 ground.

15 For ground turkey, Salmonella
16 Enteritidis is not the culprit, at least has
17 not been of late. Salmonella Hadar,
18 Salmonella Heidelberg, St. Paul, to a certain
19 extent Agona have been our issues. And so
20 those are the ones that we are currently
21 keeping sort of our eye focused on in ground
22 turkey.

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1 This is an updated slide from one
2 that I showed you last year on antimicrobial
3 resistance. It just includes an extra year's
4 worth of data in it. This is sort of the
5 generic sense of multi-drug resistance, and
6 we're looking at positives that were resistant
7 to three or more, four or more, or five or
8 more antimicrobials. And the trends that I
9 showed you last year continue, so there's not
10 really been any apparent change in those
11 particular trends. And, again, the same
12 question that was brought up last year: well,
13 what does that mean? These are sort of just
14 generic trends for multi-drug resistance. But
15 what about drugs that are considered more
16 critical than others?

17 And so this slide shows you the
18 four drugs that the FDA considers to be
19 critical in treating human illness. And the
20 red line, which is Ceftiofur, as you can see
21 in cattle and chicken shows sort of an obvious
22 trend here. And then in turkeys over the last

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1 couple of years also shows somewhat of an
2 upward tick. So this is obviously something
3 that we really need to keep our eye on and
4 keep our focus on as we move forward. And,
5 again, any information pertaining to drug
6 resistance on positive samples will be
7 provided back to the establishments in the
8 future, so this will not be a black box to
9 them.

10 So as I mentioned, the focus this
11 year is on hazards that occur before entry
12 into the establishment. And the reason that
13 I'm going down that particular road this year
14 is because if you really look at HACCP and our
15 definitions in HACCP, starting with just the
16 definitions that are outlined in 417.1, there
17 we have the definition of a food safety
18 hazard, and that is any biological, chemical,
19 or physical property that may cause a food to
20 be unsafe for human consumption.

21 If you look, however, a little
22 deeper into the regs, you'll find under 9 CFR

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1 417.2(a)(1) that every official establishment
2 shall conduct or have conducted for it a
3 hazard analysis to determine the food safety
4 hazards reasonably likely to occur in the
5 production process and identify the preventive
6 measures the establishment can apply to
7 control those hazards. Here's the key: the
8 hazard analysis shall include food safety
9 hazards that can occur before, during, and
10 after entry into the official establishment.
11 So it's right there in the regs that we should
12 be looking or the industry should be looking
13 at hazards that can occur before entry into
14 the establishment. And then, further,
15 417.4(a) states every establishment shall
16 validate the HACCP plan's adequacy in
17 controlling the food safety hazards identified
18 during the hazard analysis and shall verify
19 that the plan is being effectively
20 implemented.

21 So when I'm on different work
22 groups working on pre-harvest issues, the one

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1 question that is quite often brought up or the
2 one comment that is quite often brought up is
3 that FSIS has no authority in the pre-harvest
4 arena. And while I would agree that we don't
5 have on-farm authority, I don't necessarily
6 agree and would submit that we do have
7 authority over the pre-harvest arena as it
8 applies to what goes on in the establishment.

9 So with that, I'd like to bring
10 four questions to the Committee today. The
11 first being varying factors, such as subtype
12 or drug resistance, have historically played
13 significant roles in human salmonellosis
14 outbreaks attributed to FSIS-regulated
15 products. With that in mind, what food safety
16 hazards that can occur before entry into the
17 official establishment does the Committee see
18 as most important for establishments to
19 consider when conducting their hazard
20 analyses?

21 Question two: what innovative steps
22 can the agency take to assist industry in

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1 preventing strains of salmonella from entering
2 official establishments on source animals or
3 products that could negatively impact the
4 public's health? And it's sort of a two-
5 pronged question in that we have the
6 vertically integrated industry, such as
7 poultry or market cogs that might have
8 different strategies than in the non-
9 vertically integrated industries, such as
10 dairy and other beef industries. At this
11 point, I really would like to acknowledge the
12 really good discussion that was had around
13 animal ID from last year. Our hope is that
14 maybe we can get some different ideas around
15 that this year.

16 Question three: what does the
17 Committee see as the pros and cons to the
18 agency developing a similar approach to
19 establishments receiving salmonella-positive
20 poultry or livestock as it takes to repeat
21 residue violators? For years, we've sort of
22 taken this approach of looking at things

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1 before entry into the establishment for
2 residue, so can we take some lessons learned
3 from that and apply it to salmonella?

4 And then, finally, as I mentioned
5 before, we're planning on making some changes
6 to the End of Set letters, so we intend to
7 update the salmonella End of Set letters to
8 include PFGE and drug-resistance data.
9 Because some of the information may take weeks
10 to collect and collate, FSIS may send the
11 serotype and PFGE drug resistance information
12 in separate mailings. Does the Committee have
13 feedback on this process or any additional
14 thoughts on the End of Set letters to make
15 them more useful to industry to better protect
16 the public's health?

17 So those are the four questions
18 that I would submit to you, as a committee,
19 this year. And with that, I will take any
20 questions or comments.

21 MR. PAYNE: Thank you, Dr.
22 Linville. And before we take any questions, I

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1 do want to acknowledge and welcome on behalf
2 of the agency Ms. Carol Tucker-Foreman of the
3 Consumer Federation of America who just joined
4 us during your presentation, Dr. Linville.
5 And with that said, are there any questions
6 for Dr. Linville? Yes?

7 MS. GAPUD: Yes. Dr. Linville,
8 looking at slide number 24, FSIS estimates
9 that 472,859 people became ill with salmonella
10 from consuming FSIS-regulated products in the
11 third quarter of fiscal year 2011.

12 DR. LINVILLE: Yes.

13 MS. GAPUD: Which one do you
14 consider as fiscal year because we're talking
15 about right now it's what? September? The
16 third quarter is not even --

17 DR. LINVILLE: That's a good point.

18 And really what I should have said is that's
19 what we reported in our third quarter report,
20 so it would be second quarter data.

21 MS. GAPUD: So it would be second
22 quarter, not third quarter.

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1 DR. LINVILLE: Right. Sorry.

2 MR. PAYNE: Thank you, Ms. Gapud.
3 Ms. Donley?

4 MS. DONLEY: Thank you very much.
5 I have two questions. Number one is now that
6 FSIS has declared six additional strains of E.
7 coli, non-015 and STECs, as adulterants, how
8 is that going to impact what the discussion
9 about pre-harvest interventions for these
10 other strains, as well as 0157?

11 DR. LINVILLE: I'm sure that will
12 be a major topic in the upcoming public
13 meeting that we will be having on pre-harvest
14 that's specifically focusing around cattle.
15 So it will impact it from that perspective
16 greatly.

17 MS. DONLEY: Okay. And then my
18 second question is will somebody either now or
19 in the subcommittee give a little bit more
20 detailed explanation of what the agency
21 currently does regarding how the information
22 of repeat violators of chemical residues, for

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1 those of us that aren't real familiar with
2 that program and we're asked to discuss the
3 pros and cons of it as far as moving forward
4 for salmonella products, will that be provided
5 in the subcommittee or can someone do that
6 here for all of us? A little more in-depth
7 explanation of that program.

8 DR. LINVILLE: I mean, I can
9 provide sort of a brief explanation now, and
10 if there are further questions then we can
11 delve into those in the subcommittee. But at
12 this point in time, what is made publically
13 available on our website is if there have been
14 repeat violators in the sense that a
15 particular producer has been shown to ship to
16 an establishment animals that have been shown
17 to have a violation in them, and so those
18 particular producers are put onto our website
19 for a certain amount of time. And so the
20 thought here is that if we can develop a
21 similar type system where we could track
22 producers that have issues with salmonella and

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1 obviously, you know, there would be some
2 background work that would have to be done on
3 that in order to track those particular
4 producers, but if we could do that would that
5 be of value in having such a database and
6 providing that information back both to
7 industry and others anyone who needs to have
8 that information on our website? So that's
9 sort of the basic premise behind it is, you
10 know, somebody who has a history of the issue,
11 tracking that and making that tracking
12 available.

13 MS. DONLEY: Thank you.

14 MR. PAYNE: Thank you, Ms. Donley.

15 And next we have Mr. Shultz.

16 DR. SHULTZ: On slide 25, you
17 listed salmonella, listeria, and E. Coli
18 0157:H7 as the three significant pathogens.
19 How were they selected? Total number of cases
20 nationally or some other incidence
21 determination? And how was Campylobacter not
22 included?

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1 DR. LINVILLE: Let me start with
2 the Campylobacter piece first. Campylobacter
3 was not included because at the time we have
4 not been sort of testing for Campylobacter and
5 we just started with Campylobacter. So I
6 would say that there's probably a good
7 likelihood that it may be included in the
8 future. These are the three that FSIS has
9 historically had goals around, and so that's,
10 I think, probably the major driving factor
11 behind it, but I would have to get back to you
12 to give you an exact answer on that.

13 MR. PAYNE: Thank you, Dr. Shultz.
14 Ms. Buck?

15 MS. BUCK: As a follow-up to his
16 question and Nancy's is basically what I want.
17 Why didn't you include Toxoplasma gondii?
18 Why hasn't that been looked at? Because, you
19 know, that's a very large killer.

20 DR. LINVILLE: Again, a lot of this
21 is sort of going across various agencies. You
22 know, this is sort of a historic goal that has

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1 been set. I'm not going to say that we won't
2 include other pathogens in the future.
3 Toxoplasma gondii is something that the agency
4 has been looking at. Whether it will be
5 included in our all-illness measure I don't
6 know. In part, these are illnesses that we
7 can easily track and also find attributions to
8 our product on. And so that is a large part
9 of it, as well. It encompasses a lot of
10 different data from the CDC from our testing,
11 and so that's where these came from. So I'm
12 not going to say that it was excluded for any
13 particular reason.

14 MS. BUCK: Well, I mean, it's not
15 even tracked in our FoodNet, and I understand
16 there's problems with it. But given the
17 impact that it has and the number of deaths
18 and with the long-term health outcomes, I
19 think we need to have an agenda for --

20 DR. LINVILLE: Right. And our all-
21 illness measure is heavily dependent on
22 FoodNet data.

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1 MS. BUCK: Yes, I understand that.
2 The other, though, is a follow-up to Nancy's
3 question. When we're looking at these residue
4 violations, I gather, in part, we're looking
5 at them to detect if antibiotics are present?

6 DR. LINVILLE: That would be one
7 thing that we're looking at. I mean, there's
8 a number of different things that can cause
9 violations in our product, but antibiotics are
10 one of the major ones, yes.

11 MS. BUCK: So there's sort of a
12 program or an attachment to this residue
13 violations that might start tracking the level
14 of antibiotics in the --

15 DR. LINVILLE: Oh, I mean, we do
16 that.

17 MS. BUCK: You do that already?

18 DR. LINVILLE: We have a national,
19 we have our national monitoring program and we
20 also have inspector-generated testing that's
21 done sort of for cause in the establishments.

22 MS. BUCK: Okay, okay. Thank you.

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1 That's all.

2 MR. PAYNE: Thank you, Ms. Buck.
3 I'm trying to catch these in the order they
4 come up. Ms. Tucker-Foreman?

5 MS. TUCKER-FOREMAN: Thank you. I
6 apologize for being late and coming in in the
7 middle of your presentation and then
8 interrupting it.

9 DR. LINVILLE: Oh, no problem.
10 Glad you made it.

11 MS. TUCKER-FOREMAN: If you talked
12 about the actual operation of the residue
13 violation process, I came in too late to hear
14 it. Would you take just a couple of minutes
15 and walk through how the residue violation,
16 the residue checking system operates? I know
17 inspectors take samples and then they're
18 examined to see if there is a residue that is
19 not intended so much to prevent these
20 violations as to provide a measure of what the
21 level of violation is out there. But you do
22 have an enforcement mechanism because you

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1 mentioned that. How do you, when you find a
2 violation, what happens? When you find a
3 positive, what happens?

4 DR. LINVILLE: I mean, there are
5 two sort of separate systems that we have when
6 it comes to residues. We have our national
7 monitoring program which is a randomized
8 program which kind of helps us look at levels
9 overall. When those samples are taken, we
10 currently do not hold product. I mean, we
11 obviously provide the industry the option of
12 doing that. So if it's an inspector-generated
13 sample, if a cow comes in and they see an
14 injection site or an injection lesion, that
15 might cause them some concern, and then they
16 would do a targeted sample on that particular
17 animal. At that point in time, that carcass
18 is held until we get our results back. So
19 does that get at --

20 MS. TUCKER-FOREMAN: Thank you. It
21 does help, but what happens after that? How
22 do you identify the source of the animal, and

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1 who then takes steps with regard to --

2 DR. LINVILLE: If the sample comes
3 back positive, then a case is started actually
4 out in Omaha. And we work together with the
5 FDA on tracing that back. We have some
6 dedicated staff in Omaha that will try to
7 identify that particular producer based on
8 information that is gathered at the
9 establishment. And then that is put into a
10 database that is shared with the FDA so that
11 they can do their appropriate follow up on
12 farm.

13 MS. TUCKER-FOREMAN: Okay. So FDA
14 then does the actual on --

15 DR. LINVILLE: On farm.

16 MS. TUCKER-FOREMAN: -- farm
17 follow-up?

18 DR. LINVILLE: Yes, ma'am.

19 MS. TUCKER-FOREMAN: The last time
20 I looked at this, people who had violations
21 were required then to demonstrate that they
22 could produce animals without violations and

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1 have three or four tests before they were then
2 allowed again to bring animals to slaughter.
3 Is that still the case?

4 DR. LINVILLE: No. It depends on
5 how they deal with the issues in their HACCP
6 plan as to what our particular actions would
7 be, but we do expect them, based on the fact
8 that we expect them in their hazard analysis
9 to be looking at things that they're bringing
10 in, to deal with that.

11 MS. TUCKER-FOREMAN: One more
12 question. What does FDA do? Don't they have
13 a requirement that the producer show a, they
14 can't just the next, at least it used to be
15 that they couldn't the next day bring hogs to
16 a hog slaughter facility.

17 DR. LINVILLE: I have to be honest
18 with you. I would have to get back with you
19 on that one. What FDA specifically does I'm
20 not aware.

21 MS. TUCKER-FOREMAN: Thank you.

22 MR. PAYNE: Thank you, Ms. Tucker-

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1 Foreman. Dr. Kassenborg?

2 DR. KASSENBERG: Yes. I have a
3 question about the residue list, as well, that
4 you publish on your website. Before, you used
5 to have, as a residue was found, sort of an
6 ongoing list and now it's only the repeat
7 violator list. Can we get access to that
8 other list that used to be there?

9 DR. LINVILLE: Okay.

10 DR. KASSENBERG: Okay. There's
11 ones where they've had more than one violation
12 in a 365-day period, and so that's the repeat
13 violator list. But then there was the ongoing
14 list, kind of a running total of people who
15 only had one violation, and that list is gone
16 from your website.

17 DR. LINVILLE: Please.

18 MR. DERFLER: We took down the one
19 list because we wanted to simplify things. We
20 now have two lists. One is sort of for our
21 inspection personnel, so they'll know who the
22 repeat violators are. And then there's the

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1 simplified list that goes to auction barns and
2 other people in the industry so that they know
3 who, there are a number of agreements now
4 between plants and the barns that they tend to
5 go to so that they identify who the repeat
6 violators are, and so people take that into
7 account before they purchase the animal.

8 Dr. Linville said that we were
9 going to publish that Federal Register
10 document asking for comment on the compliance
11 guide. But as part of that document, we're
12 also going to ask for comment on how we should
13 present information on the website. So I
14 would suggest that that would be the
15 appropriate way to do it.

16 DR. KASSENBERG: Thank you.

17 MR. PAYNE: Thank you, Dr.
18 Kassenborg. Next, Dr. Tilden.

19 DR. TILDEN: Hey, Dr. Linville.
20 What's the agency's current thinking on the
21 up-tick in the proportion of salmonellas that
22 are related to Salmonella Enteritidis? Is

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1 there any indication that they're more
2 resistant to the interventions than other
3 salmonellas?

4 DR. LINVILLE: It's an interesting
5 discussion that we're having within the
6 agency. I mean, I'm not sure that we have any
7 particular idea as to what that is. It could
8 be that Salmonella Enteritidis as a whole is
9 just becoming more prevalent. It could be
10 that we're having, as you sort of mentioned,
11 better success in reducing the other serotypes
12 which is just sort of artificially inflating
13 the Salmonella Enteritidis. I don't think we
14 have an answer to that right now really.

15 MR. PAYNE: Thank you, Dr. Tilden.
16 Mr. Warshawer? Oh, Ms. Klein?

17 MS. KLEIN: I just wanted to
18 clarify what you said the agency's position is
19 on their authority under the HACCP rule. So
20 it's the agency's position that under the
21 HACCP rule FSIS does, indeed, have authority
22 over food safety hazards that can occur before

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1 entry into the official establishment?

2 DR. LINVILLE: We have authority in
3 the establishment. So in other words, it is
4 the establishment's responsibility to conduct
5 an appropriate hazard analysis and consider
6 hazards that may occur before entry into the
7 establishment. We don't have any authority
8 over those particular hazards. We have
9 authority over what is being brought into the
10 establishment.

11 MS. KLEIN: Okay. So if the
12 establishment is unable to verify that their
13 HACCP plan is controlling for those hazards
14 that are occurring before entry into the
15 establishment, FSIS has authority to?

16 DR. LINVILLE: We have authority to
17 question their HACCP plan and whether their
18 controls are effective or not. Absolutely. I
19 mean, and that's sort of why we want to get
20 this discussion going today specifically
21 around salmonella and sort of brainstorming,
22 if you will, what types of hazards would we

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1 think industry could be looking at and could
2 be controlling for.

3 MS. KLEIN: Okay. Thanks.

4 MR. WARSHAWER: I wanted to point
5 to a study that -- and, again, I'm sort of
6 slow on the uptake sometimes here, so I may be
7 missing a connection or be talking about
8 something that isn't relevant to this meeting.

9 There was a study from the GAO that was
10 released last week that states that the GAO
11 cannot find a link between antibiotic use in
12 animal agriculture and human resistance. Now,
13 is that like a completely different topic than
14 antibiotic resistance in these foodborne
15 illness pathogens, or is this a case where the
16 very idea that we can state that there isn't a
17 connection is undermining our efforts to deal
18 with antibiotic resistance in foodborne
19 illness organisms? What am I missing here?

20 DR. LINVILLE: There's a couple of
21 different ways that you can look at antibiotic
22 resistances as we, as an agency, have to deal

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1 with it. Last year, we did sort of bring up
2 the question, you know, is there the
3 possibility of a connection between on farm
4 use and antibiotic resistance. I think that
5 question is still being heavily discussed
6 among people who have much better knowledge
7 around that than I do. So, I mean, even if we
8 take that off the table for now, which I'm not
9 saying we have to, but even if we do take that
10 off the table for now antibiotic resistance is
11 a marker in the positives that is used, in
12 part, in trace-back if we're trying to go back
13 and find out what has caused illness. So
14 that's one important aspect of it and that's
15 one reason that we want to provide it back to
16 establishments.

17 The other reason is is that,
18 obviously, if a serotype has antibiotic
19 resistance, especially towards some of the
20 critical drugs, that would be something that
21 an establishment likely would want to know
22 because the potential for causing illness may

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1 be increased because of that.

2 MR. WARSHAWER: So really I'm
3 asking whether -- you picked up the question
4 behind the question better than I knew. We do
5 have sort of a role in that conversation both
6 as a committee and FSIS has a role in that
7 conversation.

8 DR. LINVILLE: I would say yes.

9 MR. WARSHAWER: And so the
10 statement that GAO cannot find a link between
11 antibiotic use in animal agriculture and human
12 resistance is not final word on the subject,
13 there's a lot of work going on and a lot of
14 conversation and it crosses over to questions
15 that we'll be addressing here?

16 DR. LINVILLE: Yes. I mean, around
17 that particular topic, I think there are a lot
18 of --

19 MR. WARSHAWER: Thanks. That's
20 what I want to know.

21 MR. PAYNE: Thank you, Mr.
22 Warshawer. And, Ms. Tucker-Foreman, you have

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1 a question?

2 MS. TUCKER-FOREMAN: I do. We
3 usually have someone, a liaison from the FDA
4 here attending the meetings. I'm wondering if
5 the FDA liaison could brief us a little bit on
6 what the process is for FDA dealing with the
7 producer who sends animals with violative
8 residues to slaughter?

9 DR. LINVILLE: We have Dr. Joshua
10 Hayes here.

11 MR. HAYES: I really wish, you
12 know, I could give you that information.
13 However, my role is purely on the pre-
14 marketing side of things. I do know that that
15 is handled by the agency in our post-marketing
16 group, but I don't know the specific policy
17 that's required to allow a violator to
18 introduce product into interstate commerce
19 after being identified as a violative residue.

20 So I can, you know, try to find out that
21 information and provide it to the group.

22 MS. TUCKER-FOREMAN: If we're going

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1 to have this discussion, obviously it would be
2 useful, I think, to know that. Maybe Mr.
3 Derfler could tell us?

4 MR. DERFLER: I don't work there
5 anymore.

6 MS. TUCKER-FOREMAN: Historically?

7 MR. DERFLER: Well, I mean, there's
8 a possibility that they will seek injunction
9 in court against the introduction of that
10 producer introducing animals, live animals on
11 the hoof under FDA case law. So they would
12 seek an injunction sometimes to prevent those
13 animals from entering commerce, and sometimes
14 they will seek criminal sanctions against the
15 producer.

16 MS. TUCKER-FOREMAN: In the dark
17 ages when I worked at USDA, there was the
18 problem with the, I've forgotten the drug,
19 sulfa drug residues in market hogs. And at
20 that time, FDA had a pretty vigorous program
21 that if they could identify a producer and
22 there was so much of it they could, that would

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1 say you can't bring hogs to market until you
2 have brought us a hog from this lot and shown
3 five times or three times that you've got hogs
4 that are free of sulfa residues before you can
5 send them to market again. Now, this was an
6 imperfectly working system, to say the least.

7 But for producers who were shipping hogs to
8 large slaughterhouses, it was pretty
9 effective. And the plant that was relying on
10 records of the companies who were slaughtering
11 the hogs to be able to track it back to the
12 producer who was sending the hogs with
13 residues into slaughter.

14 So that's an action that the
15 department was taking that had an impact prior
16 to the animals arriving for slaughter and I
17 think is relevant to what you said here today
18 and the question that you've answered. So it
19 would be good if we could get a little more
20 information about that. Thank you.

21 MR. PAYNE: Thank you, Ms. Tucker-
22 Foreman. And next we have Dr. Shultz.

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1 DR. SHULTZ: Ms. Tucker-Foreman, a
2 little bit of clarification on that because I
3 worked in the FS field through the 90s and
4 into 2008 and had a lot of experience in the
5 national residue program. But in the 90s, we
6 had the 515 policy. The 515 policy, when you
7 violated, then you were required, depending on
8 the degree and the severity of the violation,
9 to bring generally five animals to slaughter
10 as a follow-up to validate that those that
11 you're, whatever your corrective action was
12 correct.

13 And there were a number of issues
14 and problems associated with that because of
15 the very complex marketing system that we have
16 for slaughter animals and particularly in the
17 non-vertically integrated industries where you
18 have individual producers and livestock
19 markets, and it's a very circuitous process to
20 finally get that animal to slaughter. It was
21 a problem to demonstrate that those five
22 animals that were delivered as a verification

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1 were, in fact, sourced from the herd that had
2 the problem, especially in the non-vertically
3 integrated industry like dairy cow slaughter.

4 So we had a market cow working group back in
5 the 90s that discussed that at length. And
6 from that, the repeat violator policy evolved,
7 and we recommended a switch on that working
8 group from the 515 validation procedure to a
9 repeat violator procedure where once you had
10 two FDA verified violations within a 12-month
11 period you were placed on a list that was
12 published on the web and you were recognized
13 publically as a repeat violator.

14 The complication with that has been
15 the turnaround time in doing two FDA
16 investigated violations within the period of
17 12 months. It takes a long time to do a
18 complete investigation and determine
19 absolutely that a particular animal was
20 traceable to a particular producer and for
21 FSIS to prove that beyond a shadow of a doubt.

22 They have to go back to the plant, they have

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1 to go to the various livestock markets and
2 other venues that that animal moved through in
3 the process of going to slaughter and make
4 sure that it actually was traceable to that
5 producer.

6 That is even a further challenge
7 today as we're moving away from a system where
8 we had pretty much regulated trace-back
9 procedures that were associated with the
10 disease control program operated by Animal and
11 Plant Health Inspection Service where, because
12 of brucellosis surveillance in cattle and TB
13 surveillance, tuberculosis surveillance in
14 cattle, we collected ID at the slaughter plant
15 and used that for trace-back. Because
16 brucellosis and tuberculosis have dropped in
17 their public health significance, we're no
18 longer doing a 95 percent comprehensive
19 collection of ID anymore or comprehensive
20 collection of samples from those animals.

21 So now we're challenged as we move
22 forward with animal disease traceability to

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1 develop a system where FSIS and APHIS can work
2 together to have comprehensive collections of
3 all animal ID devices at slaughter. And right
4 now the traceability rule, the proposed rule
5 has been introduced pending comment. And
6 sometime in 2012 it's expected to become a
7 final rule. And once that occurs, I think we
8 will have some language on how trace-back will
9 occur, but it will be in a very important
10 component in residue surveillance.

11 DR. LINVILLE: And I guess I have
12 sort of two comments. As Mr. Derfler said, we
13 will be having the Federal Register notice go
14 out where comments can be provided on that.
15 Just as a quick refocus on what the question
16 was intended here, though, and we can delve
17 into it more in the subcommittee, salmonella
18 raw product is not an adulterant. We're not
19 looking for, you know, FDA to go out and do
20 some sort of case investigation on this.
21 We're not there. However, some of the lessons
22 that we have learned in tracking these and

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1 making these individuals known, if you will,
2 those are sort of the things that we would
3 like the Committee to focus on.

4 MR. PAYNE: Dr. Shultz, did you
5 have a question to add to that? That's it?
6 Okay. I know we have a couple of other
7 questions, but, unfortunately, we have to keep
8 the agenda moving here and go to the next
9 issue so we don't get too far behind on our
10 schedule. So with that said, Dr. Linville,
11 thank you very much for your presentation.
12 And moving on, we do have the next issue is on
13 validation and Dr. William Shaw. He is a
14 Director of Risk Innovations and Management
15 Division from the Office of Policy and Program
16 Development.

17 DR. SHAW: Good morning, everyone.
18 It is still morning. So I'm going to
19 hopefully introduce this topic and do some
20 about HACCP systems validation, and I'm sure
21 many of you are aware that we have been
22 working through this issue for a while now.

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1 And over the course of the next, I think it's
2 about 19 slides, I want to talk a little bit
3 about a review of the HACCP plan of rule from
4 1996, and that would be the regulations for 9
5 CFR 417.4, along with the agency's
6 understanding that was in the preamble to the
7 HACCP rule.

8 We'll talk a little bit about the
9 validation in two parts, and we'll talk about
10 some validation through safety concerns that
11 we have some examples of food safety concerns
12 that have led us to this point. I'll do sort
13 of an overview of the guidance document that
14 was provided to you to sort of orient. And
15 then we'll talk about the questions that we'd
16 like you to delve into.

17 As a quick review, the HACCP plan
18 of rule was published on July 25th, 1996. It
19 included the validation regulatory language in
20 part 9 CFR 417.4 and the title "Validation
21 Verification and Reassessment." And it also
22 included, within the preamble it also included

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1 the agency's understanding of how the
2 regulatory language should be implemented.
3 So, you know, there's always the written word,
4 you know, the few sentences that get caught up
5 by it in the CFR, but then there's also with
6 every rule the preamble part that sort of
7 gives the agency's understanding of what those
8 couple of sentences that are in the CFR will
9 mean on a daily basis.

10 And both pieces of that information
11 guide FSIS' implementation policies. And we
12 really have, you know, used the language that
13 was in the HACCP plan of rule to really be the
14 core and starting point of our work on this
15 guidance document.

16 Validation for us, the current
17 thinking in our agency, validation involves
18 scientifically demonstrating that a HACCP
19 system, as designed, is effective in
20 addressing the identified food safety hazard.

21 FSIS also believes that it is important that
22 validation includes some practical data or

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1 information reflecting an establishment's
2 actual early experience in implementing a
3 HACCP system within their unique processing
4 environment. We have under jurisdiction a
5 little over 6200 establishments across the
6 country, and each one of them has their own
7 unique attributes. They're not all the same.

8 And included in our understanding,
9 validation does include the HACCP system in
10 its entirety. One of the reasons that really
11 drives that understanding of the HACCP system
12 is an increased use of prerequisite programs
13 to support hazards not reasonably likely to
14 occur. Since 1996, the use of prerequisite
15 programs has increased year after year after
16 year. Prerequisite programs are a vital
17 underpinning use that establishments have for
18 their HACCP plans to operate effectively, so
19 they become a vital part of the system in
20 general. And so over those years since 1996,
21 prerequisite programs, since they are in use,
22 we have to also address them in our policies

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1 and programs.

2 Prerequisite programs are the
3 foundation for the HACCP plan to operate
4 effectively. They usually set the stage for
5 the HACCP plan to operate.

6 And also validation within the
7 preamble to the HACCP plan of rule, validation
8 was discussed in two parts, the first part
9 being scientific or technical support for the
10 HACCP system and that's usually, you know,
11 science information in the form of the
12 documentation that supports the underlying
13 theoretical principles of the process step or
14 intervention or per se. And then the second
15 part would be the initial practical in-plant
16 demonstration proving the HACCP system can
17 perform as expected, and that's really the
18 information that supports the translation of
19 that scientific information into the unique
20 environment of that particular establishment.

21 And just for some review, these are
22 from the preamble to the HACCP plan of rule,

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1 some examples of scientific support which
2 would include theoretical principles, expert
3 advice from processing authorities, scientific
4 data, peer review journal articles, could be
5 pathogen modeling programs, agency issuances,
6 or other information demonstrating that a
7 particular process control measure can
8 adequately address an identified hazard.

9 And then some examples of the
10 initial in-plant information that we are
11 talking about: in-plant observations,
12 measurements of certain parameters,
13 microbiological test results, or other
14 information demonstrating that the control
15 measures as written into the HACCP system can
16 be implemented to achieve the intended food
17 safety objective. And that, again, was
18 language listed in the HACCP plan of rule
19 preamble.

20 As sort of an introduction to the
21 reason behind the guidance document
22 development, the agency has recently become

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1 aware of some food safety concerns that we
2 have in assessing data from our performance-
3 based inspection system, which we are leaving,
4 and the food safety assessment information,
5 recalls and other foodborne illness outbreaks.

6 We found that in-plant validation may not be
7 consistently implemented by industry or
8 enforced by our inspection personnel. And
9 some of the main issues that we have found is
10 establishment personnel having difficulty
11 identifying critical operating parameters in
12 the supporting documents that they have on
13 file and then translating those critical
14 operating parameters into their HACCP system.

15 So it's translating that scientific
16 information into their system in the
17 implementation stage and then also gathering
18 information demonstrating under actual in-
19 plant conditions that this scientific
20 information has been translated into their
21 system and that they can make it work on a
22 daily basis in their unique processing

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1 environment.

2 I want to share with you a few
3 examples of food safety concerns that we've
4 run into. And I have four examples, and
5 they're more examples on a theme. Each
6 example is sort of a theme. And in the
7 deliberations, if there are additional
8 examples that you would like, I can bury the
9 theme a little bit and I can share some
10 additional examples that we have experienced.

11 Example one. The context of this
12 actual example was it was an establishment
13 that had scientific support, a study from a
14 university for the use of lactic acid as an
15 antimicrobial, and this was a beef slaughter
16 establishment. The critical operating
17 parameters within that scientific information,
18 including the concentration of the lactic
19 acid, the temperature of lactic acid and
20 product at point of delivery onto the carcass,
21 and pressure at the point of application onto
22 the carcass.

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1 Our verification findings concluded
2 that the establishment was not measuring
3 pressure at point of application and that the
4 establishment was also applying hot lactic
5 acid to a cold carcass while the study, as I
6 previously mentioned, documented hot acid on a
7 hot carcass. And so that's an example of a
8 lack of translation of scientific information
9 into the establishment system.

10 Example two. This is an example of
11 a theme of a further processor of raw meat and
12 poultry products, and this particular example
13 is that an establishment was utilizing
14 processes from other establishments to support
15 a hazard. In this case, it was E. coli 0157,
16 not reasonably likely to occur. The
17 establishment purchased intact beef primals
18 with the intention to needle tenderize.

19 Supply within the establishment's
20 HACCP system. Suppliers were expected to have
21 an intervention for 0157 and the hazard
22 analysis contains a generic letter from each

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1 potential supplier as support. The findings
2 were, in this case, that the hazard analysis
3 had no expectations of the intervention or
4 description. There wasn't information on what
5 type of intervention was expected of the
6 supplier and how they were making decisions
7 within their own hazard analysis based on the
8 information from the supplier and then, in
9 part, supporting that decision that 0157
10 wasn't a hazard likely to occur in their
11 process.

12 And, also, the hazard analysis
13 didn't specify what type of intervention,
14 whether it was a CCP or prerequisite program
15 at that supplier; where it was located in the
16 food safety system, whether it was at
17 slaughter or fabrication; or how the
18 intervention and letter related to actual
19 products purchased. It said, you know, the
20 letter was a generic letter and was not
21 updated frequently. And so this was sort of
22 an example of lack of communication between

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1 the supplier and the further processor and,
2 therefore, in this case, we would say the
3 further processor lacked sufficient
4 information about the product that they were
5 bringing in the door in order to fully support
6 that 0157 was not a hazard likely to occur in
7 their process.

8 Example three on a theme, and this
9 was, the context of this example is
10 establishment developed an allergen control
11 program from corporate data. So this is a
12 theme of the use of corporate data. And the
13 controls, basically the main parameters from
14 the corporate data instructed, you know, their
15 sister establishments within the corporate
16 structure to filter the frying oil using a 20
17 micron filter and dry flush for removing
18 residue from breading equipment. However,
19 from our inspection findings during our
20 verification, it was revealed that the
21 establishment completely based the system on
22 the findings from the corporate study, and the

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1 establishment assumed that the control
2 measures within the plant operation would work
3 without assessing the corporate parameters in
4 the study compared to their parameters. You
5 know, were the equipment comparable? Were
6 products being produced comparable? And to
7 sort of make an informed decision whether 20
8 micron would work for them or whether a dry
9 flush would actually remove the sorts of
10 contaminants that could pose allergens and
11 that sort of information.

12 So, basically, on this theme it was
13 not assessing whether the scientific
14 information that they had from corporate
15 actually reflected their process. And then
16 also the establishment did not gather data
17 during initial experience to determine if the
18 control measures were met in their processing
19 environment.

20 Then example four. So the context
21 of this example and the theme in this example
22 is validated cooking instructions. So the

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1 establishment in question produced raw pre-
2 browned stuffed poultry products. I don't
3 know if you've ever seen those, but it's a raw
4 chicken product that's stuffed with either,
5 you know, cheese or other meat products or
6 vegetables of sort, and they're sort of par-
7 fried to sort of set the breading. But it's a
8 raw product. And so the establishment used
9 the study to guide their cooking instructions
10 for the product, and they used that to support
11 that there wasn't a hazard likely to occur
12 because the end user would cook the product
13 and produce a safe product of 165 internal
14 finished product temperature.

15 Upon verification findings, it was
16 revealed that the validation protocols that
17 the establishment had on file were vague and
18 did not address critical parameters such as
19 location of oven temperature measurement, how
20 they measured the oven temperature. They did
21 not take into account variation in product
22 weights. There were multiple variations to

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1 the product. And then, just in general, from
2 a quality control situation, there were
3 various weights from product to product
4 depending on the formulation in that
5 particular type, whether it had meat in it or
6 whether it had cheese in it or whether it had
7 vegetables and that sort of thing.

8 And then there was also a lack of
9 documentation on what the whole time after
10 cooking was. Part of the instruction was to
11 hold the product for a certain amount of time
12 before consuming. And then also the protocol
13 stated that there would be three replicates
14 done as part of the study, but, actually,
15 there were not three replicates done as part
16 of the study, even though the materials and
17 methods section of the study said that there
18 were three replicates.

19 The cooking instructions also
20 required oven temperature of 375 for 35
21 minutes to reach 165 internal, but the data
22 could not support those parameters. So,

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1 therefore, the data, and not to get too far
2 in-depth, but the actual data collected as
3 part of the study and then the further
4 calculations of log reductions of salmonella
5 and their actual temperature, actually the
6 empirical data where they were collecting the
7 internal temperature of various products, you
8 could see on the various pieces of products
9 there were some trials where 165 was not
10 achieved. So that, to us, would be a
11 demonstration of a lack of validation for the
12 cooking instructions.

13 And so examples like those that we
14 have seen over the years have guided us to
15 develop a compliance guide for all
16 establishments to help further clarify and
17 provide assistance to establishments in
18 ensuring that their systems are completely
19 validated. And our compliance guide is
20 intended to provide the validation concepts.
21 I think when you reviewed it, its intention is
22 to provide the clarification on what

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1 validation is.

2 And then also we want to provide a
3 framework to follow when validating different
4 types of processes. And so this guidance
5 document, for the most part, it's designed to
6 set a framework, set a structure, a step-by-
7 step process of validating a process. It
8 doesn't necessarily go step by step into an
9 individual type of process, you know, like
10 making a hot dog. It is more of a if you were
11 making a hot dog, if you were making a meat
12 and poultry process, you would move through
13 this step-by-step process of validating. It's
14 a broader structure, not tailored product by
15 product or type of process by process. But we
16 believe the thought processes and the ideas
17 that we have within the guidance documents can
18 apply to, you know, unique processes that each
19 establishments in the 6200 across the country
20 produce. And then in order to provide that
21 sort of linkage between, you know, the concept
22 and the structure and the real life on the

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1 ground, we have provided a number of examples
2 in various types of processes where people can
3 see how it could be done and see the
4 relationship between the concepts and then the
5 actual.

6 And then it was discussed earlier
7 today the time line, the background. We've
8 really been working on this since about 2009.

9 In 2010, there was a first draft released and
10 we did receive a little over 2,000 comments.
11 There was a public meeting in 2010, and we
12 have taken information from the comments,
13 information shared at the public meeting,
14 various sort of discussions, you know. People
15 that we talk to everyday have an idea, have a
16 thought, have thoughts on how we should do
17 this. And we've been incorporating those over
18 this time to get to the point at which the
19 draft is right now that was shared with you.

20 And just as a sort of quick
21 overview, because the document was provided to
22 you in your packet, but as it is in a

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1 question, it's a question format. We're
2 trying to move into a more question type
3 format because we think that that is easier
4 for readers. It does have also some even more
5 particular Q's and A's in more of a
6 traditional Q's and A's format because over
7 the years that has been very helpful and
8 popular with our stakeholders. So even within
9 the document, the section titles are in a
10 question format. There are pieces of
11 information that are blocked off that we think
12 are very important. We also have even Q's and
13 A's that are embedded into the document.
14 There was a time when we wrote compliance
15 guidelines, we had a compliance guideline, and
16 then the Q's and A's would be afterwards or in
17 other places. We actually embedded them.

18 And those Q's and A's are various
19 things that we've been asked either in public
20 meetings or have come to us through askFSIS.
21 So, clearly, they were things that we thought
22 that were important to people.

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1 And sort of an orientation to the
2 guidance document, it starts out with some
3 background, you know, more in-depth discussion
4 of what I've already discussed about the
5 history of the HACCP plan of rule and some
6 definitions of validation, definitions of
7 HACCP system. There is also a discussion of
8 the comparison between initial validation and
9 ongoing verification. We have found that that
10 is the sort of comparison that is a source of
11 confusion fo many people. That is a very
12 difficult concept within the HACCP structure
13 because many of you know that the principles
14 of HACCP include one principle that its title
15 is "Verification." But then within that
16 principle there is validation, verification
17 again, and reassessment. And so we often
18 internally, externally often have
19 conversations, and we're using the word
20 "verification," but both parties may be using
21 it in a different context and the other party
22 doesn't really know. And so we did think it

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1 was important to include a sort of discussion
2 of validation compared to ongoing verification
3 and how that fits into the grand scheme.

4 And then we also go through the two
5 elements of validation, the scientific
6 support, and then also in-plant data, and some
7 examples of that. And then we also talk about
8 different types of processes and products, how
9 to sort of look at that in a more HACCP
10 category-wide where an establishment may make
11 multiple products within the same HACCP
12 category and how to deal with that.

13 We also talk fairly in-depth about
14 critical operating parameters and identifying
15 those critical operating parameters within the
16 scientific information the establishment has
17 chosen to support its system to be able to
18 translate those in their system. We found
19 that that is a challenge for establishments'
20 personnel, and it has become, over the drafts
21 of the guidance document it has become a
22 centerpiece of the guidance document and

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1 identifying those critical operating
2 parameters because we believe that that is
3 probably the most critical aspect of ensuring
4 food safety is ensuring that operating
5 parameters are identified from the scientific
6 information and then get translated into the
7 HACCP system itself.

8 And then there's a discussion of
9 record expectations associated with
10 validation. One of our commenters from our
11 initial draft gave us a suggestion of sort of
12 an initial validation self-assessment
13 worksheet that establishments could go
14 through. We thought that was a great idea,
15 and we incorporated that into the document.
16 And so you'll see it's a one-page sort of
17 self-assessment.

18 And then there are three
19 appendixes. One appendices, a further
20 breakdown of how to identify critical
21 operating parameters from scientific
22 supporting documentation. There's a document

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1 guidance for existing establishments because
2 the challenge with this policy is we have
3 establishments that have been operating for,
4 you know, many years, since HACCP was
5 implemented. So we wanted to provide some
6 guidance on how those existing establishments
7 can look to the records that they already have
8 on file and make decisions, whether they may
9 need to gather some additional data or, in
10 many cases, they already have it.

11 And then there's also some
12 validation worksheet examples. We go through
13 a number of types of interventions that are
14 common and sort of just give some idea of what
15 is expected.

16 And so why we're here today and
17 asking for your input is we are asking for
18 feedback on the guidance document. And to
19 help sort of focus our time, we really are
20 interested in some particular points where
21 consensus has been difficult. This process
22 has been challenging. It continues to be

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1 challenging because of the great variety of
2 product that our industry produces on a daily
3 basis. And so, therefore, a guidance document
4 of this sort of a great challenge in being
5 able to provide information and assistance
6 without being prescriptive and stifling
7 innovation because it's not a one size fits
8 all. You know, processes are different.
9 Slaughter is different. Slaughter is
10 different from further processing, further
11 processing is different from ready to eat, and
12 that sort of drives what types of validation a
13 particular establishment would want to do.

14 So we are requesting innovative
15 ideas on how to convey this information to
16 stakeholders. It's constantly on our mind how
17 do we get the message out? How do we help
18 people? And we provided three questions to
19 sort of initiate conversation on those topics.

20 And so question one: what
21 innovative strategies can the agency utilize
22 to help establishment personnel identify

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1 critical operating parameters and then
2 determine where in the HACCP system it is
3 appropriate to ensure implementation? I mean,
4 we believe this is the cornerstone of the
5 success of this guidance document is to help
6 establishment personnel, as well as our own
7 inspection personnel, be able to pick out
8 what's the critical operating parameters
9 within an intervention or a process or a
10 process step to be able to fully translate
11 that into their day-to-day operations for
12 success. And, again, the challenge among this
13 is, is that there's such a variety of
14 processes out there that what we're trying to
15 convey is a concept and a structure for how to
16 read scientific documentation and pick out
17 what is pertinent to the particular processing
18 question.

19 And then question two: we realize
20 that often establishments produce a wide
21 variety of products within one HACCP category,
22 and it may be impractical or even unnecessary

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1 to gather in-plant data as part of initial
2 validation for all of those products. The
3 agency -- and forgive me. It's on page 14.
4 But of the guidance, we have attempted to
5 describe a set of principles food science
6 principles when making those decisions with
7 some examples. You know, within a HACCP
8 category I'm going to do initial validation,
9 what product or products do I really want to
10 focus on to gather that data to demonstrate
11 that my process is operating effectively and
12 is fully validated?

13 That is a concept that we
14 constantly struggle with. We're constantly
15 looking at that section and sort of mulling it
16 over and is there a better way to describe it?

17 Can we give more information without being so
18 prescriptive that whatever we say is only
19 applicable to slaughter or what we say is only
20 applicable to ready to eat, only applicable to
21 a very narrow type of process or product? And
22 so we're asking does the Committee have

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1 additional suggestions as to how the agency
2 can better describe this important concept?

3 And then question three: in
4 general, what innovative strategies can the
5 agency use to help industry and FSIS
6 inspection personnel better understand the
7 concepts of HACCP system validation to improve
8 food safety? We're consistently and from all
9 takers interested in ideas about how to get
10 the message out, how to help people, how to
11 provide greater understanding of this very
12 important concept with respect to food safety.

13 And so we're interested in any ideas you have
14 about how to convey that information.

15 And with that, I will take any
16 questions.

17 MR. PAYNE: Thank you, Dr. Shaw.
18 Since we are a little bit behind schedule, we
19 do have a little bit of time, a few minutes
20 for questions. We will break at 12:15 for
21 lunch, so are there any questions for Dr.
22 Shaw? And Dr. Murinda?

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1 MR. MURINDA: On slide number five
2 and number ten, you mention there's pre-
3 existing programs, so what exactly are those
4 pre-existing programs?

5 DR. SHAW: Within the HACCP
6 concept, prerequisite programs, typically
7 within the HACCP framework, are programs an
8 establishment uses to set the environment or
9 foundation for the process to work. They are
10 typically sanitation programs. They are
11 typically maintenance programs, maintenance of
12 equipment. They can be pest control programs.
13 There are sometimes programs put in place,
14 purchase specification programs where if I am
15 receiving incoming raw materials, if I'm an
16 establishment and I'm receiving incoming
17 materials, I may put out a list of purchase
18 specifications that, in order for my actual
19 process to operate effectively, these are the
20 requirements of the incoming raw materials I
21 have. And then I will potentially put a
22 program in place for my employees to then, you

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1 know, at receiving, you know, go through these
2 steps, whether that's take temperature of the
3 incoming product or check a certain type of
4 label. So examples such as that.

5 MR. PAYNE: Thank you, Dr. Murinda.
6 And to my left here, Dr. Cutter.

7 DR. CUTTER: Where do I begin? It,
8 HACCP, you know, the whole validation concept,
9 especially for a lot of small plants. A
10 couple of questions I have, and one of them
11 addresses this. We're talking 90 days. If
12 there's an expectation in your prerequisite
13 program validation, plus all the critical
14 control points for all of these products, is
15 there any information from the agency to come
16 up with some kind of prioritization that maybe
17 we do CCPs first and then prerequisite
18 programs later? I mean, you're asking a lot
19 in this 90-day period.

20 DR. SHAW: From a point of view of
21 prerequisite programs, and it's throughout the
22 guidance, with respect to prerequisite, we

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1 focus heavily on prerequisite programs that
2 are tied to a specific hazard in the hazard
3 analysis not being likely to occur. So those
4 programs we focus on the most when it comes to
5 validation, and I think I'm actually
6 interested in, and I hope you're on that
7 committee --

8 DR. CUTTER: I would like to be on
9 that committee. I will --

10 DR. SHAW: To hear --

11 DR. CUTTER: -- express my concerns
12 that if I'm not on it I would like to be on it
13 right now.

14 DR. SHAW: Well, because I would be
15 interested to hear the thoughts as to how to
16 prioritize and potentially how it's
17 potentially possible to focus on certain
18 aspects during a validation period, how to
19 focus on a particular aspect without something
20 that may be, you know, dependent upon. So I'd
21 be interested to hear about that because that
22 is a challenge for us in that, especially

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1 establishments at the onset and particularly
2 small establishments that may not operate
3 every day during that 90-day period. So, yes,
4 I would be very interested.

5 DR. CUTTER: Okay. Another
6 question. These food safety concerns, I was
7 just sort of curious, are they coming from the
8 EIAOs during their FSAs and their
9 investigations on recalls and things, or is
10 this, I mean, I don't get the sense that
11 inspectors really know how to pick apart a
12 paper from a standpoint. So when things
13 aren't matching up, who's making those
14 decisions, especially with the examples that
15 you presented? And then how is that going to
16 be, what's the role of the inspector in
17 looking at the supporting document in the
18 plans? Because there's a real disconnect
19 here, and I agree that we need to, you guys
20 need some strategies to figure out how to do
21 that. But that's only experience now with
22 what we're seeing and talking with the plants

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1 about.

2 DR. SHAW: The examples that I
3 described, those types of examples typically
4 come to us via EIOs and food safety
5 assessments. These themes and these typically
6 reveal themselves during a food safety
7 assessment. They have also revealed
8 themselves during outbreak investigations
9 where EIOs and staff from headquarters were
10 involved in more in-depth investigations and
11 these ideas have come up. And so, yes, so
12 then we are in the challenge of how do we,
13 that knowledge and that process that, as
14 scientists, you know, we pick up a paper, we
15 pick up a journal article paper and it's as if
16 we, it's like reading. I mean, it's like when
17 we were five years old and --

18 DR. CUTTER: It's second nature for
19 --

20 DR. SHAW: It's second nature for
21 us. We pick it up. There are particular
22 sections we immediately go to, and they're not

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1 necessarily in the order of how the paper is
2 laid out. But we'll look at the abstract, and
3 then we'll go to this page and we'll go to
4 page five because it's how we're trained to do
5 that. And we have, especially with our EIOs,
6 we have begun to, in our advanced training
7 with them, in our one-on-one time with them
8 really start sharing that with them how to do
9 that.

10 Then also some of these examples
11 come to us via *askFSIS*. My staff, in general,
12 when it comes to the EIO methodology questions
13 and questions that come in related to, you
14 know, the pathogen control and interventions
15 and that type of thing come to me and most of
16 my staff and scenarios like this come to us,
17 and we're faced with sort of helping.

18 DR. CUTTER: I appreciate that.
19 And I hope that I can be on the validation
20 subcommittee because this is my bread and
21 butter. This is what I do, this is what I
22 teach. So I have lots of questions, but I'll

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1 defer to some other folks right now.

2 MR. PAYNE: Thank you, Dr. Cutter.

3 Dr. Williams?

4 DR. WILLIAMS: Thank you. One
5 question. Has there been any correlation of
6 numbers of problems with plants that have not
7 successfully validated or thought not to have
8 successful validation of hazard controls
9 versus actual foodborne outbreaks or recall
10 issues?

11 DR. SHAW: I guess what I would say
12 is, in the way of correlation I would say
13 that, you know, each recall, each outbreak
14 investigation, we're reviewing the data that
15 comes associated with that outbreak or recall.

16 There are food safety assessments done in
17 those establishments where that takes place,
18 and we are reviewing the information that
19 comes out of that investigation and,
20 therefore, which is where we have seen this
21 information reveal itself. So I guess I don't
22 know if I'm answering your question.

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1 DR. WILLIAMS: No.

2 DR. SHAW: Do you mind clarifying a
3 little bit more for me?

4 DR. WILLIAMS: Just as, you know,
5 as these incidents have been identified back
6 to particular plants, has it been correlated
7 back to the lack of or inadequate validation
8 of a critical control point?

9 DR. SHAW: Not always a critical
10 control point. And that's why I have
11 discussed the prerequisite program issue
12 because it's not always to a critical control
13 point.

14 MR. PAYNE: Thank you, Dr.
15 Williams. Ms. Donley?

16 MS. DONLEY: Thank you. Back to
17 the prerequisite program, you made a comment
18 that you're seeing that plants are
19 increasingly relying on prerequisite programs.
20 So it's kind of a two-pointed question. Do
21 you mean by that that there's been, for lack
22 of a better term, highly-recognized

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1 prerequisite programs that hadn't used them
2 before but are now kind of gravitating towards
3 that? And then can you explain a little bit
4 about what the difference is with prerequisite
5 programs from a regulatory standpoint versus
6 CCPs and other parts of the HACCP system?

7 DR. SHAW: That's a great question
8 in that when I say the increased usage of
9 prerequisite programs, it's more in a sort of
10 situation of just knowledge of prerequisite
11 programs, use of prerequisite programs,
12 because if you read through the HACCP final
13 rule in 1996, from an academic point of view,
14 my training was HACCP from an academic point
15 of view before coming to FSIS as a regulatory
16 agency. And if you look at early writings of
17 HACCP, prerequisite programs were always
18 there. And then if you look at the 1996 HACCP
19 final rule, prerequisite programs were
20 mentioned a few times, but there wasn't an
21 extensive discussion of prerequisite programs
22 and prerequisite programs are not in the CFR.

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1 And for the most part, when you look at the
2 HACCP regulations, they really speak heavily
3 to the HACCP plan itself and the CCPs heavily.

4 Prerequisite programs are mentioned, but
5 they're not a focal point of those.

6 And so I would say, over the years
7 of implementation, from early industry
8 experience with HACCP and then also with early
9 agency experience with verification, I would
10 probably say that emphasis was put on the
11 HACCP plans and the CCPs and, you know, the
12 monitoring and verification, and prerequisite
13 programs had, over the years, through people,
14 you know, experienced with HACCP, greater
15 learning about HACCP, have sort of found ways
16 to incorporate prerequisite programs into
17 their systems, so we're seeing more and more
18 of them. And, therefore, as a regulatory
19 agency, that means we need to move with that
20 trend and incorporate those prerequisite
21 programs more, I would guess, visibly into our
22 verification program.

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1 MS. DONLEY: But doesn't it also, I
2 mean, isn't it, and please correct me if I'm
3 wrong, aren't prerequisite programs -- well,
4 first off, I guess, again, it's kind of two-
5 pointed. Prerequisite programs, my
6 understanding, are not subject or they do not
7 receive the inspection and regulatory
8 oversight that other parts of a HACCP system
9 will, that it's certainly not passed over but
10 those programs do not get scrutinized quite as
11 much let's just say. And then a concern comes
12 is what were once CCPs or even just control
13 points be replaced by prerequisite programs
14 and, hence, aren't having the oversight that
15 they once had?

16 DR. SHAW: I would agree with you
17 to a certain extent historically. I would
18 say, historically, our verification programs
19 were designed to focus more on the CCPs and
20 the HACCP plan itself. I would say as
21 prerequisite programs have become more widely
22 used and utilized by the industry, we have

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1 been in the process of moving with that where
2 we have come to a conclusion where we're going
3 to look at the HACCP system itself and the
4 food safety provisions that are within the
5 system and verify on those lines, regardless
6 of where the establishment has chosen to place
7 that document-wise, and look at verification
8 of their food safety provisions holistically.

9 And I think you see that in this guidance
10 document. We speak a lot about interventions,
11 controls, programs, and including prerequisite
12 programs as to not sort of make that
13 historical distinction that you described.
14 Does that help?

15 MR. PAYNE: Thank you, Ms. Donley.

16 We have room for just one more question
17 before we break for lunch. Mr. Reinhard,
18 please.

19 MR. REINHARD: So I'm going to
20 comment about the validation as it is. It's
21 actually much improved than the prior version,
22 and so I think the agency has done a good job

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1 in trying to deal with the different things
2 such as safe harbors, independence A and B, to
3 identify what has to happen if you have micro
4 data or if you use the critical operating
5 parameters from some sort of scientific
6 support or other outside the facility
7 validation system.

8 One thing that isn't in there that
9 I don't know what the agency's current
10 thinking is and the subcommittee can take it
11 back and maybe talk about it, is that it talks
12 about the initial validation in the HACCP plan
13 and what facilities do. But what about when a
14 facility performs a reassessment, they may or
15 may not make changes, what's the agency's
16 thinking on how the guidance document would be
17 used in those type of scenarios, so i.e. an
18 older HACCP plan, for lack of a better term?

19 DR. SHAW: So I'm clear, so you are
20 mentioning the fact that -- this is also a
21 concept that we are challenging to bring our
22 own personnel in the idea of initial

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1 validation, ongoing verification, and
2 reassessment as sort of there's a timed
3 sequence to them and that reassessment
4 periodically takes place. And then if
5 reassessment is done and there are changes
6 revealed and modifications that need to take
7 place, how does then validation play its role?

8 And, yes, that is a challenge for us because
9 at what point, because then it becomes a at
10 what point are the changes, any modifications
11 that are made so significant that an
12 establishment would want to gather additional
13 validation information based on those changes?

14 And it is a challenge, and any and all
15 comments are very welcome in sort of where we
16 can give benchmarks and sort of guidance as to
17 when that kicks in and when it may not.

18 MR. PAYNE: Thank you, Mr.
19 Reinhard, and thank you, Dr. Shaw. We've come
20 to the point now where we should break for
21 lunch. We're a little bit behind schedule, so
22 what we're going to do is readjust our

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1 schedule and reconvene at 1:15 here in this
2 room after lunch and make sure we get back on
3 track. Thank you.

4 (Whereupon, the foregoing matter
5 went off the record at 12:20 p.m. and went
6 back on the record at 1:23 p.m.)

7 MR. PAYNE: Okay. For the sake of
8 time, we'll go ahead and get started, and I'll
9 fill Dr. Liang and Ms. Donley in after they
10 return. Basically, for the rest of afternoon,
11 we move to the subcommittee deliberations.
12 And we're going to, as always, break into the
13 two subcommittees. One will be focusing on
14 the four questions posed from Dr. Linville on
15 the pre-harvest food safety, and let me run
16 down through the subcommittee members because
17 we've had some late-changing moving around of
18 folks from one subcommittee to another. So if
19 I may have everyone's attention.

20 On the pre-harvest food safety
21 subcommittee, we have Ms. Nancy Donley, Dr.
22 Joshua Hayes, Dr. Craig Henry. Dr. Henry, are

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1 you on the phone? Can you hear us?

2 DR. HENRY: I'm on the phone.

3 MR. PAYNE: Great. Okay. Ms.
4 Sarah Klein, Mr. Robert Reinhard, Dr. Craig
5 Shultz, Mr. Stanley Stromberg, Dr. Heidi
6 Kassenborg, Mr. Leonard Winchester, Ms.
7 Veneranda Gapud. Okay. That rounds out our
8 pre-harvest food safety subcommittee.

9 And then for the HACCP validation
10 subcommittee, we have Dr. Cheryl Jones who's
11 the chair, Ms. Patricia Buck, Dr. Fur-Chi
12 Chen, Dr. Catherine Cutter, Dr. Byron
13 Williams, Dr. Arthur Liang, Dr. Shelton
14 Murinda, Dr. John Tilden, Ms. Carol Tucker-
15 Foreman, and Mr. Steve Warshawer. Have I
16 missed anyone? Okay.

17 Now, basically, the way this is
18 going to work, our pre-harvest food safety
19 subcommittee will remain here in this room to
20 convene and deliberate, and Dr. John Linville
21 will be up here as a point of contact, not to
22 give direction to the subcommittee but be on

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1 hand to answer any questions, provide any
2 clarification, questions you might have. And
3 also with this subcommittee, since we had Dr.
4 Cathy Cutter as the former chair, we just need
5 to have a new chair selected within that
6 committee. So when you convene, if you can
7 select a chair for that subcommittee that
8 would be appreciated.

9 And then downstairs, that's where
10 the HACCP validation subcommittee will
11 convene. And, basically, you want to take the
12 elevator down to G1 and look for the
13 Georgetown Room. That's where you will be
14 meeting, and Dr. William Shaw will be there,
15 again, like Dr. Linville, to be on hand to be
16 a point of contact, answer any questions, be
17 the subject matter expert. So that is
18 downstairs on level G1.

19 Folks who are in the audience, the
20 public, feel free to sit in on any of these
21 subcommittees. You can go back and forth in
22 between them. This is a transparent process.

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1 You can see what goes on in the
2 deliberations. And, Ms. Donley, I
3 just went down through the list of
4 subcommittee members, and you are on the pre-
5 harvest food safety which is up here in this
6 room. So you don't have to move anywhere.

7 Okay. Then what we'll do is
8 reconvene back up here in this room at 4:15.
9 Try to be on time so we can reconvene for the
10 day's wrap-up. And then we'll have time for a
11 public comment period then. At each of the
12 rooms, up here we have Mr. Leo O'Drudy who
13 will be taking notes for the subcommittee up
14 here. And then downstairs Ms. Janice
15 Schechter who will be with the HACCP
16 validation committee taking notes and helping
17 you with report-out.

18 Are there any questions? I take
19 that as no. So with that said, we'll go ahead
20 and break up into our subcommittees focusing
21 on the issues that Dr. Linville and Dr. Shaw
22 had put forth before the whole committee.

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1 (Whereupon, the foregoing matter
2 went off the record at 1:27 p.m. and went back
3 on the record at 4:32 p.m.)

4 MR. PAYNE: I know the subcommittee
5 up here in pre-harvest needs more time, what
6 we've discussed, and I think the other
7 committee on validation probably needs a bit
8 more time to tweak their recommendations.
9 What we discussed is to give you more time in
10 the morning and actually start the whole
11 committee meeting at 10:00 instead of 9:00.
12 That way, it's up to each of the chairs of the
13 subcommittees, Mr. Robert Reinhard and Dr.
14 Jones for their respective committees, to
15 decide when they want to convene their
16 subcommittees. We'll have this room, we'll
17 have the Georgetown Room available, and just
18 let us know, let Sally outside know or let me
19 know if you need to get in at 8:00 or
20 whenever. But what we'll do is reconvene the
21 whole committee at 10:00 tomorrow morning with
22 the reports from each of the subcommittees.

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1 And we do have a printer out there
2 on that table if you need to have your draft
3 reports printed out. I think you've already
4 contacted Sally. We'll do that for you.

5 Okay. Without further ado, what
6 we'll do is go ahead and are there any
7 comments or open it up for the public comment
8 period. And I believe there were a couple of
9 people who wrote down their names who wanted
10 to comment on the sheet outside. Mr. Corbo, I
11 think you were one of them. No? Okay.

12 MR. REINHARD: Just for the
13 subcommittee that I was chair, and we can
14 start at eight, because we'll be able to print
15 out and if we can spend some time tonight
16 before 8:00 and do your wordsmithing, and
17 hopefully we can wrap through them quicker.
18 That will give us two hours, and I think that
19 will be sufficient, unless anybody objects to
20 8:00.

21 MS. KLEIN: I don't object, but I
22 can't be here.

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1 MR. REINHARD: Okay. All right.

2 DR. CUTTER: The other group, what
3 time do you guys want to start? Do you think
4 8:30, like 8:30 for the other group?

5 MR. MURINDA: Yes, 8:30 will be
6 fine.

7 DR. CUTTER: Carol, is 8:30, if we
8 meet downstairs at 8:30 tomorrow morning, will
9 you be able to participate?

10 MS. TUCKER-FOREMAN: Yes.

11 DR. CUTTER: Okay. All right. So
12 the subcommittee on validation is going to
13 meet at 8:30 tomorrow morning downstairs where
14 we were to wordsmith and get our last
15 recommendations. Okay.

16 MR. PAYNE: Thank you. All right.
17 Any comments, other comments, open comments?
18 Other comments? Yes, ma'am?

19 MS. TUCKER-FOREMAN: I want to say
20 one thing. This was, for us, it was a really
21 productive meeting, and it was because the
22 staff gave us questions that we're qualified

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1 to address and divided them into questions to
2 us that we were capable of responding to in
3 the time allocated. So it was good staff work
4 that made our meeting very productive.

5 MR. PAYNE: Thank you. Call for
6 comments, questions?

7 MR. DERFLER: They tell me that if
8 there's no other questions or nothing else to
9 do then I guess the meeting is adjourned until
10 tomorrow morning at 10:00, okay? Last chance.
11 Well, you guys are meeting earlier, but we're
12 going to reconvene here at 10:00. The
13 subcommittees were planning to meet before
14 that.

15 MR. PAYNE: Meeting adjourned.

16 (Whereupon, the above-referred to
17 matter was concluded at 4:37 p.m.)

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