

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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PLENARY SESSION

+ + + + +

August 8, 2007

8:30 a.m.

George Mason University
3401 North Fairfax Drive
Arlington, Virginia

CHAIR: MR. ALFRED V. ALMANZA
Administrator, FSIS

MODERATOR: MR. ROBERT TYNAN
Deputy Assistant Administrator
Office of Public Affairs
Education and Outreach

COMMITTEE MEMBERS:

MS. KIBBE M. CONTI
MR. BRIAN R. COVINGTON
DR. CATHERINE N. CUTTER
DR. JAMES S. DICKSON
MR. KEVIN M. ELFERING
MR. MIKE W. FINNEGAN
MS. CAROL TUCKER FOREMAN
DR. ANDREA L. GRONDAHL
DR. JOSEPH J. HARRIS
DR. CRAIG W. HENRY

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

COMMITTEE MEMBERS: (cont.)

MS. CHERYL D. JONES
MR. MIKE E. KOWALCYK
DR. EDNA NEGRON-BRAVO
DR. SHELTON E. MURINDA
DR. MICHAEL L. RYBOLT
MR. MARK P. SCHAD
MR. STANLEY A. STROMBERG

ALSO PARTICIPATING:

DR. FAYE BRESLER
DR. LORRAINE CANNON
DR. MICHELLE CATLIN
DR. DANIEL ENGELJOHN
MR. VINCENT FAYNE
MR. CHRIS GOULD
MS. KIM GREEN
DR. KARLEASE KELLY
DR. CAROL MACZKA
MR. BRYCE QUICK
DR. RICHARD RAYMOND
DR. DANAH VETTER
DR. ISABEL WALLS
DR. PAT BASU
MR. TONY CORBO
MS. OLGA MORALES
MS. FELICIA NESTOR
MR. STANLEY PAINTER
DR. AL YANCY

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

2 (8:38 a.m.)

3 MR. TYNAN: I'm the Deputy Assistant
4 Administrator in the Office of Public Affairs,
5 Education and Outreach, and I'm also the Executive
6 Secretary of the National Advisory Committee on Meat
7 and Poultry Inspection.

8 I want to welcome you all to our spring
9 meeting, and I say that both humorously and actually.
10 We normally have a meeting probably in May or early
11 June, but because of you all being a new committee,
12 getting the Charter done and getting all those issues
13 sort of delayed us just a little bit in terms of
14 having this meeting, but we have an important agenda
15 today. So I want to begin as quickly as we can.

16 We have a little bit of a glitch with our
17 PowerPoints. So after the initial couple of topics
18 on our agenda, we may take just a short break so that
19 we can get that technical glitch fixed.

20 I'll be back in a minute to go through the
21 agenda and some of the rules of how we'll proceed
22 with the meeting, but Dr. Raymond, I want to

1 introduce him to give you some welcoming remarks and
2 he has a very tight schedule today. So we want to
3 try and allow him an opportunity to have his full
4 time. Dr. Raymond.

5 DR. RAYMOND: Thank you, Robert, and I do
6 apologize. I do have to leave, but I will be back
7 for the afternoon's deliberations and then we'll be
8 here in the morning to hear the report which for 11
9 of you will be your first report out from the NACMPI
10 deliberations. So once again welcome to Washington,
11 D.C. For those of you who live here, welcome to the
12 Committee, back to the Committee, return to the
13 Committee or new members of the Committee, whatever
14 category you do fall into.

15 For the new members of the Committee,
16 there's a couple of things I want to explain. One is
17 this Committee gets chartered every two years, and
18 when we were looking at chartering it again for the
19 '07 through '09 term, we realized that the older
20 Charters didn't place a minimum number of members.
21 They had a maximum number but not a minimum number.
22 And at times we've gone down as low as 15 members,

1 and we didn't feel as an Agency, the Office of Food
2 Safety, that 15 was an adequate number to partake of
3 the serious deliberations that we ask this Committee
4 to consider. We need more diversity. We need more
5 viewpoints and more experience.

6 So we set a minimum of 16 and a maximum of
7 18 in the new Charter. The bad news is, to fill the
8 18 there had to be 12 new members come on. We had
9 that many go off because of term limits, and we don't
10 look at 12 new members on a committee of 18 as being
11 a good way to do business, but it was what we had to
12 do to get this Committee up to the numbers we wanted.
13 Of the 12, one has already unfortunately had to
14 tender his resignation because of change in careers
15 and other personal issues that came up, and we will
16 miss him. He would have been a great member. We
17 made the decision not to fill that spot immediately
18 since the Charter does say a minimum of 16.

19 It's my intent to work with a Committee of
20 17, well within the Charter, but if we get to 16 or
21 down to 15, at that point, we will open it up for new
22 members and that will effectively help us stagger the

1 membership, instead of when the 11 of you, when your
2 terms all expire, some Under Secretary is going to be
3 looking at 11 new members all over again. So this
4 actually, unfortunately I wish Ken were on the
5 Committee, but since he's not, we'll take a look at
6 this as an opportunity to stagger.

7 We do appreciate your dedication and your
8 commitment and your willingness to apply for this
9 position. You should be proud of your selection for
10 the 11 new members here. There were over 70
11 applicants looking to serve on this Committee, and
12 that is not maybe a first, but it's certainly a first
13 in recent years.

14 I had been told when I came into this job
15 that the NACMPI Committee was sometimes viewed as the
16 rubber stamp for the Agency, got easy questions, easy
17 answers, not a whole lot of meat to it. Not a whole
18 lot of public attendance to listen to the
19 deliberations, not a whole lot of media coverage, and
20 not a whole lot of people interested in serving on
21 NACMPI. And quite frankly, in not too many years
22 past, FSIS had to call people up and ask them if they

1 would be willing to fill a spot.

2 I think we've enlivened the Committee. I
3 think we've given new work that is important enough
4 that we now see a room filled full of public,
5 industry, media. They want to know what's going on
6 with this Committee, they want to know what to think.
7 The fact that we had 70 applicants, I said over 70
8 applicants, speaks for the important work that you
9 have to do.

10 The 70 applicants were all very good
11 applicants. The fact that we picked the 11 of you,
12 we were looking for your science background. We were
13 looking for your commitment and dedication and
14 experience, and quite frankly we were looking to
15 spread the diversity within the Committee to get more
16 divergent views. And I think looking around the
17 room, we have accomplished that. We look forward to
18 hearing from you. It's an important position you're
19 in. Someone else didn't get the spot. They wanted
20 it, so serve proudly but serve well.

21 Speaking from experience, being a
22 relatively newbie myself coming on two years ago,

1 what some of you may experience, someone will call a
2 steep curve, steep learning curve. I called it two
3 years of pretty much a vertical ascent. Al, I don't
4 know if you feel like you're climbing up the side of
5 a skyscraper instead of a learning curve, it is an
6 ascent, isn't it, when you're new?

7 MR. ALMANZA: -- upside down.

8 DR. RAYMOND: Upside down. And I think
9 some of you may feel like there's a vertical ascent
10 also as we bombard you with information, and I hope
11 you get accustomed to those heights very quickly,
12 that are lofty heights, but we need you to gain
13 comfort levels quickly.

14 Now most of you were at yesterday's
15 meeting. I think some of you might be questioning,
16 what did I get into, but I want to assure you that
17 we'll continue having open and transparent
18 information exchanges. I want to assure that we're
19 looking for constructive dialogue with our food
20 safety partners and ever strengthening the already
21 strong partnerships that we do have. That will all
22 be a part of the process as we go forward with the

1 many activities that we're trying to accomplish, but
2 we will, the dialogue will continue to be
3 constructive and not destructive. That doesn't
4 benefit anyone of us.

5 In the eyes of some, the urgency and
6 necessity of NACMPI's mission has been on the decline
7 until recently. We've already talked about that. I
8 ask you to help us move with some speed but some
9 deliberation as we go to the future. As I said
10 yesterday, we're not perfect. I don't think we'll
11 ever be perfect, but we need to get better.

12 The Food Safety and Inspection Service and
13 the Office of Food Safety are very proud of the many
14 accomplishments that we've achieved over the years.
15 We have a strong track record of success after
16 success after success. But we also have some very
17 lofty goals for the near future and for the far
18 future, that will help us achieve even more success,
19 and we need your input, we need your advice, we
20 certainly need your buy in, we need your support, so
21 we can get there.

22 I know that FSIS and the Office of Food

1 Safety have an extremely strong partnership with all
2 of you as we continue to improve those procedures and
3 our data gathering and the use of our data. It's
4 only through painstaking processes like these and
5 that we've undergone this year that we can continue
6 to make sound public health decisions that protect
7 the health of all our consumers.

8 Most of you have heard this, but some of
9 the new members have not. So I'm just going to say
10 it one more time. I was very comfortable in Nebraska
11 where I lived all of my life. I was very comfortable
12 with the job I had. Those of you who heard me
13 yesterday that I probably miss not having been able
14 to hold that new grandson yet, but I left that
15 comfort to come to D.C. to do what I thought was a
16 lofty goal to try to continue to help this Agency by
17 being their spokesperson, by being their conduit to
18 the Secretary, to help improve the food safety of
19 America.

20 I didn't come here to oversee recalls. I
21 didn't come here just to oversee an already very good
22 system. I came here to try to help create change. I

1 ask you to help me create that change.

2 At this point in time, I'd like to go
3 around the room, around the table and have everybody
4 introduce themselves, our members, our FSIS staff and
5 our Agency representatives, tell us who you are
6 briefly, what you represent, so we can kind of start
7 putting names to faces and I'll start with you,
8 Kevin. You're one of the senior members of the
9 Committee but you've had one of the most recent
10 changes.

11 MR. ELFERING: I'm Kevin Elfering. I just
12 recently retired from the Minnesota Department of
13 Agriculture. I'm currently working for the
14 University of Minnesota and New Mexico State
15 University, and just recently moved to Albuquerque.

16 DR. RAYMOND: Joe.

17 DR. HARRIS: Joe Harris, with Southwest
18 Meat Association. I'm happy to be serving my third
19 and final term on the Committee.

20 DR. NEGRON-BRAVO: Edna Negron, University
21 of Puerto Rico, Mayaguez Campus, Coordinator of the
22 Food Science and Technology Program. I'm Coordinator

1 of the Food Safety Institute of our University. This
2 is my first time and I hope I will collaborate and
3 enjoy and help.

4 MS. CONTI: Hello. My name is Kibbe Conti.
5 I'm a registered dietitian. I have my own consulting
6 business, Northern Plains Nutrition Consulting. I'm
7 based in Rapid City, South Dakota.

8 DR. GRONDAHL: I'm Andrea Grondahl. I work
9 for the North Dakota Department of Agriculture, and
10 I'm the Director of our State Meat and Poultry
11 Inspection Program.

12 MR. SCHAD: Hello. I'm Mark Schad. I own
13 and operate a very small plant in Cincinnati, Ohio.

14 DR. CUTTER: I'm Cathy Cutter. I'm an
15 Associate Professor of Food Science at Penn State
16 University and also an Extension Specialist in the
17 Department.

18 DR. DICKSON: I'm Jim Dickson. I'm a food
19 microbiologist at Iowa State University.

20 MS. TUCKER FOREMAN: Carol TUCKER FOREMAN,
21 representing Consumer Federation of America. I
22 served on the Committee earlier, and have been off

1 and so I'm coming back for more punishment.

2 DR. RAYMOND: Was it your punishment or my
3 punishment?

4 (Laughter.)

5 MS. TUCKER FOREMAN: Wait and find out.

6 DR. RAYMOND: Okay, Carol.

7 MS. TUCKER FOREMAN: Actually, I do want to
8 say something here just for a minute. I believe the
9 new Charter for the Committee emphasizes the
10 importance of representatives of consumer
11 organizations, and the member who was unable to serve
12 was representing Center for Science in the Public
13 Interest. By his withdrawal, you now have only two
14 people who are representing consumer organizations,
15 and I really respectfully urge that you reconsider
16 and try to fill the seat with another consumer
17 representative. As a class of people, I think we are
18 the least represented on the Committee, and that
19 doesn't seem consistent with the Charter.

20 MS. JONES: Hi. I'm Cheryl Jones, a
21 Research Instructor at Morehouse School of Medicine
22 and Program Coordinator for the Consortium of African

1 American Public Health Programs.

2 MR. STROMBERG: I'm Stan Stromberg. I'm
3 the Director of the Food Safety Division of the
4 Oklahoma Department of Agriculture, Food and
5 Forestry.

6 DR. MURINDA: I'm Shelton Murinda from
7 California Pomona. I'm a food microbiologist. I
8 teach courses in food safety, biotechnology and meat
9 processing.

10 MR. COVINGTON: Brian Covington, Keystone
11 Foods, in the Corporate Food Safety Department.

12 MR. FINNEGAN: Mike Finnegan. I'm a
13 Training Officer of the Montana Meat Inspection, USDA
14 grader and I'm honored to serve my second term.

15 DR. RYBOLT: Michael Rybolt. I'm the
16 Director of Scientific and Regulatory Affairs at the
17 National Turkey Federation.

18 DR. HENRY: And I'm Craig Henry, Senior
19 Vice President, Chief Operating Officer for Grocery
20 Manufacturers/Food Products Association. It's
21 certainly an honor to be here, and look forward to
22 our opportunities today.

1 DR. BASU: I'm Pat Basu. I'm President of
2 APANA, which is Asian Pacific American Network in
3 Agriculture with all USDA organization nationwide.
4 I'm also the Vice President Elect of FAPAC, Federal
5 Asian Pacific American Council in the organized
6 states and also I'm a FSIS employee with OPHS.

7 MS. MORALES: Good morning. My name is
8 Olga Morales, and I'm representing the Agency
9 Association of Technical and Supervisory
10 Professionals.

11 MR. PAINTER: My name is Stan Painter. I'm
12 the Chairman for the National Joint Council of Food
13 Inspection Locals. We're the Union that represents
14 the federal meat and poultry inspectors.

15 DR. VETTER: I'm Dana Vetter. I'm a Public
16 Health Veterinarian with FSIS, and a representative
17 of NAFV, National Association of Federal
18 Veterinarians.

19 DR. WALLS: Hi. My name is Isabel Walls.
20 I'm a Senior Scientist at FSIS.

21 MS. GREEN: Kim Green. I'm a Senior
22 Scientist at FSIS and work in the Data Analysis and

1 Integration Group.

2 DR. MACZKA: I'm Carol Maczka, the
3 Assistant Administrator of the Office of Food Defense
4 and Emergency Response and I lead the Data Analysis
5 and Integration Group.

6 DR. CATLIN: Michelle Catlin with the
7 Scientific and Technical Support Staff of OFDER with
8 Carol, and I'm on the Data Analysis and Integration
9 Group as well.

10 MR. QUICK: Good morning. I'm Bryce Quick.
11 I am Deputy Administrator with FSIS.

12 MR. ALMANZA: I'm Al Almanza. I'm the
13 Administrator with FSIS.

14 MR. TYNAN: And I'm Robert Tynan, and I
15 think you all know me, and I'm also a Charter Member
16 of the Grandfather's Association.

17 DR. RAYMOND: The Association of Proud
18 Grandfathers.

19 MR. TYNAN: Proud Grandfathers. Yes, thank
20 you, Dr. Raymond.

21 DR. RAYMOND: Thank you all. This is Al
22 Almanza's Committee. He does Chair it. So, Al, I'm

1 turning it over to you and do good work, and I'll be
2 back this afternoon.

3 MR. ALMANZA: Maybe that might be a good
4 thing, just trip and get it off the way, huh?

5 Thank you, Dr. Raymond. This is kind of
6 unusual for me to see the same faces two days in a
7 row. Being here for the last I think it's three and
8 a half weeks, it's kind of unusual to see the same
9 faces two days in a row. It's usually in and out and
10 onto another meeting and on to meet another group of
11 people but I'm glad to see most of you who were here
12 yesterday. And I imagine the new members probably
13 feel the same way as I do, as far as the challenges
14 that are in front of us.

15 With the challenges that we will be dealing
16 with, I think that we can learn together as well as
17 from each other and get onto the business of
18 protecting public health.

19 The Committee's role in FSIS, in FSIS'
20 decision-making process is critical relative to
21 issues concerning state and federal programs, with
22 respect to meet and poultry inspection and other

1 important matters.

2 I also serve, as Dr. Raymond mentioned, the
3 Committee Co-Chair person. So I can assure that
4 we're going to spend our valuable time and energy on
5 substantive issues.

6 This Committee has been an excellent or has
7 an excellent diversity of backgrounds as we all just
8 heard and experience which will be valuable to our
9 decision-making process.

10 Today's meeting, we will deal with policy
11 decisions that must be based on science and our
12 science is only as good as the data which we have
13 available. One of the purposes of this meeting will
14 be to find ways for FSIS to improve how we assess the
15 data that we collect. Every single piece of data
16 that is captured is important. From every single
17 task that is performed in the plants and every
18 verification activity that is recorded, we must use
19 this data to make better decisions.

20 My goal is to use this data to help shape
21 how FSIS makes decisions in the future and be
22 proactive rather than reactive.

1 I want to thank all the members of the
2 Committee for being here today and I certainly
3 encourage an open dialogue and an open exchange of
4 ideas because that's what's going to make this
5 Committee successful.

6 With that, Robert, your turn.

7 MR. TYNAN: Thank you, Mr. Almanza. What I
8 want to do now is take just a second to go through
9 the agenda to talk a little bit about what we're
10 going to be doing today and for tomorrow morning. I
11 also have some rules of order, the rules that we put
12 in place I think maybe four or five years ago, and I
13 think those returning members are familiar with them.
14 For the new members, we'll just walk through them and
15 they're how we conduct the meetings, and they help
16 organize and keep us on track.

17 The agenda for this morning I think
18 everyone should have in their notebooks or at least I
19 hope everyone has a notebook in front of them. In
20 the front flap, we have the agenda and, of course,
21 we've done the welcoming remarks and opening remarks
22 by Mr. Almanza, and it's my turn to do charge for the

1 Committee.

2 After we finish with that particular
3 component, we'll talk a little bit about some
4 briefing papers. There are actually four that should
5 be in your book. I think three of them were perhaps
6 e-mailed to you, and what we normally do with
7 briefing papers, unlike in the past when Mrs. Foreman
8 was here originally on the Committee, I think we did
9 a presentation on each of the briefing papers, and we
10 thought we would be better served by devoting our
11 time on the major issues for the meeting.

12 So what we've done is we've provided you
13 with the briefing papers. If there are any questions
14 from the Committee about a specific briefing paper,
15 we have people in the audience that can come up and
16 perhaps respond to those specific questions. And if
17 for whatever reason, we don't have somebody that can
18 respond to that question, we'll get you an answer
19 after the meeting and send you an e-mail with a
20 response.

21 So the briefing papers are a fairly
22 straightforward part of the meeting. So if you read

1 -- if you have some questions, we'll try and respond.
2 if not, then we move onto the issues of the day.

3 The first issue that we're going to talk
4 about this morning as Dr. Raymond mentioned, we're
5 focusing on data and data collection. I think that
6 came up at our public meeting yesterday, and I think
7 it was a good segue, a good beginning to start our
8 meeting today. And the first issue we're going to
9 talk about is data collection analysis at FSIS, and
10 for our standard operating procedures. And
11 Dr. Maczka who is the Assistant Administrator for our
12 Office of Food Defense and Emergency Response is
13 going to come up and just give a very brief overview
14 and introductory piece, and then she's going to turn
15 it over to Dr. Isabel Walls to talk a little bit
16 about standard operating procedures.

17 What's going to distinguish this particular
18 issue from the other two that we're going to deal
19 with today is we're going to deal with this in the
20 plenary session. So there are some questions on the
21 issue paper that is in your notebook. I believe that
22 should be Tab 9. Yeah, Tab 9. And we're going to

1 deal with the questions that are on that issue paper
2 as part of the plenary session. So one of our staff
3 folks, I think Dr. Catlin, is going to take some
4 notes, and then perhaps tomorrow morning, we'll
5 capture those notes, talk about them a little bit
6 again, and see what recommendations the Committee has
7 as a whole and those will become the recommendations
8 of record.

9 We have a break scheduled for 10:15. I may
10 change that a little bit. We're having, as you can
11 see, we're just having a little bit of difficulty
12 with the projection screen, and so we may take a
13 break early to allow us an opportunity to do that
14 first.

15 The second discussion we will have -- we'll
16 have lunch at 12:00. That's an important thing for
17 anybody that goes to these meetings. You always like
18 to know when you're going to have lunch and breaks.
19 And at 1:15, we're going to talk a little bit about
20 another issue called linking FSIS activities to its
21 public health goals, and that will be Dr. Catlin who
22 is going to present that. And then we'll have a

1 second issue at 2:00, regarding a pilot project and
2 this was I think discussed a little bit yesterday at
3 our public meeting, and again this will be a little
4 bit more in depth exploration of that particular
5 topic. Ms. Kim Green will be doing that, and she is
6 also with the Office of Food Defense and Emergency
7 Response.

8 If you see a theme here, you'll notice that
9 all of the people are in the Office of Food Defense
10 and Emergency Response. So we made Carol's staff do
11 an awful lot of work this time.

12 But we'll talk about those two issues in
13 sort of a presentation format here. We'll allow a
14 few questions to clarify things, a little bit of
15 discussion and then what we'll do at 2:45 is allow
16 for some public comment from the audience, and then
17 we're going to break into Subcommittees, and if you
18 look in your book, the Subcommittee membership is
19 under Tab 3. We did this based on your background
20 and experience. We asked Mr. Schad and Mr. Elfering
21 to chair those two Subcommittees, and they'll be
22 dealing with -- each of those Subcommittees will be

1 dealing with the issue of linking activities and the
2 pilot project. So each Subcommittee will have one of
3 those topics, and then that will end our day. So you
4 all will have your Subcommittee session for as long
5 as it takes to respond to the questions that are in
6 those issue papers and develop some recommendations
7 in a report. So that will conclude our day.

8 So once we break up here as part of the
9 formal session, you'll go to breakout rooms, I think
10 one of them will be here, and I'm not exactly sure
11 where the other is. We'll find that out for you
12 before we get to that particular point. And we'll
13 talk a little bit about how the Subcommittee
14 deliberations go in just a moment.

15 So that will conclude your day. I'm
16 assuming that by 3:30, 4:00, 4:30, whatever time it
17 takes, that you'll have sort of a report fashion.

18 And how we'll do tomorrow on Thursday
19 morning, we're beginning at 8:30, and we can either
20 begin the session at 8:30 or if the Subcommittees
21 need a little additional time to work on their
22 reports, to smooth them out, maybe to get complete

1 agreement by everybody that is on the Subcommittee,
2 we'll allow you a little bit of time to do that first
3 thing tomorrow morning.

4 And then hopefully Mr. Almanza will give
5 just a short recap and introduction for Thursday, for
6 what we did on Wednesday, and then we'll get into
7 reports from the Subcommittee sessions. What is not
8 on the agenda and what I think we'll do tomorrow is
9 the notes that Dr. Catlin takes in our plenary
10 session, our larger discussion, I think we'll have a
11 little bit of a discussion about that as well. So
12 we'll actually be doing three reports tomorrow. The
13 one that represents our plenary session topic today
14 and the two Subcommittees.

15 So is everybody clear on the process?

16 Now tomorrow, when we do our Subcommittee
17 sessions, there is, there is our belief and desire
18 that we will have some agreement from everybody on
19 the Committee with regard to how the reports go. So
20 when each Subcommittee does their report out, we're
21 going to allow the entire Committee to have an
22 opportunity to weigh in, ask questions, make comments

1 and modify the report as the Committee as a whole
2 sees fit, and at that point, once we have general
3 agreement, we'll take a vote. If everybody's in
4 agreement, then that will become the formal report
5 from the Committee to the Agency and based on that,
6 we'll begin to consider how we can utilize those
7 recommendations in going forward with our
8 policymaking process.

9 Hopefully that will take us until about
10 11:00 tomorrow. We'll have a public comment period
11 and a wrap up and should be done by noontime, so that
12 all of you can catch flights and get back to the
13 things that people actually pay you for.

14 So with that, before I go onto the next --
15 sort of the next step, are there questions from the
16 Committee, and I certainly welcome to have questions.
17 I know this is -- for some of the veterans, it's not
18 so new. For some of the newer folks, it's a process.
19 Yes, Ms. Foreman.

20 MS. TUCKER FOREMAN: Can you tell me when
21 we will have an opportunity if we have questions
22 about the briefing papers?

1 MR. TYNAN: We will do that this morning.

2 MS. TUCKER FOREMAN: We will do that this
3 morning, and it will be probably about 9:15, 9:30.

4 MR. TYNAN: Okay. So that's generally the agenda.
5 And anytime if you have questions about it, you can -
6 - you can ask the question at the time you think of
7 it, or perhaps catch me on a break, and we'll try and
8 clarify it for you.

9 So that's generally what we're going to do.
10 Presentations today, an opportunity to go to a
11 workgroup, report outs tomorrow, and we're done.
12 Okay.

13 And with that, I'd like to ask you to maybe
14 slip over to Tab 4, and we have some meeting rules,
15 as I said, we put in place sometime ago, and
16 characteristically I go through the meetings --
17 through what has affectionately been called Robert's
18 Rules. And at one of the meetings I said I think
19 everybody knows the rules. So we're not going to go
20 through them, and Dr. Masters proceeded to say, no,
21 we're going through the rules. So I will not skip
22 over them today.

1 Let's take just a moment to go through the
2 rules. Basically Mr. Almanza, as Dr. Raymond pointed
3 out, is the Chair of the Committee, and so he
4 conducts the meetings, opens the meetings, recognizes
5 people that want to speak, may impose some time
6 limits and so on.

7 Normally, the Administrator, and I'm hoping
8 that Mr. Almanza will do the same, will delegate that
9 role to me, and I will try and manage the goings and
10 comings of the meeting, and that will allow
11 Mr. Almanza to focus on your comments and he doesn't
12 have to deal with the logistical issues. So it seems
13 to work out and I'm assuming -- I don't see him
14 shaking his head no. So I'm assuming that he's going
15 to delegate that to me again.

16 All questions, requests to speak are going
17 to be addressed to the Chair. People must be
18 recognized by the Chair before speaking. And
19 normally that sounds very formal. It's a pretty
20 informal kind of process, and what we'd ask you to
21 do, everyone has tent cards in front of them,
22 whenever you have a question regarding an issue or a

1 comment that you'd like to make, we'd ask you to
2 simply stand your tent card up on its end and so it's
3 vertical as opposed to horizontal, and we'll find
4 some equitable way of going around the room and
5 making sure that everybody gets an opportunity to ask
6 their question. So it's pretty simple,
7 straightforward.

8 The presentations and issue papers are
9 going to be followed by short question and answer
10 periods. In the interest of time, we'd like the
11 questions and comments to be limited, not that we
12 want to discourage you from saying what you need to
13 say but obviously we do have some time constraints.
14 So we want to be sure we get through the agenda and
15 so we'll ask you to be brief and try and get issues
16 and clarifying and limit your comments during the
17 presentation period.

18 Speeches or statements of opinion, longer
19 comments that you all would like to make, we'd ask
20 that you hold those perhaps until the public comment
21 period. Committee members, the public will be
22 recognized by the chair during the public comment

1 period, and Sheila asked me, Sheila Johnson and Sally
2 Fernandez are two of the folks that are helping
3 organize the meeting, and they've done a very, very
4 nice job. They asked me to ask you if you have a
5 comment that you would like to make during the public
6 comment period, if you could register at the desk,
7 sort of sign in, that will help us with the
8 transcriber who probably will have a little bit of
9 difficulty recognizing names and getting them all
10 spelled correctly for purposes of the transcript, but
11 it will assure that we acknowledge your interest in
12 making a comment and we get that done for you. So as
13 I say, Sally and Sheila have a sign-up sheet outside.
14 So if you could do that for me on a break or at
15 lunchtime.

16 The Chair approves in advance any materials
17 that are going to be distributed by the Agency. We
18 have had at times groups that come in and they
19 participate in the meeting and they leave their
20 materials on our tables outside. Normally we like to
21 know what's being put there because we want people to
22 know that things either are or are not associated

1 with our meeting. So if you have any materials you
2 want to leave for whatever reason, if you could check
3 with me, and Mr. Almanza and I will have a
4 conversation about whether or not we'll have that on
5 our table outside for distribution.

6 Number six, and this is a fairly important
7 one for purposes, since the substance of our meeting
8 has a lot to do with your Subcommittee deliberations.
9 We ask that members come to the plenary session and
10 that they attend the Subcommittee sessions and it
11 says the evening Subcommittee session, and I think
12 for the old timers, you remember at one point we were
13 doing, we were all day with the briefings and
14 everything, and you were winding up working in some
15 cases well into the evening. Because we've changed
16 the briefing paper, that's allowed a little bit more
17 time. But what we're essentially saying in this rule
18 is the Committee meetings, you're expected to attend
19 the plenary session as well as the Subcommittee
20 meeting you're assigned to. If you decide for
21 whatever reason not to do that, we are going to limit
22 your participation in the plenary session and

1 discussion of that Subcommittee. So you have an
2 opportunity to participate in the Subcommittee. If
3 you don't go to the Subcommittee and participate in
4 the deliberations there, you can't come back and
5 disagree with your Subcommittee that you were
6 originally assigned to. You have to get it out of
7 the way during the Subcommittee session. That's
8 essentially it. For the purposes of making sure we
9 get all the comments at the right time, that everyone
10 is treated fairly, we get everything done the way it
11 needs to be done.

12 Number seven, we have a Subcommittee Chair.
13 You'll notice on the listing of the Subcommittees we
14 have a person designated as a Chair and that Chair
15 has a lot of latitude in how their Subcommittee
16 sessions are handled. The Subcommittee sessions,
17 just as the plenary session here, they're open to the
18 public. We invite the public to participate in the
19 Subcommittee sessions. They're there primarily to
20 listen. If, however, you have questions and comments
21 and the Chairperson of that Subcommittee opts to
22 allow you to participate in the session, we're

1 perfectly happy to have you do that. However, at the
2 end of the day, the Subcommittee reports are
3 representative of the National Advisory Committee on
4 Meat and Poultry Inspection. So we consider them
5 that. So regardless of how much input the public has
6 into the Subcommittee deliberations, the ultimate
7 report represents the thinking of the National
8 Advisory Committee as far as the Agency is concerned.
9 But again, the Chair people have latitude how they
10 want to decide how to do that.

11 And then the rules of order, they're
12 subject to review at any of the meetings. So if
13 there are things we need to add, things we need to
14 modify, we'll certainly entertain that. We may not
15 do that as part of our session, but if you have some
16 comments or concerns about any of the rules that we
17 have or we need more, we haven't up to this point,
18 but if we need more, I'll be pleased to talk with you
19 about how we might do that.

20 So that's basically the agenda, and the
21 rules of order. So any questions up to this point?

22 (No response.)

1 MR. TYNAN: Okay. And again, anytime
2 please don't hesitate to ask.

3 I wanted to mention to you as well, that I
4 had sort of on my agenda, it's not on yours, that
5 we're going to do a couple of minutes of providing
6 some certificates to new members of the Committee.
7 We have some certificates signed by the Secretary.
8 He is the one that charters the Committee and decides
9 how the Committee operates. So he signs some
10 certificates and some appointment letters. We have
11 those here for you. What we're going to do -- I was
12 going to do it now, but didn't realize that
13 Dr. Raymond's schedule was going to be a conflict.
14 So what we may do is sometime later on this
15 afternoon, perhaps at 1:00, after lunch, we'll try
16 and do that so you get an opportunity to get your
17 certificate. We'll take some pictures and the usual
18 nice things that happen. They don't help the
19 substance of the meeting, but they're a nice thing
20 for you because it is a very important Committee, and
21 as Dr. Raymond pointed out, it's a much more diverse
22 Committee and the issues that we're bringing to the

1 Committee are much more complex than they have been
2 in the past.

3 And with that, I'm going to start into sort
4 of the first area, substantive area on the agenda,
5 and it has to do with the briefing papers. There are
6 four, and the first one is under Tab 5, and it has to
7 do with an Update on State Reviews.

8 And again, if you have for whatever reason,
9 I think we got the briefing papers to you perhaps a
10 little bit later than the issue papers, but if there
11 are some questions, and we can't answer them for you
12 today, we'd be glad to field the questions and we'll
13 get them taken care of for you.

14 So the first one is Update on State
15 Reviews. Mrs. Foreman.

16 MS. TUCKER FOREMAN: Who's handling this
17 one?

18 MR. TYNAN: Well, let's find out.
19 Mr. Fayne, if you could -- there's a microphone here,
20 if you'd like to sit up at my chair, that will be
21 fine, and then you'll have a microphone available.
22 And, Vince, if I could ask you to introduce yourself

1 and let everybody know who you are and where you're
2 from, and what organization as opposed to -- or
3 someplace like that.

4 MR. FAYNE: Hello. My name is Vincent
5 Fayne. I'm the Director of the Internal Control
6 Staff. It's a part of the OPEER. I have
7 responsibility for the Federal/State Audit Branch.

8 MR. TYNAN: Okay. Thank you. Ms. Foreman,
9 if you have a question.

10 MS. TUCKER FOREMAN: Good morning. Thank
11 you. It would help incidentally if we could get
12 these reviews in advance because it leaves me
13 shoveling through papers --

14 MR. TYNAN: Yes, ma'am, and I apologize for
15 that. I seem to do that at every meeting, and as
16 hard as I try, I'd like to think I'm organized but it
17 sometimes doesn't work out the way I want it. So in
18 this particular case, they are late. I apologize for
19 that. We each time try to do better in getting them
20 out. We target for two weeks. Obviously two hours
21 or two days is not satisfactory, and we'll do better
22 on that.

1 MS. TUCKER FOREMAN: My questions will be
2 perhaps not very well organized since I didn't have
3 access, but I'm particularly interested in the
4 Agency's response to the Office of Inspector General
5 Audit Report that was dated September 2006. In it
6 OIG makes a number of recommendations to the Agency
7 and I believe that you had reached management
8 agreement on all of the issues that were raised. But
9 there are a number of actions that FSIS committed to
10 taking with specific dates attached to them, and in
11 order to avoid walking through each of those, have
12 you met all those dates for completing the work to
13 where you made a commitment to OIG?

14 MR. FAYNE: That's my understanding that --
15 yes, we have.

16 MS. TUCKER FOREMAN: Okay. Particularly on
17 recommendation 8, I sense that there was some
18 disagreement that was not resolved between the
19 Committee and OIG. This was the recommendation that
20 said the Agency should develop and implement
21 procedures to verify the laboratories conducting
22 analyses for State MPI programs provide accurate,

1 reliable and reproducible results. The Agency said
2 you'd like to do that, but current state laws don't
3 provide I assume the funding for that in some cases.
4 And OIG's response was that it was really essential
5 that you have a method to insure that the
6 laboratories used by the states were, in fact, equal
7 to those in the federal system or you couldn't assure
8 that the programs were equal to. I don't --

9 MR. TYNAN: Excuse me. Mrs. Foreman, may I
10 interrupt? Is that on the issue paper? I'm kind of
11 glancing at it. I'm not sure where --

12 MS. TUCKER FOREMAN: Well, the issue paper
13 is your implementation of state programs. It seems
14 to me that whether or not you have complied with all
15 the agreements you made and all the recommendations
16 from the Office of Inspector General is an important
17 element of whether or not you have -- what's
18 happening in this program.

19 MR. TYNAN: No, ma'am, I don't question
20 that. I don't question that at all. I just -- the
21 other members of the Committee may not be looking at
22 what you're looking at. Is it in the issue paper?

1 MS. TUCKER FOREMAN: They are not because
2 it's in the -- you did not provide us with the copy
3 of OIG's Audit Report.

4 MR. TYNAN: That's true.

5 MS. TUCKER FOREMAN: In fact, it might be
6 easiest if we could get for the Committee a list of
7 all the recommendations that OIG made in that report
8 because they're really very important, and then maybe
9 we could have five minutes or so to discuss it
10 tomorrow.

11 MR. TYNAN: I'll look into that,
12 Mrs. Foreman.

13 MS. TUCKER FOREMAN: Okay. And then I
14 wouldn't take any more time today going over the
15 specifics, except with regard to one issue and it may
16 fall into the legislative area. The Congress -- the
17 House has passed legislation that would allow state
18 inspected plants with up to 50 employees to switch
19 from federal inspection to state inspection, and at
20 the end of any four year period to switch back to
21 federal and then four years later switch back to
22 state.

1 According to numbers I got from the Agency,
2 that makes 80 percent of the plants, if you consider
3 only size, eligible to switch from federal to state
4 inspection, and not all of those plants are in states
5 with state programs, but I want to know if the Agency
6 is prepared to have a substantial exodus from federal
7 inspection over to state programs, and if anything's
8 being done to set up a system to deal with that.

9 MR. FAYNE: Are you referring to the House
10 legislation?

11 MS. TUCKER FOREMAN: Yes.

12 MR. QUICK: Yes. I know that the Agency --
13 I'll go ahead and take a stab at that. I know the
14 Administration hasn't taken a position on that but
15 the Agency has been asked to assess the impact of
16 both the Senate and the House language on our
17 operations and how many plants would come over is one
18 of the key elements of that analysis. We haven't
19 completed that yet but we have expressed some concern
20 to the authors of the language as to the impact that
21 would have on particularly recalls, the public health
22 impact that would have on recalls. But the number of

1 plants coming over and how fast that would happen is
2 certainly one of our considerations. But we haven't
3 completed that task as of today.

4 MS. TUCKER FOREMAN: The House has already
5 passed the legislation which I think means that the
6 battle is half over. It's probably time that
7 somebody --

8 MR. QUICK: We are taking it very
9 seriously, and -- but it's something that -- it's not
10 going to happen overnight, but our analysis is going
11 on as we speak.

12 MR. TUCKER FOREMAN: Well, I would say to
13 all the members of the Committee, that it is a very
14 serious issue if suddenly well over 4,000 of the
15 5,603 plants on the PBIS system were eligible to move
16 from federal inspection to state inspection, and then
17 move back four years later, I think, I think it would
18 be a chaotic process and I really believe that it is
19 the string that would unravel federal inspection. I
20 don't think you can have that back and forth.

21 If we could get the copy of the
22 recommendations from the OIG report, and maybe have a

1 little discussion tomorrow, I'd be happy not to take
2 any more time with this now. Thank you.

3 MR. FAYNE: Well, first of all, thanks for
4 the questions. I'm not really prepared to answer the
5 detailed questions of the OIG Report, but we can
6 certainly get you the answers.

7 With regards to the laboratories that you
8 mentioned, each of the states that we've looked at,
9 you know, their laboratories in the state, we found
10 the information that the states were getting to have
11 quality information and defensible for enforcement
12 purposes. So if you will, all of those met our at
13 least equal to standard.

14 I guess I'll just come back with the OIG,
15 and the concern I think with the OIG and our ability
16 to assess laboratory performance, the Agency's
17 ability again, that's something that we're working
18 with our management, developing procedures and
19 protocols to get the necessary assurances that the
20 data is quality data, that it is something that is
21 legally -- that can stand legal scrutiny.

22 MS. TUCKER FOREMAN: One other point on

1 that. Thank you. It's really very disturbing that
2 according to OIG the Agency initially found four of
3 the eight states that it reviewed in the first
4 comprehensive reviews in the first year, to actually
5 not be equal to, and you had to defer action on those
6 states while the states took the actions to become
7 equal to.

8 Now that's fine for FSIS and the states,
9 but that means that in those states, there were a lot
10 of plants that were operating under your system that
11 was not equal to and that people were buying products
12 produced in plants under a system that wasn't equal
13 to, and in the plants that you visited when you did
14 on site visits to actual plants, that I believe none
15 of those in Mississippi were meeting all of their
16 HACCP and SSOP requirements. That's really -- now
17 that might pass with the Agency for being equal to,
18 but I don't think the public thinks that when a state
19 gets months and months to go back and fix the
20 deficiencies, but continues to have plants operating
21 under the state inspection system, I don't think the
22 public would think of that as a system that's

1 operating as was intended.

2 I don't know how to suggest that this
3 notion of you get forever to come into compliance
4 lines up with the responsibility to protect public
5 health.

6 MR. FAYNE: I would just say that we are
7 improving our process. We're certainly trying to
8 make the manual and the protocols that we use to be
9 very transparent and clear to the states. I guess I
10 would just say for those four states, they were not
11 equal to, but we defer a determination. There were
12 some problems but we are -- about being balanced.
13 There were some problems that needed to be corrected
14 and we were working with the states to do that.

15 The timeframe for, you know, making that
16 happen, it varies with the circumstances, but I do
17 agree with what you're saying in terms of working to
18 make sure that we can make that determination as soon
19 as possible.

20 MS. TUCKER FOREMAN: Thank you.

21 MR. TYNAN: Dr. Henry.

22 DR. HENRY: I think Ms. Foreman brings up a

1 good question. However, to go a little further, the
2 question I have, were any of the establishments
3 inspected either by state or federal employees,
4 whichever category they were in, were any of them
5 found to be deficient such with the inspection was
6 withdrawn by the state? Was there ever identified to
7 be a public health threat from the products coming
8 from those states? Or, you know, not knowing the
9 details of the lack of equivalency, you know, we're
10 kind of talking around the subject, but did we really
11 have a concern there where inspection was pulled?
12 Thank you.

13 MR. FAYNE: Again, I don't have all the
14 details of any individual establishments like that.
15 I think that in some cases where we were on site, we
16 made sure that the -- and we found deficiencies that
17 the state personnel didn't, that they took immediate
18 action. So there was no food safety problem or
19 public health issue that didn't go -- that wasn't
20 addressed immediately once we observed it.

21 DR. HENRY: Just as follow up, did that
22 result or was that previewed by any recalls?

1 MR. FAYNE: Not to my knowledge.

2 DR. HENRY: Thank you.

3 MS. TUCKER FOREMAN: Robert, can I --

4 MR. TYNAN: I apologize.

5 MS. TUCKER FOREMAN: The OIG Report quotes
6 FSIS visits to 11 meat plants in Mississippi in
7 October 2003, and reported such things as cutting
8 boards that were heavily contaminated with meat
9 residues from the previous day's work. Some plants
10 failed to monitor cooking temperatures and several
11 other things that I think would have stopped the line
12 in any federal plant but have not stopped the line in
13 the plants in question. So I think that's a public
14 health risk and OIG was certainly concerned about it.
15 I'm concerned that the Agency's too differential to
16 not stepping on the toes of state program operators.
17 I suspect there's some people here today who disagree
18 with that.

19 With regard to no recalls occurring, I'm
20 not confident that that's because there's not a
21 problem. I'm thinking it's because nobody's checking
22 and you don't know what it is that's making people

1 sick out there. It's just part of our continuing
2 concern about state inspected.

3 MR. TYNAN: Dr. Henry, I'm going to allow
4 you to make one comment but I didn't anticipate as
5 far as the agenda was concerned, that we were going
6 to have a discussion on the briefing paper. We could
7 have done this differently had I realized that.
8 We'll talk after the break, see how we can respond to
9 your questions and perhaps spend a little bit more
10 time with it tomorrow if that's agreeable to you.

11 Dr. Henry.

12 DR. HENRY: If I may, I think that, you
13 know, going forward should any of the members of the
14 Committee have substantive information like this,
15 that they anticipate bringing to the Committee during
16 our session, getting that out well in advance of the
17 meeting would be very helpful for everyone so that we
18 have time to evaluate the background information, try
19 to reach any consensus or substantive discussion.

20 MR. TYNAN: That's fine.

21 MS. TUCKER FOREMAN: And let me say that I
22 sure would have done that if I had had the briefing

1 paper on which my questions were based.

2 MR. TYNAN: What I was going to say,
3 Dr. Henry, it was partially our fault. I think if we
4 had recognized, I think Mrs. Foreman probably would
5 have called to our attention that there needs to be a
6 little bit more substantive discussion about. So
7 that's partially our fault. We'll try and correct
8 that for the morning, and see if we can't deal with
9 the issue then.

10 Under Tab 6, we have an update on the
11 National Advisory Committee on Microbiological
12 Criteria for Foods. Thank you, Mr. Fayne. That's
13 Tab 6.

14 Again, this briefing paper is just an
15 update on where the Committee is.

16 If we can at this point, given the fact
17 that -- if there's no questions that come to mind
18 immediately, given the length of time you've had, why
19 don't I give you an opportunity to review the papers
20 perhaps sometime during the day and maybe we can
21 review the issue tomorrow if there are any questions
22 then. And as I say, even after the meeting, if

1 you're looking at the briefing paper and you have
2 questions, you can certainly send me an e-mail,
3 Dr. Cannon, you can send her an e-mail, and we'll try
4 to get a response to those questions for you. So
5 please don't feel obligated to try and review it and
6 have some kind of a substantive question at this
7 point.

8 (Pause.)

9 MR. TYNAN: I'm sorry. Mr. Covington, I
10 apologize.

11 MR. COVINGTON: Just a quick question on
12 these Subcommittees that are still working. Is there
13 any timeframe on a report coming from those
14 committees, in particular the committee to look at
15 technologies going into the future for micro testing
16 and the other Subcommittees that are still
17 deliberating?

18 MR. TYNAN: Okay. Just a minute, Brian.
19 Faye, would you like to come up. And if you would
20 introduce yourself and your affiliation.

21 DR. BRESLER: Hi. I'm Dr. Faye Bresler,
22 and I'm a Technical Assistant with NACMCF. And in

1 regard to the Subcommittee that is looking at
2 technologies going into the future, they're meeting
3 for the first time actually yesterday, today,
4 tomorrow. So they're simply at this time reviewing
5 the charge itself and determining how to go forward
6 and we do not yet have a timeframe.

7 MR. TYNAN: Other questions on NACMCF?
8 Mr. Schad, you're up and you're down. Come up. You
9 have a question.

10 MR. SCHAD: I have a question on another
11 issue.

12 MR. TYNAN: Okay. That's fine. Are there
13 others on the Microbiological Committee?

14 (No response.)

15 MR. TYNAN: Okay. Thank you, Faye, very
16 much.

17 Okay. There's also under Tab 7, we have a
18 briefing paper regarding an update on our small and
19 very small plants, and I can see Mr. Schad is
20 prepared. I have Dr. Kelly in the audience, and I
21 think she's probably the resident expert on that.

22 MR. SCHAD: Yeah, this is Mark Schad. Just

1 a question regarding the application for federal
2 inspection. I'm reading here a start up package. Is
3 that in addition to what's on the FSIS website?

4 DR. KELLY: It is on the FSIS website, the
5 entire package.

6 MR. SCHAD: I tell you the reason I'm
7 asking the question is some very small operations
8 that I converse with that are thinking about applying
9 for federal inspection or applying for federal
10 inspection, those of us who have gone through the
11 process, of course, are familiar with it. Going
12 through it for the first time, not sure what the rule
13 is of the frontline supervisor, the EIAO and the IIC
14 particularly when it comes to writing your HACCP
15 plans. They might get three different opinions on
16 their HACCP plan, you know, who decides if the
17 facility is okay or not. Is the HACCP plan
18 acceptable or not, and I looked at what was on the
19 FSIS website for maybe some clarity or some
20 definition on that, and at least in my reading, I
21 didn't quite see that, and that might be helpful to
22 plant owners that are applying for federal

1 inspection.

2 DR. KELLY: Okay. Thank you. I think we
3 can make some updates.

4 MR. ALMANZA: There's also a CD that's
5 available for the people, for the plants that don't
6 have access to a computer at each of the District
7 Offices. I know we got something like 15 copies to
8 send out to plants that didn't have the capability to
9 look at it on the website. Also when there are
10 plants or very small plants, or really it doesn't
11 matter what size plant, that want to come into
12 federal inspection. We encourage them to call the
13 District Offices and they can speak to anybody but
14 some of the EIAOs that are in the District Offices
15 are very helpful when it comes to that.

16 MR. SCHAD: So when they called the
17 District Office, they would just specifically ask for
18 this CD?

19 MR. ALMANZA: Yes, or for help.

20 MR. SCHAD: What I'm getting at, sometimes
21 they don't even know it's there. That's what I'm
22 getting at.

1 MR. ALMANZA: Yes, uh-huh.

2 MR. SCHAD: That's all I have at this time.

3 MR. TYNAN: Dr. Harris, did you have a
4 comment?

5 DR. HARRIS: I did. We really, as an
6 organization that has a lot of small members, we
7 really appreciate the Agency's efforts in outreach to
8 particularly small and very small plants. I think
9 that a lot of what's being done is extremely
10 valuable.

11 A couple of comments on them, the packet on
12 companies that are interested in coming under
13 inspection, that was a long overdue addition that is
14 definitely important. And the EIAO visits going to
15 those small plants as just an informational visit,
16 those have been very well received as well.

17 We'd like to comment though on the
18 regulatory education sessions and absolutely support
19 the idea of doing those and have attended some of
20 them. I think they're good. However, just in my
21 experience in attending them and hearing from members
22 that attended them, what seems to be happening is

1 it's a little bit of -- the ones that show up for it
2 are the ones that already know the information, and
3 they seem to be going there with specific compliance
4 related questions that the presenters are not
5 prepared to answer in many cases. So I just kind of
6 wanted to point out that that has sort of been a
7 little bit of a sticky spot at those meetings is
8 that, you know, those guys really need to know what
9 the regulations say, tend to be the ones that also
10 don't take the initiative to show up for that kind of
11 a meeting. And so we wind up with presentations that
12 say here's what the regulations say about HACCP and
13 SSOPs and everybody in the audience says, well, yeah,
14 we know what they say. We've got compliance
15 questions. So I just wanted to throw that out as a
16 comment, that that's an observation that we've had
17 and maybe those can be tweaked a little bit to
18 incorporate some of that.

19 DR. KELLY: Thank you very much for that
20 comment. We've also heard that we start it at a very
21 basic level, and I think that's part of what is
22 reflected in your input. We are moving gradually

1 forward to having sessions that are more tailored to
2 the needs of the specific group. For example, this
3 summer we're having some Netcast that are
4 specifically on compliance guidelines, and hopefully
5 that will do a better job at getting more specific
6 information out to people with compliance questions.
7 We're making them educational in nature, in that it's
8 not just an Agency delivered message. We get
9 somebody with some expertise, scientific expertise in
10 the field say for our *Listeria* compliance guidelines
11 and *Listeria* control, who know the research applied
12 to small plants. And then we have some Agency
13 experts available to answer questions. So we
14 appreciate that and will appreciate ongoing input on
15 how we can improve as we go. Thanks.

16 MR. TYNAN: Mr. Elfering?

17 MR. ELFERING: With the recent designation
18 in New Mexico, are you planning to have any
19 additional type of outreach to those plants that will
20 very likely be coming in under federal inspection?
21 And the reason I ask is we just held a HACCP workshop
22 down in Las Cruces and unfortunately the timing

1 didn't -- a lot of those plants didn't -- there
2 weren't a lot of meat and poultry plants attending.
3 We had wonderful attendance but not by meat and
4 poultry plants. And I think it would be of benefit
5 to those plants there were previously operating under
6 state inspection to at least have some additional
7 opportunities or contacts so that that transition to
8 federal inspection goes smoothly. And more of a
9 suggestion, maybe you're already planning something
10 like that.

11 DR. KELLY: We don't have anything that's
12 on the schedule immediately, but we're definitely
13 willing to work with you on that, and we would be
14 willing to work with others that have an interest
15 like that. Thank you.

16 MR. TYNAN: Down to the end of the table to
17 Dr. Henry.

18 DR. HENRY: Thank you, Robert. I have
19 three questions. On page 2, the top bullet that
20 characterizes CSREES to conduct a study on the
21 training of the needs of those plants, do we know
22 what the status of that is at this stage?

1 DR. KELLY: I believe I see Dr. Cutter may
2 actually give us some information on that. Thank
3 you.

4 DR. CUTTER: Yes. We just had a conference
5 call on Friday. The project right now, we have
6 queried the Extension educators and consultants who
7 are doing training with the small plants. We are now
8 in the phase of fine-tuning the questionnaire that
9 we're going to be sending out to the plants for their
10 feedback on their training needs. Once we have that
11 completed, we're planning a meeting in spring of
12 2008 to bring FSIS educators, industry, altogether to
13 discuss how we go with the information that we
14 collected, and where we go for developing the
15 training materials and reaching out to the plants
16 with regard to that. And I'm collaborating with
17 Diane Hersh at University of Connecticut on this
18 particular projects, and I'm a co-PI on it. So
19 that's why I have knowledge of this.

20 DR. HENRY: Great. Question 2, the next
21 two bullets, it speaks with an action plan to improve
22 services to these plants as well as what the

1 International HACCP Alliance technical resources
2 brought to them. How are we measuring the
3 effectiveness of those efforts?

4 DR. KELLY: I would say since we're just
5 about a year into this process, our measurement of
6 effectiveness is in its infancy. Some of our
7 measures of effectiveness are as simple as asking
8 participants if they learned things, if their needs
9 were met, if they would recommend some of these
10 things to other people. I know that probably a
11 better measure of effectiveness would be something
12 like have you made changes in your program as a
13 result of attending this program? So we're looking
14 at that as our next step in terms of our measures of
15 effectiveness.

16 DR. HENRY: I was also thinking that
17 whether we saw any difference in regulatory action,
18 NRs or anything else, that might be tied back to the
19 plant's food safety system or program might also be
20 measured?

21 DR. KELLY: I know that we do have a group
22 that has plans to look at that. However, I think at

1 least initially up to this point, we felt like our
2 efforts were sub-preliminary, that it was a little
3 bit too early to take a look at that, but we do have
4 some plans to do that.

5 DR. HENRY: Okay. My last question is
6 relative to the food defense plan guidance that was
7 supplied, is FSIS seeing more food defense plans
8 implemented at these plants?

9 DR. KELLY: I wish I knew the answer to
10 that question. It looks like Carol knows the answer.
11 Thank you.

12 DR. MACZKA: Right now it's about the same
13 percentage, about 30 percent, but we're in the
14 process of analyzing some recent data. So we'll have
15 some more information in the near future, like within
16 weeks.

17 DR. KELLY: And I do know we are expanding
18 in terms of reaching out to provide that kind of
19 information in the guidelines to a broader audience.
20 So --

21 DR. HENRY: I think that's great. Thank
22 you very much.

1 MR. TYNAN: Just as a reminder for purposes
2 of our good and very diligent transcriber, it would
3 be nice if we identified ourselves so that he can
4 make sure he credits the comments to the right
5 person. So with that, I'll turn back over. Are
6 there other questions for Dr. Kelly?

7 (No response.)

8 MR. TYNAN: All right. There being none,
9 Karlease, thank you very much.

10 And last but not least under Tab 8, we have
11 our Legislative Update, and I have Mr. Chris Gould
12 from our Congressional Public Affairs Office that can
13 answer some questions. Is that a holdover from the
14 last one? A new one. Okay. Come on up, Chris.

15 MR. ELFERING: This is Kevin Elfering. I
16 have a question on horse slaughter. Do you have any
17 feel on how that's going to go? And does the Agency
18 have a position on this? And my concern is that
19 horse slaughter has been a very efficient way of
20 humanely euthanizing horses, and believe it or not,
21 there's a lot of horse lovers out there that are
22 really upset that this is a method for them to be

1 able to humanely dispose of their companion animal.
2 And I'm just wondering if the Agency has a position
3 on horse slaughter. I know it's in the House version
4 but not in the Senate, and where do you think that's
5 going to come together?

6 MR. QUICK: We did oppose earlier efforts,
7 other legislative efforts that passed the House.
8 It's kind of a work in progress. We're trying to
9 figure out how we will comply with the most recent
10 suggested legislation. I really don't have an answer
11 for you. We will just have to continue to assess the
12 impact that's having outside of Washington. That's
13 not a very good answer but --

14 MR. ELFERING: No, I understand.

15 MR. QUICK: We have been consistently
16 opposed to the legislative efforts to do away with
17 horse slaughter. I know that that has -- I'm pretty
18 sure that that has been the Administration's position
19 until the past three years.

20 MR. ELFERING: Well, it's a very passionate
21 issue.

22 MR. QUICK: It really is.

1 MR. ELFERING: And has APHIS weighed in on
2 this at all?

3 MR. QUICK: They have. I mean this has
4 been a Department-wide deliberation, and the impacts
5 are still coming forward. We haven't anticipated
6 that the opponents and those that are supportive of
7 that legislation have not taken into consideration.
8 So I hope that helps but it's kind of an ongoing
9 process, the assessment of the impacts of this
10 legislation and future legislation. It's far bigger
11 than just FSIS.

12 MR. TYNAN: Other questions on legislative
13 update? Dr. Harris.

14 DR. HARRIS: Joe Harris. One of the issues
15 that is not covered in our paper here that is
16 probably pertinent to a lot of discussion that's
17 already happened this morning, is the status of the
18 interstate shipment bills that were introduced.

19 MR. GOULD: Right. It is briefly mentioned
20 in the description of the Farm Bill. We didn't get
21 into a lot of detail on it. I think a lot of the
22 earlier discussion between Carol and Bryce probably

1 covered that, and I'll just leave it at that.

2 MR. BRYCE: I think you've watched pretty
3 closely the debate on interstate shipment. The most
4 recent piece of legislation that our office reviewed,
5 it's all basically in the packaging of that
6 legislation, and the words -- the current, in the
7 House version, it centers around identical, and it
8 requires states to be identical. The latest that
9 we've seen out of the Senate is requiring them,
10 what's the exact, it's a new terminology to be at
11 least -- we'd have to get that for you but it's -- I
12 know that NASDA organization, the State Departments
13 of Agriculture opposed the House version that was
14 passed, and I believe that they may be supportive of
15 the Senate version, that I think it's Senator Harkin
16 is sponsoring that legislation, and it's kind of a
17 take on identical but not quite identical. So stay
18 tuned. I mean it's something that will probably be
19 with us, this debate, for the next six months, unless
20 the Farm Bill miraculously moves at a faster pace
21 than it is now.

22 MR. TYNAN: Mrs. Foreman.

1 MS. TUCKER FOREMAN: December 22nd.

2 MR. BRYCE: You think that's when it's
3 going to pass. We have a clairvoyant in the room.

4 MS. TUCKER FOREMAN: Hello, Chris. How are
5 you?

6 MR. GOULD: Hi, how are you?

7 MS. TUCKER FOREMAN: It's my understanding
8 that there are a number of differences between the
9 Senate Bill and the House Bill including some
10 different language on those issues where I raised
11 concern about the impact on the federal inspection
12 program. If Senator Harkin has introduced his bill,
13 it might be nice if the Committee could have copies
14 of --

15 MR. GOULD: My understanding is that he has
16 not introduced it.

17 MS. TUCKER FOREMAN: Okay.

18 MR. GOULD: But it has been, and I may have
19 spoken out of school. I know that we have received
20 language. I don't know that it's been introduced
21 yet. So I may have misspoken.

22 MS. TUCKER FOREMAN: I don't know either

1 because I looked this week, but there are some Senate
2 Bills that are -- one of which I think simply lifts
3 the federal ban. I think that's the whole --

4 MR. GOULD: I think there's about six of
5 them out there that are floating around.

6 MS. TUCKER FOREMAN: Since there's six,
7 it's not worth bringing copies of all of them.

8 MR. GOULD: We can get those for you
9 though.

10 MS. TUCKER FOREMAN: But it might be useful
11 if people saw what passed the House.

12 MR. GOULD: We can provide that to the
13 Committee.

14 MR. TYNAN: Other comments on the
15 Legislative Update.

16 MR. GOULD: I think for clarity sake, the
17 Committee needs to know that the Administration, as I
18 referred to before, has not taken a position. We
19 have presented our technical thoughts on the
20 legislation that Carol referenced, that passed the
21 House, and we will continue to provide comments to
22 pieces of legislation that come in. But it is on a

1 technical basis and really doesn't take a position
2 either way.

3 MR. TYNAN: Okay. That wraps up the
4 briefing paper portion of the meeting. As I
5 mentioned earlier, the briefing papers are something
6 that we normally do as a short update on things that
7 we covered at previous meetings or emerging issues.
8 Again, I apologize for not getting the material out
9 to you so that there could be a little bit more
10 substantive discussion but we will try and do that
11 definitely for the next meeting that we have.

12 And with that, it appears that our
13 technical glitch with the PowerPoints is fixed, and
14 so what I'm going to do at this particular point in
15 time is get into the substance of the matter. We're
16 going to talk about our first issue that I mentioned
17 to you earlier as we were going through the agenda.
18 We're going to discuss this as part of a plenary
19 session, and I'm going to introduce Dr. Carol Maczka
20 who is our Assistant Administrator for the Office of
21 Food Defense and Emergency Response, and Dr. Isabel
22 Walls, who is a Senior Scientist also in OFDER.

1 And with that, if no one has an objection,
2 I'm going to let Dr. Maczka and maybe Dr. Walls stay
3 where they are to do their presentations or would you
4 prefer to come up here to the --

5 DR. MACZKA: Actually I was going to say I
6 was going to do it from here.

7 MR. TYNAN: Okay. That's cool. See, I
8 read your mind.

9 DR. MACZKA: First --

10 MR. TYNAN: How would you like me to help
11 you with the PowerPoints?

12 DR. MACZKA: Well, right now I don't need
13 any because I don't have slides, and I'm going to be
14 very brief, but Isabel, you might want some
15 assistance.

16 MS. WALLS: No, I prefer to go up to the
17 podium.

18 MR. TYNAN: Okay. Cool.

19 DR. MACZKA: Okay. So just very briefly,
20 today we're going to be presenting on the collection
21 of related papers, and they are all related to data
22 issues.

1 On the first paper, Dr. Walls will be
2 presenting, and it's standard operating procedures
3 for data collection and analysis. And what this
4 paper is trying to do is establish a formalized
5 mechanism or process for data collection and
6 analysis. And at the heart of this process is the
7 development of a technical plan and a paper, and that
8 was a suggestion that we kind of jumped off on in
9 response to some stakeholder comments.

10 And what we're doing on this paper, we're
11 seeking advice on when to open the process of
12 stakeholder input and peer review. We're also
13 seeking advice on whether to form a standing
14 committee under this Committee that will deal with
15 data issues.

16 A second paper that we'll be discussing,
17 linking public health goals to FSIS activities will
18 be presented by Dr. Catlin here. And what we're
19 seeking here is advise on how to actually link our
20 activities to public health goals.

21 And the third paper will be presented by
22 Ms. Green, and what we're seeking here is to develop

1 actually a pilot, an actual pilot for using industry
2 data, and perhaps we're going to make a couple of
3 suggestions in the presentation about possible
4 pilots, which would be very useful in sort of giving
5 us some more data with respect to risk-based
6 inspection when we finally move once again in that
7 direction.

8 So I'm going to turn this over to Isabel at
9 this point.

10 DR. WALLS: Good morning, everybody. And
11 thank you for the opportunity to present this issue
12 paper to you. The issue paper we're going to be
13 talking about is a standard operating procedure for
14 data collection and analysis.

15 And what I'm going to do is just give you
16 an overview of the presentation here, the purpose of
17 the draft report, roles and responsibilities of the
18 data collection and analysis teams. This is all part
19 of the report. The process for data collection and
20 analysis at FSIS, and those of you who were here
21 yesterday, heard a little bit about this from
22 Dr. Maczka. The position of which we're going to ask

1 for stakeholder input, independent peer review, the
2 use of data in decision-making and then we're going
3 to talk about program evaluation.

4 So then the purpose of this draft document
5 is to describe a standard operating procedure for
6 data collection and analysis at FSIS, and this
7 document has been developed in response to
8 stakeholder input and stakeholder comments.

9 And at the end of this presentation, we're
10 going to ask you to address some questions. So I'm
11 going to give you the questions at the beginning so
12 you can be thinking about these as I go through my
13 presentation.

14 So first of all, we're going to ask you, do
15 you have any suggestions for improving what we're
16 telling you in this report, process for data
17 collection and analysis?

18 Do you have any suggestions for other
19 points in the process where we might want stakeholder
20 input?

21 Do you have any other suggestions for
22 conducting external, independent peer review?

1 And again as Dr. Maczka mentioned, should a
2 NACMPI form a subcommittee specifically to assist us
3 with data issues?

4 So those are the questions that we're going
5 to be asking the Committee to address and again,
6 we'll come back to them at the end of the
7 presentation.

8 Very briefly, I want to mention the roles
9 and responsibilities of the data collection and
10 analysis teams. You've heard mention that we are
11 members of the Office of Food Defense and Emergency
12 Response. That's true for myself, and the others
13 here but I'm spending about 25 percent of my time
14 right now with the Data Analysis and Integration
15 Group which is headed up by Dr. Maczka. And this
16 group was created to characterize, coordinate,
17 analyze and integrate data within and across the
18 different program areas. And it works very closely
19 with the Data Coordinating Committee, which is senior
20 Agency representatives, and the data coordinating
21 committee then serves as a liaison between the
22 various program offices, and what we call the DAIG

1 affectionately, the Data Analysis and Integration
2 Group.

3 Briefly, the roles of the Data Analysis and
4 Integration Group, to ensure data analyses are
5 relevant to the Program Office business processes and
6 the Agency's mission, ensure data analyses are
7 consistently of high quality, conduct analyses to
8 inform Agency decisions, provide automated tools to
9 facilitate data analysis and display, conduct
10 analyses to identify data gaps and needs within and
11 across Program offices, and also develop
12 sophisticated analytical models to integrate data
13 streams and identify events, trends and anomalies,
14 and ensure, of course, the analyses are consistent
15 with our policies and OMB guidelines. So quite a
16 lot.

17 Okay. Moving on then to the actual process
18 that we're presenting to you for data collection and
19 analysis, again this was developed in response to
20 stakeholder comments, and it does formalize our
21 process for data analysis, and the process involves
22 the development of a technical plan which will

1 describe the problem to be addressed, the problem
2 which requires data collection and analysis to
3 answer, the strategy for data collection and
4 analysis, results in interpretation of data analysis
5 and a technical report will be developed from this.
6 Of course, it will be built upon IT systems which
7 exist in house and currently under development, and
8 will indeed include both stakeholder input and
9 independent peer review.

10 This just demonstrates the process. You
11 can't hear me? Okay. This just illustrates the
12 process in terms of figure.

13 The starting point in the process is
14 problem definition, and you can see from this figure
15 that we do want to have stakeholder input into the
16 problem definition part of the process.

17 Having defined the problem, hopefully in
18 terms of specific questions to be addressed, we will
19 develop the technical plan and this is the role of
20 the DAIG, to develop the technical plan. Again, the
21 plan includes the details of how we go about doing
22 the data collection and analysis, and we will ask for

1 stakeholder input at this point, and we will have the
2 plan independently peer reviewed.

3 Having developed the plan, we will then go
4 ahead and collect data and perform the analyses as
5 specified in the plan, and that will also have
6 opportunity for stakeholder input, and it will be
7 peer reviewed. We will then go on to use the data
8 collected in decision-making and then we will
9 evaluate the programs or the notices or activities
10 that were implemented based on the data collection
11 perspective.

12 So I'm going to go into each of these in a
13 bit more detail now.

14 So in terms of problem definition, we
15 anticipate having all stakeholders help us to
16 determine the specific issues, which need to be
17 addressed which can be answered through data
18 collection. So we would have our policy managers,
19 data analysts and other Agency officials work
20 together to develop the problem or issue that needs
21 to be addressed. Of course, the purpose and
22 justification for data collection analysis should be

1 stated, thinking about the impact on Agency resources
2 and, of course, the timeframe that we're working
3 within, and opportunity for stakeholder input.

4 And one thing I would say here is that if
5 the issue is something which requires rapid data
6 collection and analysis, the framework we are working
7 with here is very flexible, so that we wouldn't
8 anticipate having to have, you know, many, many
9 public meetings if we need to rapidly collect data
10 and make some decisions based on that data. But if
11 we're looking at a more long-term situation, perhaps
12 developing baseline data or something which would be
13 more long term, then we could indeed do this as a
14 series of public meetings, but the framework we're
15 presenting is very flexible and would allow for
16 whatever the situation would demand.

17 The technical plan which will be developed
18 by the DAIG would include the summary of the issues
19 or questions to be addressed. It would discuss how
20 we would identify, collect and review existing data
21 because it may be that when we've looked at the
22 question, we actually already have the data to answer

1 the question, and it's recommending that we look at
2 all sources of data at this point. So this could
3 include industry data. It could include surveys
4 which have been developed on consumer attitudes. It
5 could involve expert elicitations, and one of the
6 things you're going to be asked to do later today is
7 to think about criteria for use to accept data
8 specifically for industry data. Anytime we're going
9 to be looking at data, we want to make sure that we
10 have very clear criteria to make sure that we're
11 avoiding any bias in our data sets.

12 The technical plan will also include the
13 data collections strategy and, of course, if we're
14 going to be collecting new data, if we've determined
15 that we don't have enough existing data to answer the
16 question, then we will have to collect new data and
17 if we're going to collect new data, of course, we
18 need to start with discussing it with a statistician,
19 make sure we have a statistically valid sampling
20 plan, make sure standard methodology are being used,
21 and that will all be specified in the plan, and there
22 will be opportunity for stakeholder input at this

1 point. Again, stakeholders are aware of data that
2 can be helpful to us, are aware of different
3 statistically sampling methods that might be
4 appropriate that will be an opportunity for input at
5 this point.

6 The plan will also describe the data
7 analysis methods that we're going to use, whether
8 it's probabilistic methods or standard descriptive
9 statistical inference methods. That will all be in
10 the technical plan, and again when this plan is
11 written, it will be subject to independent peer
12 review.

13 In terms of program evaluation, if you want
14 to evaluate programs, very often you need to make
15 sure that right up front you collected appropriate
16 data and you've done your study in a manner by which
17 you can indeed evaluate what you've done. So this
18 might mean, for instance, doing a pilot study where
19 you have a group that's in the treatment and a group
20 that's not in the treatment.

21 And so when we're in the planning stage,
22 we're going to be thinking about how are we going to

1 evaluate the programs that come out of this, so that
2 we build that into the planning stage and we collect
3 the right data in the planning stage. Again, there
4 is room here for both stakeholder input and peer
5 review.

6 When we go to collect and analyze the data,
7 we'll be following the methods that are described in
8 the technical plan. Of course, anytime you do this,
9 you need to consider the sources of uncertainty and
10 variability. This will be stated in the technical
11 report. We need to discuss the validity of any
12 assumptions made and again, these will be spelled out
13 in the technical report. And when you look at the
14 figure that I showed before, you'll see that the
15 arrows go both ways, because it might be that once
16 you've collected your data and you start to analyze
17 the data, you might need to go back and collect
18 additional data, and that might require going back
19 into the planning stage, or even back into the
20 problem formulation stage.

21 So again, this is a very flexible
22 framework, which allows us to move backwards and

1 forwards if needed.

2 So then the technical report that comes out
3 of this data collection and analysis strategy, will
4 include the policy issues driving the analysis, the
5 sources and quality of the data, the methodology
6 used, the results, sources of uncertainty and
7 variability, data gaps and assumptions. It will then
8 be subject to internal review and external,
9 independent peer review.

10 So there are a number of opportunities for
11 stakeholders' input within this framework. The first
12 thing, you know, at the beginning in the problem
13 definition phase and this could be input, for
14 example, into framing and context of the issue. It
15 could be reviewing questions to be addressed. It
16 could be reviewing and providing input into purposes
17 and justification.

18 Again, within the technical plan,
19 stakeholders could provide additional sources of
20 data. This is where we would do any call for data,
21 if we needed to do that and, of course, could review
22 any proposed methods for data collection and

1 analysis. Within the technical report, this would
2 also have opportunity for stakeholder input.

3 We do want to have any of these documents
4 independent, external peer review, and that could be
5 by this group, the NACMPI. It could be by the NACMCF
6 group or National Academy of Sciences or subject
7 matter experts. We consider the points where we
8 would want independent peer review to be the
9 technical plan, to be sure that we have addressed
10 data quality issues, we are avoiding bias in the data
11 sets, we are using appropriate methods of analysis
12 and we are looking at the validity of any
13 assumptions. And, of course, we would want a peer
14 view of the results of the data analysis itself.

15 Having developed our technical report, we
16 would then go on to use the data in decision-making.
17 So again when we go back to the problem definition,
18 problem formulation part of this, we need to be
19 thinking about how those data are going to be used in
20 decision-making, which, of course, decision-making to
21 improve public health.

22 Already mentioned program evaluation. We

1 do want to evaluate the outcome of any programs. So
2 we would need to consider right in the beginning, the
3 planning part, what kind of data we want to develop.
4 We want to look at how well is the program achieving
5 its objectives. Is there a need to improve the
6 program, and ideally we want to be able to look at
7 this in terms of the public health outcomes and later
8 on today, you're going to have an opportunity to look
9 at the link between our data and public health
10 outcomes.

11 Okay. So I've briefly gone through the
12 SOP.

13 Hopefully you all had an opportunity to
14 read it. I know it was sent to you in advance with
15 the questions we'd like you to address.

16 So again these are the questions. I
17 mentioned them at the beginning. Do you have any
18 suggestions for improvements on this report?

19 Do you have any suggestions for where we
20 would want to have stakeholder input into the
21 process?

22 Do you have suggestions for conducting peer

1 review?

2 And do you believe it will be worthwhile to
3 have an ongoing subcommittee to assist FSIS in the
4 data issues? And if so, please provide the rationale
5 as to why and how it would be structured and how it
6 would operate. Thank you.

7 MR. TYNAN: Thank you, Dr. Walls. At this
8 point, I think how we should handle this is maybe
9 have some questions, some issues regarding this
10 particular presentation, if you have some comments,
11 something you want to clarify at this particular
12 point. We'll stop, take a break, allow you a few
13 minutes to think about it, and then we'll come back,
14 and actually deal with those four questions that
15 Isabel framed for you, and talk a little bit about
16 them so we can come to some conclusion about our
17 standard operating procedures for data analysis.

18

19 So I'm going to open it up to the group.
20 If there's some comments or questions at this
21 particular point, that we need to address or

22

1 Dr. Walls needs to address.

2 DR. WALLS: Yes, Jim.

3 DR. DICKSON: Dr. Walls, Jim Dickson from
4 Iowa State. I guess more of a comment, when you talk
5 about peer review, I would encourage you guys to look
6 very carefully at subject matter experts, especially
7 those in the field of statistics, not saying you guys
8 don't have excellent statisticians, but I would
9 encourage you to take advantage of those subject
10 matter experts especially on statistical design.

11 DR. WALLS: We acknowledge your comment.
12 You're absolutely right.

13 MR. TYNAN: Mr. Elfering, why don't we
14 start with you, and then I'll work my way around.

15 MR. ELFERING: Yeah, Kevin Elfering. It's
16 kind of a monster. I mean not really knowing how
17 you're collecting data right now, we really don't
18 know how you collect data. I know there have been
19 discussions in the past and some suggestions, and I
20 think whenever you look at data collection, is after
21 you start collecting the data, all of a sudden
22 somebody comes along and says, why didn't you collect

1 this? And then it's kind of difficult to start back
2 again and start. So I think you really need to get
3 subject matter experts involved at the very
4 beginning.

5 DR. WALLS: And that is our intention,
6 stakeholder input would include any of those
7 individuals who will be appropriate to help us to
8 formulate the questions so that we do start off on
9 the right track, absolutely.

10 DR. ELFERING: So I think that if -- your
11 first question is actually answered, is when do you
12 get stakeholder groups involved? No.

13 DR. WALLS: Yep, we agree.

14 MR. TYNAN: Thank you for making our job so
15 much easier, Kevin. We just took care of that one
16 completely.

17 I'm going to ask, Ms. Jones, if you had a
18 comment or a question.

19 MS. JONES: I do. As he was saying, data
20 collection and analysis is huge. One of the things I
21 know you mentioned is that specifically in the
22 diagram, there's built in the ability to -- it's very

1 flexible. You can go back and forth and needing to
2 make adjustments, whether it's in redesigning the way
3 data is being collected, after beginning to collect
4 the data, seeing issues or concerns. One of the
5 things that would be interesting, especially at the
6 point where you have program evaluation, is to
7 actually have -- to reflect in the diagram the fact
8 that after program evaluation or as a result of
9 program evaluation, there is an actual opportunity to
10 make modifications because even though it's built in,
11 you don't see it within the context of the diagram.

12 DR. WALLS: Yeah, we could develop an arrow
13 that would loop right back to problem identification
14 because that might be what we have to do.

15 MS. JONES: Thank you.

16 DR. WALLS: Thank you.

17 MR. TYNAN: Dr. Henry.

18 DR. HENRY: Thank you, Robert. Isabel, do
19 you have -- have you tried to project a timeframe for
20 this process from start to finish? It seems pretty
21 voluminous, pretty consumptive.

22 DR. WALLS: Well, again I think the

1 framework can be very flexible so that if we need
2 data in a hurry, we should be able to do this fairly
3 quickly but if we need data, you know, if we have
4 more time and more resources, then we can be more
5 thorough in terms of how we go about doing this. Is
6 that what you're asking?

7 DR. HENRY: Well, if you start out with
8 project one, let's reduce *Salmonella* on all inbound
9 poultry product, I mean that's a definition of a
10 problem and it could take us the better part of a
11 year to get our hands around all of the components as
12 outlined here. So, you know, that's what I was
13 trying to get at? I mean have you tried to put the
14 what if scenario to this?

15 DR. WALLS: Well, indeed. I mean however
16 we tackle the data collection analysis issue, depends
17 on the question to be addressed. And something as
18 big as that, we might have to break down into a
19 series of questions, but I think it's better to get
20 the question right and get the data collection and
21 analysis right than to rush out and collect a load of
22 data and then try and figure out what to do with it.

1 So I think it's really, really important
2 that we, you know, start at the beginning, we break
3 this down, we look at how we're going to go about
4 doing this, and formalize the process and get it
5 right at the beginning. But again, it would depend
6 on the issues, some are going to be more complex than
7 others.

8 DR. HENRY: Craig Henry again. So bottom
9 line, this could be a very long process depending on
10 what we pick for a problem?

11 DR. WALLS: That's not our intention. I
12 think the goal would be to just formalize the process
13 so that we can, you know, clearly be very thorough
14 about it, but depending on the issue to be addressed,
15 the different parts of the process should be either
16 done more rapidly or more slowly as needed.

17 DR. MACZKA: If I could add to that, I also
18 think the Agency is very committed to whatever issues
19 we need to address and will put whatever necessary
20 resources on this to get the job done.

21 DR. HENRY: That's really where I was going
22 because it's going to take some funding to make this

1 happen with some real commitment, not only behalf of
2 the Agency but also on the subject matter expertise,
3 you know, as to what's being brought to bear, either
4 the short term or long term.

5 Other question, basis your slide that you
6 had here, identify, collect, reviewing existing data.
7 Again, one of the things I found not clear in the
8 paper and I had to kind of pull it out was who we're
9 defining as stakeholders. Sometimes I saw that being
10 referred to more internal stakeholders between state,
11 federal and different departments, et cetera, and
12 then later on implying stakeholders as those
13 represented here on the Committee.

14 But when we say reviewing existing data,
15 again if we're going to bring in the stakeholder
16 input through each of the developmental components as
17 they come to bear, then that review of data, would
18 that also include external data, potentially industry
19 data?

20 DR. WALLS: Yes, it would.

21 DR. HENRY: Okay. Okay. Very good. Thank
22 you.

1 MR. TYNAN: Mrs. Foreman.

2 MS. TUCKER FOREMAN: Thank you. I think
3 this is a terrifically well thought out paper that
4 opens obviously so many questions we can spend a lot
5 of time just trying to figure out what the questions
6 are.

7 I agree with the others that subject matter
8 experts are very important here. Among subject
9 matter experts, there are different points of view.
10 We're all influenced by what we bring to the table in
11 addition to our expertise. And I think it's
12 important to find a way to have stake holder input,
13 you know, thinking further they're going beyond those
14 within the Agency, Craig.

15 Enabling stakeholders who may not have a
16 capacity or the staff people to be able to analyze
17 data, to be able to find a way to do that, I'm not
18 sure how you'd do it. I probably would come up with
19 some suggestions but, you know, you can say, for
20 example, to a consumer group, give us an analysis of
21 this and you might as well say, well, fly me to the
22 moon tomorrow. It may not just be possible. And

1 that can be time consuming in the beginning.

2 I think what this design helps you avoid is
3 a lot of criticism because you've gone way too far
4 down a particular path that began with a narrow point
5 of view and excluded those important issues that
6 others have mentioned here, and that pursuing this
7 saves you time in the end and also a lot of -- along
8 the way.

9 Finally, I was particularly impressed by
10 the program evaluation segment at the end, and I sure
11 think that's very important.

12 DR. WALLS: Thank you. I think we intend
13 to think of stakeholders very broadly as being the
14 type of people who are on this Committee who would
15 have input at all the different stages in the
16 process.

17 MR. TYNAN: Do we have any other general
18 comments or questions on the paper?

19 (No response.)

20 MR. TYNAN: Could I guess then that -- I'm
21 sorry.

22 DR. RYBOLT: I was just going to suggest --

1 MR. TYNAN: Dr. Rybolt.

2 DR. RYBOLT: -- it sounds like Kevin
3 recommended that we the stakeholder group now, and I
4 think that part of that needs to be -- as part of
5 that, we need to have a clear definition of what the
6 role of that group is and what the focus is, and so
7 that we stay focused on the intent of the
8 Subcommittee. I think a lot of this is data
9 analysis. So that group obviously needs to be those
10 that are familiar with data analysis. Obviously
11 everybody has different ways of analyzing data but we
12 need to make sure that there is a clear definition
13 and I guess an intended outcome for whatever the
14 problem may be for that so we maintain focus there.

15 MR. TYNAN: Okay. Thank you, Michael.
16 Mrs. Foreman?

17 MS. TUCKER FOREMAN: One last thing. I did
18 notice that Kevin Kowalcyk's not here yet, and I
19 think he had some technical questions to raise. So I
20 hope there will be an opportunity to do that later.

21 DR. WALLS: Yeah, we have additional time
22 until I believe until 12:00 to discuss this paper.

1 MR. TYNAN: Yes, that's correct. We'll
2 take a break now for about 15 minutes. We'll come
3 back and then try and address the questions that
4 Isabel framed out. We'll try and conclude at least
5 the preliminary discussion today, and then I believe
6 someone on Carol's staff is going to take some notes
7 of our discussion and we'll revisit that first thing
8 in the morning. So if Michael is not here during
9 this part of the conversation, he will have an
10 opportunity again to participate.

11 So with that, unless there's any other
12 comments or questions at this point, I'd suggest we
13 take a break. Maybe if we could come back around --
14 I'll give you until about 20 minutes to the hour,
15 until 11:00. For those of you that are on Central
16 and Western time, that's about 20 minutes --

17 UNIDENTIFIED SPEAKER: Whatever time.

18 MR. TYNAN: Okay. We'll see you back in a
19 few minutes. Thank you.

20 (Off the record.)

21 (On the record.)

22 MR. TYNAN: We should have told you that

1 down on the first floor, there is a little bookstore.
2 It doesn't have a lot but it does have some coffee
3 and some little snack things down there. If you
4 didn't find it for this one, I'll help you find it
5 for the next break.

6 But prior to the break, we talked a little
7 bit about the data analysis SOP. Dr. Walls took you
8 sort of through the process that we're using. We
9 have several questions. I hope you had an
10 opportunity to think a little bit about them, and
11 what we'd like to do now is take the next hour and 15
12 minutes, hour and 20 minutes, and talk about the
13 various questions.

14 Dr. Catlin is going to take some notes.
15 She will take them the old fashioned way with a piece
16 of paper since we don't have the log in for our
17 computer. As soon as we get that, she'll go to the
18 technological world. But what I'd like to do is
19 start off and open up some of the comments and
20 questions regarding or comments and recommendations
21 regarding the very first question which is do you
22 have any suggestions for improving our strategy for

1 data collection and analysis?

2 So Dr. Walls laid out sort of the process
3 that we were going to use. I know all of you had an
4 opportunity to look at the material, and so the
5 question on the table is, do you have any suggestions
6 for improving our strategy for data collection and
7 analysis? Mr. Elfering.

8 MR. ELFERING: Kevin Elfering. I'm going
9 to go back to my kind of original comment and
10 question. What data are you looking at? Data can be
11 a monster. And, you know, again we don't know what
12 you collect now. We don't know what your intending
13 to collect. So it's kind of hard to suggest how you
14 go about it until we know what you're really looking
15 for. What kind of data are you looking at? I guess
16 that would be the first question.

17 DR. MACZKA: Pretty much every single piece
18 of data that we collect, such as pathogen data. If
19 you think a little bit about RBI I and some of the
20 data behind some of the factors there, like NRS,
21 information on recalls, consumer complaints, any
22 single piece of data. And basically what we're doing

1 right now is characterizing all the data streams in
2 FSIS. That's one of the activities of the DAIG.
3 We're characterizing the data, how frequently it's
4 collected, and any limitations. But it's every piece
5 that you can imagine. And for each office to do its
6 job.

7 DR. WALLS: We would see this framework as
8 being flexible enough to accommodate any kind of data
9 that we want to collect.

10 MR. ELFERING: Okay. But then with a
11 follow up to that, is what is the intent of the use
12 of that data? We've talked about this at previous
13 meetings, especially in relationship to risk-based
14 inspection and whether or not NRs are appropriate
15 data to be collecting for identifying or establishing
16 a risk. We don't think it is because if they can,
17 you know, NRs are not very consistent.

18 DR. WALLS: That's why we need the problem
19 definition phase, because we need to have an
20 discussion of, you know, why are we collecting these
21 data? Are they the appropriate data? And I think,
22 you know, one of the things this Committee could do

1 is to come up with a series of questions for that
2 problem definition phase to take us through that so
3 that we make sure that the data we're collecting are
4 appropriate for the public health question that we
5 want to address.

6 MR. ELFERING: So I think first of all,
7 then you have to have your final answer, what is the
8 data going to be used for.

9 DR. WALLS: Absolutely.

10 MR. ELFERING: Is it going to improve
11 public health.

12 DR. WALLS: Absolutely.

13 MR. ELFERING: Or is it going to be used
14 for improving resources.

15 DR. WALLS: Absolutely.

16 MR. ELFERING: I think that's where it
17 needs to come from first.

18 DR. WALLS: The first phase, the process is
19 to define the question you want to answer, that can
20 be answered with data collection and the question
21 should be tied to improving public health.

22 MR. ELFERING: Okay. So what do you want?

1 What do you want to try to resolve?

2 MR. TYNAN: Well, I think the question,
3 Kevin, as I understand it, and hopefully this will
4 help, is we're looking at not a specific data set or
5 data problem. We're looking at if we have a problem,
6 here's the process that we're going to use. Is that
7 process applied to this problem, another problem, a
8 third problem, is that process adequate? Is it
9 appropriate? Are there points in that process that
10 are missing? So it's not so much what the issue is
11 as if I applied this process to an issue, is it going
12 to be a workable process? Is that a fair statement,
13 Carol?

14 DR. WALLS: Yes, it is.

15 MR. ELFERING: You want to have kind of a
16 standard operating procedure for all the data that
17 you gather, and then maybe if there is a situation,
18 you can use that original plan --

19 DR. WALLS: That is correct.

20 DR. ELFERING: -- and then modify it from
21 there if you need to.

22 DR. WALLS: That is correct. This is a

1 process by which we would identify, collect and
2 analyze any kind of data that we need to do. This is
3 not specific to any one situation. This is a
4 framework that will be appropriate for any data that
5 the Agency needs to collect and analyze.

6 MR. TYNAN: Does that leave you with any
7 comments or if you want, I'll come back to you. I'll
8 come back to you. Dr. Henry, you had a comment or a
9 thought regarding the question.

10 DR. HENRY: Yes, I do. Thank you, Robert.
11 I have a very strong recommendation that FSIS have a
12 very close discussion with Mike Taylor and the work
13 that has been going on for the past year with the
14 Food Safety Information Infrastructure. Myself along
15 with multitudes of other stakeholders from all walks
16 of life have been engaged with Mike and his team to
17 characterize data sharing, what's required, what are
18 the obstacles, all of those things, and I certainly
19 would find it to be a huge waste of time to reinvent
20 the wheel because I think everything that we have
21 been working with Mike on for the past year is
22 directly applicable to the process put forward.

1 I would absolutely take hats off to the
2 write up that is here. I think it does shed light on
3 excellent receiving of comments through the process,
4 the interpretation of those comments and the proper
5 characterization in the document.

6 The other thing which I think gets back a
7 little bit to what Mike was saying is, you know, you
8 should use the process as outlined, you know, this
9 should not be a process of collecting nondescript
10 data out of context without focus which is something
11 we've kicked around for three and a half years that I
12 know of through this Committee and others, which is
13 data sharing and, you know, opening -- I mean just
14 coming in and saying, okay, here's all the data that
15 every plant in the United States has. One, the
16 Federal Government does not want to put that much
17 money to try to characterize nondescript data. Two,
18 it's open to complete misinterpretation and scrutiny
19 because you don't understand why it was collected.
20 That lends itself to, I think the process definition,
21 problem definition, that both and Carol and Isabel
22 have characterized.

1 We have to go out, and this comes back to
2 what Mike was saying. It is absolutely imperative
3 that we have our eyes on the right bouncing ball. In
4 this case, what is the public health issue, whatever
5 the *Salmonella* serotype is, what is it that we know
6 we need to fix that's correlated with products that
7 are under FSIS inspection? You know, the shotgun
8 approach is useless if we're going to move the
9 needle. So they'd be my two recommendations
10 regarding question one. Thank you.

11 MR. TYNAN: Thank you. Carol, Isabel, did
12 you want to --

13 DR. WALLS: Thank you for those.

14 MR. TYNAN: Mr. Kowalcyk, it's nice to have
15 you with us.

16 MR. KOWALCYK: Thank you. I think Kevin
17 and Craig really hit on the essential issue in my
18 mind as well as defining what the data is going to be
19 used for. And an example would be, is it going to be
20 used for collaborative research or is it going to be
21 used for, if it came out in an RBI context, is it
22 going to be used for regulatory purposes to manage

1 the inspection force. Those are completely different
2 animals that we're talking about here, and has the
3 Agency put thought into that.

4 DR. WALLS: Yes.

5 MR. KOWALCYK: And I think a follow up
6 question before I take your answer on that, I
7 apologize, I may have missed this earlier on, the
8 Data Analysis and Integration Group, can you explain
9 a little bit about the makeup of that group, staff,
10 staff levels, because one recommendation I would have
11 is engaging at pretty high levels I would think,
12 people that have doctorates in statistics, people
13 that are very experienced in database management
14 because like Kevin mentioned earlier, this data can
15 turn into a monster and run away from the Agency very
16 quickly if you don't set that foundation from the
17 start.

18 DR. WALLS: To your first question, in the
19 process we've outlined, we do describe the use of
20 data in regulatory decision-making but there's no
21 reason why it can't be used for research or for any
22 other purposes. This is a very flexible framework,

1 but we do believe that in the problem definition
2 phase, you should be thinking about how you're going
3 to use this to improve public health.

4 I'll allow Carol to answer the second
5 question on the DAIG.

6 DR. MACZKA: Well, the DAIG right now is
7 growing but it's made up of mostly Ph.D.'s,
8 microbiologists, risk assessors, let's see. We also
9 have some statisticians. We also have contracted
10 services out to other experts outside of FSIS, namely
11 some statisticians that are sitting in the room
12 today. So that's pretty much what we're comprised of
13 right now.

14 MR. KOWALCYK: For this working group, what
15 is --

16 DR. MACZKA: Can I just make one more
17 comment? You mentioned database management. We work
18 very closely with our OCIO Shop, and they are
19 basically -- a lot of the analysis we're doing, we're
20 looking to see if they can be automated because it's
21 large amounts of data. So when we want to look for
22 trends and patterns, we've actually been working with

1 Carnegie Mellon to actually take data strains and lay
2 them over each other to look for trends and patterns.
3 So we've been working with them for the last year on
4 coming up with algorithms that's self-learned. So --

5 MR. KOWALCYK: Okay. Aside from algorithms
6 and all that, what is the expected time horizon goals
7 for putting together an initial structure? That
8 seems to be, in the public meetings, especially last
9 fall, it was discussed for quite a while about where
10 all the data would be coming into a centralized
11 location. Where are they at with that process? Do
12 you know?

13 DR. WALLS: Right now we have a warehouse
14 where all of our data is housed. That has been
15 developed -- that is your question, right?

16 MR. KOWALCYK: Yeah.

17 DR. WALLS: Yeah. So we do have that
18 warehouse developed. There are some systems that we
19 call silo systems right now, which we're integrating
20 into the warehouse. An example is our consumer
21 complaint monitoring system for that. Migration is
22 happening now. So basically we're putting together

1 the warehouse and then right now we're looking to do
2 this, what I called predictive analytics. It's a
3 tool to overlay the warehouse for extracting
4 information and looking for patterns and trends.

5 MR. KOWALCYK: Okay.

6 MR. QUICK: If I could just comment on
7 that, Mike. I think it's important to recognize
8 where the Agency has come from. I mean we had 220
9 stovepipe systems that Carol referred to. It's a
10 major accomplishment. We're down to a handful now.
11 And getting those into a single warehouse was no
12 small feat. So over the last two, three years, it's
13 been a building process, and that has really led to
14 the formation of the DAIG and furthering that whole
15 data effort.

16 MR. KOWALCYK: Okay. For someone who works
17 in data, working with large masses of data, I can
18 appreciate that. Is there anything that could be
19 shared with this Committee to give people a sense for
20 where the Agency is with respect to how the data is
21 being stored, and then I guess, you mentioned
22 predictive analytics. That leads to the question as

1 to what are the researchers trying to predict? I
2 mean is there any information regarding that research
3 that can be shared with this Committee as well?

4 DR. MACZKA: We can share with you several
5 papers that we have developed which talks about the
6 data warehouse and predictive analytics. What are we
7 trying to predict? Well, it's largely based upon our
8 business practices. So basically we've gone around
9 to the different program offices and we asked them,
10 you know, what are you using your data for? How do
11 you look at your data? And then that's what we're
12 building into the algorithm. So it's programming the
13 way we do our business.

14 MR. TYNAN: Mr. Covington.

15 MR. COVINGTON: Brian Covington, and I
16 think that just hits on my question. First, I can
17 just say wow, because this is such a large task that
18 you're trying to put a standard protocol to, and I
19 applaud you for that because as everyone's indicated,
20 the amount of data that's collected without some
21 structure to it, can just be overwhelming to try to
22 analyze.

1 So from that standpoint, I just want to
2 make sure I'm clear in my mind because I've heard a
3 lot of identify a problem, go out and collect data
4 and analyze it, but I want to make certain that I'm
5 understanding that there's a lot of data collected
6 now, and I think that's what you were getting to,
7 that the Agency has a lot of data and that the
8 emphasis will also be on the analysis of that data
9 that's already in house.

10 DR. MACZKA: And that we presently collect
11 on a daily basis, yes.

12 DR. WALLS: Absolutely. That is to say,
13 the framework allows for looking at what existing
14 data do we have, can we use that to address the issue
15 and, of course, putting it into the databases that we
16 have.

17 MR. TYNAN: Mr. Painter, I overlooked you
18 before. I apologize. Do you have a comment that you
19 wanted to make?

20 MR. PAINTER: Yes, I do. Thank you,
21 Robert. Stan Painter with the National Joint
22 Council.

1 I had several points that I wanted to make.
2 One regarding the issue of the use of the experts for
3 expert elicitation, and that's all well and good if
4 you give them all the information. And what I've
5 seen the Agency do in the past, they only gave them
6 the good information and you tell us how good it is.
7 Give everything to the people that's going to be
8 evaluating what you're going to be looking at as far
9 as the data.

10 Another issue that was raised was the NRs.
11 I would recommend to the Agency or anything working
12 through the process to not -- to use a term that I
13 heard yesterday, cherry pick locations in which there
14 was short staffing, and there was not any or little
15 ability to look, see, find any deficiencies in order
16 to write them.

17 And the third and final point would be in
18 getting input from the field, input from the
19 inspectors, input from the field level supervision,
20 that's where the rubber meets the road. Thank you.

21 MR. TYNAN: Thank you, Mr. Painter.

22 DR. MACZKA: I did want to comment on the

1 expert elicitation. Really expert elicitation should
2 be used when there is no data available, and any
3 existing data should be used -- should be sought and
4 used and then expert elicitation should be done on
5 top of that. And so I want to make sure that's how
6 we move forward in the future.

7 DR. WALLS: And I absolutely agree. And
8 also to be very clear in the process that we avoid
9 bias in data sets.

10 MR. TYNAN: Okay. Dr. Murinda, you had a
11 comment or a question.

12 DR. MURINDA: It's a question. How does
13 the organization verify the validity or the accuracy
14 of the data being collected?

15 DR. MACZKA: Well, it depends upon which
16 data you're talking about. Are you talking about
17 industry data or just, you know.

18 DR. MURINDA: Since you're going to be
19 collecting data, say it's from various situations.
20 It could be industry, medical health issues and what
21 have you. How do you verify the accuracy of that
22 information before you can derive any intelligence

1 from it?

2 DR. WALLS: This is one of the questions
3 before the Committee today. We're going to be asking
4 you to come up with criteria for looking at industry
5 data and how we can use industry data because it's
6 very important I think to verify clear criteria for
7 accepting any kind of data, and I think also we need
8 to use a weight of evidence approach because data
9 which is being published and peer reviewed in the
10 literature, should be considered of higher value than
11 data that has not been. And also to look at perhaps
12 geographic location or how recently the data has been
13 collected, and to use a weight of evidence approach
14 that data more recent or more geographically relevant
15 should have a higher weighting than data that are
16 not.

17 And that is a question for this Committee
18 this afternoon when you look at, specifically today
19 focused on industry data, but again, I think the
20 criteria we're going to want to be thinking about
21 applicable to any kind of data that's outside the
22 Agency.

1 MR. TYNAN: I'm going to take Mrs. Foreman
2 and then Dr. Vetter, and then I think what we might
3 do is close out this question and begin the next
4 question and then I'll remind you that we'll try and
5 get these notes together, and then we'll review this
6 issue again first thing in the morning. So it will
7 give you an opportunity to think about it and put
8 your two cents worth in one more time in the morning
9 before we conclude.

10 Mrs. Foreman, did you have a comment?

11 MS. TUCKER FOREMAN: I came back in a
12 little late, and so I don't know if question 4 to us
13 was discussed at all, and --

14 MR. TYNAN: No, ma'am. We're proceeding --
15 we're dealing with the first question about
16 suggestion for improving the strategy.

17 MS. TUCKER FOREMAN: I apologize. I'll
18 hold both my questions for later.

19 MR. TYNAN: Okay. That's fine.
20 Dr. Vetter, you had a comment or a question?

21 DR VETTER: I would just add that probably
22 one of the first steps in the process ought to be

1 looking at the databases that you presently have,
2 which I know you are doing, and what doesn't work
3 with those databases and what does work.

4 Working with Mike Taylor would probably be
5 helpful in that respect, but also getting comments
6 from people in the field that use these databases
7 most often and are putting probably the largest
8 amount of information in, particularly when you
9 consider PBIS and AssuranceNet, and that is reflected
10 on what's going on in the field. And finding out
11 what works and doesn't work so that you don't -- that
12 we learn from our mistakes and successes and not
13 necessarily repeat them.

14 MR. TYNAN: Okay. I'll give one last
15 opportunity for this question and then we're going to
16 move on. Ms. Jones.

17 MS. JONES: Cheryl Jones. As we're talking
18 about data, I think of two different kinds of data,
19 quantitative and qualitative, and the quantitative
20 data comes from the data sets, and I understand --
21 being new, just work with me, I understand that, and
22 how it's stored and analyzed. But when you speak of

1 information from supervisors, from expert
2 elicitation, I wonder if that would not be
3 necessarily considered the qualitative data or --
4 and, you know, knowing that a lot of times, the
5 quantitative data, especially some of the questions
6 that come up, concerning validity or if this is
7 really what is occurring, what the data looks like,
8 is the actual picture, a lot of times qualitative
9 data supports what the quantitative data is saying,
10 and I was wondering if this process took into
11 consideration how to utilize and store qualitative
12 data.

13 DR. WALLS: I think the framework is
14 flexible enough to deal with any kind of data or
15 information that we're going to receive, given that
16 it's a very flexible process, we should be able to
17 deal with any kind of information.

18 DR. MACZKA: I do think that your point is
19 well taken, that usually qualitative data will
20 support quantitative data. And there is ways to take
21 qualitative data and actually try to quantify it. So
22 those are the things we look at.

1 MR. TYNAN: Mrs. Foreman.

2 MS. TUCKER FOREMAN: Yeah. Just following
3 up on that because I think it's an important
4 question, then the strategy perhaps ought to make it
5 explicit that this should be designed to address
6 issues of qualitative as well as quantitative data.

7 MR. TYNAN: Okay. Thank you. That
8 actually sort of a segue into our perhaps our second
9 question, and we might transition to that if we could
10 for a moment. And the second question is do you have
11 other suggestions for stakeholder input in this
12 process? And I think Isabel outlined sort of a
13 stakeholder process that she had in mind. Would
14 there be any comments or thoughts in regard to that
15 specific question?

16 And I think there's specifically three
17 places where that comes in in the plan. I think in
18 the problem definition there was discussion of
19 stakeholder input. I think in the development of the
20 technical plan, there was stakeholder input, and
21 there was a collection of the data analysis and
22 developing the technical reports that also

1 incorporated stakeholder input. So just sort of as a
2 quick review on that, if there's some comments that
3 you have in that regard. Dr. Henry, I'll let you
4 start off.

5 DR. HENRY: Thank you, Robert. Certainly
6 relative to the stakeholders and I would include
7 under these circumstances I think with the desired
8 end result, that being improved public health, that
9 includes Congress. You know, I saw at some recent
10 Appropriation Committee meetings where there was a
11 clear declaration or lack of linkage between CDC
12 reports relative to the various pathogens, and the
13 appropriate dispensation of inspection as executed by
14 FSIS. And I think when you go through this process
15 to look at problem definition and the development of
16 the process laid out here, that it's time for a lot
17 of fingerprints to be all over this so that
18 unwarranted criticism does not ensue thereafter.

19 Certainly the chance to improve the process
20 would be greatly gained especially if we're using
21 public funding in any guise to make this happen.
22 There should be a lot of buy in on this from the get

1 go, and that way we won't have any misguided
2 expectations for what the desired result is at the
3 end of the day, and I think that one of the things
4 which was brought to bear at yesterday's meeting, and
5 we've heard many times before, you know, time is
6 money and I think it's very clearly required that
7 there should be a very clear defined expectation of
8 beginning and end, and there should be a cause and
9 effect relationship. If I'm spending X amount of
10 money, X amount of time, X amount of resources, we
11 should see the expected result, be it good or bad,
12 delivered on time, on schedule and with appropriate
13 documentation.

14 So that would be my only recommendation
15 relative to stakeholder input. Thank you.

16 MR. TYNAN: I'm sure you'll have another
17 one before we're through. So I'll go over to
18 Mr. Kowalcyk.

19 MR. KOWALCYK: Thank you. My comment is
20 regarding the collection of the data. I think it's
21 imperative that the Agency really engage with the
22 field workforce, the inspectors, the supervisors out

1 in the fields in the various districts. When you
2 look at the data with respect to inspection, I'll
3 throw NRs out there, and that opens up the question
4 about qualitative, quantitative I know, but being
5 able to have a system that will last and be robust as
6 various things emerge going into the future, having
7 that collection down pat, I think is very essential
8 because if there's not consistency across the field,
9 you could have issues where you have dirty data and
10 so I think having feedback from the field is critical
11 because if there is miscommunication from the field
12 in any way, it could cause confusion on the front
13 lines, and it could provide you with incomplete data
14 if the Agency was not careful.

15 MR. TYNAN: Thank you, Michael. Mr. Schad.

16 MR. SCHAD: Mark Schad. I just want to
17 back up like Mr. Kowalczyk just said, and I think he
18 brought up an excellent point. As a very small plant
19 owner, not only on data, but just seeing a lot of
20 issues, you'll see inconsistencies from one circuit
21 to the next, one district to another, and I think
22 it's very important for the quality of the data input

1 into the system, that such as NRs and other type of
2 data that the inspectors and EIAOs put in, that it be
3 good quality consistent data.

4 DR. MACZKA: Right now we are doing some
5 analysis on some of the data we've gotten from the
6 field in terms of volume data, and we're trying to
7 see if there's consistency in that volume data, if we
8 can verify that volume data using different methods.
9 So we are, you know, acutely aware of the issue in
10 terms of validating that data, making sure it's
11 consistent.

12 MR. TYNAN: Does that help, Mark?

13 Okay. Other comments on the stakeholder
14 input? Oh, I'm sorry. Dr. Vetter. Thank you,
15 Dr. Rybolt.

16 DR. VETTER: I would just add that, and I
17 know this might not work in all circumstances, but it
18 is true that there's inconsistency in how the data is
19 input particularly from the field, and like you said,
20 it can vary from circuit to circuit and district to
21 district. And it may be helpful to develop standard
22 operating procedures for entering the data into

1 specific systems, so that you do have a more
2 consistent entry and less incomplete data.

3 And I know that training is crucial and we
4 get some of that in FSRE, but it doesn't actually
5 cover inputting the data into the system.

6 DR. MACZKA: One of the things we are
7 doing, we are going to do a survey of the field and
8 their capabilities, the different district offices,
9 and we're hoping that once we assess the
10 capabilities, that then we could put standard
11 operating procedures in place and also tools for
12 automation.

13 MR. TYNAN: Mr. Finnegan.

14 MR. FINNEGAN: Yeah, Mike Finnegan. One of
15 the very valuable tools that would be available
16 through FSIS is the food safety assessments that the
17 EIAOs are doing. And those are very detailed and if
18 they could somehow be broken down, I think that would
19 be a very valuable tool.

20 DR. MACZKA: Thank you. That's exactly
21 what we've done. We've taken the food safety
22 assessment and we've now put it on a form that is

1 more structured and that will be part of our data
2 warehouse where you input the data and then we can
3 extract the data. So we've actually computerized the
4 form.

5 MR. FINNEGAN: And you say you're shrinking
6 this down to give the substance out of these FSAs?

7 DR. MACZKA: Yes, because the FSAs right
8 now are narrative.

9 MR. FINNEGAN: Right.

10 DR. MACZKA: And so we've moved the
11 narrative to capturing the data in a form.

12 MS. GREEN: It's an initiative under way to
13 really make them more quantitative rather than
14 qualitative.

15 MR. TYNAN: Mr. Elfering.

16 MR. ELFERING: This is Kevin Elfering. I
17 want to apologize. I stepped out for a minute.
18 Somebody may have brought this up, but one thing I
19 think that we really have to look at from a
20 stakeholder is getting away from the Agency and even
21 look at those who investigate foodborne illness
22 outbreaks and really work with other -- even with

1 other commodities, and understanding some of the
2 complexities of all of the other different industries
3 out there, and I think that's one of the things that,
4 you know, we look at meat and poultry inspection.
5 You almost get too narrow of a perspective and
6 there's other people that are doing this out there,
7 already, and maybe even learn from some of their
8 experiences by, you know, talking to people who do
9 other types of work other than just meat and poultry
10 inspection.

11 DR. MACZKA: Now we have been working with
12 FDA a bit because they're dealing with some of the
13 same issues, trying to develop a data warehouse and
14 how they should capture their data. And also with
15 the EPA who has a lot of nice structure in place.

16 MR. ELFERING: And one of the things I
17 guess I would recommend, there are some state
18 agencies that are very progressive that may even give
19 you some insights as well.

20 DR. MACZKA: Also, Bryce said something to
21 me which I should mention, is CDC. We are working
22 with them. In fact, there was a comment that we

1 should treat Congress like our stakeholder, too, and
2 we have and, in fact, we are presently working on the
3 MOU which we hope will be signed very shortly between
4 FSIS and ARS to capture, to marry the VetNet data
5 with the PulseNet data, and so we'll have access to
6 that data and the serotypes.

7 MR. TYNAN: Dr. Negron.

8 DR. NEGRON-BRAVO: Yes, I would like to
9 commend the Agency for taking this operation of data
10 collection because I know it's needed. There's a lot
11 of data already in the warehouse, probably that could
12 guide some training problems and research. So as
13 soon as we get that information and going, it will be
14 very helpful to develop new programs. So where would
15 that information be after you run some programs?
16 Would that be on the website? How will you inform --

17 DR. MACZKA: Well, I think what we heard
18 initially was like can we have some characterization
19 of the warehouse and the predictive analytics and I
20 was going to give that to Mr. Tynan to distribute to
21 the Committee. So that could be a first step.

22 MR. TYNAN: That would be fine. Yeah, we'd

1 be glad to do that for you, Carol. Does that help
2 you, Edna?

3 MS. NEGRON-BRAVO: Yes.

4 MR. TYNAN: Okay.

5 DR. WALLS: But again to definitely use
6 this framework to look at the existing data and to
7 spell out how we're going to do analysis on existing
8 data and use that.

9 MR. TYNAN: Mr. Schad, I'm going to allow
10 you to be the last word on this particular question.

11 MR. SCHAD: I just want to make one more
12 quick comment about Dr. Vetter's statement about the
13 standard operating procedures for the field. And it
14 would always be good to have the industry input
15 working with the inspector, the EIAO, whoever it may
16 be. We don't want to have assumptions from the field
17 inspectors on what they might think the volume might
18 be and have incorrect data.

19 DR. MACZKA: This afternoon when we talk
20 about the possible pilots, one of the things we're
21 proposing is to look at volume data, and it would
22 verify the idea -- we would verify what industry has

1 input. So this is, you know, hand-in-hand kind of
2 thing.

3 MR. TYNAN: And with that, perhaps we could
4 transition to the next question, which has to do with
5 having suggestions for conducting the peer review.
6 So as I mentioned earlier, in two of the steps, peer
7 review is also a component and that would be
8 developing the technical plan and that would be
9 collecting data, performing analysis. So that would
10 be sort of the second part of that process.

11 DR. WALLS: And just for clarification, we
12 are talking about external, independent peer review
13 here.

14 MR. TYNAN: I put the slide up, if that
15 will help you at all in the process, and as you can
16 see, those two points will be the peer review.

17 And so with that, I'll invite comments.
18 Dr. Henry, you want to start us off?

19 DR. HENRY: Thank you, Robert, again.
20 Yeah, regarding the expert or external peer review,
21 in, in -- from our organization and others I
22 participated in which we have operated upwards of 20

1 separate committees across the industry, with a huge
2 number of participants in them, I would strongly
3 recommend and support the use of subject matter
4 experts that are consistently convened and not
5 arbitrarily substituted. You know, to me this
6 process is no different than the HACCP process. You
7 have to establish a HACCP team. We trained HACCP.
8 We've been asked for online HACCP. Can I get
9 certified by taking an online course? Those of us
10 who do it professionally say, no, you can't. And
11 why? Because you need to participate in a team
12 environment. You need to be educated in the
13 background for all of the tools used to develop the
14 data. I think Stan Painter brought up a good point.
15 All of the information needs to be brought to bear.
16 Once that team's established, they're going to be a
17 lot more effective going forward if they continue to
18 operate as a team similar to what's been established
19 here with NACMPI, and it may be multiple teams, not a
20 single team, and I think that Isabel made a very good
21 point of that.

22 So if you have that latitude, I would

1 certainly advocate that very strongly, and I think
2 it's applicable to both 3 and 4, depending on how you
3 approach that. Thank you.

4 MR. TYNAN: Okay. Thank you, Craig.
5 Mr. Kowalcyk.

6 MR. KOWALCYK: I think to follow up with
7 what Dr. Henry said, subject matter experts I think
8 are a great resource that the Agency can reach out to
9 and consistency, I would have to agree is important
10 because these folks are looking at these problems
11 every day. And you want to glean from them as much
12 as you can.

13 One comment I want to make about peer
14 review, I think it's essential to have that piece
15 there because it was actually in the paper talking
16 about certain assumptions that would be taken in an
17 analysis based on budget constraints, human resource
18 constraints, whatever that may be. My recommendation
19 is that Agency should be very careful in how they
20 make those assumptions, and to be very transparent to
21 all stakeholders because when that happens, it could
22 lead to misinterpretation of the results, and that's

1 certainly not a path I don't think anyone in this
2 room would want the Agency to go down in the future.
3 So I think peer review is an essential step and that
4 should be given a good amount of resources to looking
5 into what structure that would be and I think it
6 would be great if the Agency came back to this
7 Committee or NACMPI or some advisory committee to get
8 their advice on how that would work.

9 DR. WALLS: Thank you. Of course, we live
10 in the real world and so in any kind of data
11 collection and analysis, we have to make certain
12 assumptions and we have to be transparent about
13 matters. I think that's the key in this framework is
14 to be transparent and lay it out and to get buy in
15 that these assumptions we're making are appropriate.

16 MR. TYNAN: Dr. Dickson, it's come down to
17 you.

18 DR. DICKSON: Jim Dickson. One comment I'd
19 like to make on the use of subject matter experts is
20 using them in the sense of giving them very specific
21 tasks rather than just saying here's the project,
22 review it and let us know what you think, and I

1 wouldn't think you'd do that. But giving them very
2 specific tasks within their area of expertise.
3 That's all I have.

4 MR. TYNAN: Thank you, Dr. Dickson.
5 Dr. Harris.

6 DR. HARRIS: Joe Harris. In relation to
7 the question of peer review and I guess this may be
8 linked back to the design of the process in general,
9 I do think that it would be important for peer review
10 of the process for new data versus existing data. I
11 know one of the challenges that the Agency is
12 grappling with is how to characterize all of its
13 existing data. And one concern that I've had with
14 doing those kinds of things is trying to take
15 existing data and use it for a purpose for which it
16 wasn't collected in the first place. And I think a
17 peer review process for that will be important as
18 well because, you know, while the Agency has tons and
19 tons of data, you know, it was collected for a
20 specific purpose, whether that be NRs or whatever
21 kind of data we're talking about. So I just wanted
22 to make the comment that I think peer review on the

1 process for handling existing data is important as
2 well.

3 DR. MACZKA: So if that on any product that
4 we did peer review on, any analysis, we would
5 definitely ask the experts, was the data
6 appropriately used, is it the appropriate data, are
7 there limitations in the data? So that is something
8 that we would naturally ask.

9 MR. TYNAN: Other comments from the group?
10 Mrs. Foreman.

11 MS. TUCKER FOREMAN: Thank you. I want to
12 address really this question and the preceding ones
13 as well. And I think it's important for the Advisory
14 Committee to say something on the subject of the
15 Agency having the adequate resources to be able to do
16 this kind of project. We don't have to talk
17 specifically about money but it's not reasonable or
18 responsible for us I think to say that we think it's
19 important to move forward on this without making note
20 of the fact that it will require resources that are
21 not in the Agency's budget right now. And I was
22 drawn especially to the peer review part of the

1 question because we've been critical of the peer
2 review done in previous cases because it was obvious
3 that there was no budget to do peer review, and so
4 the Agency did what it could do within the resources
5 available, but if we all want to go in this
6 direction, and I've heard nothing around this table,
7 that wasn't enthusiastic about going in this
8 direction. We have to be reasonable and know that
9 the overwhelming majority of the Agency's budget is
10 in the field and there has to be some budget now for
11 this kind of serious work to be done.

12 DR. MACZKA: One of the projects we're
13 undertaking is to revisit the RBI algorithm and we're
14 doing a lot of analyses on that, and we intend to
15 develop a technical plan and paper and subject that
16 to peer review. We have budgeted for that. And
17 pretty much anything that is on our plate right now
18 in the DAIG, we have budgeted for peer review. I
19 don't know if Bryce wants to say anymore.

20 MR. QUICK: We have looked across all the
21 program areas and Carol's right. I mean this is a
22 resource intensive exercise, but the Agency has

1 reviewed all of the program area budgets, to find the
2 funding because it really does affect all of the
3 program areas. We wanted to make sure that we fully
4 fund the data effort, but in the future, I mean we
5 will continue to ask for additional resources for
6 this effort. I mean this is probably the most
7 important thing we'll do as an Agency in the next two
8 years. But I mean you're right. It is a resource
9 intensive exercise. Taking our systems from 220
10 stovepipes down to a handful of 5 or 6, was done on a
11 shoestring. I mean we did that within the Agency's
12 resources, and I think it's a tribute to our policy
13 staff and our technical staff within the OCIO of FSIS
14 that they were able to do this.

15 We did, because of the way FSIS was funded
16 under the supplemental, we did not receive our
17 appropriation until well into the fiscal year, and we
18 used that funding and we've spoken very frankly and
19 honestly with our appropriators, we've used that to
20 fund the data infrastructure development effort to
21 some extent. I mean it's still a multiyear effort.

22 MS. TUCKER FOREMAN: May I ask a follow up

1 on that?

2 MR. TYNAN: Please.

3 MS. TUCKER FOREMAN: Is there a specific
4 line now in the budget that's identifiable for this
5 data collection work, the overall data collection and
6 analysis work?

7 MR. QUICK: There is. We've taken the
8 facts and fame that you're familiar with of previous
9 years. We have renamed that. I believe the exact
10 name is Public Health Data Infrastructure, and it
11 looks like facts and fame. I know it's a re-labeling
12 but it is done with an eye towards getting our data
13 infrastructure in line. So it is a line item in some
14 ways but we are pulling from the program area budgets
15 to fund certain aspects of this.

16 MS. TUCKER FOREMAN: Two things. One,
17 although I may have some comments about name changes,
18 I think that giving this one a plain, up-front name
19 instead of something that works as an FSIS acronym
20 would be well advised.

21 MR. QUICK: Yeah.

22 MS. TUCKER FOREMAN: And I think it's

1 really important to be able to put it into one line
2 as much as you can and to be able to talk to the
3 Congress and your stakeholders about what that money
4 is as plainly as its been laid out today.

5 MR. QUICK: I would agree with that, and I
6 think one of the reasons that we did the name change,
7 and as a veteran of Capitol Hill, we were experts in
8 changing names of programs to further their progress
9 but one of the things we wanted to make sure is that
10 people knew that this was as important as computers
11 in every establishment with our inspectors and
12 printers. This was more about the way we collect,
13 analyze and respond to data. We know that we have to
14 get that infrastructure in place so that we can move
15 data. The faster we move it, the faster we respond
16 to it, the more protections for public health that we
17 actually develop. So I would agree with that, and
18 that is really what's behind our effort to -- when we
19 did rename it, that's what our intentions were.

20 MS. TUCKER FOREMAN: Well, I hope the
21 Subcommittee will take all this into consideration
22 when they --

1 MR. QUICK: We're open to your
2 recommendations on names, too.

3 MR. TYNAN: We're going to have a contest,
4 a naming contest.

5 (Laughter.)

6 MR. TYNAN: Are there other comments on
7 this particular one regarding peer review?

8 (No response.)

9 MR. TYNAN: I think the last two questions
10 are linked. So I'm not going to separate them for
11 purposes of our discussion, but I think the question
12 here is do you believe it would be worthwhile to form
13 an ongoing Subcommittee as opposed to the
14 Subcommittees we're talking about here. So this
15 would be a standing Subcommittee that we would
16 convene hopefully within the next month or so, and
17 that committee would then work forward through the
18 term for this Advisory Committee which would take us
19 until 2009 I believe. And so you all would have a
20 set of duties and responsibilities that would be
21 independent of this group but would come back to this
22 group. So it's an ongoing standing subcommittee and

1 then if you believe that's a good idea, then we'd
2 like to talk about the rationale and why you think
3 so.

4 Is that a fair assessment of that question,
5 Carol?

6 DR. MACZKA: Yes.

7 MR. TYNAN: Okay. Cool. All right. And
8 with that, I'm going to start with Dr. Dickson, if
9 that's okay, and then I'll come over to Mr. Elfering
10 next.

11 MR. DICKSON: Okay. Just a comment on
12 that. I think that a standing subcommittee might be
13 of value particularly in the area of problem
14 definition. I guess the only condition I would put
15 on that is I believe it was Dr. Henry mentioned how
16 long does this process take, and as long as this
17 standing subcommittee would not become a burden or
18 impediment to moving forward with the project, I
19 would say it would be a reasonable idea to proceed
20 with it but I wouldn't want to a subcommittee to
21 become just one more step in the process that has to
22 be accomplished.

1 MR. TYNAN: And I don't think that was our
2 intent. I think it was to be helpful to try and move
3 the ball forward. I think as a couple of folks have
4 pointed out at previously Advisory Committee
5 sessions, we talked about data analysis and
6 collection, and we've talked about it and we've
7 talked about it, and I think last April we had a
8 public meeting for half a day, and I think the
9 purpose when I spoke with Carol about our Advisory
10 Committee meeting, I think the purpose was to move
11 the ball forward. So we're hoping that this,
12 whatever the subcommittee would be, is not an
13 impediment but rather would facilitate the process
14 and allow all of you to help us frame how we move
15 forward with data analysis.

16 And with that, Mrs. Foreman, did you have a
17 comment that you wanted to make.

18 MS. TUCKER FOREMAN: I thought Kevin was
19 going to be next.

20 MR. TYNAN: Oh, I'm sorry. I apologize.
21 Thank you. I need a little help here.

22 MR. ELFERING: Yeah, Kevin Elfering. I

1 certainly would suggest that it would be a good idea
2 and the rationale would be just the expertise that
3 you have. It's a little bit different than what you
4 have within the Agency. It just gives a much
5 different perspective, and I think you hear that at
6 every meeting.

7 MR. TYNAN: There's also a component of the
8 question in terms of how should it operate, and so we
9 need to be thinking and perhaps talking about that as
10 well. Mrs. Foreman?

11 MS. TUCKER FOREMAN: I endorse both the
12 previous speakers on this about the importance of
13 having a group. I want to talk a little bit about
14 the detail here. Is there a precedent for having
15 this kind of a subcommittee from within NACMPI? I'm
16 not aware of any ongoing subcommittees that have ever
17 existed, and follow up to that, are we doing this
18 because it is the easiest organizational option
19 available to the Agency for outside expertise under
20 the Advisory Committee Act, or is there a real reason
21 to have it from this Committee?

22 MR. TYNAN: On the first question, I can

1 try and answer that one, and in our previous term, as
2 you recall when we were beginning our discussion of
3 risk-based inspection, we did structure a
4 subcommittee of the Advisory Committee to help us
5 with the stakeholder input process. So of the 16
6 members we had at that time, we constructed a group
7 of eight that had representatives, two people from
8 the consumer groups, industry, state. So we had a
9 very balanced approach, and each time as we got to a
10 different step in our process, we convened that group
11 through a conference call, and those discussions were
12 brought back to the full committee, and we moved
13 forward. And that resulted in the RESOLVE group
14 being contracted with, the RESOLVE Report, and a lot
15 of the information that we generated through that.
16 So we do have a precedent in that regard, and I'll
17 let Mr. Quick perhaps answer the second question.

18 MR. QUICK: No, I think Carol characterized
19 it fairly accurately in that the Advisory Committee
20 Act limits the number of these committees we can put
21 together but as Kevin said, it's a logical place to
22 go with the level of expertise and the diversity

1 represented on this Committee, it was very logical
2 for us to turn to NACMPI for the type of advice that
3 we're looking for on data. So, yes, it did factor
4 into our consideration in that we are bound by a
5 statute, not to create advisory committees beyond a
6 certain number.

7 MS. TUCKER FOREMAN: And so I assume from
8 what you said that you do think that we have
9 sufficient expertise on this Committee now to get a
10 subcommittee that would have enough breadth of
11 stakeholder interest and expertise to be able to
12 advise.

13 MR. QUICK: I think we have the basis to
14 move forward with the expertise that we have now, and
15 this Committee can also draw on other stakeholders to
16 provide the Committee with additional resources
17 similar to when we do our breakout sessions today.
18 The public and others are still allowed to
19 participate in them, and they would be under this
20 Committee as well.

21 MS. TUCKER FOREMAN: Good. So the
22 Subcommittee could ask the opinions of other people,

1 not members of --

2 MR. QUICK: Absolutely.

3 MS. TUCKER FOREMAN: -- either the overall
4 group or the Subcommittee.

5 MR. QUICK: We would welcome --

6 MS. TUCKER FOREMAN: It sounds good to me.

7 MR. TYNAN: And in that regard, we're in
8 the process of developing some rules and
9 responsibilities. We didn't want to get too far not
10 knowing where the total Advisory Committee. So we
11 didn't want to set up roles and responsibilities and
12 then come here and have you say that's a bad idea.
13 So if at the end of this discussion you're amenable
14 to do that, we'll put roles and responsibilities
15 together sort as an idea of what -- how the Committee
16 would operate based on some of the conversation we
17 have here today, and we'll get that out to you as
18 well.

19 Dr. Henry, you have a comment?

20 DR. HENRY: You've already addressed the
21 one. The second I would like to suggest that
22 whatever this subcommittee's task and function is

1 going forward, we see how that integrates with
2 additional working groups subject matter experts are
3 going to be integrated down the process because you
4 could have a multitude of working groups, and we've
5 still got to figure out what is the responsibility of
6 each one, and then secondly, I think bringing in
7 other outside stakeholders, subject matter experts
8 from a public opinion, or public input aspect, again
9 there needs to be a little efficiency here as to how
10 many people we need. I mean let's cut to the chase.
11 Get the right people on there so that you get the
12 right answers to the questions you pose without
13 typing a lot of people up in a variable process.

14 MR. TYNAN: I think, and my own impression
15 was when we discussed having a subcommittee, that the
16 subcommittee would be composed of only Advisory
17 Committee members. So it will be a subgroup of the
18 17 here, it will be 8 perhaps to 9, depending on cut
19 it. So the conversations would be within this group
20 and ultimately brought back to the larger group for
21 further discussion.

22 DR. HENRY: I'm totally with you. I think

1 that again that speaks to your prior challenge that
2 you're going to go back. I mean let's look at the
3 scope and function of this subcommittee. I'm not
4 real clear in my mind what all it's going to do with
5 all of the components that we've already addressed in
6 this because it's a pretty complex process as it is
7 when you start applying subject matter experts
8 throughout each of the components that are there but
9 I think let's see what you come back with and then we
10 can have a better discussion at that point.

11 MR. TYNAN: Well, we're kind of hoping that
12 part of the question that we have here is how should
13 it be structured and how should it operate, a part of
14 the burden would be you helping us figure out how
15 that would operate. So I'm going to let you mull
16 that one over and then I'm going to come back over to
17 Ms. Jones and then we'll come back to you for some
18 response on that one.

19 MS. JONES: Cheryl Jones. I think my
20 question is an extension to a certain degree of
21 Dr. Henry's question. When I think about various
22 data issues, I think about various questions. So

1 when you're talking about the functioning of the
2 subcommittee, we have a lot of data sets. You can
3 come up with a number of questions. So this
4 subcommittee just address the questions and in what
5 chronological order, and how do you consider, one of
6 the other questions that was asked before was
7 timeframe, the timeframe of actually conducting or
8 going through the problem of the definition phase.
9 Would questions overlap? So would the subcommittee
10 only be looking at one concept or one problem at a
11 time? Logistically how would that work?

12 MR. TYNAN: Well, that's a good question.
13 I'm going to let Carol take a stab at it, and then
14 I'll --

15 DR. MACZKA: Well, I would think in any
16 year you would have a number of issues that you're
17 tackling, and one of the things this committee can do
18 is help us do is prioritize which ones, you know, the
19 Agency and this Committee feels are most important to
20 tackle. One of the things we would like this
21 subcommittee to deal with is the use of industry
22 data, which you'll hear about later, but that was one

1 of the things that we were going to ask if it would
2 take on as an example.

3 MS. JONES: Thank you.

4 MR. TYNAN: Other comments on the idea of a
5 standing subcommittee to help the Agency with the
6 data analysis process? So there could be any number
7 of questions, prioritizing and so on. Other comments
8 or thoughts? Mr. Finnegan.

9 MR. FINNEGAN: Yeah, I could see the
10 benefit of a subcommittee but the subcommittee
11 definitely would have to have statisticians available
12 to them. Michael's a statistician. Most of us are
13 not. Especially in predicting trends. Statisticians
14 are great at predicting trends of all this data.

15 MR. TYNAN: Okay. Thank you, Michael. I
16 think -- I'm sorry. Mrs. Foreman, did you have
17 another comment?

18 MS. TUCKER FOREMAN: I do please because I
19 want to be sure that I understand. I thought the
20 role of this subcommittee was going to be to advise
21 FSIS kind of on overall process, not to analyze data.
22 Is that -- tell me if I'm wrong.

1 DR. MACZKA: Yes, it's process, so when I
2 mentioned the industry, the use of industry data,
3 their thinking help us develop criteria for what data
4 should be used, how we accept the data, how do we
5 validate that data, not to actually get into the
6 actual analysis of the data.

7 MS. TUCKER FOREMAN: I think you're pretty
8 sneaky because I seem to recall that this issue came
9 this Advisory Committee once before, and they kicked
10 it back to the Agency saying you all set up a third
11 party entity or you tell us how you want to get the
12 data. So now I see that we're back to this Committee
13 playing that role.

14 DR. MACZKA: Well, hopefully we do -- we
15 are coming up with some idea. So --

16 MR. TYNAN: You have a good memory,
17 Mrs. Foreman, on some of those questions. I think
18 the other issue may be to talk a little bit about --
19 I'm sorry. Dr. Henry, did you have another comment?

20 DR. HENRY: No.

21 MR. TYNAN: Okay. One of the issues to
22 talk about is how we identify folks from this

1 Committee to serve on the subcommittee, and the
2 precedent that I mentioned earlier on our last term,
3 we simply asked for volunteers from the Committee,
4 people that felt more comfortable in this particular
5 case with data, data analysis and understanding some
6 of that. So we perhaps would ask for volunteers from
7 the group and construct a subcommittee as many as
8 eight from this Committee if that's an acceptable way
9 to do that. So sometime after this session, you can
10 send an e-mail to me or to Dr. Cannon and based on
11 that, we'll select from the group how that
12 subcommittee should be formed. Is that a workable
13 arrangement? So in other words, you would volunteer,
14 you're comfortable with data, data analysis and would
15 like to serve on that subcommittee. Send an e-mail
16 to me, and if we have 12 or 13, then the Agency will
17 sort of construct the group of 8 from the 12 or 13.
18 Is that a workable arrangement?

19 (No response.)

20 MR. TYNAN: I'll let you think about that
21 one, and I'm going to let Dr. Henry maybe make a
22 comment.

1 DR. HENRY: Yeah, and I think Carol just
2 opened up the gate a little bit wider, you know, we
3 need to take into consideration such as how to handle
4 industry data, you know. That's blue sky. It's a
5 very good possibility that this subcommittee is going
6 to now reach down further because now identify the
7 project. Then we'll figure out who we need to get in
8 here to identify the data. That may take, you know,
9 a bunch of the swine guys, a bunch of the beef guys.
10 It may take small operators, large operators. We're
11 going to have to be able to carry that down because
12 we can't shotgun. You know, we've got to get back --
13 I totally concur with Carol brought to bear just a
14 moment ago, you know, reinventing the wheel, re-
15 discussing, I think we've got to cut to the chase,
16 have a very specific goal, have a very specific task,
17 and then we'll figure out how to get the quickest
18 answer from the best people to move that ball forward
19 so we don't prolong that agony.

20 DR. MACZKA: There's two pilots that we're
21 suggesting in industry data that you'll hear about
22 later, and that's the use of volume data in RBI, and

1 the second one is the *Salmonella* Initiative. So we
2 did try to hone it in.

3 MR. TYNAN: Mr. Kowalcyk.

4 MR. KOWALCYK: I think to follow up on the
5 earlier comments and questions, I think the charge of
6 the subcommittee, if it's going to be looking at data
7 issues surround where FSIS wants to go, I would
8 encourage the Agency to really try to define as
9 specifically as possible what direction you're
10 looking for, and it comes down to in my mind when you
11 talk about building algorithms and trending and
12 things like that, you can have the best minds putting
13 together the best algorithms out there, but if the
14 information going into it is not right, the tool is
15 essentially worthless. So getting this right is
16 critical in my mind to going forward.

17 So I would even as far as how the
18 subcommittee would work, it may require intensity
19 than the prior subcommittee that was convened for
20 what ended up with the RESOLVE recommendation, and
21 maybe even engage in this full Committee because I
22 don't want to speak for other Committee members, but,

1 you know, if I was or was not on the subcommittee, I
2 would want to make sure that the rest of the
3 Committee was aware of what work was coming out of
4 that committee in a timely fashion, so that they can
5 provide input as well because essentially we're all
6 on the same committees. So I think the Agency needs
7 to be sensitive to that as well.

8 MR. TYNAN: That's an excellent comment,
9 Michael, and we certainly will be.

10 Again, we haven't finalized the duties and
11 responsibilities for the Committee but that's a good
12 point, and we will add that in there and how we'll do
13 it.

14 I should point out, and Faye is still here,
15 that the NACMCF does a lot of homework in between
16 their meetings. So we're sort of putting this
17 subcommittee to doing a little homework in between
18 the meetings as well, and in this particular case,
19 the data analysis.

20 Any other comments or thoughts on this
21 standing subcommittee?

22 (No response.)

1 MR. TYNAN: Okay. There being none,
2 Michelle has been typing away, trying to catch all
3 your notes, and we do have a printer here in one of
4 the rooms. So what we're going to do is we're going
5 to get this printed out, we'll give it to you and
6 we'll talk again about it in the morning.

7 Mr. Quick, being less patient than I am,
8 suggested that rather than you sending me an e-mail
9 after the meeting, that perhaps when we get to talk
10 about this report in the morning, that sometime
11 during the morning session tomorrow, that if you are
12 interested in participating on that subcommittee, if
13 you could let us know at that particular point in
14 time, and then we'll sort of rap that up maybe before
15 the Committee goes home from this meeting.

16 Yes, Mrs. Foreman.

17 MS. TUCKER FOREMAN: And we will have from
18 the staff tomorrow morning some ideas about roles and
19 responsibilities to help us narrow this down?

20 MR. TYNAN: I will try and do that, yes.

21 DR. WALLS: Yeah, I think we can try and
22 create sort of a mission statement. I think we need

1 to be very clear what we want this committee to do,
2 and how it would involve external subject matter
3 experts if necessary as well as getting advice from
4 the core group.

5 MR. TYNAN: Other thoughts and comments?

6 (No response.)

7 MR. TYNAN: Okay. Then I think what we'll
8 do is close out this portion of the agenda. It's
9 getting very close to our normal break time for
10 lunch. So why don't we go ahead and break for lunch,
11 and if I could impose on you all to be back here at
12 1:15 please. And then we'll get started again on the
13 next two issues. My hope is that Dr. Raymond will be
14 back at that particular point in time, and maybe we
15 can do the certificates that I talked about earlier
16 this morning, and then get into the two Subcommittee
17 topics. And with that, we'll adjourn for the
18 morning, and move on. Thank you very much.

19 (Whereupon, at 11:50 a.m., a luncheon
20 recess was taken.)

21

22

1 Okay. The first certificate, and this is in
2 no particular order, is Dr. James Dickson.

3 MR. ALMANZA: A Nebraska graduate I might
4 add. No particular order. Who was I telling this
5 morning that he mentions something about Nebraska
6 every single day. Arkansas will be last.

7 MR. TYNAN: We have Dr. Shelton Murinda.
8 Does Cal Poly play Nebraska at all?

9 (Pause.)

10 MR. TYNAN: And we have Dr. Edna Negron.

11 (Pause.)

12 MR. TYNAN: You notice how professionally
13 posted this whole thing is. Dr. Harris.

14 (Pause.)

15 MR. TYNAN: Michael, your timing was perfect
16 for getting your jacket on. Mike Finnegan.

17 (Pause.)

18 MR. TYNAN: And the next folder I picked up
19 is Carol TUCKER FOREMAN.

20 (Pause.)

21 MR. TYNAN: Mr. Michael Kowalcyk. Mike,
22 that's perfect. You were on the other side of the

1 room. How good's that?

2 (Pause.)

3 MR. TYNAN: Dr. Catherine Cutter. Penn
4 State versus Nebraska.

5 DR. RAYMOND: They took a championship away
6 from us one time.

7 MR. TYNAN: I seem to remember that.

8 (Pause.)

9 MR. TYNAN: Dr. Grondahl. Andrea, your
10 turn.

11 (Pause.)

12 MR. TYNAN: Mr. Kevin Elfering, and
13 Mr. Elfering just informed me that he is also going to
14 be a proud grandfather in January. Is that correct?

15 (Pause.)

16 MR. TYNAN: Dr. Craig Henry.

17 (Pause.)

18 MR. TYNAN: Ms. Cheryl Jones.

19 (Pause.)

20 MR. TYNAN: Mrs. Kibbe Conti. I hope I
21 pronounced that okay.

22 MS. CONTI: Yes.

1 MR. TYNAN: Okay. Good.

2 (Pause.)

3 MR. TYNAN: Mr. Mark Schad. How's it
4 looking?

5 (Pause.)

6 MR. TYNAN: Stan, you're up next.
7 Mr. Stanley Stromberg.

8 (Pause.)

9 MR. TYNAN: We have Mr. Brian Covington.

10 (Pause.)

11 MR. TYNAN: And last but certainly not
12 least, Dr. Michael Rybolt.

13 (Pause.)

14 MR. TYNAN: What we'll do at the break,
15 rather than take everybody's time, at the break, we'll
16 do a group photo if that's okay. So we'll make you
17 put your jackets back on in this heat again.

18 Thank you for being patient with us while we
19 did that. I appreciate it very much. It is an honor
20 to be on the Committee. As Dr. Raymond mentioned in
21 his opening remarks, there was quite a bit of
22 competition. I think that's reflective of the issues

1 that we're bringing to the Committee and the interest
2 that we're generating. So we're very pleased to have
3 you all and are looking forward to this next two year
4 term.

5 At 1:15 our issue for our Subcommittee, our
6 next issue, was to be linking FSIS Activities to its
7 Public Health Goals. So I'd invite Dr. Catlin to come
8 up and maybe talk a little bit about her presentation,
9 we'll go to the next issue paper and then we have to
10 get the curtain up. It makes it much harder to do
11 that, doesn't it. Vanna White Randall is up there
12 helping.

13 DR. CATLIN: Well, first I have a request
14 from our AV person. If everyone, I know all the feds
15 have their Blackberries up near their microphones,
16 anyone with a Blackberry near the microphone, that
17 actually interferes with all the AV, all the audio
18 system. I said I know the feds. Some people probably
19 do as well. But if you could just keep the
20 microphones away from or the Blackberries off the
21 table by the microphones, it would be most helpful to
22 our audit folks, and I'm guilty as well.

1 So as was mentioned, the title of my talk,
2 the topic of the talk, presentation, is linking FSIS
3 activities up to its public health goals.

4 Just to give you a brief overview of what
5 I'm going to talk about, I'll give you a little bit of
6 background about this issue, and then I'll talk about
7 some of the approaches that we've thought of and we've
8 tried internally within FSIS, some of which you may be
9 aware of already, and then I have questions for the
10 Subcommittee to consider around this topic, so that we
11 can hopefully get some really good input from all of
12 you on how we should approach this issue.

13 As we all know, FSIS' mission as a public
14 health agency is to protect public health through food
15 safety and food defense. In doing this, we are
16 looking to explore ways to allocate our resources to
17 be able to better protect public health. What we're
18 doing, a technical plan, out of the same issue, sort
19 of following the format that Isabel talked about
20 earlier today, once again these issues arose of how do
21 we link up our inspection activities and what we're
22 doing as an Agency to our public health goals.

1 So we thought this would be a good topic to
2 come and address with NACMPI in hope that you could
3 give us some good feedback and ideas on how we should
4 approach this issue.

5 Just as a little bit of background, many of
6 you know that we have public health goals that are
7 posted. One set comes from the Council on Food
8 Safety, and those are goals for percent decrease in
9 food related illness in the public by 2005 and we also
10 have the goals from Healthy People 2010, once again
11 linking up public health illness and how we're going
12 to try and decrease food related foodborne illnesses
13 out there in the U.S. population.

14 So that is what we are trying to link our
15 activities up to.

16 With respect to background, and this gets to
17 a little bit of the questions we want you to address,
18 so once again, like Isabel, we'll give you the
19 questions up front to mull over while you're listening
20 to me.

21 One recommendation we're seeking is how we
22 can link our inspection activities up to microbial

1 contamination in FSIS regulated foods. So this is
2 sort of step 1, linking A, FSIS' inspection activities
3 up to the actual contamination in a food product
4 that's going out the door, going onto someone's table,
5 which I'll call B. I tried to simplify this with As
6 and Bs.

7 The second question that we're looking for
8 recommendations on is how we can then link microbial
9 contamination information up to the food related
10 microbial human illnesses. So how can we link that B
11 parameter, contamination rates in the food, up to
12 human illness.

13 And then the third part of this question is
14 can we directly link FSIS' activities up to human
15 illness. So that would be linking our inspection
16 activities or what I'll call to C. And can we do that
17 just indirectly by linking up the two to B in the
18 middle or is there a way to directly link A to C.

19 When we've been thinking about how to link
20 our inspection activities up to food contamination, we
21 have looked at a couple of different ways to do this,
22 and one is to look at the correlation between certain

1 subsets of our noncompliance records and the actual
2 microbial data that we have, and also the possibility
3 of using microbial risk assessments, and I'll talk
4 about both of these in a little bit.

5 With respect to the correlation analysis
6 between the various subsets of noncompliance records
7 and microbial contamination, we have been looking at
8 and investigating the possibility of using a subset of
9 the noncompliance records that would be specifically
10 related to a given microbial contamination. So many
11 of you are familiar with what was done in RBI, risk-
12 based inspection, where we sort of looked at those NRs
13 that would be most related to public health goals.
14 This takes that one step further and looks at what
15 activities the people, the field inspectors are
16 actually doing in the establishments, trying to figure
17 out which ones would be most likely to be related to
18 say *Salmonella* and then looking to see if there's any
19 correlation between the rate of having a violation
20 under that NR and the contamination data from that
21 facility.

22 With that, you can compare the probability

1 of having a positive NR to the probability of having a
2 positive in your *Salmonella* results. Different ways
3 you can do this, you could look at the presence or
4 absence of positive *Salmonella*, so sort of a yes/no.
5 you can look over different periods of time, so you
6 can look in a given, you know, daily rates versus a
7 week versus a month, or you could look at the number
8 of positives on *Salmonella* and how that relates to the
9 number of NRs that a facility has. So rather does it
10 have or doesn't it have an NR, it's how many NRs does
11 it have. So those are some ways we've been sort of
12 thinking about exploring to be able to attack this
13 question.

14 Another set of work that has been done has
15 been done from our RAD division, our Risk Assessment
16 Division with in the Agency, in the Office of Public
17 Health Sciences, and that is the actual use, formal
18 quantitative risk assessments to try and link our
19 activities up to contamination levels.

20 For this you can look at data on the
21 prevalence of microbials, microbes in the product.
22 You can enumerate the levels within the products and

1 you can also look at the serotype information, more
2 specific information on the contamination, and you can
3 look at the control measures that are in place in
4 different facilities and look forward through the food
5 supply to estimate given what the various levels are
6 of the different points in processing, what the
7 contamination level would be as it's going out the
8 door or on someone's plate.

9 To do this, you take into account growth
10 curves at the various points as well as decline or
11 survivability based on what's going in and on in the
12 processing facility at that particular point. Using
13 this, you can estimate what the contamination levels
14 would be even at the point of consumption. You can
15 build uncertainty analyses into these types of
16 analysis and assessments, and you can estimate the
17 impact of FSIS' HACCP procedures on pathogen levels.
18 These are different things that you can do, and we
19 actually as an Agency have done some of these
20 internally and they will eventually be going public.
21 One of them is the poultry slaughter has done this a
22 lot with the *Salmonella* data, and that's the risk

1 assessment you heard about yesterday that will be
2 posted up on our website and made available.

3 The next question we had is how do we link B
4 to C, which is if you know what the contamination
5 level is on the food while it's being consumed, how do
6 you link that to the public health outcomes.

7 There's once again different ways of doing
8 this, potentially correlation analyses, looking at
9 expert elicitation data for information, analysis of
10 outbreak information, former risk assessments or risk
11 assessments in conjunction with food safety
12 objectives.

13 With correlation analysis, this is a very
14 simplistic way of doing it, and that's looking at the
15 contamination levels in our products and trends in
16 those levels, and comparing that to trends in public
17 health rates of the various illnesses from CDC and on
18 FoodNet.

19 Another way of getting at this question is
20 expert elicitation which we have done as an Agency, as
21 I'm sure all of you are well aware. For this, you
22 seek expert opinion regarding which FSIS-regulated

1 foods are of greatest hazard from a food safety
2 perspective. You can then, using the results of that,
3 get a relative risk ranking of the inherent hazard of
4 food products from a foodborne illness standpoint, and
5 when you combine that information of the inherent
6 hazard up with consumption information, or a surrogate
7 for consumption, you can then see which foods would be
8 accountable for the greatest proportion of foodborne
9 illness.

10 And this type of approach was presented at
11 one of the meetings back in the spring, in April.
12 Carolyn Smith-DeWaal used this type of approach to see
13 what would be the attributable portion of foodborne
14 illness to our food as well as there was someone from
15 Resources from the future who did a similar type
16 analyses.

17 Another method to get at this or potential
18 method would be to use outbreak information, and this
19 would be using data from outbreaks and outbreak
20 investigations that have identified the food and the
21 pathogen involved. And for this we might want to look
22 at very specific information on the contamination such

1 as the PFGE patterns for *Salmonella* or the various
2 microbes and see which ones are counting for the
3 illnesses that we're actually capturing, our CDC is
4 actually capturing out there. And from that, we can
5 get a better handle on trying to determine the
6 percentage of the outbreaks that would be associated
7 with a particular FSIS-regulated food.

8 Another method, once again, as with the
9 other one, is microbial risk assessment. We at FSIS
10 are fortunate to have a very good risk assessment
11 division who are capable of doing these analyses. For
12 this, they can use statistical models to quantify the
13 contribution of food sources to human illnesses in a
14 pathogen specific manner.

15 They can incorporate prevalence, once again
16 prevalence and enumeration data, as well as subtype or
17 serotype data for the microorganisms. They can do
18 this specifically for microbes paired up to specific
19 FSIS regulated foods and link it out to public health
20 endpoints, foodborne illness.

21 To do this, you generate a dose response
22 curve, and for a given pathogen, you can build in an

1 uncertainty analyses into that dose response curve and
2 from that, you can estimate the number of cases that
3 would be associated for a given illness with a
4 particular food type.

5 And another way which combines the risk
6 assessment, it combines the risk assessment with food
7 safety objectives. In this case, it's a formalized
8 method to link a stated public health goal to pathogen
9 prevalence in foods. To do this, you use a dose
10 response curve that would have been generated from
11 something like a risk assessment, to connect that
12 level of pathogen, estimate what level of pathogen
13 would have been present in the product, to get that
14 level or that goal of public health illness, so you
15 can then calculate or connect from your performance
16 goal, your public health goal to what level you could
17 have on the plate and even calculate up through the
18 food supply to different points in time looking at the
19 survivability of the organism through the food chain
20 and the growth curves to be able to estimate what
21 would be the performance objective at different points
22 in the food supply to get you to that amount on the

1 plate and then the public health goal.

2 The last two, the risk assessment and the
3 food safety objectives can be a little bit confusing.
4 So I tried to put them into a diagram that might make
5 them more understandable. I don't think I have a
6 pointer, so I'll just have to walk you through.

7 With the microbial risk assessment, you can
8 estimate the prevalence and use enumeration and
9 serotype information to start from primary production
10 and work forward to estimate pathogen levels of the
11 various points in production, and go -- oh, thank you.
12 And like that, I have a pointer. What service! So
13 you can start at your primary production and work
14 forward to figure out what would be there and estimate
15 what levels would be on consumption, given a certain
16 level at various points in processing, and come out
17 and estimate what level would be present or what level
18 of illness would be present in the public.

19 Once again, you get a dose response curve.
20 This is a very simplified dose response curve, our RAD
21 group would probably be horrified that I don't have
22 little uncertainty analysis around this, but it was

1 too hard to draw. So this is a very simple version of
2 a dose response curve. You use the dose response
3 curve to figure out and estimate what level of illness
4 would be associated with the level on the food. With
5 the food safety objectives, you determine a public
6 health goal like we have in the Healthy People 2010 or
7 the Council of Food Safety for 2005, and once again
8 you use the dose response curve to connect your public
9 health goal back up to your food safety objective at
10 the point of consumption and then work your way back
11 to figure out what your performance objectives are at
12 the different points along the food supply. That's
13 sort of the two ways of doing it in a nutshell.

14 So that's challenge number one, and number
15 two I've talked about so far which is linking A to B
16 and B to C.

17 The overall challenge we have as an Agency
18 is to link A to C, or link our activities, our
19 inspection activities with our public health goals,
20 and with our public health impacts. So the question
21 here is if you link A to B and you've linked B to C,
22 is that enough to say therefore A and C are somehow

1 linked, and try and make some estimates of level of
2 linkage there and quantitate it, or is there a way to
3 directly link A to C and have that linkage
4 established.

5 So that brings us, and I've already alluded
6 to these questions a lot, but just to recap the
7 questions that we're hoping to get some insight on
8 from all of you on the Committee is what analyses or
9 approaches would you propose to determine the
10 relationship between FSIS' inspection activities and
11 contamination rates in FSIS regulated food? That's
12 the A to B.

13 What analyses or approaches would you
14 propose to determine the relationship between
15 microbial contamination on FSIS regulated food
16 products to public health illness? That's the B to C.

17 And do you have any suggestions to directly
18 link our inspection activities to public health
19 impacts? That's the A to C.

20 That would be it, and I'll sit down.

21 MR. TYNAN: Again, we're going to have this
22 as a topic of a Subcommittee meeting. So we don't

1 need to get into an in depth discussion at this point.
2 But before you get to the Subcommittee, if there are
3 questions from the group, we'd like to hear them now.
4 Questions or comments, and I can see Mr. Elfering is
5 getting ready. So we'll start with Mr. Elfering.

6 MR. ELFERING: This is Kevin Elfering. I'm
7 not on that particular Subcommittee. I think we still
8 need to get back to one of the most important things
9 is attribution data, and what is really causing
10 foodborne illness. I can't necessarily criticize an
11 Agency that wants to reduce the prevalence of
12 *Salmonella* in raw poultry, but I don't think reducing
13 the prevalence of *Salmonella* in raw poultry equates to
14 less foodborne illness outbreak. I just -- I'm not
15 convinced of that. There's too many other cases of
16 *Salmonella* that have been investigated from tomatoes,
17 cantaloupe to ice cream and, you know, I think all
18 these systems always have some kind of a failure.

19 Patients get misdiagnosed. Bridges
20 collapse. And you have to find out the root cause
21 before you can really find a solution, but because
22 bridges collapse and patients are misdiagnosed,

1 they're not going to stop me from driving over bridges
2 or going to the doctor. And I think that it's really
3 important to really know what is getting people sick.
4 It might be poultry but it might be a specific
5 poultry. It might be a chicken entrée product that is
6 ready to cook. So why look at reducing *Salmonella*
7 levels or pointing the finger at raw whole chickens as
8 the problem.

9 So I still think that that's such important
10 data that we don't have. We don't have that
11 attribution data what is getting people sick, and to
12 me, that's really the most important thing that we
13 need.

14 MR. TYNAN: Mr. Kowalcyk. I'm sorry. Did
15 you have a comment? No. You don't want to argue with
16 Kevin? Okay. Mr. Kowalcyk.

17 MR. KOWALCYK: Thank you. Yeah, I think to
18 reiterate what Kevin just put forth about the food
19 attribution data, I mean that was the first thing I
20 thought of when I saw the paper come out in our pre-
21 read materials. Also, it seems like you're trying to
22 draw associations with inspection activities and

1 microbial contamination rates. So at this point of
2 your proposed analysis, it's at a plant level.

3 DR. CATLIN: It would be a plant specific
4 level that we'd be looking at this.

5 MR. KOWALCYK: Okay. Has the Agency put any
6 thought into how your looking at the population of
7 plants? There's a lot of variance in plant size,
8 things like that, that would need to be addressed in
9 taking an approach like this.

10 DR. CATLIN: Yeah, this is something that we
11 are working -- we'd be working with some people who
12 are doing the sort of high -- analyses outside the
13 Agency for us, and they can look at individual
14 facilities and looking at their results, we can cut
15 the data for different time periods, regional
16 variations, and do sort of different types of analyses
17 on it, to see what we can learn from them.

18 MR. KOWALCYK: Okay. And just to clarify,
19 correlation analysis is that a route you're going down
20 right now. So you're just looking at associations?
21 You can't --

22 DR. CATLIN: Not causality.

1 MR. KOWALCYK: You cannot determine
2 causality.

3 DR. CATLIN: No.

4 MR. TYNAN: Dr. Negron.

5 DR. NEGRON-BRAVO: Yes. I agree with Kevin
6 also in his statement and there are so many other
7 steps through the plant to table that is important and
8 not necessarily strictly related only FSIS activities
9 that we have been -- once we were helping one company,
10 and we trained, for example, all their employees that
11 cleaned. They didn't know what was really cleaning,
12 and the relation of the job to having not a NR. So at
13 the end of the training, the supervisor of the team
14 that asked for the training said, well, this is the
15 first time the company doesn't have a NR on sanitation
16 related. So he was very proud of having that
17 training, these janitors and training. So it's not
18 really necessarily an activity related to usual
19 regulated FSIS activity but is part of the whole thing
20 from plant to table.

21 And also beef, animal production, that
22 company had a problem with *Salmonella*, but it was not

1 the company. It was the cleaning, the cleaning on the
2 farm that was bringing the problem to the, to the
3 industry, to the slaughterhouse. So we have to also
4 through the whole chain think what is the important
5 part.

6 MR. TYNAN: Thank you, Dr. Negron.
7 Dr. Vetter, I think you had a comment.

8 DR. VETTER: Are you currently looking at
9 this using the existing PBIS database?

10 DR. CATLIN: Currently, yeah. We have to
11 work with what we have. So --

12 DR. VETTER: I would just say that I believe
13 that it's next to impossible to do this using the
14 current database and I'll explain why. Even if you're
15 just looking at PBIS codes which designate sanitation
16 performance standards and sanitation and HACCP as your
17 subsets, you could have *Listeria* follow any of those
18 depending on the approach that the company took to
19 address *Listeria* within their plant.

20 So I think it would be very difficult to do,
21 what you're trying to do, as far as linking A to B
22 with the existing database. And I don't think you

1 could do it based on regulations alone either because
2 you might be writing a sanitation noncompliance that
3 would pertain to potential *Salmonella* issues.
4 Depending on where that company has decided to put
5 that within their program, it may not be -- so to link
6 it back to a specific microorganism at this point, I
7 could see would be very, very difficult.

8 DR. CATLIN: There are definitely some
9 challenges to it, and you do have to look carefully at
10 what you're looking at, but the risk assessment
11 division has actually had some success being able to
12 link our activities up to the *Salmonella* endpoints for
13 the facilities and some initial work we've done has
14 also some hopefulness that it can be done. I mean
15 there are difficulties in any analysis as with any
16 analysis would have to associated with -- we'd have to
17 state what assumptions went into it and what some of
18 the uncertainties are and some of the limitations of
19 those analyses. But it does it appear like we might
20 be able to get some useful information from it.

21 DR. VETTER: Are you doing that based on
22 regs or based on PBIS codes?

1 DR. CATLIN: I'm trying to remember now off
2 the top of my head. I think it was codes linking.
3 Yeah, it was the codes with some thought after what
4 regs were behind it, but mainly on the codes and how
5 they would play out for different endpoints.

6 DR. VETTER: Okay.

7 MR. TYNAN: Mr. Covington.

8 MR. COVINGTON: Brian Covington, and
9 Dr. Vetter actually hit on the majority of my topic
10 because in the relationship of trying to show a
11 correlation from A to B, and using a specific subset
12 of NRs that are written, I go under the assumption
13 that that would be a similar breakdown to the RBI
14 processing model as a component of the algorithm using
15 either the reg citations or task codes to break those
16 out.

17 In your initial analysis, what happens if
18 you cannot draw a correlation between the number of
19 NRs and the micro contamination or incidence rate of
20 the pathogen of concern at a particular facility?

21 DR. CATLIN: Okay. First of all, we're
22 doing the analysis on a facility-by-facility basis but

1 we're not looking at individual ones to see what
2 they're saying in particular, but using those
3 individual comparisons basically, to look at the
4 overall rates nationally. So we're not trying to draw
5 specific associations or conclusions about the
6 association in one facility, more look at those across
7 all facilities but using the actual paired data from
8 the facilities themselves.

9 Given that, if there -- I mean this is one
10 of those analyses to see is there a correlation. So
11 there's the analysis and the question at hand, and
12 then there's the answer, and then you go with what the
13 data tells you as far as the answer.

14 MR. COVINGTON: And just a follow up to that
15 as one of your slides indicated, when you look at
16 trying to draw a correlation between a NR in a day, a
17 week or a month or over time, would that be looking at
18 that particular subset of NRs or would that be looking
19 at the total NR data base that's generated by PBIS?

20 DR. CATLIN: It would be looking at the
21 subset. When you start getting the total NR rate,
22 there's just too much out there, too many and too much

1 noise to try and draw any conclusions.

2 MR. TYNAN: Mrs. Foreman, you had a
3 question?

4 MS. TUCKER FOREMAN: Yes, I too think that
5 it's hard to go anywhere without having the food
6 attribution data first and we still don't have the
7 risk assessments. So we can't reference that. And in
8 terms of microbial contamination, would you be looking
9 at it on a plant-by-plant basis or would you be
10 looking at the verification data?

11 DR. CATLIN: For this, we would be looking
12 at -- what we'd do is we would look at a single plant,
13 you analyze and look at their NR rates compared to
14 their actual results from *Salmonella* results say,
15 microbial data results, and then you take the averages
16 across the nation to see if there's any trends or
17 associations that are seen in general. Does that make
18 sense?

19 MS. TUCKER FOREMAN: Well, the first part
20 might if the *Salmonella* testing were done with more
21 frequency and a much tighter basis than it's done
22 right now, but averaging the *Salmonella* verification

1 data, is something that --

2 DR. CATLIN: Oh, I'm sorry. I must have
3 misspoke. I didn't mean that we're averaging the
4 *Salmonella* data. We're looking at the relationship
5 between verification and *Salmonella* --

6 MS. TUCKER FOREMAN: *Salmonella* and NRS.

7 DR. CATLIN: -- on an establishment-by-
8 establishment basis.

9 MS. TUCKER FOREMAN: Okay.

10 DR. CATLIN: And then looking at the average
11 of that relationship sort of across the nation.

12 MS. TUCKER FOREMAN: Okay. I clearly think
13 that there are problems about the *Salmonella* data and
14 the data sets and lots of mechanical issues there that
15 get in the way of making that a reliable tool, but a
16 more basic question, is it reasonable to ask what is
17 FSIS' goal in terms of reducing foodborne illness? We
18 know what the national goals are. Don't you then have
19 to ask what discreet part of that is, and I really
20 don't know the answer here, what discreet part of that
21 is FSIS'? I don't know how you can do that without
22 having food attribution data, but it might be easier

1 to wrestle this bear if you knew what the
2 institution's role is in the overall picture.

3 DR. CATLIN: Well, the Healthy People goals
4 were actually signed onto by all the agencies, by FDA,
5 CDC and FSIS. We were altogether came up with those.
6 The other questions within FSIS is what shall our
7 targets be for contamination levels, but going back to
8 what Kevin Elfering said, was how do those targets
9 match up to the public health goals is the other
10 question on there.

11 MS. TUCKER FOREMAN: Yeah.

12 DR. CATLIN: So --

13 MS. TUCKER FOREMAN: They keep coming back
14 to you've got to have some better attribution data
15 than we have.

16 DR. CATLIN: And we're trying to get more
17 and more of the PFGE patterns worked in which we think
18 is getting down to the subtyping of the microbial
19 contamination is moving in the right step we think to
20 get attribution, but we'd like to hear your thoughts
21 on that as well.

22 MR. TYNAN: Dr. Harris.

1 DR. HARRIS: Thank you, and really following
2 up to Kevin's comments, we've been talking about
3 attribution data for sometime, and it's a recurring
4 theme, and I know that we even had a public meeting in
5 recent months specifically on attribution data. I
6 guess my question is do we have any sort of a -- can
7 anyone give us sort of a status update on where that
8 effort stands? I know things take time but I just --
9 I'm not familiar with sort of where we are exactly on
10 following up on attribution data.

11 DR. RAYMOND: I think it's a good question,
12 Joe, and it's a good thought, and we had an
13 attribution summit in April, and it might be a good
14 idea for the next meeting of NACMPI to perhaps have an
15 abbreviated form of that presentation. We wouldn't
16 want to take probably a whole four hours, but we could
17 have CDC and FDA and FSIS come and tell you where
18 they're at, some individually and some as a group and
19 also have people like CSPI come and talk about their
20 attribution data, and it might be good for this
21 Committee to know because everybody that's spoken on
22 this subject is exactly right. And we kind have

1 assumed here, if it does come from what we regulate,
2 it comes from poultry but we know we've got a little
3 *Salmonella* in the pork, a little *Salmonella* in beef,
4 too. So we can't even make the assumption to poultry,
5 that it came from our regulated products. So we need
6 to do better.

7 Michelle mentioned the PFGE and VetNet and
8 other areas that we definitely know we can do better,
9 and we've been receiving some very constructive
10 comments about how we don't do the best job there. We
11 recognize we don't. We will do better, but the best I
12 can do today as the Under Secretary for the Office of
13 Food Safety is say if we can get the rate down of
14 product contaminated with *Salmonella*, it can't hurt
15 the public's health, and I can't guarantee you that it
16 will help the public's health, but with other products
17 that we regulate, when we have seen the pathogen
18 counts come down in the product, we generally have
19 seen the human foodborne illnesses come down until
20 last year when we had several outbreaks related to
21 several different products that kind of shot that
22 theory down. But as we saw *E. coli* come down, we saw

1 human foodborne illness from *E. coli* come down. As
2 *Listeria* came down, we saw human foodborne illness
3 from *Listeria* come down. We haven't seen *Salmonella*
4 come down until the last two years. We haven't seen
5 the result in foodborne illnesses come down yet, but
6 we have had everything Kevin mentioned in the last
7 year plus peanut butter. You forgot the peanut butter
8 outbreak. And so there's a lot of people that got
9 infected from *Salmonella* from other products besides
10 what we regulate.

11 So in a nutshell, we're trying to do what we
12 can do and I know the other agencies are going to do
13 what they can do, and attribution is something that is
14 near and dear to all of our hearts. The summit we
15 had, we hope is a kickoff to do better. We definitely
16 got it in the radar for FSIS in budget requests, et
17 cetera, and we'll make due with what we've got and we
18 hope to get more.

19 MR. TYNAN: Dr. Murinda, you had a comment?

20 DR. MURINDA: I --

21 MR. TYNAN: Okay. Mr. Kowalcyk.

22 MR. KOWALCYK: Thank you again. Just

1 another follow up question or comment about linking
2 inspection activities with microbial contamination
3 rates at the plant level. In going about setting up
4 this analysis, did you consider -- what time period
5 are you looking at these plants, over how many months?
6 And are you considering -- we had a lot of discussion
7 in the public meetings last fall and in our Committee
8 meetings about the use of NRs in taking the
9 qualitative information that's on a NR report and
10 putting it into a format that would fit nicely with,
11 you know, a relational database that can be managed.

12 With that said, did you look at or did you
13 challenge your theory that certain NRs were likely to
14 be associated with contamination to really confirm
15 that theory because there was some concern in the
16 discussions I was part of, where there could be a NR
17 that isn't necessarily, on the surface would seem food
18 safety related but it might be indicative of some
19 other process problem at the facility? Have you
20 considered that as well?

21 DR. CATLIN: First I'll address the time
22 question. And, yes, that is something luckily with

1 some of the automated tools that are being used, it's
2 actually fairly quick to look at, okay, to look at a
3 day's worth of NRs or two days or a week or two weeks
4 or a month or six months. So we have been able to,
5 what I call cut the data that way to look at those
6 different durations and see how using different time
7 points affects the associations that are seen. So we
8 have looked at that and do plan on doing more of that
9 because we think it's a useful exercise especially if
10 we were ever going to use this resource allocation to
11 be able to see what is the most appropriate timeframe
12 to be looking at.

13 MR. KOWALCYK: Right.

14 DR. CATLIN: With respect to the other NRs,
15 we haven't played around with that too much, but it's
16 definitely something that we could easily do with
17 these automated tools, look and see, we actually did
18 do all of them and that's not a good way to go, but we
19 could look and see what different NRs would be
20 included and see what would be the optimal -- the ones
21 that appear to be most associated.

22 MR. KOWALCYK: Okay.

1 MR. TYNAN: Dr. Murinda, I'm back to you.

2 DR. MURINDA: Considering that there are
3 more than 2,500 -- for *Salmonella* including some that
4 are of no relevance to human pathogenesis, are there
5 going to be any efforts to serotype those organisms?

6 DR. CATLIN: We definitely are. We work
7 with ARS. We're trying to formalize an MOA to make
8 sure we have the information on serotyping and
9 subtyping of the isolates. We do serotyping in house.
10 They do subtyping. We also, you know, when you hear
11 about different initiatives and the one that Kim is
12 going to talk to you about, the industry data,
13 whenever we're looking to get more data that we can
14 use, we're trying to make sure we can also have the
15 serotyping type data and subtyping type data that
16 could help us get more information to get that closer
17 to the attribution.

18 So in the back of our minds, when we're
19 looking to get more data, we're trying not only to get
20 the data but to get the most useful data that we can
21 get.

22 DR. MURINDA: My second question is with

1 relevance to O157:H7. It appears there's been much
2 emphasis on the detection of that organism, ignoring
3 that there are probably more than 100 other members of
4 the enterohemorrhagic *E. coli* family. Are there any
5 efforts to assist whether some of these species are
6 emerging, whether serotypes are emerging, like 026 or
7 114 or 128?

8 DR. CATLIN: I will defer to our *E. coli*
9 expert, Isabel, on that one.

10 DR. WALLS: I think it's a very important
11 question, and I do think that it's something that we
12 need to consider when we look at *E. coli* O157:H7.
13 It's not the only pathogen and serotype. We know
14 that. So I think it's something very, very important,
15 that I'd like to see us at this more broadly.

16 DR. MURINDA: Thank you.

17 MR. TYNAN: Did you have a follow up
18 question, Dr. Murinda?

19 DR. MURINDA: No, that's it.

20 MR. TYNAN: Okay. Mrs. Foreman, you had a
21 question or a comment?

22 MS. TUCKER FOREMAN: Yes, Carol TUCKER

1 FOREMAN with Consumer Federation. I'm going to --
2 Dr. Raymond used some numbers that I quarrel with
3 every time he uses them. So I'm not going to break
4 the record by not raising the objections now.

5 The National Advisory Committee for
6 Microbiological Criteria for Food, as well as any
7 number of other scientific groups have said that it is
8 not appropriate to suggest that reduction -- that the
9 verification -- reductions in verification numbers
10 from FSIS testing presents a valid estimate of the
11 national prevalence in cell numbers of microorganisms.
12 So you can't say because you don't have the data that
13 carcass contamination rates, the prevalence of carcass
14 contamination has fallen. Everybody on the scientific
15 side disputes that that is an acceptable correlation
16 to make.

17 On the foodborne illness side, it is true
18 that this year, for 2006, CDC said that we had gotten
19 back to 1996 levels for *E. coli* O157:H7 and for all
20 *Salmonella* serotypes combined. But the Agency both
21 last year and this year pointed out that there have
22 been no improvements in *Campylobacter* since 2001 and

1 *Listeria* rates have gone up since their lowest point
2 I think in 2003.

3 So the fact is we have not continued the
4 kind of progress in reduction in foodborne illness
5 almost across the board. Some types of *Salmonella*
6 have dropped, but the improvements in *Campylobacter*
7 stopped four years ago, and it's really important I
8 think that we not overstate these because it
9 undermines the effort then to lay out a program that
10 will actually address the problem that exists besides
11 I'll follow you around and keep saying this.

12 DR. RAYMOND: Consistency is good. And my
13 message wasn't as consistent this year as it had been
14 in the past, or my attempted message because the
15 numbers have gone back up, and we don't know exactly
16 why and it's harder to make correlations even if it's
17 unscientifically sound to me because I try to make
18 them because the only thing I've got to use right now
19 is the product samples that we've got to see whether
20 we're doing a better job or worse job, and our *E.*
21 *coli* numbers are not where they should be either. I
22 mean when we have a problem, we address it and

1 *Salmonella* has been an embarrassment to the Agency
2 and fortunately at least the product is turning
3 around.

4 MS. TUCKER FOREMAN: You don't know though
5 if your *E. coli* contamination rates have actually
6 gone down or not because you don't have a national
7 prevalence. All you know is that the plants you
8 tested last year came out that way, you know, again
9 and again. It only applies to that plant on that day
10 and has no significance before or after. So I don't
11 think it's appropriate to compare even those figures
12 year to year because you've got a different group
13 each year. And it only makes the issue harder to
14 discuss because it -- because we have to dispute it
15 every time it comes up.

16 DR. RAYMOND: We need Carol to have a visit
17 about the new *E. coli* plan. I don't know if you've
18 had a discussion with Dan about it. I think you'll
19 be happier. We will try to make it more consistent
20 from year to year. I don't argue with you. It is
21 amazing to me that three years in a row it was 0.17
22 percent. I don't know how you get the same numbers

1 but this year it's not going the right direction. We
2 have a higher rate this year, but since you said it's
3 not scientifically sound, then you can't beat on us
4 for having a higher rate this year.

5 MR. TYNAN: I'm going to let Dr. Vetter
6 have the last word before we transition to the next
7 topic.

8 DR. VETTER: Good. I like the last word.
9 Just for clarification purposes with what you're
10 doing with the existing data and maybe what you might
11 plan to do with future data, in linking A to B,
12 you're just really right now looking at rates of
13 noncompliance, like rates of SSOP noncompliance and
14 correlating that or looking for some type of
15 correlation between that and say *Salmonella* positives
16 or failures, subset failures.

17 DR. CATLIN: Yes. And it's a specific
18 subset of the --

19 DR. VETTER: Versus being able to take, for
20 lack of putting it better, a subset within that
21 subset, like a specific NR that might relate to
22 *Salmonella* or relate to *Listeria*.

1 DR. CATLIN: It's specific NRs in the
2 subset.

3 DR. VETTER: Versus -- okay. That's where
4 I'm a little confused. Is it specific NRs or is it
5 just a quantitative number of SSOP noncompliances in
6 relationship to it?

7 DR. CATLIN: We've looked at a specific set
8 of NRs and looked at the results for those, for that
9 activity basically. So for each one of those
10 activities, that were designated as being of interest
11 or possibly related, we looked at the results for
12 each establishment within -- on those verification
13 procedures and compared that to the rate of the
14 positives on *Salmonella*.

15 DR. VETTER: I guess that's kind of what
16 I'm getting at, but you're not like looking at, for
17 example, a particular SSOP noncompliance might
18 pertain to a company that was controlling *Listeria*
19 through their sanitation program only and received a
20 noncompliance in that area. It seems like you're
21 more looking at the total number of sanitation
22 noncompliances.

1 DR. CATLIN: Yes.

2 DR. VETTER: Okay.

3 MR. TYNAN: And with that, we're going to
4 close out this topic. I'm going to introduce the
5 next topic, which has to do with a Pilot Project to
6 Explore Mechanisms for Sharing Industry Data with
7 FSIS. And I have Ms. Kim Green who is a Senior
8 Scientist with Office of Food Defense and Emergency
9 Response.

10 MS. GREEN: Good afternoon. As Robert
11 said, my name is Kim Green. I'm in the Office of
12 Food Defense and Emergency Response, and I work with
13 Carol, Carol Maczka.

14 UNIDENTIFIED SPEAKER: Louder.

15 MS. GREEN: Louder. Okay. Thank you.
16 That is not a comment I normally get, you realize
17 that.

18 All right. So the issue we want to bring
19 before the NACMPI Subcommittee this afternoon is as
20 Robert said, is one of using a pilot program --
21 presenting to you some pilot projects for
22 consideration as a possible way to explore sharing

1 FSIS industry data with FSIS.

2 Quickly I'll take you through the purpose,
3 background, possible data pilot projects that we have
4 in mind, and then I'll walk you through the questions
5 that we're going to be asking the Subcommittee to
6 deliberate this afternoon.

7 So we're seeking this afternoon NACMPI's
8 recommendations on a pilot project that we could get
9 into to really look at using industry data. We're
10 also seeking for further guidance on the type of
11 industry data that might be shared in the pilot,
12 mechanisms for collecting this data and also
13 mechanisms for verifying it.

14 Non-FSIS data has historically been used in
15 other aspects of what we do at the Agency including
16 risk assessment, economic impact analysis and
17 regulatory development. But to date, the data that
18 we've received from industry has been aggregate, it's
19 not specific to individual establishments, with one
20 exception that I'll just quickly go through, and that
21 is our *Listeria monocytogenes* program or *Lm*
22 Alternative program as we refer to it, and under this

1 program, establishments that do produce post-
2 lethality exposed, ready-to-eat product, report to us
3 the alternatives that they're going to fit under 1
4 through 3, for how they're going to reduce *Listeria*.
5 They report to us both annual production volumes and
6 other information, and they do this by submitting an
7 FSIS Form 10,240-1 to us. They either fax it to us
8 or mail it to us or more recently, we have an
9 electronic version of the form. It's a fillable pdf
10 on our website that they can fill out and e-mail to
11 us.

12 As Carol TUCKER FOREMAN mentioned, this is
13 not a new issue. In 2004, we came before the NACMPI
14 and we asked you all to consider a variation of this.
15 And at that time, we asked you to talk with us about
16 a data repository, a third-party data repository as a
17 way to help us anticipate foodborne illnesses. The
18 recommendation of NACMPI at that time is that FSIS
19 identify, and that's what we're here to do with you
20 today, a pilot program that could look at sharing
21 industry data.

22 Also for those of you who were with us last

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1 April, we did have a public meeting where we talked
2 about using data from other sources including
3 industry.

4 So what we'd really like to do today, and
5 I'll use a phrase that Robert used earlier, is we'd
6 like to move this forward. You've given us some
7 recommendations. We've taken them to heart, but
8 we're really like to see if we might be able to move
9 on to the next step. And what we're talking about
10 here is a pilot project on possible collection of
11 industry data.

12 The context that we're coming to you with
13 these pilot projects on is the possible allocation
14 and the use of this data in how we do our inspection,
15 and how we allocate our resources for inspection.

16 So I'm going to go through two possible
17 pilot projects that we've thought about. It doesn't
18 mean that they're the only two, but I'll give you our
19 thoughts on them, and again this afternoon, we're
20 open to your thoughts and ideas on them.

21 So the first one would be possible use of
22 volume data, and the question that we're asking you

1 is, is this one that would work for what we want to
2 do? And we really envision sort of two ways that
3 this might work. The first would be that industry
4 would voluntarily supply us production volume ranges.
5 Ranges, that's an operative word there. And in terms
6 of verification that might come from our field
7 personnel, looking at random samples of the
8 information. Or as a model or alternative for how
9 this might work, the industry, as part of their own
10 recordkeeping could voluntarily record production
11 volume ranges on a form that they would develop.
12 They would keep that in plant and our inspection
13 personnel could potentially verify and report
14 information or ranges of information into our
15 database, PBIS.

16 The second pilot project that we've
17 conceived of for your consideration, would have to do
18 with what you heard Dr. Dan Engeljohn mention
19 yesterday, and that is the fact that we're
20 considering a new *Salmonella* control incentive
21 initiative, a voluntary program, that if you agree to
22 be in that program, it would involve the submission

1 of data to the Agency for participation. Again, a
2 voluntary program, as you heard Dr. Engeljohn mention
3 yesterday, that's for broilers and turkeys, and I've
4 listed there the types of data that we are currently
5 considering for requiring for participation in that
6 program. I won't go through it but you can see that
7 it could consist of a fair amount of data.

8 In addition to what I listed before,
9 participation in that initiative could involve
10 submitting isolates for positives that would be
11 serotyped and then again we would capture that data
12 and put it into PulseNet. And again just -- that's
13 just sort of the *Salmonella* initiative that we're
14 talking about, but what we would perceive the pilot
15 project to be, would really be a subset of that,
16 again focusing on how we would use industry data and
17 how it would work with looking at it from a FSIS
18 perspective.

19 Again, our thinking here is that there
20 could be two models of how this could work. Industry
21 could maintain its pathogen testing records as part
22 of that initiative. And our field personnel could

1 potentially review, verify and collect the industry
2 data. That's one model.

3 Or industry could provide the data directly
4 to us, either as raw summary data, and again we would
5 look for ways to verify that data, and it maybe that
6 again we might turn to our field personnel to verify
7 it.

8 So I'm ready to take you through what the
9 questions are that we've developed for the
10 Subcommittee to consider. I'll start off by saying
11 that this would be in the context of establishing the
12 pilot program to collect and possibly use industry
13 data in allocating inspection resources.

14 Our first question, what type of industry
15 data would be appropriate for use in risk-based
16 inspection, specifically the risk-based inspection
17 algorithm for processing establishments? And we've
18 listed four types of data that we think we'd like you
19 to consider. Pathogen data, presence or absence,
20 enumeration, serotype or subtype; perhaps plant
21 environmental monitoring data, again presence,
22 absence, enumeration, serotype, subtype; volume data;

1 or maybe some other data that we hadn't given some
2 thought to.

3 The second question, so the first question
4 was around risk-based inspection in processing
5 facilities. The second one we'd like you to be
6 thinking about is what type of industry data would be
7 appropriate for use in a public health based
8 inspection algorithm for slaughter establishments?
9 Again, this is what you heard discussed in our public
10 meeting yesterday. And in the issue paper, we've
11 listed four categories of data. They're the same as
12 the ones that are up there for question number one,
13 pathogen data, environmental data, volume data or
14 other data.

15 The third question we'd like the
16 Subcommittee to take a look at is how should we as an
17 Agency obtain industry data? What are the actual
18 mechanisms that we should be looking at? Should data
19 come to us direct from industry into our database via
20 the Internet? We've heard discussion before during
21 our public meeting in April of a third party
22 repository. Contract laboratory data, is that

1 another mechanism or another way of getting at data?
2 And as you've heard me mention before in the context
3 of the possible pilots, how about collection on the
4 part of our inspection personnel as part of what
5 they're doing in plants?

6 And then the fourth question that we have
7 for the Subcommittee today is if we do use industry
8 data, how do we insure its quality? And some of the
9 considerations there would be verification by our
10 field personnel, possible use of standardized
11 methods, laboratory certification, use of third party
12 audits, et cetera.

13 Okay. I'll sit down and, Robert, I'll turn
14 it over to you.

15 MR. TYNAN: So we'll take a few minutes and
16 discuss this issue that Ms. Green raised, and I'll
17 open up the discussion. I have Mr. Elfering on my
18 right.

19 MR. ELFERING: Yes, this is Kevin Elfering.
20 I was actually on the Subcommittee that we discussed
21 this in 2004, and I think one of the things is
22 there's always going to be a little bit of a concern

1 of whether or not this information becomes public
2 information. And I'm just going to give you an
3 example, and please bear with me. The poultry
4 industry, the breeder industry, belongs to a program
5 called the NPIP Program, the National Poultry
6 Improvement Plan, and they're required to do a lot of
7 testing for that particular project. And they do
8 additional testing as well, and many of the poultry
9 industry's work in cooperation with APHIS and state
10 veterinarians. And there was a situation a couple of
11 years ago where there were three breeder flocks in
12 the United States that were found positive for
13 *Salmonella enteritis* phage type 4. In two of the
14 states, they vaccinated those breeder flocks, and the
15 third state, the state veterinarian made a
16 determination that *Salmonella enteritis* phage type 4,
17 is a foreign animal disease and depopulated a \$2
18 million breeder flock.

19 Now that company is not even required to do
20 testing for *Salmonella enteritis* phage type 4. But
21 yet in cooperation with state veterinarian's order,
22 and that information was taken to an extreme where a

1 company lost \$2 million, when in two other states all
2 they did was vaccinate the breeder farm.

3 So I think that the industry, and I don't
4 want to try to protect the industry, that's not my
5 goal. I would like to be able to see data to be able
6 to be used by an agency but yet it needs to be
7 cooperative. Meat and poultry inspection plants
8 should not be the only processing plants in the
9 country that produce or supply testing data. I mean
10 there's companies, there's pasta plants, there's
11 every other type of food product that does testing
12 that there's no requirement or no suggestion of ever
13 sharing that data with FDA.

14 I just think you really have to look at
15 where this data is going to be held, and I think
16 that's why we really made the recommendation of a
17 third party repository. So that the data could still
18 be used and be utilized by the Agency to track
19 foodborne illness and really see what types of
20 problems there are out there, but yet have some kind
21 of anonymity for the processing plant as well by
22 providing good data but with the security of it not

1 getting into a situation where, you know, sometimes
2 data that becomes public is not used in the best
3 ways, and sometimes it can be used even for
4 competitive reasons, and those would not be good.

5 So I think that's one of the first
6 questions I have, and I apologize for going on so
7 long, but this is going to be public data.

8 MS. GREEN: It's a good point, and it's
9 actually -- we have been doing some outreach to some
10 of our industry stakeholders on this very issue
11 around this. And one of the points that we really
12 want to make is that participation in any pilot that
13 we might do would be voluntary. And the other point,
14 if you will, that we got to in some of our recent
15 discussions with the industry is that we really would
16 probably be looking more at using ranges data rather
17 than specific data.

18 But you bring up a good point and one that
19 probably does need to be said in this. If data were
20 given to the Agency that, as a result of us looking
21 at it, it would appear that we need to take a
22 regulatory action, and Dr. Engeljohn is in the room,

1 and so he can always bolster what I'm saying here,
2 then we would consider that we would need to make
3 that data public. So that is something to be aware
4 of.

5 But again, one of the things that we looked
6 at, you know, that we're getting to look at is
7 possible verification by our personnel of information
8 versus actually having the numbers or also we've been
9 talking about could we put in ranges, and would that
10 protect some of the competitive type issues that you
11 raise.

12 MR. TYNAN: Dr. Henry.

13 DR. HENRY: Thank you, Robert. First
14 blush, as we go through this, I think the volume data
15 is an issue that certainly industry and through the
16 RBI coalition have conveyed very specific
17 recommendations to the Agency that has taken months
18 and months and many hours to develop. So I think
19 that that issue is relatively well defined. It needs
20 to be dealt with. It's a matter of how the algorithm
21 incorporates that data. Certainly Dr. Engeljohn is
22 very much aware of it because of firsthand handoff.

1 Regarding the rest of the data that's in
2 here, you know, what I read through here is a much
3 more broad, wide ranging baseline accumulation
4 process. It comes back to, you know, we have lots of
5 information that are collected for various reasons,
6 *E. coli* data as was brought up yesterday. *E. coli*
7 data, *Salmonella* data, are available to the
8 veterinarians, to FSIS, at any point in time. I
9 think one of the things we have to separate out here
10 because we're talking about a carte blanche, is a
11 huge difference between raw and ready-to-eat.

12 Ready-to-eat is one thing that is already
13 dealt with because you're dealing with the CCP with a
14 wide range and a host of interventions. That's a
15 given, done deal.

16 The raw side, I think we must always
17 acknowledge the fact, no matter how good we are, we
18 have not yet been able to outrun Mother Nature. No
19 matter how low we try to drive this, Mother Nature
20 will continue to throw us a change, and if we don't
21 think so, how long ago was it that we just started
22 talking about O157? I know when we started in the

1 industry we didn't know about it, and that was 30
2 years ago. Phage type 4, where did that come from?
3 I mean we can go on and on.

4 So I think, you know, this speaks to what
5 we brought up earlier this morning. I think if we're
6 out trying to capture a baseline, and say, hey,
7 industry, can you help us do it? That's great and I
8 look at this more like an early warning system, and
9 how low do you go, you know. If you capture all the
10 *Salmonella*, all of the *E. coli*, all of the
11 *Campylobacter*, what I thought Dr. Raymond brought up
12 earlier was exactly on point, and I think it was
13 brought up over here, too, by other colleagues.
14 We've addressed O157. We've addressed *Lm*. We've
15 addressed serotypes. We've addressed specific
16 pathogens with high pathogenicity at low count.

17 Moving forward with this, we've got to say,
18 what are we looking for and what is the net result
19 that we want to get out of this?

20 So that comes back to our let's make sure
21 we stay focused on two things, one, if we want an
22 early warning system to see what Mother Nature's

1 giving us, that's fine, looking at the raw side.

2 However, if we want to move the needle and
3 address illnesses on the other side of the puzzle,
4 then I think we have to be much more specific.
5 There's a lot, and I mean at the end of the day, we
6 have to look at the available resources both from a
7 federal standpoint, a state standpoint, and the
8 industry's standpoint as to what are we really
9 expecting to get out of this because we'll populate
10 -- I mean if turn it loose today, I can guarantee
11 you, your IT system can't handle it. It's that
12 simple. Not only that, but you don't have enough
13 staff to look at it if it came in under those
14 circumstances. So I think we've got to have a
15 reality check as we step through this.

16 It's only a comment. Thank you.

17 MR. TYNAN: Thank you, Dr. Henry.

18 MS. GREEN: I do think the intent here was
19 not to focus in on aggregate data but to actually
20 look at industry specific data. We've been trying to
21 get a handle on the data that our inspectors see
22 every day in a plant, because we were thinking that

1 we would be able to use that information in a risk-
2 based algorithm and so it was sort of an incentive to
3 industry to share that because we might be able to
4 use it in a risk-based algorithm.

5 DR. HENRY: Craig Henry again. And
6 acknowledging that we're still doing the algorithm,
7 we're still looking I think at all of the components
8 that have been forth for risk-based inspection with
9 what's available there. You know, again, two
10 different processes. One, certainly trying to reduce
11 risk which has a multitude of actions, tied to a
12 number of noncompliances and regulatory statute, we
13 understand that. I think coming back though again
14 being specific to when we're looking at this amount
15 of data, the data may not be extracted and taken off
16 premises now and put into a given data base, but
17 we've got to say again, what are we going to do with
18 it when we get to it in trying to do the algorithm.
19 That's a broader algorithm than just strictly dealing
20 with the pathogen side. It's a different animal in
21 itself.

22 MR. TYNAN: Dr. Vetter.

1 DR. VETTER: I was just going to speak to
2 some of what Dr. Henry talked about, in which you
3 talked about what we do on a basis now, in looking at
4 a great volume of data, that does come from the
5 establishment and not from FSIS. And that involves
6 looking -- not only looking at the results of that
7 data, but they usually have standard operating
8 procedures for collecting that data, and we will
9 observe them to insure that they're following those
10 procedures, and that can certainly be used as part of
11 your verification because it's ongoing right now.

12 They have programs in place to control
13 *Salmonella*, whether it be a multiple -- approach or a
14 CCP, and they're testing daily and sometimes multiple
15 times daily. So it's a greater amount of
16 information, and that's going on right now, and
17 certainly at some point, it might be applied to an
18 algorithm, but I think that particularly when you're
19 talking about raw product, you need to consider that
20 on a day-to-day basis, there are many variables that
21 will affect those results. And that can be disease
22 presence, and it can be seasonality. Although

1 there's been some talk about not really showing up in
2 some of the national data, I think it does show up
3 when you look at it on an individual plant basis to
4 some extent because there's more of it and you see
5 it. So I think that you have to keep in mind that
6 the inspection staff is currently looking at that,
7 and should continue to do so, so that you have some
8 real time results. And they certainly can be used as
9 a tool for verification because that's what's going
10 on right now.

11 MS. GREEN: Right. Excellent point, and
12 again knowing that, what we're looking to do is can
13 we build on that.

14 MR. TYNAN: Other comments and questions on
15 the issue of the pilot mechanism? Mr. Kowalczyk.

16 MR. KOWALCYK: Thank you. In setting up
17 the pilot programs that are being proposed here, and
18 Dr. Henry pointed out that there's mountains of data
19 out there, and has the Agency established in your
20 pilot design a way to capture how scalable is it?
21 Let's say if you were capturing volume data from
22 poultry processors, and you wanted to test if FSIS

1 personnel would validate the data before it gets
2 entered into the system, is that a realistic
3 requirement because I think one of the things that
4 relying on data that would potentially be fed into a
5 risk-based inspection algorithm, that would then
6 drive intensity of inspection. There's a whole other
7 set of issues that arise when that could occur, a
8 legal notwithstanding but as far as what your
9 workforce would be required to do as far as making
10 sure that that data is accurate as possible in
11 designing the pilots. Have you had those discussions
12 about scaling --

13 MS. GREEN: We have begun those
14 discussions, and again, one of the points you'll see
15 that I put up there was that one of the thoughts
16 we've given to this is random verification, as a way
17 to really be checking in on this, checking every bit
18 of data, is probably as you so well point out, not
19 realistic but we have given some thought to what the
20 mechanisms might be there. And again, we're looking
21 for other input, too. If there are some things we
22 haven't thought about that you'd like to share with

1 us.

2 MR. TYNAN: Dr. Henry.

3 DR. HENRY: I think Kim brings up -- thank
4 you, Robert. I think Kim brings up a key point here.
5 Random verification of what?

6 You know, just take it a little further. I
7 mean logically what should be happening, again I come
8 back to the early warning system, and that's what I
9 see carte blanche. Logically speaking, we have to
10 get back. If we draw conclusions or correlation
11 between the raw inbound load and the outbound load
12 that the consumer is exposed to, because all raw
13 product, I don't care where it comes from, all raw
14 product has a certain level of risk dependent on the
15 pathogen, dependent on the susceptibility of the host
16 and the dose. In this case though, we need to carry
17 forth and look at, if I had to verify something, if
18 we were able to get back to look at specific
19 interventions that had specific impact on specific
20 serotypes and/or pathogens, such as what we did for
21 O157, which the industry brought those interventions
22 to bear, now we can come back and say, okay, we're

1 going to go out here and look at this, and if
2 everybody's applying the intervention, now we can
3 verify the efficacy of the intervention and the net
4 impact on the load or exposure going out to the
5 consumer. That I think has great correlation.

6 And not saying that, you know, we shouldn't
7 do, you know, the baseline or early warning system,
8 but we've got to have a reality check again with what
9 can we manage and what are we going to do with it
10 because as I stated earlier this morning, time is
11 money. Show me what we're going to do, when are we
12 going to do it, and what's the net result from that
13 across the board. Now we're moving the ball forward.
14 Because I hate to see all you people in here on
15 weekends trying to go through the data that we could
16 certainly barrage you with. Thank you.

17 MS. GREEN: That's an excellent point, and
18 I think what Dr. Henry has brought us is exactly the
19 type of input we were looking to get back from the
20 NACMPI today. So I hope he's on my Subcommittee.

21 And the other one, the other one, I'll give
22 you though to think about is, so that was pathogen

1 data, what about volume data? And sort of think
2 about that. Maybe that's something a little easier
3 to embrace.

4 DR. HENRY: And I'll just say, Joe Harris
5 is on your team, and he can handle the volume data.
6 We've got total confidence in him.

7 MR. TYNAN: I just want to remind everybody
8 that even though you're on a Subcommittee, that
9 tomorrow whatever the Subcommittee comes up with, is
10 open for the entire group. So even though you're not
11 in that discussion, if you participate in the other
12 Subcommittee, you get an opportunity to weigh in on
13 it.

14 Before I come to Mrs. Foreman,
15 Mr. Covington, you had a comment.

16 MR. COVINGTON: Just a quick one. If we go
17 down this road and let's take the option that the in-
18 plant inspectors do verification activity, I'm
19 assuming that would be generated in PBIS on some
20 frequency, do you have the resources dedicated for
21 them to do that? I mean do you have the training or
22 will you have the training in place so that they can

1 understand some of the complex data that we generate
2 because I'm going to be quite honest with you, we
3 generate some data that I don't even understand
4 whenever I look at it, and I see that as a potential
5 problem. And it's not fair to industry. It's not
6 fair to the inspectors, to put them in a position to
7 try to analyze data like a statistician if that
8 training is not taking place.

9 MS. GREEN: No, I understand. We really
10 think more of the data coming up to Headquarters. If
11 Dr. Karlease Kelly is here -- yep -- we would
12 consider if we were moving in this direction, this
13 would be a component of the programs that she's
14 trying to get off to base, more sort of consistency
15 in how we're training and what we're training our
16 inspectors in.

17 MR. TYNAN: Mrs. Foreman.

18 MS. TUCKER FOREMAN: Yes, Carol TUCKER
19 FOREMAN with Consumer Federation. I'm glad you
20 mentioned the information about the Subcommittees. I
21 have noticed that Mike Kowalcyk and I are both on one
22 committee, Subcommittee. I mentioned this morning

1 the problem that you now have only two
2 representatives of consumer organizations. In the
3 Charter for the Committee, it is pointed out under
4 3(c) that you want to assure a balance of different
5 views and you list some groups, specifically consumer
6 organizations.

7 In the Committee responsibilities, there
8 are several lines that indicate that the thorough
9 discussion takes place in the Subcommittee, that
10 that's where recommendations are made, that's where
11 an action plan is developed, so on and so forth. So
12 I would respectfully request please that I be moved
13 from Subcommittee 2 to Subcommittee 1, because as it
14 is right now, it has two representatives from state
15 government, three of industry, three for academia and
16 none from consumer organizations.

17 MR. TYNAN: That's correct, but in the
18 Charter, we don't have specific designations for each
19 of those groups. We try and have the balance, but we
20 don't have anything that says we have to have X
21 number of industry and X number of consumer groups.
22 And when we got our applications in, as I think

1 Dr. Raymond mentioned earlier, we had so many and
2 they were such high quality candidates, that in some
3 of the cases we wanted to introduce some new
4 individuals. So Dr. Jones and Ms. Conti are both --
5 Ms. Jones is with an academic institution --

6 MS. TUCKER FOREMAN: Yes, she is.

7 MR. TYNAN: -- but she -- yes, she is, but
8 she also has a public health background.

9 MS. TUCKER FOREMAN: She is not a
10 representative of a consumer organization, and I
11 really object and my tone is about to get pretty
12 hostile about it, that you have got a Subcommittee
13 that is absolutely basic to what every consumer
14 organization comes to this Department to talk about
15 and you have constructed it so there's no
16 representative of a consumer organization on it. I
17 really find that it is absolutely unacceptable. I
18 know you did it having giving it consideration, and I
19 am objecting vigorously to that. And I request
20 please to be moved. You don't need two consumer
21 organization representatives on the task force on
22 industry. You do need one talking about public

1 health. And I'm actually -- I'm just astounded that
2 you decided that you're going to intentionally keep
3 one of us off of it.

4 MR. TYNAN: I think you're making
5 inferences about what I did in constructing the
6 Committee that you can't make because --

7 MS. TUCKER FOREMAN: I am and I will.
8 Neither of these ladies represent a consumer
9 organization. They have no constituency. I
10 represent 326 state, local and national consumer
11 organizations, with a membership that totals
12 something like 50 million people. We occupy
13 different niches in this organization.

14 MR. TYNAN: That's correct. And,
15 Mrs. Foreman, I think what you've asked for is not an
16 unreasonable thing to ask. When we put these
17 together, we did it looking at everybody's
18 background, and tried to match them up. Not knowing
19 completely what everybody's background was, we made
20 our best guess. We talked a little this morning.
21 There was a couple of folks that wanted to change.
22 We talked with other people to make that switch.

1 They didn't want to switch, so we left the status
2 quo. Had I realized at the time that you wanted to
3 be on a different committee, or Michael should be on
4 a different committee, we would have made that
5 change. It is --

6 MS. TUCKER FOREMAN: Well, you can do it
7 now, and I request that you do it because you are
8 putting me in really an untenable position here. I
9 cannot sit here and be kept off the public -- one of
10 us has to be on that committee.

11 MR. TYNAN: Which one would you like to be
12 on?

13 DR. RYBOLT: Put her to Committee 1.

14 MR. TYNAN: Okay. That's fine.

15 DR. RYBOLT: And then if we have a
16 volunteer to move from Committee 2 up or -- from 1 to
17 2, I'd be open to that as well. Michael, thank you.
18 So let's do that.

19 MR. TYNAN: That works for me. Ms. Conti,
20 you had a question or a comment.

21 MS. CONTI: I just had a comment about the
22 -- looking at the slide about the possible pilot

1 projects and the two scenarios, one being that
2 industry would provide pathogen data directly to FSIS
3 versus industry would maintain pathogen testing
4 records as a part of a new *Salmonella* initiative, and
5 the field personnel could verify and collect industry
6 data, it just seems like you're missing out on the
7 opportunity to verify during the collection process
8 if you have industry directly send the information to
9 FSIS. And you may as well verify during the
10 collection process with the field personnel is my
11 suggestion.

12 MS. GREEN: The intent was to verify in
13 both models. But you're saving a step I guess with
14 the first example.

15 MS. CONTI: So you're saying if we have the
16 inspection floor or field personnel collect it in the
17 first place, they could collect and verify.

18 MS. GREEN: Which might be cost effective.

19 MS. CONTI: Yeah.

20 MS. GREEN: Okay. And by the way, we
21 wouldn't mind doing both of those pilots.

22 MS. CONTI: Okay.

1 MS. GREEN: We didn't really want you to
2 choose. We would really like to do both.

3 MS. CONTI: Great.

4 MR. TYNAN: Okay. We're at quarter 'til on
5 our agenda, and we're at the point of doing the
6 public comment period but before we do that, I would
7 take you to Tab 3, and we have outlined there the
8 Subcommittee groups. We've made one adjustment. If
9 somebody on Subcommittee 1 wants to participate on
10 Subcommittee 2, we're welcome to make that adjustment
11 so that we can have at least an even number of people
12 at that particular point.

13 What I would mention to you is linking FSIS
14 activities is going to be breakout room 335. LaVonne
15 Johnson who is over here on the left-hand side of the
16 room, will guide you to that, and she will hang out
17 to see if you need some help in getting things done.
18 Mr. Schad is going to be the Chairperson of that
19 group.

20 Subcommittee 2 is going to stay here in
21 this room, and we'll have somebody here to help you
22 with notes and whatever you need. Mr. Elfering is

1 going to be the chair of that particular group.

2 So those are the breakout sessions. As I
3 mentioned earlier, the Chairperson has a lot of
4 discretion of the public, if you want to sit in, in
5 terms of how much input and so on the public will
6 have in the session, and before we get to the public
7 comment period, are there any questions about what
8 we're proposing to do?

9 (No response.)

10 MR. TYNAN: Okay. With that I'm going to
11 open it up for the public comment period, and do we
12 have some -- we have three individuals that signed
13 up. So we're going to start with those folks first.
14 Mr. Corbo, and let me get you a microphone.

15 MR. CORBO: Tony Corbo from Food and Water
16 Watch. First of all, I want to compliment the staff
17 presentations today. They were very thought
18 provoking and I look forward to the continued
19 discussion. I think, you know, the caliber of the
20 work that you've done and what you've put into the
21 presentations was excellent, and I just look forward
22 to continuing the discussion.

1 I have a couple of process concerns, and I
2 want to echo the comments that Carol TUCKER FOREMAN
3 has made about the vacancy of a consumer
4 representative on this Committee.

5 There has been a precedent that the Agency
6 has used in the past. When a similar situation
7 occurred in 2003, right after the Committee was named
8 in 2003, one of the consumer representatives took
9 another job, resigned from the Committee, and the
10 Agency then issued a Federal Register notice,
11 limiting nominations to fill that vacancy to a
12 consumer representative. So there is a precedent to
13 fill in that vacancy.

14 The magnitude of the issues that the Agency
15 is going forward in the near future, I think require
16 that you have a full compliment of the consumer
17 representatives on the Committee. So I urge the
18 Agency to revisit this issue. You do have a basis to
19 fill the one vacancy. You've done it in the past,
20 and I urge you to do it again.

21 The second process concern, Chairman
22 Almanza, your predecessor, Dr. Masters, made it a

1 point to allow the public to participate in these
2 Subcommittee deliberations. What I've heard today is
3 that the Chairman of the Subcommittee have latitude.
4 She made distinct instructions to the Subcommittee
5 Chairman to allow the public members sitting in those
6 Subcommittees to participate, and I urge you to
7 follow her previous instructions to the Subcommittee
8 Chairs. Thank you.

9 MR. TYNAN: The next person we have
10 registered for comment is Felicia Nestor.

11 MS. NESTOR: Felicia Nestor, Food and Water
12 Watch. Probably a number of you yesterday heard me
13 talking about the Agency's programs, statistical
14 programs, and I apologize to Dr. Raymond for using
15 the word laugh test. It was a little blip on my
16 radar screen, and that was yesterday. Today I agree
17 with Tony. I'm so impressed with the presentations
18 this morning, and really hope that this is not going
19 to be another situation where it's good on paper,
20 good in the beginning, and doesn't get the support
21 from the Agency. So I'm going to be watchdogging it
22 and doing everything I can to make sure that this

1 group gets support.

2 I just wondered. I thought that Loren
3 Lange yesterday said something about that recently
4 the Agency started doing the *Salmonella* sampling on a
5 different protocol because they wanted to focus on
6 the plants that were in the worst category. And I'm
7 not sure, maybe I remember that incorrectly, but if
8 that's the case, then it seems like if you don't have
9 a consistent protocol for the sampling, to do any
10 sort of analysis across time, I would think that that
11 would be a factor you would have to consider.

12 And my second comment and last comment is,
13 you know, I hate to be a broken record, but if you
14 think of the inspectors in the plants that can write
15 NRs, as a machine, if the inspector is there, he or
16 she, and is able to write NRs because they are not on
17 the line, then the machine is on. If there are
18 vacancies and in some places there are chronic
19 vacancy and the inspector is not there or there is an
20 inspector there, and the inspector is pulled to the
21 line and is not allowed to write a NR about anything
22 that he or she sees while on the line, then the

1 machine is off. So I really don't see how you can do
2 any correlations at all without taking into account
3 whether the recording machine for one of your factors
4 was on or off.

5 When I got my HIMP FOIA, one of the three
6 plants or something that I've gotten, there were
7 absolutely no NRs. I got it for a six month period,
8 NRs between June 1 and July 11. None. And then the
9 NRs that the plant did get through the remainder of
10 the period are so similar and severe, the inspector
11 writes about contamination on the equipment that she
12 can scrape off with her fingernail.

13 It's very hard for me to believe that, you
14 know, that the problem could be so severe on one day
15 and then the plant is just perfect through the rest
16 of the period. I also know from speaking with
17 inspectors, that very often there is not an inspector
18 that can write a NR. So as the data collection
19 proceeds, I think you have to note whether the
20 recording machine was on or off on any particular
21 day. Thank you.

22 MR. TYNAN: Those are the only -- Tony and

1 Felicia were the only public folks that registered.
2 I'm going to open it up to other people in the
3 audience. Is there anyone else that would like to
4 make a comment at this time regarding the meeting and
5 the subject of the meeting?

6 (No response.)

7 MR. TYNAN: Okay. There being none, I'm
8 going to introduce Mr. Almanza again, maybe to wrap
9 up, and adjourn the meeting for today so that you can
10 go into your Subcommittee sessions.

11 MR. ALMANZA: Well, this was -- I've got to
12 tell you in almost 30 years that I've been with this
13 Agency, I've never been in a meeting that was this
14 interesting. I believe that this is what the process
15 is meant to be, and everybody voices their opinion,
16 everybody has their perception of the way it should
17 be, and I encourage that. I encourage everybody to
18 state their opinions and for it to be a healthy
19 exchange of information. That's the way it's
20 supposed to be.

21 And with that, I want to let the
22 Subcommittees get to work and, Tony, in response to

1 your question, yes, your request is granted. I love
2 saying yes by the way. But I think what Robert was
3 alluding to was that the Chairperson would control
4 the Subcommittee and that's fair enough. I think you
5 can live with that.

6 So with that, we'll see you all tomorrow
7 morning, and is that it, Robert? Anything else?

8 (No response.)

9 MR. ALMANZA: Thank you.

10 (Whereupon, at 2:55 p.m., the meeting was
11 concluded.)

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C E R T I F I C A T E

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

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

PLENARY SESSION

Arlington, Virginia

August 8, 2007

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

DOMINICO QUATTROCIOCCHI, Reporter
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