

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE 1

ISSUE I: DATA COLLECTION, ANALYSIS, AND TRANSPARENCY

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September 30, 2010

9:15 a.m.

USDA South Building Cafeteria

Washington, D.C.

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Morehouse School of Medicine

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MR. CHRIS WALDROP

I-N-D-E-X

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2 (9:15 a.m.)

3 DR. JONES: Good morning. I would like to
4 suggest that Committee 1 begin our discussion. I
5 guess if we could go around one time and just say
6 our names and our affiliations, and then we can
7 begin the discussion of the various questions that
8 we have to address today.

9 I'm Cheryl Jones, Morehouse School of
10 Medicine.

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

13 DR. LIANG: Art Liang, CDC, Food Safety
14 Office.

15 DR. TILDEN: John Tilden, Michigan
16 Department of Agriculture.

17 MR. WARSHAWER: Steve Warshawer, Mesa Top
18 Farm.

19 DR. KASSENBERG: Heidi Kassenborg,
20 Minnesota Department of Agriculture.

21 MR. REED: Todd Reed, FSIS.

22 MR. ALVARES: Christopher Alvares, FSIS.

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

3 MR. REINHARD: Bob Reinhard, Sara Lee
4 Corporation.

5 MS. BUCK: Patricia Buck, Center for
6 Foodborne Illness Research and Prevention.

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

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

11 DR. NEGRON-BRAVO: Edna Negron, University
12 of Puerto Rico, Mayaguez.

13 DR. VETTER: Danah Vetter. I represent the
14 National Association of Federal Veterinarians.

15 DR. JONES: Okay. Thank you very much, and
16 thank everybody for being here and participating.

17 We have approximately five questions that
18 we need to address in the next three hours or so. I
19 would like to suggest that we just start with the
20 questions one by one and go through them and discuss
21 them. If there's another way that people would like
22 to proceed, you could suggest that now.

1 Okay. The first question is "Who are the
2 likely audiences or primary customers that FSIS
3 should consider in data collection, analysis, and
4 transparency?"

5 DR. TILDEN: Do we have to say our name
6 every time we say something?

7 COURT REPORTER: No.

8 DR. JONES: No.

9 COURT REPORTER: As long as you're on a
10 microphone. That's good. Thank you.

11 DR. TILDEN: Okay.

12 DR. JONES: One second please.

13 MS. TUCKER-FOREMAN: This is Carol Tucker-
14 Foreman from Consumer Federation. In the past,
15 going back, oh, I think to the first Bush
16 Administration, people who, the public has been
17 invited to participate in the Subcommittee meetings,
18 not to vote, but to sit at the table or in the
19 chairs and participate in the discussion, and I'd
20 like to propose that we do that now.

21 There is FSIS minders who are around who
22 are familiar with this. We've certainly did it.

1 DR. JONES: Yes, that's fine.

2 MS. TUCKER-FOREMAN: Okay. Thank you.

3 DR. JONES: Uh-huh.

4 DR. TILDEN: So a way of starting it might
5 be to break it down into internal and external
6 stakeholders that use it, you know, and you can just
7 do all the internal FSIS folks, how the data is used
8 and shared internally, and then look externally.
9 That might be a way of breaking it out.

10 DR. JONES: Okay. That sounds good to me.
11 So we can start with internal stakeholders.

12 DR. TILDEN: Yeah, and I can frame it a
13 little bit --

14 DR. JONES: Okay.

15 DR. TILDEN: -- just to get it started
16 because we heard yesterday about how the field staff
17 used the data for their operational needs. We also
18 have heard from training that they use data to see
19 where things are going well and where it's not going
20 well, and where staff would need to be trained, and
21 then program management people evaluate whether
22 operationally they're achieving operational goals,

1 and then we had talked just briefly about some of
2 the policy types that would use some of this data to
3 develop those predictive modeling programs that are
4 yet to be fleshed out, and then senior staff that
5 would have to describe to the funders whether FSIS
6 programs are doing what they're supposed to be doing
7 with the resources that they've been entrusted with.

8 DR. JONES: Okay.

9 MR. WARSHAWER: Can our typist go to a
10 bigger font so we can follow better on the screen.

11 DR. KASSENBERG: And then can we -- this is
12 Heidi Kassenborg. Can we define what you mean by
13 internal stakeholders? Do you mean just internal to
14 FSIS, internal to the USDA? A better description of
15 that.

16 DR. TILDEN: Yep, a good point. I was just
17 thinking FSIS staff, but it obviously could be
18 different.

19 DR. JONES: Do we feel that internal
20 stakeholders would be others than FSIS staff?

21 MS. BUCK: Are we talking about the
22 internal data at this point or the external?

1 DR. JONES: We're actually talking about
2 the stakeholders.

3 MS. BUCK: Okay.

4 DR. JONES: Who will use the data? I don't
5 think we're actually talking about what types of
6 data yet.

7 MS. BUCK: Okay.

8 DR. JONES: Just the people who will use
9 the data once it's collected.

10 MS. BUCK: Okay.

11 DR. MURINDA: Actually, I think you're on
12 the right point. If we were to restate that
13 question, the way I appreciate the question is that
14 who is interested in this data and what do they want
15 to use it for? That's probably the question here.

16 DR. JONES: Any comments on that? Any
17 agreement?

18 MR. REED: Yeah, I would say we're really
19 looking for outside stakeholders as well. I mean if
20 you want to itemize internal ones, that's fine, but
21 we're really we're hoping for external stakeholders.

22 MS. BUCK: I would concur with that. It

1 would be more to the external.

2 MS. TUCKER-FOREMAN: It seems to me that
3 it's okay to have these provisions, internal and
4 external, because the internal ones are really
5 important for being able to have the right data in
6 order to defend the Agency's budget within the
7 departmental budget making process and, you know,
8 being a public health agency in a Department of
9 Agriculture requires you to do a great deal of
10 outreach to the institution or within the
11 institution as well as to those outside.

12 MS. GAPUD: Well, I concur when Dr. Tilden
13 mentioned something about internal. I think it's
14 critically important that the people internally know
15 what is happening and so they will know if it's
16 working or not and what they are doing. Okay. And
17 then the external, of course, we have to share that
18 with them, the industry, the customers, you know,
19 and other regulatory agencies in order for them to
20 see what we are doing and get some feedback from
21 them, if there's some other things that need to be
22 improved or whatever.

1 DR. NEGRON-BRAVO: Edna Negron. I would
2 like to add since I participate in outreach programs
3 and training for us, it's very important to be sure
4 that we are addressing the right things that must be
5 addressed. So that information is critical for
6 developing new training program outreach or research
7 from the university perspective. So we are very
8 interested in getting information.

9 DR. JONES: Okay. It sounds to me that
10 from the discussion, that there is actually -- the
11 question is who is going to use the data, and it
12 sounds like FSIS is definitely going to use the
13 data, but also people external to FSIS will use the
14 data. So the stakeholders are both internal and
15 external, and they're both just as valuable, you
16 know, neither group, external or internal, are less
17 valuable, and it sounds like the internal
18 stakeholders would be FSIS. The external
19 stakeholders would be agencies outside of FSIS.
20 Also the establishments that the data's collected
21 from and also I guess other public health agencies
22 that are interested or concerned about the issues

1 that we have around prevention and actually the
2 communication of information.

3 MS. TUCKER-FOREMAN: Could I suggest, if we
4 made it kind of a Roman numeral I and II, I would
5 make it that the internal is internal to the
6 government.

7 DR. JONES: Okay.

8 MS. TUCKER-FOREMAN: FSIS personnel, USDA
9 personnel, other public health agencies, and other
10 government agencies, and external would be or I
11 might refer to it as -- well, for me it's the
12 public. The external would be the public and the
13 industry. External, it's not perhaps the best word
14 for that. You might say government stakeholders and
15 the public stakeholders and the public stakeholders
16 would include industry, the public, public health
17 experts and so forth.

18 UNIDENTIFIED SPEAKER: Academia.

19 MS. TUCKER-FOREMAN: Academia, absolutely,
20 yes. If those words work.

21 DR. JONES: So the suggestion is that
22 internal would be basically governmental agencies,

1 FSIS and other governmental agencies, and external
2 would be all others who are interested in the data,
3 public health organizations, other establishments,
4 academia. Is that -- yes, ma'am.

5 DR. VETTER: I just have a question. If
6 you said government, would you be including state
7 government in that, or would you limit it to federal
8 and state would be part of the external?

9 DR. KASSENBERG: This is Heidi Kassenborg.
10 I strongly urge state and local included in there,
11 particularly because a lot of the foodborne
12 outbreaks are detected at the state level.

13 DR. VETTER: They'd be under external or
14 internal?

15 DR. KASSENBERG: They would be internal.
16 Anything sort of regulatory.

17 DR. VETTER: So state and local would be
18 under internal?

19 DR. KASSENBERG: Yeah.

20 DR. TILDEN: John Tilden again. Except for
21 I think don't assume that unless you explicitly
22 identify this as an objection, that communicating

1 with the state and local agencies is going to happen
2 because as we're trying to move forth the National
3 Integrated Food Safety System, one of the roadblocks
4 that we all recognize is getting these systems from
5 different agencies to talk and communicate with each
6 other. So I'm assuming that's already built in, as
7 long as it's being built in, that that's an
8 objective.

9 DR. JONES: So one of the items that needs
10 to be built in or one of the comments that needs to
11 be included is that to ensure that when the system
12 is developed, that it's developed in a manner such
13 that state, local, and federal levels of government
14 all have the same access to the data.

15 DR. TILDEN: Or to role appropriate data.

16 DR. JONES: To role appropriate data.

17 DR. TILDEN: Role appropriate data.

18 DR. JONES: Okay. So that it's built into
19 the development of the actual. So that would
20 require that there's participation from state,
21 federal, and local agencies in the actual
22 development process when it comes to the development

1 of the data system.

2 DR. TILDEN: Of the appropriate parts.

3 DR. JONES: Right.

4 DR. TILDEN: So a specific example, OPEER
5 goes out and does work at the retail level. State
6 and local agencies are already doing a lot, and if
7 we could coordinate our efforts and share
8 information back and forth, we'd avoid redundancy
9 and duplication of effort. That's an operational
10 object that we could do a better job of
11 coordinating, and then there's strategic objectives
12 that we use FSIS data all the time for our risk-
13 based calculations. So it would be nice if state
14 users can access information just like the external,
15 university type people.

16 MS. BUCK: As a comment to that, role
17 appropriate might -- we might want to reconsider how
18 we phrase that. We don't want to say that because I
19 think that we need to make clear that the data is
20 going to be allowed to be accessed, you know, if
21 requested in an appropriate fashion, you know, by
22 all groups, and I would include in the external, the

1 public which are the consumer groups, but I'd also
2 include the health groups. This is another big area
3 that needs to have reach, that we need to reach out
4 to are the health groups.

5 DR. NEGRON-BRAVO: I have a question. When
6 we are thinking about who is interested or who is
7 likely our audience, I am asking you if that
8 information would be available for me to go there
9 and get it, or is that somehow it is going to be a
10 communication circle that when the information is
11 ready, you get it because sometimes we don't
12 communicate, you know. So maybe the information is
13 there but I don't know it's there because if it is
14 something like, right now that I am connected to
15 receive all recalls, all new directives. So if
16 there is something like that, the information might
17 be there but not really reaching the person that you
18 want to get the information.

19 DR. JONES: Two things. I guess we do
20 really have to address the issue of role appropriate
21 and put that in the correct terminology. As far as
22 it was suggested that the information be shared or

1 communicated in a manner, and that's addressing
2 you're saying the issue about ensuring that the
3 stakeholders do know that the information is there,
4 what type of information is there and what type of
5 information is accessible for them, and I'm assuming
6 this would all go into the comment, that that is
7 clearly communicated, how to access the information,
8 how to access the data. And my suggestion is that
9 the actual stakeholders be involved to some degree
10 in the method or the process, when you develop the
11 data collection and analysis and dissemination
12 process, that the actual stakeholders have some
13 input so that we can clearly understand what it is
14 that they need and how they need to see it, and
15 that's going to define the role adequate or role
16 specific amount of data. We won't use that
17 terminology, but that will define who has access to
18 what kind of information because academia may not
19 need to have the same access that FSIS will have.
20 So those things will be defined if we have some kind
21 of representative, whether it be an expert in the
22 area or just an expert, a person who will be the end

1 user of the data.

2 MS. TUCKER-FOREMAN: I fully endorsed that
3 when I spoke yesterday about transparency as
4 openness. It really works best if FSIS is saying to
5 its audiences what is it you need from us? Now
6 obviously there may be financial limitations on
7 that, but if you want to sell a data-driven
8 inspection system, to the public, it seems
9 reasonable to find out what it is that will make us
10 feel most comfortable with it, what kind of
11 information do we need to have.

12 And also second, on the issue of involving,
13 treating the state government agencies as part of
14 the internal audience, between the state governments
15 are running, some of them are running meat and
16 poultry inspection programs. They're supposed to be
17 equal to. We want them to be equal to. FSIS is
18 going through a major transition here, and we have
19 to make sure that the state governments have what
20 they need in order to be able to keep up. They've
21 got to transition as well, and so we need to have
22 better communication there. Thanks.

1 DR. JONES: Looking back at the question,
2 who will be the audience or who are the people who
3 will need the data, I think I'm going to suggest
4 that we have kind of covered that question with the
5 answers we have, both internal and external. We
6 defined who the external and internal customers are,
7 and the comments that we've made, suggestions that
8 to address the issue of transparency or to begin
9 looking at the issues of transparency that the
10 stakeholders be involved to some degree in the
11 development of the process of how this information
12 and data will be accessed and disseminated and when
13 it's needed. Yes.

14 MR. WARSHAWER: Steve Warshawer from Mesa
15 Top Farm. I wonder, are we making a clear boundary
16 between the data and reports and alerts? Because I
17 think it would be a whole different question in
18 terms of transparency when it comes to the output
19 from the system as opposed to the data itself, and I
20 think that there would be privacy, there would be
21 other kinds of issues that would have to be
22 addressed to determine who is on report lists and

1 who is on alert lists versus to who has access to
2 data in order to work with it.

3 DR. JONES: I assumed that that was covered
4 under the terminology that we were readdressing when
5 we talked about the role specific data. Some of the
6 data, some of the information will be more in a
7 reporting format is kind of what I'm understanding,
8 and then the other agency organizations, whatever,
9 I'm assuming that the internal customer was FSIS,
10 may have more ability to manipulate the data and
11 actually create various kinds of reports.

12 I would also like to suggest perhaps that
13 that issue of who will have specific access to data
14 from a reporting perspective and even from the
15 ability query the data, that that be something that
16 be decided when this group of representatives comes
17 together to define what it is exactly and precisely
18 that they need, that they also define at that point,
19 you are able to identify who has ability to
20 manipulate what data.

21 MS. TUCKER-FOREMAN: If I could suggest
22 that the maximum amount of openness is both

1 government policy. I'm going to agree with you
2 here. And having the maximum amount of openness
3 simply helps FSIS' Freedom of Information Act staff
4 not be completely buried by demands for information.
5 The more open you are, the less likely you are
6 constantly to have people filing FOIA reports which,
7 you know, requires a certain amount of extra work on
8 everybody. Let it all hang out to begin with, and
9 then you won't have people filing FOIA reports.

10 MR. WARSHAWER: I'm just not so sure that
11 access to reports and alerts should be approached
12 with the same criteria of openness because data is
13 for the purpose of interpretation. Reports and
14 alerts could be misinterpreted and misused more
15 readily and have other adverse effects. I
16 completely agree that the data needs to be totally
17 transparent, that access to data should be as
18 universal as possible, and it should be in a forum
19 that's as user friendly as possible, but the reports
20 that are generated by the system are really targeted
21 to specific audiences, and I just want to put into
22 our consideration the idea that we have to be very

1 clear, and we have to make sure that we aren't
2 creating essentially a free-for-all around the
3 reports and around the alerts that come out of the
4 system. That isn't to say that no one should have
5 access to any reports or alerts, but I think that's
6 where the real question will come about whether
7 transparency is a boomerang or whether it's an
8 asset.

9 MS. TUCKER-FOREMAN: Steve, I may not be
10 understanding you. What do you mean reports? What
11 kind of reports?

12 MR. WARSHAWER: Well, I'm just thinking
13 back to some of the preliminary conversation that
14 came out yesterday where, you know, an
15 establishment's name appears on a list, and that
16 list triggers other actions. That establishment
17 list could be used in ways that would be more or
18 less helpful depending on who gets hold of it. So
19 I'm trying to draw a line between data and
20 interpretations of data and uses of data and say
21 that I think we're all in agreement that the data
22 needs to be universally accessible in a user

1 friendly fashion and that we need the experts to get
2 together and figure out how to do that, but the
3 system is designed to produce an incredible range of
4 analysis. Who has access to that analysis is a
5 whole different question I think.

6 DR. JONES: Excuse me.

7 MS. TUCKER-FOREMAN: I don't want us to end
8 up restricting information that is currently out
9 there. FSIS publishes now a huge range of
10 information that is company specific, and it would
11 be unfortunate if we were to decide that that's not
12 appropriate.

13 MR. WARSHAWER: I would agree with that.
14 I'm just asking that as we look at a more
15 transparent system, we look at some boundaries
16 between access to different levels of information.
17 I certainly don't want to restrict access to reports
18 that are currently available, and there may be new
19 reports that this system will produce that will be
20 more valuable. To me that's simply a more complex
21 process and a more complex question than that of
22 access to data itself.

1 DR. JONES: Okay. I think that there are
2 kind of two things going on. There's a question of
3 access to data, and then there's a question of
4 adequate reporting, and I think that those are the
5 types of questions that will have to be addressed in
6 the more detailed development of the system and will
7 be addressed by those representatives from internal
8 and external agencies. And that should be clearly
9 defined, and that can be our recommendation, that
10 access to data based on the needs and the roles that
11 the particular individuals play must be defined as
12 well as reporting of alerts, whatever other types of
13 information must also be clearly defined and
14 accepted as adequate by those people who will be
15 listed as our internal as well as external
16 stakeholders. Okay.

17 MR. REINHARD: I just wanted to get back on
18 task of the question, and I think what's been
19 proposed, for the Subcommittee to decide is, the
20 Subcommittee, the proposal is the Subcommittee
21 recommend to FSIS that they bring in stakeholders,
22 and I assume it would be in a public format, that

1 decide and discuss and go over the design and how
2 data and information should be made available to the
3 public and the different stakeholders and that based
4 off the outcome of that exchange with the different
5 stakeholders, that then FSIS would go forward and
6 put together the data in an appropriate format. And
7 I think the other issues then get cleared up in that
8 stakeholders' discussion around it.

9 So I thought that was really the
10 recommendation for the Subcommittee to consider, and
11 I would like for us to decide if that's what we want
12 to state in this. We listed the stakeholders
13 already and then state that that's our outcome, that
14 we recommend they do this, meet with stakeholders in
15 a public format, go over how to design the
16 collection of data, how to put outputs of data out,
17 how to analyze data that makes it of value for all
18 the stakeholders who can then at that meeting say
19 this is why we want the information, this is what we
20 use it for. This is the output then you get, and it
21 affects public health would be what's on the table
22 now for us to consider.

1 DR. TILDEN: Just a question. Does that
2 effectively tie FSIS' hands in their ability to keep
3 moving forward because then everything depends on
4 collective decision making?

5 MR. REINHARD: I would not think it would
6 actively tie their hands at all.

7 DR. JONES: I agree.

8 DR. LIANG: This conversation makes me
9 think of what I thought about yesterday when
10 Mr. Painter made his comments, and it's my
11 understanding, and I've actually been part of this
12 problem, that applications development is a
13 hazardous business, that it transcends many
14 agencies, I think, I could be mistaken, but I think
15 the IRS blew, what, millions of dollars trying to
16 redesign some of their information systems. So I'm
17 not sure what to do with this except that, you know,
18 I think there is some hazard in clearly what the
19 process is. I don't know the answer. I just know
20 that it can go wrong having been part of a problem
21 myself, when I was a state epidemiologist.

22 So I don't know what would be helpful to

1 FSIS in terms of, you know, language that would help
2 them maybe learn from other folks' mistakes. I tend
3 to want to think that, you know, the stakeholders
4 could definitely have valuable input in terms of
5 what do they want out of the system. They may be
6 less knowledgeable on how to get that output.

7 DR. VETTER: I would just like to kind of
8 piggyback what he said. I think it could be very
9 complex, like you said and expensive as well, to add
10 to an expense that we already have, but possibly a
11 more simple solution is to ask what do you need and
12 then figure out a way to supply that in a readily
13 accessible form for the various stakeholders and
14 actually give them what they're asking for, to the
15 best of our ability, and that might be a more simple
16 approach to having access to the data.

17 MS. TUCKER-FOREMAN: My response to that
18 would be I don't know what I need until I know what
19 you've got. There has to be, you know, nobody
20 except people in the Agency really know what the
21 Agency has until the Agency says this is what we've
22 got. This is how we're going about it. So there is

1 some obligation to make known publicly, and that's
2 what data.gov is, and FSIS I think does a terrific
3 job of it. This is pretty much what we have, but if
4 you have some mechanism such as we've been
5 discussing, I think you move toward a more open
6 process. How to get it is a different question, and
7 the answer from the Agency may often be we can't
8 afford that or we can't put the data together that
9 way.

10 DR. JONES: Okay. Dr. Tilden.

11 DR. TILDEN: Maybe it would help to be able
12 to break this relatively complex subject into short,
13 medium, and long-term objectives, and what does FSIS
14 need in the short term to keep their process moving,
15 and then what do we do in the mid term and long term
16 to move forward with this goal of a participative
17 process where we're learning from each other, and
18 that way we're not tying their hands but we're also
19 trying to get us moving in a collective direction
20 that we can all support.

21 DR. JONES: That sounds very good. I do
22 think, however, we're getting a little bit off

1 track. I think we've clearly answered number 1. I
2 think we can move onto number 2, not saying that the
3 comments aren't relevant. I know some of the
4 challenges that we come up when you're developing a
5 new system is you have to look at the big picture
6 first and say what it is that we want, and then
7 leave it up to the experts to develop it and to say
8 this is what our budget is, this is what they want,
9 this is what can happen. So I think we've answered
10 the first question unless somebody feels really
11 strongly that we haven't, I would like to suggest
12 that we move onto the second one.

13 MR. REINHARD: Do we need to state what the
14 answer was?

15 DR. JONES: You wrapped it up very well.

16 MR. REINHARD: We'll go back and pull that
17 out, whatever it was I stated, so I don't repeat it
18 and mess it up, if everybody agrees, basically that
19 we asked them to get together stakeholders and go
20 over what information needs to be collected and how
21 that information and data is used in an output
22 format in which it's valuable to drive and protect

1 public health or any other outcome that stakeholders
2 may need. But I recommend we just go back and read
3 it then out of there and take it as I said it the
4 first time.

5 DR. TILDEN: So as I'm listening to it,
6 that's really good stuff. Is there any reason why
7 that would create roadblocks short term to what FSIS
8 is doing?

9 MR. ALVARES: I guess off the, you know, at
10 first glance I don't see any real issues with that.
11 I think the requirements that we've defined for the
12 system are such that we can, if there are new data
13 needs that come from that kind of stakeholder
14 exchange, that we could integrate that into the
15 system that we're developing. I think that to some
16 extent it would come down to again short-term,
17 medium, long-term goals. There's some short-term
18 data needs that could easily be adopted. There are
19 probably I would anticipate long-term data needs,
20 not necessarily for information system reasons or
21 limitations, but simply based on regulatory
22 authority, based on where we are and how we're

1 currently conducting inspection, that we might need
2 to make changes in order to collect certain kinds of
3 data. So I think it really depends on the outcomes,
4 but it's possible.

5 DR. JONES: Okay. So we can move to
6 question number 2. Okay. Question number 2, "FSIS
7 is considering posting more detailed sampling
8 results, both microbiological and chemical in
9 inspection results." Two questions under that
10 statement are, "Does the Committee consider these
11 the highest priority datasets to make available?
12 What other datasets does the Committee recommend as
13 high priority?"

14 MS. TUCKER-FOREMAN: Are you skipping over
15 bullet 2?

16 DR. JONES: Am I skipping over?

17 MS. TUCKER-FOREMAN: Bullet 2, the website,
18 the --

19 DR. JONES: I'm on question number 2.

20 MS. TUCKER-FOREMAN: Okay. Sorry.

21 DR. JONES: So does the Committee consider
22 these the highest priority datasets to make

1 available?

2 DR. KASSENBERG: I have a question. When
3 they say more detailed sampling results, is that
4 more details about the microbe that has been
5 isolated or is it about the characteristics of the
6 sample or both?

7 DR. JONES: I'm not sure. That's a good
8 question. Could you say the question one more time?
9 I don't think --

10 DR. KASSENBERG: Sure. I was wondering
11 what the definition of more detailed sampling
12 results is? Is it about, you know, you pull up a
13 *Salmonella* isolate? Do you add the serotype and the
14 subtype and that type of molecular information? Or,
15 is it about where the sample came from and some of
16 the tracking and some of the descriptions of how the
17 product was made and where it was made? So is it
18 one or the other or both?

19 MR. REED: I mean honestly we're looking
20 for the Committee to recommend what you would
21 consider would be more detailed results if it was
22 needed. So really we're trying to get

1 recommendations on criteria in general for data
2 posting that would be useful.

3 DR. KASSENBERG: Then I'd recommend both.

4 DR. TILDEN: I agree short-term those are
5 the two, but I would strongly recommend that we
6 communicate the limitations and constraints on those
7 data and then how they were gathered so that -- one
8 of my favorite phrases that I learned from one of my
9 mentors was data is not information. And so you
10 need to help people put it into context and
11 understanding how would you use it and what are the
12 strengths and what are the limitations of this
13 dataset that they're working on.

14 MS. GAPUD: I think we have to really be
15 very, very careful on what we put out there because
16 it can be misused and misinterpreted, and that can
17 really backfire.

18 MS. TUCKER-FOREMAN: -- collected and that
19 the stakeholders have to have access to it.

20 MR. REINHARD: I think it would be my
21 recommendation if the Agency is asking what their
22 highest priority datasets should be, that be placed

1 out there, I think the easy, straightforward answer
2 is they should pick those datasets which drive
3 public health improvements or which meet the primary
4 objectives of the Agency as they're stated out in
5 their 10 highest priority items. I think it's very
6 simple to state it that way, and whether it's
7 microbial or chemical or inspection type results, I
8 think the Agency will have to look at that. I have
9 specific examples where I think they're of specific
10 value in data that's collected by the Agency. If
11 you look at the way Agency runs microbial analysis
12 for *Listeria monocytogenes*, they have four different
13 projects, they each have different value, and
14 they're designed a little bit different and how
15 that's done is already public. It is done out on
16 the site, and quarterly they post the results of
17 those projects and a total combined information on
18 those projects, but there's detail behind those
19 results that isn't necessarily posted.

20 For example, in RML sampling, where they do
21 environmental sampling, for *Listeria monocytogenes*,
22 the Agency gets results on specific sites that are

1 commonly found to be positive within industry, that
2 if they were to show the information, and they have
3 at different times showed this information, but that
4 they sampled a floor mat 132 times and 22 percent of
5 the times floor mats have been positive for *LM* is
6 very valuable information for an industry
7 stakeholder to say, we need to make sure our
8 sampling programs either address sampling of floor
9 mats or cleaning of floor mats or eliminating floor
10 mats or what the outcome is.

11 So I think there are a lot of data that the
12 Agency has that drives real public health
13 improvement and I think they should focus on that
14 data in putting that in a format in which it's
15 useable, which goes back to the first question of
16 getting the stakeholders together so they can say
17 this is the information that would be of value.

18 DR. JONES: Ms. Buck, did you have a
19 comment?

20 MS. BUCK: I don't know it's appropriate to
21 bring up these questions now. It might be better
22 for a later time, but again I think when you're

1 looking at this, when we're looking at this, we have
2 to look at the goals and objectives that are part of
3 the public health inspection system, and let that be
4 our guide, you know, in deciding what data the
5 Agency is going to collect.

6 I think also you have to look at what we
7 have the capability to be collecting because there
8 are below that all sorts of issues on the
9 availability of laboratories and the lack of
10 standardization of forms, and so I think when we're
11 setting the priorities, things that are what I'd
12 call a tier 2 consideration are very, very important
13 if you're going to put together something that you
14 can realistically accomplish, and I don't know if we
15 want to consider that now or later.

16 MR. WALDROP: Chris Waldrop, Consumer
17 Federation of America. I had a clarifying question
18 to Dr. Tilden's comment. Did you mean that the
19 Agency should be including the type I and type II
20 errors, the power, the confidence level? Is that
21 what you're talking about, about more information
22 about their programs?

1 DR. TILDEN: That kind of information can
2 be really helpful to the right audience. It can be
3 completely mystifying to others. So I'd be careful
4 about mixing. Maybe that goes back to Rob's point
5 of getting the right way of communicating it to the
6 right audiences. I mean you've got such a range of
7 diverse stakeholders that potentially want
8 information that you've got to be careful about how
9 you present it, so that it can be used by each
10 group. I think there is a specific group like
11 National Academy of Sciences, NACMCF, I mean, you
12 know, the right place where absolutely that should
13 be part and parcel of it, but you wouldn't put that
14 if you were just doing it with the general public
15 kind of a thing, I don't think, because that may not
16 be helpful information.

17 MS. TUCKER-FOREMAN: I disagree. I think
18 it's important in holding the Agency accountable.
19 What's the number of type I and type II errors that
20 come about in sampling? And I really get worried
21 when I hear a government official say if we put that
22 information out there, it might be misused, or

1 that's not up to you to decide, you know. It is up
2 to the public to decide, and maybe somebody will get
3 hold of it and say something about it, that
4 misconstrues it. It's your obligation and those who
5 share that position to rebut it, but it seems to me
6 that we started out here talking about making more
7 and more and more information available, and all of
8 a sudden I hear, well, maybe we better not because
9 that might not be useful. Again, if we go to this
10 group, but I believe the policy is that the Agency
11 should err on the side of making more information
12 available.

13 MS. GAPUD: Well, I agree. You know, of
14 course, the public, they are entitled to know what
15 is happening out there, but we, you know, we don't
16 want to scare unnecessarily the public with what we
17 put out there.

18 MS. TUCKER-FOREMAN: What's unnecessarily?
19 Who's to decide?

20 MS. GAPUD: Well, the thing here is like
21 people right now, of course, they want to know what
22 is happening, but again people can be panicking on

1 something that they don't really understand, you
2 know, what do these things mean that we put in
3 there, okay. So I don't think it's necessary to
4 scare them. Again, they are entitled to know, but
5 we don't want to have that situation.

6 DR. JONES: I suggest, once again, we're
7 getting kind of back into defining who's going to
8 see what data, and our recommendation was that there
9 would be an interest group that would define all of
10 those things. We suggested that there were going to
11 be short-term, medium and long-term goals which I
12 think is going to cover all of the concerns that we
13 have, but the question that we really need to be
14 looking at is the datasets themselves and what type
15 of detailed information needs to be in those
16 datasets, who's going to use that information, and
17 how that information will be disseminated. We can
18 make recommendations on how that is decided, and
19 those are very relevant concerns about people
20 getting the wrong data and not understanding it, and
21 data is snapshot in time. It can be manipulated to
22 say many things.

1 So what we need to decide, I believe, is
2 what data should be in the dataset, and we could
3 recommend how the decision is made on who it's
4 available and who it's available to.

5 MS. GAPUD: I concur.

6 DR. JONES: Yes, Ms. Buck.

7 MS. BUCK: In response to that, I don't
8 think this Committee has all the information to set
9 the priorities for FSIS about what datasets should
10 be collected. FSIS has more information about the
11 factors that go into which datasets should be looked
12 at or collected based on what they are setting as
13 their public health goals, and I think that comes
14 back to the question of has the Agency, and I read
15 the charter last night, it was very broad, and I
16 understand a goal has to be very broad, but still
17 does the Agency have a plan that says for the next
18 three years, this is what we want to do as our
19 public health goal because I think until we know
20 that, we cannot help to really define what datasets
21 should be prioritized.

22 DR. TILDEN: And I think Carol and I aren't

1 disagreeing in substance as much as maybe just
2 words. So we'll let it drop, but I don't think it
3 has to be either/or, and I think we've all agreed
4 that it's not like, but the way different datasets
5 may be more appropriately used by different people
6 because they have different outcomes that they're
7 looking for, and what I have learned is that we're
8 all getting busier and busier and have less time,
9 and sometimes less is more. So if you don't drown
10 people with data, sometimes they can get to date
11 more efficiently if they know which dataset to use
12 for which purpose.

13 MS. TUCKER-FOREMAN: I understand, but I
14 think that that kind of issue can be addressed by
15 having an explanation of what the dataset is
16 accompanying them and, you know, it is a snapshot
17 of. It may not indicate this. It may indicate
18 that. So that if it's out there, you know.

19 The FDA publishes their tolerances for rat
20 hairs in baking flour, and it used to be that if I
21 was really bored, I'd go over and get the reports or
22 get that, just the standards, and put out a press

1 release and say, you know, that they permit rat
2 hairs in the flour, and I noticed somebody did it
3 just recently and, you know, by and large in the
4 scheme of things, if there's no company's name
5 associated with it, it doesn't cause anybody any
6 grief.

7 DR. TILDEN: If I can say a dataset that we
8 haven't talked about that I think goes back to what
9 Ms. Buck was talking about, it would be great if
10 FSIS, if you already have your public health
11 objectives identified and you've got indicators, and
12 you've got metrics for those, and then you can show
13 how you can use operational data, inspectional data
14 and sampling data towards those as a part of that.
15 So you've got, like here's the overarching theme,
16 here's the indicators and here's the metrics for
17 those indicators and looking at how we're currently
18 doing on our inspectional data and our sampling
19 data, this is where we're at, and then you just give
20 updates on that. That might be a way of moving
21 forward.

22 MR. REINHARD: I'd agree with that, that

1 that would be the recommended way for them to
2 prioritize around which data they start with and how
3 they go forward.

4 DR. TILDEN: Identify your public health
5 objectives and then what are your indicators, you
6 know, what are the things that you're going to
7 measure to move towards that, and then what are the
8 metrics that you want to accomplish, you know, set
9 some measurable kind of a outcome and then publish
10 the outcomes of that, and the basic two kinds of
11 sampling, the data that we've got in our hands are
12 the inspection data and then the sampling data, and
13 there may be new kinds of data that come out in the
14 future, but that's what we're starting with.

15 MR. GOLTRY: Scott Goltry, and my thanks
16 for allowing the public to participate in this
17 Subcommittee. One of the questions I would like to
18 get some follow-up on, I think the original question
19 talked about data results and inspection results.
20 What do we feel is meant by inspection results? Are
21 those like food safety assessments, enforcement
22 actions? And I would suggest that the enforcement

1 actions are already posted on the quarterly
2 enforcement reports. So I think there's two issues,
3 the data issue and then the inspection result issue
4 which I don't know what that really means and maybe
5 get some feedback.

6 MS. TUCKER-FOREMAN: What are the
7 inspectional results that you're talking about?

8 MR. ALVARES: Well, I think to Scott's
9 point about the adverse event data, that's really I
10 think in some cases a subset of overall inspection
11 data. In a high level general sense, when we talk
12 about inspection data, we're talking, at least I'm
13 thinking about every task that's performed, every
14 day at every establishment, and whether it's
15 compliant or not compliant or whether it ultimately
16 becomes a suspension or not. That's the set of data
17 that I'm thinking about with inspection data.

18 MR. GOLTRY: Okay. So when you say
19 inspection results, those would be tasks that are
20 generated through your data collection systems
21 versus quarterly HAVs or monthly HAVs or food safety
22 assessments?

1 MR. REED: I mean the issue isn't really
2 where they're generated from because right now
3 inspectors are doing inspection tasks every day.
4 And so even when we change to a different IT system,
5 that doesn't change how tasks are generated or what
6 tasks are performed. I mean really what we're
7 asking is our inspectors do a lot of things every
8 day in establishments which we would call inspection
9 tasks, the entire gambit. We really are trying to
10 put it open-ended to hear what the Committee thinks,
11 and we're looking for criteria from the full
12 Committee on what you think would be inspection type
13 tasks that we should consider. So we're not wanting
14 to define it for you. We're actually looking for
15 your input on that.

16 DR. TILDEN: And I think we heard yesterday
17 that some of those tasks are clearly regulatory
18 compliance issues that may not be related to public
19 health outcomes, and some are more closely, and that
20 you've done some triaging and sorting, and I
21 personally don't have firsthand knowledge of where
22 we're at on that triaging and sorting, but I fully

1 endorse the idea of don't include regulatory
2 enforcement activities that aren't directly related
3 to public health outcomes in this kind of an
4 assessment.

5 MR. CORBO: Tony Corbo, Food and Water
6 Watch. For example, your food safety assessments,
7 and I have a pending FOIA on one establishment that
8 you all are giving me a hard time on, but those
9 would be helpful at least to us especially those
10 that are for cause FSAs, or in the case of your new
11 hazard analysis verification, if you wind up
12 deciding that a particular establishment needs a
13 monthly HAV procedure, I think that would be
14 extremely helpful because that directly relates to
15 public health. So those are the sorts of things
16 that I think would be very helpful in terms of
17 posting.

18 You know, a few years ago, the Agency
19 wanted to post the *Salmonella* results for those
20 plants that were in category 3, and we went through
21 a series of meetings with the Agency, the consumer
22 groups asking when this report card was going to be

1 published, and we'd get the same old song and dance.
2 I wound up filing weekly FOIA requests for that
3 information for two and a half months before the
4 Agency posted that report card. That is very
5 helpful.

6 So in terms of those issues that are
7 directly related to public health, where you have,
8 for example, a for cause FSA, or you're finding that
9 because an establishment's HACCP plan isn't the
10 paper it's written on, and you're making them do
11 monthly HAVs, that would be the sort of thing that I
12 think would be very helpful to the public because
13 you already have a precedent there with the
14 *Salmonella* report card.

15 DR. JONES: Okay. It seems that, just to
16 kind of wrap up here, to get us back on point, one
17 of the major issues that has been brought up since
18 yesterday was the idea of specifically defining what
19 the public health goals are. When you define what
20 the public health goals are, I think Dr. Tilden was
21 mentioning actually developing your objectives for
22 meeting those goals, which have to be measurable,

1 which would be those metrics that we're defining.
2 I'm trying to wrap up what I'm hearing. What would
3 the metrics be that would ensure that we meet those
4 goals which will define what type of data we're
5 talking about having available in the dataset? It
6 would include both types of data, the inspection
7 data as well as the chemical microbiological. All
8 of that would potentially add to the datasets, but
9 it will be a function of what the public health goal
10 is and what those metrics are that have been
11 developed to meet those public health goals.

12 Ideally, it would be great if we had the
13 public health goal because we could comment on what
14 the objectives should be and what some of those
15 metrics should be in those datasets.

16 MS. BUCK: I think what you're asking us to
17 do, which may be beyond the scope and time of this
18 meeting, is to develop a strategic plan for FSIS,
19 and quite frankly, I just don't see until we have
20 some guidance from the Agency themselves as to what
21 they have the capability to do, for us to actually
22 say to you, this is what we think you should do,

1 given the parameters and limitations of your system,
2 the Agency has not provided that. I do know that
3 not in the too distant past, you had to sit down and
4 write down goals and objectives for PHIS. It was
5 not really in the document that they provided
6 yesterday. Can you share that information with us?

7 MR. ALVARES: We should be able to. I'm
8 not sure why it wasn't in those documents that were
9 provided, but we can certainly look into that.

10 MR. REED: I mean the one comment I would
11 say, though, is that data in general is independent
12 of the question of PHIS in the IT system, and so
13 really we're looking for criteria of data in
14 general, and whether or not the current system can
15 do it or not, that could be a long-run goal if it
16 can't. So I wouldn't want you to limit your thought
17 process by what our current capabilities are. I
18 would more hope that the Committee can suggest
19 criteria that we should be looking at long run
20 because that would help shape the way we modify our
21 systems and our practices.

22 MS. BUCK: Well, of course, some of the

1 criteria will be what types of things can you be
2 collecting that will give us the power and the --
3 what is the other term that -- clean data, accurate
4 data and data that can move us forward where you
5 have enough power behind it and confidence levels
6 behind it so that you can actually do something with
7 it. And right now, I am clueless as to where you
8 are in your collection designs, and until I have a
9 clearer picture of that, I don't see how we can help
10 you. I think that's about the best I can do as a
11 non-statistician.

12 DR. JONES: Dr. Tilden, did you have --

13 MS. TUCKER-FOREMAN: I just wanted to
14 respond to Pat's question about the objectives which
15 the reason we had asked for the charter, which is
16 mentioned in the first few pages of the decision
17 criteria paper, I think it's that one, and everybody
18 got them yesterday, is that it says that the goals
19 and objectives of the system, the PHIS system are
20 laid out there. The FSIS goals or the Food Safety
21 and Inspection Service is a public health agency
22 whose mission is to protect the public by ensuring

1 that meat, poultry, and egg products are safe,
2 wholesome and accurately labeled, that's number one,
3 and two, FSIS supports the 2002 Homeland Security
4 Act. Those are the strategic goals and there's a
5 similarly brief objective listed for each one.

6 So the fact is that you might say that
7 there is still not a document that lays out in some
8 short narrative what FSIS' goal and key objectives
9 are in a way that communicates effectively with the
10 public about that. I don't think it's in the
11 papers. It's referenced in this, but this is
12 obviously not something that's very helpful to those
13 of us who are interpreting the Agency.

14 MS. BUCK: I'd like to see something in
15 there like FSIS will, as an objective, use da-da
16 intervention or da-da sampling to reduce *Salmonella*
17 30 percent over the next two years, just as an
18 example. I'd like to see some really specific ideas
19 of what it is you want to do.

20 DR. JONES: So the recommendation, to wrap
21 it up, is that, to me it seems to be flowing
22 directly from the first question, is that FSIS

1 should come up with some clearly stated goals and
2 objectives with measurable indicators on them,
3 giving a timeframe even, to ensure that these goals
4 are met, that there should be some involvement from
5 the same group or some representation of the same
6 group of stakeholders that we mentioned in question
7 number 1, and that group of stakeholders would
8 clearly identify the type of information that they
9 would need to be able to follow and understand how
10 FSIS is stating its goals, measuring its ability to
11 meet those goals over some period of time. Is that
12 what I'm hearing?

13 MS. TUCKER-FOREMAN: Yes, and FSIS does say
14 that they are trying to meet the Healthy People 2010
15 or Healthy People 2020 goals, but that point I think
16 is well taken, that's all the food that's out there
17 and FSIS only has responsibility for maybe 10
18 percent of that food. So what is FSIS' objectives
19 within that overall I think is --

20 DR. JONES: So actually have FSIS set its
21 objective relative to the whole as opposed to just
22 some, and also to look at it from a perspective of

1 short, medium, and long term, what can you give us
2 in the short term? What is really needed in the
3 long term, and in addition to that, how would that
4 ensure that this system that's developed is
5 developed in a way such that it is constantly
6 checking itself to ensure that as the goals change,
7 as the public's needs change, as different issues
8 come up, the system is able to readjust whether it
9 needs to collect additional data or changing the
10 type of data or making the data acceptable to more
11 or less people, and all of that would be a part of
12 the short, medium, and long-term range of goals set.

13 MR. REED: Yeah, I have something that
14 might help. I think if we separate two issues or
15 give you two data points, it might help the
16 Committee.

17 So FSIS' general public health goals that
18 are publicly available, that are online, right, we
19 have our strategic plan, we have our public health
20 goals, there are the Healthy People goals that had
21 been released before, those are our overarching
22 public health goals. PHIS is an IT system where we

1 implement our processes that will help us as an
2 Agency achieve those public health goals, and in my
3 opinion at least, they're independent. The Agency's
4 public health goals are our public health goals in
5 general. And so I hope that helps clarify where
6 we're going.

7 MS. BUCK: Yeah, it does but, of course,
8 the other part of the issue is that the PHIS has to
9 have its own set of goals and objectives, okay, and
10 I think that that's where we need to have those
11 clearly define what you want to do with this system
12 so that we can help you set the criteria for the
13 datasets or, you know, whatever you're asking us
14 for, and I think that's important for that to happen
15 soon.

16 DR. JONES: Dr. Negrón.

17 DR. NEGRÓN-BRAVO: I have a question or
18 maybe some comments. I don't know. Several years
19 ago I was in a meeting with FSIS group, and we were
20 discussing about things that should be done or what
21 things to be addressed, and we talked at that time,
22 we said, well, the information is with the FSIS

1 because you have collected a lot of data. What is
2 happening with that data? How do you use that data?
3 Do you use that data for finding out what must be
4 done in order to improve the inspection system or
5 just collecting data because there is an inspection
6 system that you say, well, a NR, a NR, a NR, NR,
7 what that NR is doing, is saying? Is it HACCP? Is
8 it prerequisite? Is it planning? Is it the
9 inspector? The way they express, so is kind of two
10 different things with that, that we are dealing
11 here. The public information system, we gather the
12 information that should help the Agency direct their
13 efforts toward achieving the public health. We've
14 been getting this only for compliance for the
15 industry, to be that they are in compliance or just
16 to improve ourselves, our system?

17 And then from us, from the public
18 perspective, from the University, I can use that
19 data to see, oh, I think there is an opportunity,
20 there is a gap here with this data that I am looking
21 at. Of course, it would be good to have something
22 that directs me, like a sentence or something,

1 because that can be misleading if I don't use it
2 properly or cannot understand it properly.

3 But there are two things here, one,
4 collecting data for improvement of FSIS as an
5 Agency, and another is the collection of data for
6 us, the public, to be sure that we are getting the
7 information, that can help us guide that the Agency
8 is really trying to meet their objectives, or if we
9 have to say something about it so that they go in
10 the right direction. I don't know if I make myself
11 clear.

12 DR. TILDEN: So trying to get back to the
13 questions, the first one was, what do we consider
14 the priority databases, and I think reading the body
15 English, everyone was saying, yeah, the sampling and
16 then the inspectional activities that are clearly
17 related to public health outcomes, they said those
18 should be the priorities. Can we say that, or do we
19 all agree to that, for the answers to A, 2A?

20 DR. JONES: Yeah, I think we already agreed
21 to that one.

22 DR. TILDEN: Okay. And then I think I also

1 heard that for 2B, what other datasets should be a
2 high priority, and I think that's where we go at, it
3 would be really great for all of us to clearly
4 understand how the Agency is assessing progress
5 towards high level strategic objectives and, you
6 know, what you guys are using as your measuring
7 sticks, and then we can react to that and say, yeah,
8 that sounds appropriate or not. The thing that gets
9 a little fuzzy for me, when you say we're all about
10 the Healthy People objectives, it's like, okay,
11 that's what you want to do. Now help me understand
12 how you're going to get there, and which of your
13 inspectional activities do you think are directly
14 enough related to public health outcomes that you're
15 using that as an indicator, and then we can have
16 that discussion, say is that true or is that not?
17 And once we build that consensus, then we can start
18 moving forward, and I think that's what transparency
19 is all about.

20 And one other thing, I just wanted to thank
21 you guys for sending us this thing because you look
22 at it. I don't think sometimes we give enough

1 credit to FSIS for working really hard to create a
2 more transparent process. You know, when I look at
3 this, and to be honest with you, I don't understand
4 absolutely all the acronyms and nomenclature, but it
5 looks like a really good faith effort in moving
6 forward. So I just wanted to applaud you guys for
7 making some steps in the right direction.

8 DR. JONES: Okay. It sounds like
9 Dr. Tilden has wrapped up question number 2 with his
10 synopsis.

11 MS. TUCKER-FOREMAN: Did our reporter take
12 that down because there was good language there? Do
13 you have the language down?

14 DR. JONES: Okay. If you scroll up, I'll
15 read what you have. Scroll up just a little bit.
16 Scroll up a little bit more. Okay. I think that's
17 it right there. Going from question 1, FSIS should
18 come up with some clear data goals with indicators
19 giving a timeframe to ensure the goals are met.
20 There should be some involvement from the group or
21 the stakeholders. That's what I was saying, right?

22 Okay. And I think what Dr. Tilden included

1 was just that he tied it all together by saying
2 that, yes, we do need the goals and objectives. We
3 also need the indicators, and we need to identify
4 the plan of how that's going to happen over time and
5 to be able to assess that over time, ensure that
6 those goals, the goals and objectives are being met,
7 and that the information informing the meeting of
8 those goals and objectives be pulled from the
9 datasets that are there, that would be the
10 inspection datasets as well as the sampling
11 datasets, and with the assessment would come the
12 development or the enhancement of those datasets
13 over time as needed.

14 DR. TILDEN: Yeah, and then so FSIS could
15 say on their quarterly report card or however they
16 want to do it, say this is where we're at, and if
17 you want to check the data, it's there, take a look,
18 you know, we're not hiding anything.

19 MS. BUCK: And when you're doing it, you
20 need to give the confidence intervals and the power
21 under which you want to collect the data. I mean
22 there are tradeoffs here. I mean you can collect

1 huge and huge amounts of data and have a much higher
2 power, but then you may have to cut back on your
3 FSAs. So we have to make some tradeoffs as to what
4 is most important for the Agency to be pursuing. I
5 think that's very important to include that.

6 DR. JONES: Okay. So an additional
7 recommendation is that the Agency definitely
8 identifies the priorities when it comes to the goals
9 and objectives and how they're going to address
10 those priorities.

11 Can we move onto question number 3?
12 Dr. Murinda.

13 DR. MURINDA: Can we also make a
14 recommendation that the data be well analyzed and
15 interpreted so that it's ready for use by the
16 various consumer groups?

17 MR. REINHARD: That's in the next
18 questions.

19 DR. JONES: It sounds like Dr. Murinda is
20 moving us onto question number 3, and this is the
21 sampling data and results. And under question 3 is
22 "What criteria should FSIS use to evaluate what

1 information to release publicly?" B is "Under what
2 criteria and conditions should FSIS consider posting
3 establishment-specific data in which the
4 establishment is identified?" And C is "What should
5 we consider posting that we don't now and at what
6 frequency?"

7 So I guess we could start with A. What
8 information should be released publicly?

9 DR. TILDEN: Okay. I'll take a bite. So
10 that assumes that it's not all being shared now. Is
11 that correct? All the sampling data.

12 MR. ALVARES: It's not so much that it's
13 not being shared, but that maybe it's not being
14 shared in a way that meets the needs of the
15 consumers or meets the needs of academics. So I
16 think it's fair to say that we are sharing, as far
17 as I can think off the top of my head, all the data
18 that we have as far as sampling, but maybe not
19 necessarily in a way that meets the needs of the
20 people who are digesting that data or interpreting
21 that data.

22 Just maybe to follow up and give an

1 example, if we give you, for example, if we report
2 that there were 10,000 *E. coli* test results done in
3 a 12-month period, is that really sufficient or is
4 there more criteria about that data? Are we looking
5 for aggregate data? Are we looking for details? If
6 we provide details, what other information about
7 that besides just the number should we consider when
8 we're moving to more granular levels of reporting?

9 DR. TILDEN: So I don't have specific
10 experience with FSIS sampling data, but we do have
11 experience with our regulatory program at the state
12 level, and we went from a culture where we did not
13 share all the information with specific identifiers
14 and linking all of our regulatory activities with
15 specific establishments, and it was a big unknown
16 for us, and we thought it was going to be just a big
17 mess when we started doing that, but there was a big
18 demand at the Michigan level that we start doing
19 that. When we started doing that, it actually made
20 life easier for most everybody because it was a
21 level playing field and everybody had the same
22 information. So it made life simpler for everybody.

1 And I wanted to share one quote that I read
2 in the *New York Times* last week about transparency.
3 It was some guy who was beat up by a bunch of thugs
4 in Kazakhstan, and the thugs were, you might
5 remember it was on the second or third page, but he
6 said, the problem is when you have a lack of
7 transparency, both the good and the bad look the
8 same. And I think, you know, that good and bad,
9 obviously there's value judgments there, but if you
10 have clear criteria and it's a level playing field,
11 and it's out there, and everybody has the same
12 access and information, it makes life easier, at
13 least that was our experience.

14 MS. TUCKER-FOREMAN: I have a question.
15 You've raised an interesting thought, John. Is it
16 your view that you would rather not have your
17 company's name mentioned period, or would you rather
18 have them when Sara Lee does everything right, get
19 on the gold star list? Is it better to never have
20 your name in the newspaper, you know, the old thing
21 was except when you were born, you get married, and
22 you die? Or is it good to be there with the Agency

1 saying, these are the companies that had no
2 problems, were above the average, whatever?

3 MR. REINHARD: I think that's really more
4 they're two different things. Right, there's the
5 stick and the carrot, and how do you drive the
6 industry to the highest standards of compliance
7 within two different things. I mean in one side we
8 drive regulatory compliance. On another side, we
9 drive continuous improvement in public health, and
10 it's outside of really how regulatory drives us as
11 we come up with new and better ways to inform our
12 customers on how to handle products and cook
13 products and new antimicrobials are discovered and
14 added to products to prevent cross-contamination in
15 a deli, at retail establishment, where we're driving
16 public health outside of maybe a regulatory model
17 that people don't know about. So I think the
18 question is when do you want your name put up? I'd
19 prefer my name not to be in the paper ever because
20 most of the ways my name gets in the paper is
21 negative probably speaking right now, but from Sara
22 Lee's standpoint or from an industry standpoint, I

1 think what's important is confidential commercial
2 information, and not having that go into a public
3 format, I think that was the discussion earlier when
4 Steve tried to bring up what his concerns were, that
5 that confidential commercial information not go out
6 to the public because it puts at risk what we do to
7 get an advantage in our industry. Other than that,
8 the information that is available, the traditional
9 methods of forwarding the information and giving
10 them information, names are associated with it, and
11 I don't see it as a big ordeal. When you compile
12 data, I think it probably becomes more valuable to
13 us as we make overarching policy decisions, but at a
14 granular level, if you're at that detail and a name
15 is associated with it, and in an appropriate format
16 without the confidential commercial information,
17 that would be our biggest concern first.

18 MS. TUCKER-FOREMAN: There was an objection
19 to the Agency running the names of the poultry
20 plants that were not making an acceptable standard,
21 but I think they also ran the names of the companies
22 that were doing a good job, the class 1. I can't

1 remember what they called it.

2 MR. REINHARD: Yeah, the question is on
3 category 1 establishments, category 2
4 establishments, and category 3 establishments for
5 *Salmonella*, and for those on the Committee, the
6 Subcommittee that don't know what that is, that's
7 where the Agency collects samples and makes a
8 determination of where you as an establishment are
9 related to a performance standard, the performance
10 standard being if you fail to meet the performance
11 standard of category 3, in general terms, category 2
12 is you're 50 percent to 100 percent of the
13 performance standard, and category 1 is 50 or less,
14 to summarize in the short term, and what FSIS did
15 was went forward with those establishments that were
16 category 3 and those establishments that were
17 category 2, and they post their names and their
18 ratings and the question is, what if you were
19 category 1? Do you want to be posted? I think the
20 concern that existed in the categories and how that
21 happened with international trade and how it gets
22 reacted to in the public related to how certain

1 countries would do things and when they bring up
2 tire tariffs versus poultry imports or whatever,
3 that somehow this would get put into that model, and
4 to be cautious about it, I think that was the
5 industry's request around the categories.

6 So I would want to be cautious on that as
7 if it would drive those customers to then go to a
8 naming level, when it comes to trade or those types
9 of scenarios, that it would be available, but those
10 establishments that are category 1, right, are
11 exceeding or doing more or doing what they can to
12 exceed the standard to the highest level and, of
13 course, we appreciate, the public appreciates that
14 they're doing that. And so the question is when
15 does it become overly burdensome to go list them
16 all. I don't know. In turkey it's easy. There are
17 only 34 slaughter establishments I believe, close to
18 34, plus or minus a few that are seasonal.

19 MS. GAPUD: I agree with what you said,
20 Bob, and again, as a representative of the industry,
21 it really hurts, you know, like, of course, a small
22 processor, for example, they do their best. In

1 fact, they contributed also to this lower, you know,
2 of course, the standard before it was 20 percent,
3 and now because people, they work so hard, so they
4 obtain the 7.3 percent for *Salmonella*, and now here
5 comes the Agency, they try to put it and tighten it
6 to 7.5 percent, which is great, okay. However,
7 again, there's some question for small processors or
8 medium size processors. It's a little bit difficult
9 because now the customers, you know, the way they
10 see it, it's just like, well, I just want to work
11 with you, if you are in the category 1, okay, which
12 is very hard for smaller, you know, processors. If
13 they have only three or four plants and then one
14 plant is a little bit low, you know, in that
15 particular aspect and this one doesn't want to work
16 with them because they're not in the category 1,
17 it's difficult for the small processor. But if you
18 have like big company and you have say 43
19 facilities, you can easily move your production or
20 that processing to another plant, and it won't hurt
21 you much, but we have to realize the small
22 processors, some are very good ones, too. Okay.

1 And, again, that categorizing really is something a
2 little bit a concern, and again I hear some issues,
3 of course, I am new to Fieldale Farms, but I'm
4 trying to learn and curious on what's going on.

5 There are issues about their concern and
6 other people also. There's some concerns about,
7 well, the *Salmonella* issue, well, from 2000 to 2009,
8 you know, you're going to see the graph that they
9 were showing yesterday, it's still quite flat, okay,
10 despite the fact that the processors, they try to
11 work so hard to lower from 20 percent to about 7.3
12 percent in instance of *Salmonella* in the meat. And
13 still it's almost flat. Despite the fact that the
14 consumption of chicken is higher and lower
15 *Salmonella* in the product, still it's flat. So we
16 can't just punish the chicken suppliers or
17 processors, especially the small ones, even for
18 putting this category issue, you know, and the way I
19 see it, it's like we should just put fail or pass,
20 and then it will be easier for those people who are
21 also working very hard.

22 DR. KASSENBERG: I have a question. I'm a

1 little confused as to what we're trying to do here.
2 Are we supposed to look at the specific criteria for
3 all questions, all the information, or are we
4 supposed to develop a process to determine what
5 information to share? Because I don't know if we
6 can make a blanket statement about all criteria.

7 DR. JONES: Right. The question actually
8 asks for the specific criteria. I think my
9 suggestion would be making recommendations to the
10 types of criteria and how the criteria should be
11 developed because I don't know if we have the
12 specific, as we were saying before, I don't know if
13 we have specific enough information to actually --

14 DR. KASSENBERG: So are you talking more
15 about the process to determine those criteria, those
16 recommendations?

17 MR. REINHARD: Well, this is where, for
18 example, when Shelton said he believes that FSIS
19 should analyze the data and explain the data and how
20 it was developed and where it came from and what it
21 meant, so that it was then in a useable format when
22 it got issued, I think that's what the Agency's

1 looking for to be listed for, right. What
2 information should they use to evaluate, to release
3 publicly, I thought what Shelton, correct me if I'm
4 wrong, was saying was that when they release it
5 publicly, they should make sure they can explain not
6 what the results were and what they mean
7 necessarily, but how the data was collected? Where
8 the data was collected? If we go to Pat's example
9 of power, what's the power of the data? What's the
10 quality of the data? What did they do to ensure the
11 quality of the data? That that's what they're
12 saying they want us to tell them here. When you go
13 release it, do these things, right, I think.

14 MS. BUCK: Yeah, I would agree with that
15 because I think what needs to happen is there has to
16 be some decision making, and one of the things that
17 I think the public has a right to know is how you
18 came to your decisions. How did you make your
19 review? And I think that's very important to put
20 that into the recommendations because we need to
21 have a good review of the data and you may, once
22 you've done your review, actually want to consult an

1 outside source to make sure you've done it
2 correctly, like NAS or NACMCF as opposed to NACMPI,
3 okay. Just some suggestions.

4 DR. KASSENBERG: I think that describes the
5 data once they release it, but isn't the question
6 which data to release, which information? I mean
7 it's good to have those subscriptions once you do
8 release the data, the power, how it was collected,
9 how it was analyzed, if there's any, but what about,
10 I think more the question appears to me is what type
11 of criteria to actually release, putting aside what
12 sort of descriptive values are on it.

13 MS. BUCK: I think you're right. There are
14 probably two different things there. When we're
15 talking about sharing the data, one of the things
16 that we are most concerned about, you have to have
17 some agreed upon standards and definitions and
18 formats so that that data then becomes shareable
19 between the silos, and so that the other groups, the
20 external groups we've identified can understand, you
21 know, what it is that they are looking at. So I
22 think it's very important to have standard data

1 definitions and formats.

2 DR. VETTER: I would just like to maybe
3 give an example that's part of question 3 because it
4 says, and you brought up as an example, the *E. coli*
5 data and it says, you know, what should we consider
6 posting that we don't now and at what frequency, and
7 that might lead to some criteria that might apply
8 across the board, and using the *E. coli* data as an
9 example, it's total samples taken and total
10 positives, but that's really more detailed that can
11 be drilled down quite a bit. It's not actually
12 published in that matter, such as the types of
13 samples that were taken because there's what eight
14 or nine different types of *E. coli* samples that
15 we're taking, and then also the months that those
16 positives occur in because they tend to be seasonal.

17 That information is currently not published
18 in that manner and could certainly be more useful to
19 industry, consumer groups, and academia to see it in
20 that way, in that manner.

21 So the other side of that would be that
22 currently that type of information is in PDF format.

1 Well, to do your own sort of analysis and look at
2 that, you can really do that in a PDF format. So to
3 be able to have it available say in Excel, where it
4 could be manipulated and used, would certainly be
5 more beneficial.

6 So I just wanted to offer that as sort of
7 an example that you might could gather some criteria
8 from or glean that from.

9 MS. TUCKER-FOREMAN: On the criteria, I
10 think Pat and Bob were laying them out over there.
11 We should certainly know that it's robust data, that
12 the power is high, that you have the technical
13 details of what defines good dataset at a high
14 level.

15 Beyond that, I'm not sure that you will get
16 an agreement from the people on this Subcommittee
17 about what kinds of data ought to go on the Internet
18 because deciding to post names of companies, for
19 example, is a policy decision that was made to drive
20 a particular policy goal, and we're probably going
21 to disagree about whether it was useful and whether
22 it was appropriate. So I'm not sure you're going to

1 get much more from us in terms of naming of
2 companies. I just don't know you're going to get
3 any agreement from the group on that. We can sure
4 explore it, but my guess is we're going to have very
5 different views.

6 DR. JONES: Can I kind of do a real quick
7 synopsis of where we are right now when it comes to
8 this question?

9 It sounds like that if we continue to look
10 at things from a short, medium, and long-term
11 perspective, kind of keep the flow going through
12 that we started with question number 1, is that we
13 are recommending or we are suggesting that in the
14 short term, that the data that we're looking at,
15 regardless, short through long term, that the data
16 should be robust, that it should be clean. We know
17 that part.

18 The criteria for what data is released to
19 the public would be based on what those objectives
20 are, what FSIS' goals are relative to public health
21 and also policy-related issues. That data that we
22 decide should be released to the public should be

1 based on the meeting of those goals, the information
2 relative to establishments. It sounds like it's
3 something that should be based on policy and how
4 policy is developed around whether it's the
5 categories or some other criteria that's developed
6 over time by the interest group that's going to come
7 together, and also it sounds like that the frequency
8 and the type of data over time should have the
9 ability to change. The frequency of releasing the
10 data, the type of data should change.

11 Kind of that's where we are right now with
12 question number 3. I just kind of wanted to wrap
13 that up, and I know that you have a comment.

14 MS. GAPUD: Yeah, I just want to make a
15 comment, and I am with Bob, with Robert, I don't
16 want my establishment, whether I'm good or bad, I
17 don't want it to be in there. The main thing for me
18 is like I know if there's some issue, that I will do
19 my best to fix it because again, it can have an
20 economic impact on the company, on the
21 establishment, and again nowadays, like what I said
22 to you, people, the consumers are very, very

1 particular. If you're not category 1 even for one
2 incident, they don't want to work for you, and that
3 can be a disaster to people who are not as big as
4 the other processors.

5 MR. REINHARD: Yeah, I'll follow up on the
6 issue, food safety. Industry looks at food safety
7 as a non-competitive issue, and so what we do and
8 what we do as an industry as a whole is we
9 constantly work to get everyone in the industry to
10 highest standard and if we're already at category 1,
11 and we know how to be a category 1, and there are
12 certain establishments that are a category 2 or
13 category 3, we spend a lot of resources to help
14 those establishments move up to category 1. And the
15 idea that the naming, what happens in the naming
16 then is it becomes very competitive, and it then
17 starts separating and differentiating the
18 establishments when really everyone has the same
19 goal. And until we went to really non-competitive
20 food safety, a lot of the improvements were very
21 specific to single establishments or single
22 companies, and no one else in the industry knew what

1 was going on, and when we said it was a non-
2 competitive issue, going back to the late 1990s,
3 early 2000, and the different trade organizations
4 said let's bring this together and drive the
5 industry results because it really is bad for
6 industry when anyone has a problem, we made vast and
7 massive improvements, and it's where you see a lot
8 of the data get better quickly. And so that's why
9 we tend to stay away from the naming of
10 establishments on the good side, okay, and I
11 understand why FSIS did the category 2 and
12 category 3, but we want those establishments to
13 still reach out to others for assistance. How do
14 you get there? What do you do? How can we get
15 better? Because the public health part is what the
16 ultimate goal is, and we don't look to market,
17 right. We do spend a lot of money marketing our
18 different organizations and getting our name out
19 there in a positive format. We don't look to food
20 safety to be that vehicle. So that's where that
21 really plays in my opinion.

22 DR. JONES: Dr. Tilden, did you have --

1 MS. TUCKER-FOREMAN: I'd like to respond to
2 that, if I may, because that's a really basic issue,
3 and my view is entirely different.

4 The reason that you have food safety
5 regulatory programs is that food safety is the
6 essence of a market failure. I can't look at the
7 chicken and know that chicken isn't contaminated. I
8 can't see the *Salmonella*. So traditionally there
9 has been no motivation for a company to do better
10 than the other company because I not only can't see
11 it on the chicken, if I get sick with *Salmonella*,
12 the possibility that it's going to be found whose
13 product made me sick or what product made me sick is
14 very small. That's the essence of health and safety
15 regulation, and food safety is the epitome of it.

16 Now I was here in the 1970s. Food safety
17 is not a competitive issue for us was something the
18 industry said then, and it did not come up in the
19 '90s. It was said then and, in fact, it was when
20 FSIS began to test for *E. coli* O157:H7 that the
21 industry both shared its data, it has always done
22 that, but also people began to understand that there

1 was a real price to be paid for that market failure,
2 for failing to produce a safe product.

3 I want the public to make a choice between
4 your product and somebody else's product based on
5 whether or not they think that's the safest product
6 to sell to their children. I want it to be a
7 competitive issue. I think that it must be.
8 Otherwise, what you're doing is you're saying to the
9 American consumer, you go out and buy that, it's
10 good for me for you to buy that. I want them to
11 know that's the safest product out there, and I want
12 you to advertise my products always come out highest
13 on the USDA's roll. I think people ought to do
14 that. I understand that puts pressure on business.
15 I'm sorry. This is market capitalism. You're
16 supposed to have that. The value is, has been make
17 a pretty product, make a cheap product. What we're
18 trying to do here is make the value be, make a safe
19 product.

20 DR. TILDEN: And I think I'm somewhere in
21 between because I work with both the large groups,
22 the large industry that's very well plugged in with

1 the national associations and, Bob, I think you
2 articulated exactly the corporate ethic of that
3 segment of the industry. We also deal with a lot of
4 the independents who are not at all plugged in and,
5 you know, they're the folks that you would love to
6 get to the table and to take food safety seriously,
7 and so we have had decades of challenges of trying
8 to find strategies that work for a full range of
9 industry. And so I think it's not an either/or. We
10 just have to figure out how to work together to make
11 both tools in the toolbox.

12 A couple of times in the last two days,
13 we've talked about running this back by the National
14 Academy of Sciences or NACMCF, and there was a
15 letter where it was shared back with those, but
16 there wasn't a specific ask, hey, how are we doing?
17 Would you be willing to weigh in on it? And I
18 personally think that would be a good idea, is
19 whatever you come up, to take it up and then run it
20 back by them. I don't know how logistically a
21 nightmare that is or if that creates a whole bunch
22 of drama in and of itself, but continuing to check

1 in with external folk, an external scientific basis
2 to have it kind of reviewed by some of them to
3 validate that you're heading in the right path, I
4 think, would be a wise thing.

5 MS. TUCKER-FOREMAN: John, if your proposal
6 is, are you checking back on the science of it --

7 DR. TILDEN: Right.

8 MS. TUCKER-FOREMAN: -- I absolutely agree.
9 If you're checking back on how you market things and
10 whether something's going to be a competitive
11 disadvantage or not, those two committees don't do
12 competitive advantage.

13 DR. TILDEN: No, no, it was like this is
14 our best approximation of, for example, the
15 inspectional activities that are most directly
16 related to public health outcomes. And this is why
17 we've come up with these, and are we thinking in the
18 right direction because I think you're probably
19 going back to that short, medium, and long term. It
20 will evolve as we learn more.

21 MS. GAPUD: Well, I would like to make a
22 comment. I was with the food service side for

1 almost 14 years, and I can tell you, to me food
2 safety is non-negotiable. I saw that, and I am
3 proud to tell you I never have any foodborne illness
4 outbreak wherever I work, okay, and that's why to me
5 food safety is very, very important. Now, I am here
6 on the suppliers' side and the way I can see, we
7 have to balance things together because there can be
8 economic impact also on the other side. The other
9 side, I can tell you right now, with the economy,
10 lots of companies there are trying to cut corners.
11 They don't even want to buy something that is quite
12 expensive because if they put more things in order
13 to make really the product very, very safe.

14 So my point here is we have to balance
15 things together. We have to look at the economic
16 impact and, at the same time, not compromise food
17 safety because I can tell you I will be the first
18 one say, food safety is non-negotiable. I was on
19 that side.

20 MS. TUCKER-FOREMAN: If you're a public
21 health agency, then we don't --

22 DR. JONES: Can I -- I'm sorry. Can I get

1 Ms. Buck in.

2 MS. BUCK: I would agree with the lot that
3 has just transpired on that side of the table and,
4 of course, you all know my background and how deeply
5 I think it's important for food safety to serve, you
6 know, public health needs. We simply must be doing
7 better, and part of the reason you asked us to
8 convene and talk about these important issues is so
9 that you can do better. So I applaud you for this
10 effort.

11 But when it comes to the question of what
12 criteria should FSIS use to evaluate what
13 information to release publicly, I think again you
14 have to go back to looking at what you're
15 capabilities are and you have to consider the fact
16 that you're going to need to take the lead. You
17 have to put out there what do you need as far as
18 standardization of forms? How does production
19 volume impact? How do all these other factors
20 impact on how you're going to collect the data? And
21 that's going to take a team of experts, and once
22 you've come up with those ideas, those indicators,

1 those plans, that can build the metric system that
2 John was talking about, then you can come to us and
3 say here's what we want to do. Do you think this is
4 a good idea? And maybe then we can respond more
5 fully.

6 DR. JONES: Okay. So the answer to kind of
7 provide a synopsis for the answer for -- I'm sorry.
8 Ms. Foreman.

9 MS. TUCKER-FOREMAN: I just, in my view,
10 the criteria and conditions about posting
11 establishment specific data is if you have high
12 quality data, and if it serves the public for the
13 purpose of improving public health, then posting
14 establishment-specific data should be appropriate.

15 DR. JONES: Okay. I'm going attempt to
16 make my synopsis of this question, of the answer.

17 Once again, it seems as though we have to
18 make sure that an expert group is convened and works
19 well together with representation from both sides,
20 actually from all sides because there's more than
21 two. And also that we know that the objective is
22 public safety and public health, improving the

1 public health. We know that we are in need of the
2 development of the metrics that allows us to have
3 some goals and measures to follow using this data
4 that we're collecting. The recommendation sounds
5 like the criteria for releasing information to the
6 public also needs to be defined by this working
7 group, this expert working group, but the objectives
8 should be, of course, as I stated earlier, to ensure
9 that the public health is the number one priority,
10 and that the public health goals and objectives that
11 have been listed are the ones that we're addressing
12 and attempting to meet.

13 Also the frequency of distribution of
14 information and the individuals and the agencies
15 that should have this information will be defined in
16 the short, medium, and the long term. Did I miss
17 anything?

18 UNIDENTIFIED SPEAKER: Standardization
19 forms.

20 DR. JONES: And that the forms and the
21 reporting should be standardized.

22 UNIDENTIFIED SPEAKER: And reviews.

1 DR. JONES: And reviewed. So the review
2 process or the period of time, the frequency of
3 review will be recommended also by the Committee,
4 not by the Committee, I'm sorry, the expert group
5 that comes together.

6 MS. BUCK: Not knowing who's going to serve
7 on the expert group, it's a little hard to say, but
8 I think that we need to have the expert group, be
9 the ones to look at this question in particular,
10 okay, and whatever falls out from that, we may have
11 to regroup, I don't know.

12 DR. JONES: Should we make a recommendation
13 as to the type of individuals that we are talking
14 about? I don't know that we clearly defined the
15 expert group. That might be one of the things that
16 we might need to go back and look at. Who should be
17 represented on this group of individuals that
18 significantly impacts the way this system is
19 developed as far as stakeholders are concerned?

20 DR. VETTER: Can I comment on that?
21 Because I kind of listed out like different -- I
22 know we had external and internal, but I sort of

1 made a list, and I think consumer groups, academia,
2 and I guess the expert panel would be
3 representatives, possibly more than one
4 representative from each of these different types,
5 consumer groups, academia, and then I also have
6 other federal agencies, and I broke those down sort
7 of into two parts. Those within USDA and those
8 outside of USDA. Those within USDA might be AMS,
9 ARS, APHIS. Outside of USDA, of course, we have
10 FDA, CDC. We also have OIG that frequently wants
11 data from us and Congress. Then I broke it down
12 into state and local governments because I think
13 they kind of have similar interests and needs, and
14 then internally within FSIS, we also have various
15 levels that use the data in different ways similar
16 but different ways, and that's the inspectors
17 themselves, PHVs, EIOs, frontline supervisors, and
18 then you have senior level executives, like SES, the
19 Administrator, and then even the Under Secretary and
20 Secretary and what their needs, you know, might be,
21 and I'm not saying that you'd have all these people,
22 but that's just kind of how I'm thinking. And then

1 the establishments themselves, the federally
2 inspected establishments.

3 And one group that we really haven't talked
4 about, and we haven't really mentioned, but my
5 experience with FOIAs is we get a lot of requests
6 for information from them, and that is humane
7 handling groups. They also want to know about our
8 humane handling activities and noncompliances and
9 enforcement actions. So that's kind of what I have
10 possibly represented, and if anybody can add to
11 that.

12 MS. BUCK: I didn't hear the last group she
13 mentioned.

14 DR. JONES: Humane handlers.

15 MS. TUCKER-FOREMAN: I will have to oppose
16 any recommendation that suggests that the FSIS
17 leadership, the Office of Food Safety, USDA's
18 leadership, should be constrained in making public
19 data that is helpful to promoting public health and
20 constrain that. Don't let a group of stakeholders
21 to be able to lay down conditions that restrain the
22 best judgment of the Office of Food Safety about

1 what information the public needs in terms of
2 protecting public health. The B here is not
3 something that I think is, as it has been stated,
4 suitable for being handled by a stakeholder
5 committee, and there are a number of reasons for
6 that. Stakeholder committees meet maybe once or
7 twice or maybe even once or twice a year. The
8 policy officials are doing this every single day.

9 But stakeholder committees at the
10 Department of Agriculture, in particular, are made
11 up as this Committee is, and you look around the
12 room, and there's a small business, a medium
13 business and a big business, and a pork business and
14 a chicken business and a beef business, and state
15 government officials from the Departments of Health
16 and from Departments of Agriculture, and academics
17 from various disciplines, and there are two
18 consumers, and we are, after all, the people whose
19 health is at stake in an agency that's devoted to
20 public health.

21 When it comes down to these kinds of
22 negotiations, we are always in this situation of

1 having to compromise away from public health, and
2 not on this issue. So I just have to oppose that.

3 MS. BUCK: I would agree with you, Carol,
4 on that, and I think John already has very much laid
5 out the fact that when you make all of the data
6 transparent, it's not as big of a headache as you
7 think it's going to be, and it does help drive
8 public acceptance and public understanding about
9 what's going on within our food safety systems.

10 I think what's important here is like Carol
11 had mentioned earlier, identification with the data
12 of what that data is doing and what the limitations
13 are of the data and that type of thing. I think
14 it's really, really important, if you're going to be
15 reviewing the data and aggregating it, that you go
16 ahead and give a very good accounting about how you
17 made certain decisions about the data. So I mean I
18 think we need to have transparency. If I didn't say
19 that publicly, I would hear from somebody and we
20 need to have transparency with the data, and I think
21 some of the concerns that you've raised and some of
22 the concerns I think that you will raise, that the

1 little guy is going to get hurt in the process, I
2 don't think that's the intention, and I know, well,
3 you know, that's not good. But I think that there
4 is a commitment on the part of a lot of people to
5 reach down and help the smaller processor to achieve
6 the food safety standards that they need to help
7 protect the public.

8 MR. WARSHAWER: I think that the issue
9 about data versus interpretation is where the
10 dividing line is right now. For me, the notion that
11 food safety is pre-competitive coexists quite fine
12 with the notion that it's also non-negotiable. If
13 those two are put together, the calculus changes a
14 bit. So I'm going to say that transparency and
15 maximum data access actually solves the problem if
16 we can also avoid interpretation, for example,
17 giving a tiered grading system to different
18 establishments in different situations. So, for
19 example, pass/fail is different than A, B, C, D. If
20 we do A, B, C, D, we penalize a full range of
21 operations that for different reasons may not be yet
22 ready to achieve status A.

1 So I think the nuance, the challenge here
2 is the nuanced problem of how to make food safety
3 non-negotiable and pre-competitive while still
4 providing incentives for best practices to improve,
5 and it seems to me that the regulatory side is
6 pass/fail, and that the industry self-improvement
7 side is the continuation of pursuit of best
8 practices.

9 And what we're having is a debate and a
10 problem over how to do both in one process, and I
11 don't know that that can be done. If we try to do
12 both in one process, we will ultimately homogenize
13 the system to where the larger entities are favored
14 and smaller and mid scaled entities are penalized
15 simply on the basis of availability of resources and
16 capacity.

17 So I think the two processes have to
18 somehow coexist. The public health outcome is the
19 highest pursuit of the regulatory process, and the
20 continuation of pursuit of best practices is a
21 market-based process that ultimately I just don't
22 know how that part of the process can be placed into

1 the market as a competitive process without it
2 having more adverse than beneficial effects.

3 DR. JONES: Dr. Tilden.

4 DR. TILDEN: Yeah, I'm still processing
5 what you said because there is a lot of good ideas
6 there, but let me just say, I think FSIS did some
7 good things where you had those box and whisker
8 plots, you know, very kind of intuitive things where
9 you don't comment so much on the data, you just
10 present it, and this is where this data point is
11 compared to all the other data, and it is what it
12 is, and then people can make determinations based on
13 that. That I think is helpful.

14 And I think sometimes though we don't give
15 people enough credit to be able to sort that out
16 because I know at least in Michigan, there's a lot
17 of folks that they look at sampling data, and that's
18 not the only way they make their decisions. But
19 they do want to be able to look and make the
20 decision for themselves. So if we can figure out a
21 way to clearly communicate the facts, the facts and
22 not clutter people's minds up with our

1 interpretation of those facts, that might be the
2 best way.

3 DR. JONES: Okay. Ms. Foreman, did you
4 have a comment?

5 MS. TUCKER-FOREMAN: I'll pass for now.

6 DR. JONES: Okay. So I think I did a real
7 quick synopsis of question number 3, and it sounds
8 like I need to add to that, that the whole idea of
9 trying to ensure that the issue around food safety
10 is, I think you said non-negotiable. How do we
11 ensure that food safety is non-negotiable and also
12 that all of the establishments have adequate
13 opportunity to remain competitive?

14 MS. TUCKER-FOREMAN: I will object, and I
15 will just simply have to be listed as opposing
16 anything that says that it is part of the obligation
17 of this Agency to ensure a competitive, even keel.
18 I just object to that. Steve, I believe that you do
19 not have to have a homogenized system if safety is
20 your highest priority. There can be companies who
21 determine we're going to sell within a very small
22 area because we're going to sell the very highest

1 quality and safest product that's out there. It
2 does mean that I may not be able to expand any
3 further than a certain place because my systems
4 won't let me do that, and somebody else may be
5 saying, I'm going to sell internationally and sell
6 at a level below that. This is a public health
7 agency, and even though it will always balance the
8 economic interests of the industry, that is not part
9 of the charter, and I will not be able to support
10 anything that suggests that it's appropriate for the
11 public health decisions of the Agency be
12 circumscribed by what is competitively important to
13 some parts of the industry.

14 MR. WARSHAWER: I really enjoy this
15 discussion, but I think that if we take it as far as
16 we will want to, it will probably prevent us from
17 moving through the questions, and so I just want to
18 know how to respect the opportunity to do both, you
19 know, to carry this discussion forward. I am sure I
20 have a lot to learn from your perspective,
21 particularly as new as I am to this Committee, and
22 hopefully some of the experience that I have, at

1 some point, may move you to see some other
2 possibilities, but how do we do what we're mandated
3 to do here today and then also respect the
4 opportunity for thorough civil dialogue about the
5 best ways of approaching both public health and
6 opportunity.

7 In my world, as a producer, I look at it in
8 two different ways. I look at creating opportunity
9 for producers and choice for consumers, and I don't
10 want it to end up with only the people with either
11 the most money or the most access can afford the
12 safest food, and the idea of safest food to me
13 becomes really difficult if it's a competitive
14 point. I really -- I mean I'm sorry that I love
15 this discussion. It's brilliant. I learn so much
16 about it, but I don't know that it will get us where
17 we need to go today. So, Subcommittee Chair, how do
18 we parse this so we can move together collectively
19 and still preserve an opportunity for this
20 discussion or facilitate it at a later time?

21 DR. NEGRON-BRAVO: I just want to say that
22 I agree with Mrs. Carol, and the competitiveness of

1 the Agency will come when they can prove that they
2 have a safe product, and that's it. If they have a
3 safe program, they will be competitive. The issue
4 is not competitiveness.

5 MS. GAPUD: Well, I just want to make a
6 comment regarding Mesa Farm comment here. I support
7 him in what he's saying, and this is what I can say.
8 I have worked, you know, in a company, a big
9 company, one of the biggest companies here in this
10 country, and maybe in the world, and I can tell you
11 not all big companies are great, okay. There are
12 good and bad all the time. Even the small
13 companies, there are good and bad there, too, and we
14 should give them the opportunity to improve
15 themselves and not just be punished because they are
16 maybe one time they were in category 2 and then the
17 other consumers don't want to buy anything from them
18 anymore, okay. Wherever you go, and like what I
19 said, I work with one of the biggest companies, and
20 I can tell you I saw lots of things out there and
21 now if you are also in the smaller company, I have
22 seen a lot. Even the food service, I have seen a

1 lot. That's why I'm just here to try to express
2 what I have, what my perspective is and experience
3 from all of these. That's why I'm trying to share
4 it with you, not only small companies are bad, not
5 the small or not all big companies are great.

6 DR. JONES: So for the interest of time, I
7 suggest that we, in comments, place the priority of
8 this Committee, Subcommittee, that, of course, food
9 safety is the main objective, the non-negotiable
10 objective, and that in our comments, to ensure that
11 as this group of experts gets together that meet, to
12 clearly define what the indicators are, that we also
13 ensure that we suggest that some specific time be
14 dedicated to identifying how establishments will be
15 dealt with when it comes to categorizing them as far
16 as their ability to meet objective and how that
17 information will be disseminated.

18 MS. TUCKER-FOREMAN: We're going to have to
19 be very vague on that, or I will have to just simply
20 oppose it. The Subcommittee can go ahead and do it,
21 but let me take a step back. Perfection is never
22 demanded by FSIS regulations. Nobody has ever

1 proposed a regulation that says that, for example,
2 that the product has to be *Salmonella* free or
3 *Campylobacter* free. We're always negotiating how
4 much is okay, and the one place that there's a zero
5 tolerance in a raw product right now is O157:H7
6 because we know there is no dose that appears to be
7 safe for human consumption. Everything else, there
8 is a tolerance for a certain level of *Salmonella* and
9 a certain level of *Campylobacter*, so not demanding
10 perfection. We do believe that companies that meet
11 or exceed this standard, that the Agency should have
12 the freedom to say publicly, these companies exceed
13 the standard, these companies meet the standard,
14 these companies, well, hell, they wouldn't even say
15 they're not meeting the standard. They said wishy-
16 washy, we're not sure they are, and I think that the
17 balancing occurs in the setting of those standards
18 and always in what the Agency releases publicly.

19 So I would have to oppose having this group
20 get into discussions that might be construed as
21 constraining the Agency's leaders from determining
22 what is the best action to take in order to protect

1 public health including the naming of names of
2 companies that aren't meeting the standards.

3 DR. JONES: When you said this group,
4 you're speaking of this Subcommittee?

5 MS. TUCKER-FOREMAN: No, the --

6 DR. JONES: Expert group.

7 MS. TUCKER-FOREMAN: -- expert group. See
8 I don't want them to get into a discussion in which
9 they say to the Under Secretary for Food Safety,
10 it's not appropriate for you to list establishment
11 names under these circumstances. They can't go
12 there. They just can't.

13 DR. JONES: Okay. So can we put in the
14 notes that we have a concern, a specific concern
15 about listing the names of establishments relative
16 to their ability to meet.

17 MS. TUCKER-FOREMAN: We'll just, you know,
18 if it comes down to it, we'll just have to -- I
19 can't, I can't agree to that. I can't agree to that
20 because I don't have a concern about naming names.

21 DR. JONES: Okay. Maybe I misunderstood
22 you then.

1 MS. TUCKER-FOREMAN: I'm saying that I
2 don't want this expert panel to get into that
3 question and suggest that it is inappropriate to
4 name names.

5 DR. JONES: Okay.

6 MS. TUCKER-FOREMAN: I'm sorry. I just
7 clearly --

8 DR. JONES: So is it possible with the
9 interest of time, that we move onto questions 4 and
10 5, and --

11 MS. TUCKER-FOREMAN: No.

12 DR. JONES: Okay. So we have to resolve
13 this issue before we can move forward. I'm trying
14 to get to the bottom line of understanding. When we
15 look at this expert group of people that are going
16 to define the system, I'm not saying that they have
17 the -- I'm not thinking that they have the ability
18 to impact policy. I'm saying they have the ability
19 to represent the organizations that are going to
20 need the information to say what kind of information
21 it is that they need.

22 Once they establish what kind of

1 information that they need, FSIS is then responsible
2 for identifying how that information will be
3 collected and how that information will be
4 disseminated to them. That expert group does not
5 decide that part. It just decides the type of
6 information that they need.

7 Now, deciding how that information should
8 be utilized or putting restrictions on the data, on
9 the raw data and deciding how that information will
10 be utilized is going to be more the responsibility
11 of the policy development, which is going to come
12 out of FSIS from what I understand. Am I correct
13 or --

14 MS. TUCKER-FOREMAN: I got this problem
15 with question 3B, under what criteria and conditions
16 should FSIS consider posting establishment-specific
17 data in which the establishment is identified, and
18 perhaps the best thing that this Subcommittee can do
19 is say this Subcommittee was not in agreement on
20 that issue.

21 DR. JONES: Dr. Tilden.

22 DR. TILDEN: Yeah, and I think it's

1 important that it's not just Carol Tucker-Foreman
2 that has that position because I think in general as
3 I've stated, we have not had a problem with sharing
4 information. So I don't think it's just consumer
5 rights versus the rest of the world kind of a thing.
6 I think it's a broader issue, and so if we can't
7 reach consensus on it, that's okay, but I just
8 wanted to say that.

9 DR. JONES: Okay. Ms. Buck.

10 MS. BUCK: Yes. I would have to agree with
11 John. Carol does not stand alone on this. I mean
12 we have to have some way of identifying where
13 progress is being made. Consumer groups do. The
14 public does. We have to have some way of evaluating
15 that. Posting names is just one way. There might
16 be others that we have not thought of, but that's
17 one way that this can happen.

18 I think when we talk about the expert
19 panel, what you defined was very good as far as, you
20 know, what criteria should the data look at, you
21 know, that type of thing. But when it comes to this
22 issue under what circumstances, that is going to be

1 a policy decision that's going to be made by FSIS,
2 and we will continue, the consumer groups, as well
3 as others, to push for as much disclosure about the
4 rankings of the food producers so that we can tell
5 our clients, which is the general public, in terms
6 that they understand, what the risks are associated
7 with certain foods, and I think that's our role. I
8 mean our obligation is to the consumer. It's not to
9 industry. We look to industry for help in the sense
10 that we feel that they can do more and actually
11 there's a lot of the people here that have done
12 more, and we appreciate the efforts that they've
13 made, but yesterday we did look at what's going to
14 be happening with trends and multidrug resistance
15 *Salmonella*, and that is very scary. So what we're
16 trying to do is prepare for the future and what some
17 of the food challenges might be. So we have to keep
18 our eye on that as well.

19 MR. WARSHAWER: I think it's best not for
20 us to have a recommendation on 3B, and I'm in
21 agreement with you that there's more work to be done
22 to find a way forward with establishment

1 identification and with the role that that plays in
2 assuring public health and assuring pursuit of best
3 practices. I'd raise again my question, you know,
4 how do we carry that conversation forward outside of
5 this venue. It's a big topic. It has lots of
6 different ramifications and deserves consideration
7 and also deserves not to impede our progress with
8 stuff that we can't answer. So how do we do both?

9 DR. NEGRON-BRAVO: I also want to say that
10 I agree to eliminate that B because that's the
11 Agency role to determine the legal implications on
12 whether they are saying names or not saying names.
13 We don't know the laws and regulations and the
14 policy that they have. So that should be within the
15 Agency to decide.

16 DR. JONES: Okay. So can we say that we do
17 not have a recommendation for number B?

18 MS. TUCKER-FOREMAN: You ought to ask if
19 that's a general view, that that seems to be the
20 only way. I don't see how we can get out of it.

21 DR. JONES: Is everybody strictly opposed
22 to that?

1 Okay. We can move onto question number 4,
2 which asks "How should FSIS determine which
3 variables are priority, time intervals, and also
4 levels of aggregation that are most useful and most
5 appropriate?"

6 DR. KASSENBERG: Is this an opportunity to
7 talk about the expert panel again? This kind of
8 fits in a little bit with that because I don't know
9 that we have all the information that we need to
10 make that determination. So I think it's more of
11 the process of determining those variables and
12 looking at an expert panel that has that information
13 and expertise.

14 DR. JONES: Dr. Vetter.

15 DR. VETTER: I would just say that in
16 general I think the specificity of what FSIS
17 publishes currently should possibly be increased,
18 and by that I allude to the example that I gave
19 earlier with the *E. coli* data. Breaking it down,
20 just not by total samples taken, but those types of
21 samples, the months that they were taken in, those
22 types of things I think would be more useful, and I

1 think certainly quarterly and then annually is very
2 good so that people can get an ongoing picture of
3 what's going on throughout the year and then maybe
4 compare from year to year. And, of course, I am
5 speaking specifically about microbiological data,
6 but I think right now we publish in very general
7 terms of what we have. So I think if that data was
8 able to be drilled down more, that it would be more
9 useful even to those within the Agency because we
10 wouldn't have to be going straight to you guys to
11 ask for it, which is what I currently do. I go to
12 Doug and say, okay, I need this. Can you break it
13 down for me? And if it was there and published on
14 the website, I could simply pull it off and not have
15 to do that.

16 DR. JONES: Dr. Tilden.

17 DR. TILDEN: And I thought yesterday there
18 was some really good examples of the right kinds of
19 things to be doing. So, for example, you had the
20 *Salmonella* general and you could see a trend, and
21 they said but, if you look at it in subcategories,
22 look where all the progress has been made,

1 *Salmonella* Kentucky. Look at the areas where
2 progress is yet to be made. So our interventions
3 and our approaches have been successful in some
4 categories but not other categories. So I think
5 this is getting back to what you were saying, is be
6 more and more targeted and focused on where can the
7 next increments of change be made, and what does the
8 Agency propose to focus on to get those subsets and
9 start working on? It's not an amorphous mass of
10 generalizations. There's a bunch of specifics that
11 we need to be targeting.

12 And then if the Agency could lead the
13 process by identifying here are the categories that
14 we propose breaking this general information down
15 into, small, medium, large, you know, category A, B
16 and C, whatever it is, start making what seems
17 complicated and amorphous understandable and clear
18 and actionable, and I think that that might be
19 beyond the scope of what we can do, but just to say
20 that that direction that you're already moving on,
21 keep going.

22 MS. TUCKER-FOREMAN: I agree with John. I

1 think this is a question frankly that would be far
2 more appropriate to ask of the Advisory Committee on
3 Microbiological Criteria for Food than it is for
4 this stakeholder committee, and that's what we are
5 around this table. And that's true to a certain
6 extent of the question 3A and 5A as well.

7 MS. BUCK: I think it's very important to
8 structure the data, and I think that that's
9 something that I think John was referring to, is
10 that we need to find a way of structuring it. With
11 regard to PHIS, I think we have to look at how the
12 technology is going to be impacting on the structure
13 of the data, and how is this predictive analysis,
14 you know, going to work because that's sort of to me
15 seems to be the brain and who is running that is
16 very, very important. So when you're structuring
17 your data, maybe you've already done that.

18 MR. REED: I mean I would say in general
19 that data in PHIS is just like data in any other IT
20 system. It's contained in tables and a data
21 structure that can be manipulated and exported in
22 many different ways. So really it's not that

1 different than what we would have in our current
2 data warehouse, and that we could make it or modify
3 it or, you know, transform it, not the values, but
4 the structure, to meet stakeholder needs.

5 MS. BUCK: Well, then maybe I've
6 misrepresented what I was trying to get at. For
7 example, you have a new technology. All of FSIS'
8 input is coming from your inspection fields as they
9 enter this for the continuous loop so that you can
10 make better assessments.

11 If you're heavily relying on your
12 inspection force, you need to, when you're looking
13 at all of your data, you need to understand that
14 they may not be trained at the level to do the job
15 and how does that impact on what you're receiving.
16 And stepping back and looking at the whole of your
17 data organization or where your data sources are is
18 more I think what I'm trying to get at, because
19 without that, I don't see how we can answer which
20 variables have the highest priorities, what time
21 intervals would be the most useful, and what levels
22 of aggregation are the most useful. I mean there's

1 always going to be a time lag in your data, but some
2 data, if you have the minutiae, will really point
3 you in the direction you need to go whereas there
4 are other times your aggregated data is going to do
5 that for you.

6 So you need to step back and look at the
7 whole system and design something that will bring
8 together the data that will give you the outputs.
9 I'm stating this really badly. I'm sorry. I did
10 the best I could with it.

11 MR. REINHARD: I think what really is
12 getting asked here and what's happened is with PHIS,
13 the Agency has really taken a lot of different
14 stovepipe type systems, and they've put it into a
15 single data warehouse that ultimately makes you
16 extremely efficient with your data, and on the
17 public health side, it gives you improvement where
18 data wasn't appropriately noted when something
19 occurred because in the old system, it required an
20 analyst in between.

21 And in the current system, if a facility
22 isn't scheduled for a sampling for *E. coli* O157:H7,

1 but they're making ground beef, which could have
2 occurred in your old system, and the only way it
3 gets caught is with an analyst intervening, now
4 we'll probably be caught by PHIS and that gap will
5 get filled.

6 But it really is a very efficient system,
7 and you have now all of this data that you could
8 rapidly analyze or you could do a quarterly or you
9 could do it annually, what FSIS deems to be
10 appropriate, and you've kind of given us these open-
11 ended question of how should we do things, and we
12 can't answer --

13 MS. BUCK: No, we can't.

14 MR. REINHARD: -- per se that except for
15 what I think is we go back to originally what we
16 said, the highest priorities should be around the
17 public health driving data and around the objectives
18 of the Agency, almost like what we said at the
19 first, up front, and then all these other things,
20 really it depends. And there isn't a correct answer
21 for us to say, time intervals, for example *E. coli*
22 O157:H7, you release weekly your sampling results.

1 For *Listeria monocytogenes*, you release it
2 quarterly.

3 I think if we had specifics like that, I
4 may have a reason why I think you should do *Listeria*
5 quarterly or maybe I may have a reason you should do
6 O157:H7, you know, I mean *Listeria* weekly, too, or
7 O157:H7 quarterly, but absent of that, I think it's
8 hard for us to answer this question for you in a
9 format that doesn't just lead to more questions
10 because you haven't said what variables exist.

11 MS. BUCK: And I think once you have this
12 group of experts, they're going to run into some of
13 the same problems that he just expressed.

14 MR. REED: I think we should clarify that I
15 think the discussion you guys are having in the way
16 that you're presenting this is actually very useful
17 to us. I can honestly say from my side, I assume
18 that you guys would have a checklist of I want this
19 and this and this, and so which is why we presented
20 it to you, to get the recommendations from the
21 Committee.

22 So I think when we hear your discussions

1 and the way you're describing it, in my mind, you
2 actually are presenting criteria to us and we're
3 taking notes, even though in my mind and your mind
4 you may be framing it different, because you're
5 setting out ways that we need to evaluate that data
6 so that we can make the decisions to show you
7 something so that you can respond to it. So I don't
8 just want everyone here to get frustrated because I
9 think we're actually making a lot of progress and it
10 is valuable input.

11 MR. REINHARD: You've made a lot of
12 progress on PHIS, too.

13 DR. TILDEN: Okay. I don't feel so
14 retarded then. But, you know, it's fun listening to
15 Pat and Bob kind of struggling with it because it's
16 like, okay, somewhere in there, what they're saying
17 I agree with.

18 A couple of things that might be helpful.
19 In the last year, we've learned a heck of a lot in
20 non-meat and poultry area in food safety that might
21 be helpful and relevant to the meat and poultry
22 world. So the FDA folks have spent a fair amount of

1 time trying to help reinforce the concepts of the
2 zones within food processing environments, and if
3 we've learned anything from peanut butter is you're
4 just doing finished product sampling and waiting to
5 catch the problem, then you're a day late and dollar
6 short because there's niches in the environment.
7 And there's a whole literature out there on zones,
8 you know, there's government documents and industry
9 government documents that talk about how finished
10 product relates to the environment that created the
11 finished product.

12 So if there were ways that FSIS could take
13 some of those best practices and include them in
14 their processes, that might be something that would
15 be helpful.

16 The other thing is from the CDC side of the
17 world, they have a thing called EHS-Net, and it's on
18 the web, and they are advocates of what they call
19 the systems approach, and basically what they say is
20 food processing or any kind of a food establishment
21 can be thought of as a system that's a complex,
22 interaction of effects between employees, equipment,

1 facilities, and the foods themselves. So you have
2 to look at all those things, and so I think that's
3 what Bob's saying is there theoretical frameworks
4 already out there that say it's not that simple to
5 just say pick a variable because it depends on the
6 context from which, you know, in all those things.

7 But what would be nice from a state
8 perspective is if we don't have one way of doing
9 things in CDC, another way in FDA, and a third way
10 in FSIS because I think that the scientific basis is
11 largely the same or it could be if we move in that
12 direction. So by just looking at a couple of those,
13 folks, and talking to people like Carol Selman from
14 CDC, you might be able to get some ideas would be
15 helpful for you in your processes.

16 MR. REINHARD: For John, he probably
17 doesn't know the FDA methodology for zoning and for
18 environmental monitoring and timing with finished
19 product sampling. It actually all came from FSIS,
20 and we went to FSIS and shared that information, and
21 they've adopted a lot of the good scientific things
22 that are out there, and how industry do our best

1 practice sharing has driven environmental
2 contaminants for *LM* and put together the
3 environmental contaminants for *Salmonella*. So just
4 to get that on the record. Thank you. Truth in
5 advertising.

6 DR. JONES: So in the essence of time, I'm
7 going to try to wrap this up. It sounds like for
8 question number 4, that we're making a
9 recommendation that, one, the expert team actually
10 look at the variables in defining the variables,
11 also defining the frequency that reporting is given.
12 It sounds once again like we're looking at the whole
13 short, medium, and long-term slant at what can be
14 provided. It sounds like you already have good data
15 in place. What can you do in the short term, what
16 can you do in the medium term, and what can be done
17 in the long term, based on the expert teams advice?
18 And also looking at the best practices, that seem to
19 be FSIS' anyway, and looking at some of those best
20 practices and see how those can be included in the
21 development of these variables or the prioritizing
22 of the variables in considering taking, of course,

1 approaches that look at the entire process, the
2 entire system.

3 In addition, it sounds like, and I think I've heard
4 it before, that some of the concerns with the data
5 are ensuring that in looking at the whole system,
6 that those people that are inputting the data are
7 inputting it accurately and adequately and therefore
8 you're ensured that you're getting adequate data. So
9 a recommendation from the Committee is to ensure
10 that there is some kind of data check or check on
11 the data that's being entered to make sure the
12 training is being done appropriately.

13 Something else I need to add?

14 DR. TILDEN: Just the opportunity, I think
15 we all talked about emphasizing, making sure that
16 data is clean and checked, doesn't happen by itself,
17 and there's a fair amount of time and effort that's
18 got to go into that, and we all recognize that.

19 DR. VETTER: Okay. And I would just build
20 on that, data going in, making sure it's clean, one
21 thing that would be very helpful and useful is an
22 SOP for entering that data, that if it's something

1 that field employees that are actually going out
2 there and inputting it into the system can refer to,
3 then you're going to have a more consistent entry
4 method. So actually having SOPs for data entry
5 would be helpful in ensuring that.

6 DR. JONES: Okay. So we're including SOPs
7 for data entry also. Anything else for number 4?
8 Did I miss anything in that quick synopsis?

9 Okay. So we have our final question. Let
10 me stop for a minute, though, before we move to the
11 final question. We're at quarter of 12:00. I think
12 we're supposed to break for lunch at 12:00. I'm not
13 sure if we'll be able to finish question number 5 in
14 15 minutes. My recommendation would be if we could
15 do somewhat of a working lunch, start in question
16 number 5 now and go as far as we can for the next
17 15, 20 minutes, take a break, get some food and come
18 back and eat. Can we eat in this room?

19 MR. TYNAN: Yes.

20 DR. JONES: Does that sound good?

21 MR. REINHARD: Can I make a recommendation?
22 In 15 minutes, it's going to get very crowded. If

1 we break now, we come back in 15 or 20 minutes, then
2 we can work through lunch. It'll be much quicker in
3 the cafeteria.

4 DR. JONES: Thank you. Okay.

5 MR. TYNAN: I thought you all were going to
6 say, and the Agency's going to buy lunch.

7 MR. REINHARD: And Robert may or may not.

8 (Whereupon, at 11:45 a.m., a luncheon
9 recess was taken.)

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1 FSIS consider in designing verification sampling to
2 also provide reasonable measures of pathogen
3 prevalence in products? Ms. Foreman.

4 MS. TUCKER-FOREMAN: I think FSIS has to
5 accept that it's very difficult to use verification
6 sampling to determine prevalence, and it may require
7 a separate sampling system. Verification sampling,
8 as the National Advisory Committee on
9 Microbiological Criteria for Food has said, is a
10 snapshot in time. It doesn't repeat the same
11 companies each year. It has a different group of
12 companies that get sampled, and so there is nothing
13 from year to year that makes it show prevalence, and
14 it's just what's happening in that plant on that
15 day. It was never intended to be used this way.

16 It is not a public health measure. It was
17 established, the *Salmonella* standard was established
18 as an industry best practices, not a public health
19 measure and, of course, there's the problem that in
20 many cases there's a pre-announcement of when you're
21 going to be sampled. So I just think that you need
22 to go and find a different way to do it and stop

1 trying to use the verification sampling data to make
2 that determination.

3 MR. GOLTRY: Scott Goltry, MI. I think one
4 point of clarification is there is a difference
5 between verification sampling and performance
6 standard sampling. For sure, on performance
7 standard sampling, I agree that it may not be done
8 routinely. It may be done once a year depending on
9 the results of the sample set. It could be
10 repeated, but on verification sampling, especially
11 with O157:H7 in ground beef, those samples are taken
12 more routine. The large plants are being sampled
13 four times a month. They are sampled more routine.
14 So I think maybe a point of clarification, that
15 there's a difference in some types of verification
16 sampling versus --

17 MS. TUCKER-FOREMAN: Good point.

18 MR. GOLTRY: -- *Salmonella* set
19 requirements.

20 MS. TUCKER-FOREMAN: Yeah.

21 MR. GOLTRY: I agree that *Salmonella* sets,
22 you know, depending on your results, you may get

1 sampled more or less.

2 MS. FOREMAN: Absolutely valid. I should
3 have -- I stand corrected. The advanced notice
4 problem is, of course, much worse with *E. coli*
5 because the sampling kit arrives at the plant a
6 couple of days before and they know they're going to
7 be sampled. So --

8 DR. VETTER: I have a question about PHIS,
9 and will the Agency be collecting information about
10 the plant's sampling program in PHIS? And by that,
11 I mean will they be somehow reporting positive
12 results that the establishments are getting, and I'm
13 not suggesting that this is something that we
14 publish, but I'm suggesting it's something that can
15 be useful to determine prevalence, also to determine
16 high risk products, the types of testing because I
17 know you're going to be gathering establishment
18 information. So is this part of what you'll be
19 gathering and particularly with *E. coli* O157:H7 and
20 *Listeria monocytogenes* because I think that could be
21 used in an aggregate sort of manner to make some
22 determinations.

1 MR. REED: Honestly whether or not PHIS
2 involved, I don't think is relevant to the
3 discussion. We could collect or not collect the
4 data independent of that. I just wanted to throw
5 that out there so it doesn't lead you guys in your
6 discussion and --

7 DR. VETTER: How would you collect it
8 outside of PHIS though as far as establishment
9 results?

10 MR. REED: Well, currently as you know,
11 we're working on the program, and that's not
12 completely developed, but we're kind of in pilot
13 programs, and that's where the establishments are
14 providing us the data, and that happens now without
15 PHIS. And so that's really -- I guess we could use
16 those mechanisms.

17 DR. VETTER: And that's a good example for
18 *Salmonella*, but what about *E. coli* and *Listeria*?

19 MR. ALVARES: Well, certainly collecting
20 data I think -- there's different ways to collect
21 the data. I think PHIS is one mechanism. In the
22 past, we've used other mechanisms. We've included,

1 you know, just to put out an example of a very kind
2 of rudimentary data collection method, we've used
3 approaches where we've asked inspectors to e-mail us
4 the results when a positive occurs, and so there are
5 different ways to collect the data. Some are more
6 efficient than others. Some are more amendable to
7 analysis than others. I think depending on the type
8 of data and the need, the opportunities exist.

9 MS. TUCKER-FOREMAN: We have suggested on
10 occasion that if you really want to get prevalence
11 data, say on *E. coli*, one way to do it is for FSIS
12 to establish the protocol for testing and require
13 the plants to test at a certain level using that
14 protocol and report the results to FSIS not for
15 individual use but for aggregation because that
16 would come a lot closer to giving new prevalence
17 data. If that were just anathema, another way to do
18 it might be to establish a third party recipient, so
19 that all of the data would be reported to the
20 private third party and they could report the
21 prevalence data based on the information they
22 collected. Obviously we haven't drilled down into

1 the details of what would be involved in that, but
2 it would seem to be far better than anything that's
3 currently underway at least with regard to *E. coli*.

4 MR. LANGE: This is Loren Lange of FSIS.
5 On the question of advanced notice, I've always
6 believed that it's our policy of providing plants an
7 opportunity to hold the product, which is more of an
8 advanced notice than the boxes. When the boxes and
9 forms show up, the inspector has a 30-day window to
10 randomly pick that. So in my mind, certainly for *LM*
11 and *E. coli*, they have a 30-day window from when
12 they get the supplies. So they can really pick
13 that, but they also still have to give a plant a
14 reasonable time to hold the product, and I think
15 that's more of the advanced notice issue that could
16 bias the results.

17 MS. TUCKER-FOREMAN: I don't know any other
18 way to get the test and hold, unless you have to
19 test and hold everything, which I think has been
20 recommended.

21 MR. REINHARD: I think from a notification
22 standpoint, at least in the establishments that I'm

1 familiar with and the way the sampling occurs,
2 generally speaking all the facilities are doing
3 nightly sanitation. So the morning before the
4 sample is collected, the inspector would notify the
5 establishment that they'd be collecting a sample. I
6 don't know of any scenario, I'm not saying it
7 doesn't ever happen, where the plant then went back
8 and recleaned or did something different in their
9 process before that sample was collected, and I
10 believe at that point that FSIS, the inspector still
11 has the ability to say, I've decided not to take a
12 sample today because it's not representative of what
13 you would normally do.

14 So I don't think the advanced notice that
15 morning, so you can hold the lot, which is important
16 and there's a reason behind it, and we support
17 establishments doing that.

18 I think for this question that's out here,
19 and everyone's correct in I think what they're
20 saying the concerns are, and there are potential
21 answers with industry data even though there's a
22 whole bunch of questions then on how are their

1 samples are collected and how well were their
2 methodologies and all these other things that go
3 into that type of model.

4 For FSIS, it would be beneficial if we
5 looked at this in different scenarios, and so the
6 sampling I'm most familiar with would be sampling
7 for *Listeria monocytogenes* and the four project
8 codes underneath it, and each of the project codes
9 in and of themselves are a verification sample for a
10 regulatory purpose that FSIS has defined, and
11 anyhow, they're weighted in different ways to target
12 sampling at specific scenarios, and so a producer
13 who is producing a high risk product such as
14 lunchmeat would be targeted for 001 sampling, and if
15 their volume is higher, there's a weighted thing
16 that they get targeted more often and samples are
17 collect, but if you take all of the verification
18 sampling and this is, I don't know this is the
19 answer, I think this is FSIS should look at to see,
20 if you take in that example, all of the verification
21 sampling as a whole, it leads to probably very good
22 random distribution of data selection for *LM* and

1 very good information about because you do enumerate
2 every positive within the establishments, very good
3 information about potential exposure, and because it
4 is also tied to production volume, which the Agency
5 had on the 10240-1 forms and now we'll have in the
6 facility profile that is collected and put in PHIS,
7 potentially those as a composite group, all of those
8 programs together are closer than any one of those
9 by itself and for sure any one of those by
10 themselves, to giving you the ability to estimate a
11 reasonable pathogen prevalence in a national
12 scenario.

13 I don't know that it ever becomes exactly
14 right because that just may not be possible based
15 off the way things are set up, but then you would
16 have the alternative option then to augment that
17 data with another project to more normalize it for
18 any areas you're missing. I think you could look at
19 it in that way.

20 With *E. coli* O157:H7, there are lots of
21 project codes, and again it's 12,000 to 15,000
22 samples, that they take different samples for. They

1 take raw ground beef. They take trim. They take
2 the other species and parts that go into raw ground
3 beef as a separate program. They do bench trim for
4 those facilities that trim beef, and that's a
5 separate verification, and you have all the follow
6 ups that happen after that. So any individual one,
7 I can say it's not a good estimate because it's very
8 targeted to a specific verification of regulatory,
9 but when you do roll all those together, it gets
10 very powerful I believe and very significant when
11 you look at the data then and want to try to see
12 whether or not you can make an estimate of
13 prevalence. I wouldn't say it's perfect, but it is
14 an option for FSIS to look at.

15 DR. TILDEN: So has FSIS already identified
16 how they use this data to estimate prevalences? Is
17 that already out there?

18 MR. ALVARES: I'm not quite sure I
19 understand the question. Have we identified how to
20 use it.

21 DR. TILDEN: Are you already doing this?

22 MR. ALVARES: We are calculating percent

1 positive rates for our programs, particularly the
2 routine sampling programs. We do try to adjust
3 those percent positive rates by production volume in
4 order to give us a volume weighted percent positive
5 rate, but I think we're resistant to calling that
6 prevalence, and I'm not convinced that -- I don't
7 think that we've put forth a good statistical basis
8 for calling that prevalence yet.

9 There's certainly design issues from our
10 internal discussions. *Salmonella* is the most
11 obvious one, but all of, you know, I think with any
12 sampling program, there's always design issues that
13 could be improved. There's biases that you need to
14 watch out for and address, and those are the things
15 that we're trying to look at to really improve those
16 programs, and whether we really can achieve a level
17 of sampling and the design of the program that we
18 could agree would be a measure of prevalence.

19 I have just one last thing to add. We do
20 often try to estimate prevalence through our
21 baseline programs. So we have baseline sampling
22 programs that are conducted periodically, and we are

1 in some of our internal evaluations using those as a
2 standard or a model for comparing our verification
3 programs.

4 MS. TUCKER-FOREMAN: John, there have been
5 claims made on behalf of the Agency's results that
6 they represent prevalence and even going so far as
7 to suggest that some declines in cases of *Salmonella*
8 in the mid-1990s were a direct result of this
9 decline in prevalence, in *Salmonella* counts on
10 poultry that came in as part of the HACCP program.
11 So it was, in large part, because people decided to
12 be a little overly ambitious about how they used
13 those data that they've become an issue, but as the
14 guys have pointed out, it's not really very good
15 data to be used that way.

16 When's the last time that you did the
17 baseline study on poultry?

18 MR. ALVARES: Well, we just completed the
19 young chicken baseline and turkey baselines. I
20 don't know exactly when the data collection was
21 ended.

22 MS. TUCKER-FOREMAN: And when was the one

1 before this one?

2 MR. ALVARES: Before this most recent one,
3 I don't recall.

4 MR. LANGE: There was a baseline study in I
5 think 1980. The first broiler baseline was '93-'94.
6 Then there was a baseline that was going to look at
7 *Campylobacter* and *Salmonella* but it was just
8 positive, negative, and that was round 1980, and
9 that is up on the website, the *Salmonella* results,
10 and then I think the samples were collected in 2006,
11 you know, for the broilers.

12 MS. TUCKER-FOREMAN: I had a little trouble
13 hearing you, Loren. How many years in between?

14 MR. LANGE: Well, there was 6 years before
15 that and then probably 6 years. But broilers are
16 the only ones where we really have three data
17 points, so approximately 6 years between each one.

18 MS. TUCKER-FOREMAN: So the baseline datas
19 are not very current or precise.

20 MR. LANGE: True, but the point we talked
21 about earlier is today even trying to repeat a
22 baseline study for raw ground beef, we'd have that

1 same issue of providing opportunity to hold the
2 product and we did that in the beef trim baseline.
3 We, you know, gave notification and recommended that
4 the establishments hold the product because it would
5 be adulterated. So that issue there always presents
6 a problem in trying to construct a baseline. So if
7 we go back to what was originally said, this may be
8 a topic that's most appropriately given to the
9 National Advisory Committee, NACMCF, Microbial
10 Criteria in Foods, and for them to answer this
11 question versus this Committee. I think some of the
12 things that were brought up are very good and very
13 reasonable and right, but I think it's best for them
14 to say what it would look like and how it would be
15 designed than this Committee.

16 MR. WALDROP: Chris Waldrop, Consumer
17 Federation. It would also probably be helpful for
18 FSIS to present some of its thinking or maybe an
19 initial stab at how an ongoing baseline or how it
20 would change the sampling program to do prevalence
21 before presenting it to NACMCF, because I think
22 NACMCF might have the same problem, but they just

1 don't have enough information to really given you
2 adequate feedback.

3 DR. TILDEN: And I really do appreciate the
4 way you guys are being cautious with the word
5 prevalence and proportion positive. I think that's
6 entirely appropriate, and being able to give
7 specific examples of which datasets might lend
8 themselves to being incorporated and which ones
9 aren't and why you think that way, in putting that
10 into a position paper and then giving it to them I
11 think would be really helpful.

12 MR. GOLTRY: I think also when you do your
13 baseline or more in-depth study, we can have the
14 same percent positive rate from year to year, but
15 over a period of years or maybe one year, your
16 quantitative level could actually go down. Now I
17 know you're not doing quantitative work on routine
18 samples, but I think that would be good to know if
19 we have, you know, a sample is 100 CFU program, you
20 know, in 1990 and it's less than 3 now, I think
21 that's important where you could have the same
22 percent positive rate. There's been some, you know,

1 you would show either improvement or not
2 improvement, but we need to do some quantifying on
3 these samples also.

4 DR. TILDEN: One last thing. I think it
5 might be helpful, that whole definition, maybe it's
6 not a prevalence from a pure standpoint, but maybe
7 getting to Bob's point, it's good enough to be used
8 as a working indicator that you can move forward
9 with and try to weigh in, when it is good enough for
10 the purposes of what it's intended for. You know,
11 that might be a good thing to, you know, how much
12 precision do you need operationally to be able to
13 use it as a performance indicator.

14 MS. TUCKER-FOREMAN: Yeah, that's really an
15 interesting issue, John. If you're going to use it
16 in terms of there's been improvement in the
17 industry, there's one level of precision that's
18 needed. If you're going to say we have reason to
19 believe that the number of *Salmonella* cases or *E.*
20 *coli* cases has diminished as a result of this
21 decline, which is what the Agency has said, none of
22 the people present, of course, but others, and what

1 certain trade associations have claimed widely, it's
2 going to be very different kind of data, how do you
3 all want to use it? Do you want to use it to show a
4 public health, that somehow there's a relationship
5 between what you do and public health, right?

6 MR. ALVARES: Certainly we believe that
7 reductions in pathogen rates in the product coming
8 out, the product being produced, should have some
9 relationship to the number of illnesses that we're
10 seeing, but we also certainly recognize there are
11 points in the process after production that may
12 affect that as well, but positively and negatively.
13 So I wouldn't argue at any point that it's a direct
14 one-to-one cause/effect relationship, but I think
15 it's fair to say that there should be some
16 relationship between the amount of pathogen we're
17 finding in product and levels or outbreaks in
18 illnesses that are occurring.

19 MS. TUCKER-FOREMAN: Well, I think the
20 National Academy of Sciences, in their report back
21 to you, questioned how direct that could be for
22 exactly the reasons that John mentioned. You don't

1 know what happens to it afterwards, and you don't
2 know, you know, whether the salad-related outbreak
3 was because of it coming in contact with
4 contaminated meat, you know. Was it the sandwich?
5 Was it the lettuce or the meat? And FSIS is limited
6 in its ability to make claims about public health
7 because you start at the slaughterhouse door and end
8 at the final processing door, and the lack of
9 responsibility for what happens afterwards is really
10 a seriously limiting factor in terms of drawing
11 direct public health conclusions. If you know a way
12 to fix that, we'd be happy to help you address it.

13 MR. ALVARES: We're working on it.

14 DR. VETTER: I wanted to just comment
15 briefly on B of Question 5, and I would just say
16 that you need to know the different variables within
17 the establishments and certainly, you know, sizes
18 are variable, but I wouldn't say it's the variable
19 because I wouldn't say it's strictly limited to
20 large, small, and very small. I would say plant
21 size plays a role in that because if you've got a
22 4-acre plant, and I'll give you just an example of

1 SSOP noncompliances, they're more likely to have
2 more areas subject to inspection more frequently.
3 Therefore, they have a high probability of having
4 noncompliance. However, in their certain situation,
5 they may be performing very well.

6 So I think you need to know all the
7 different variables that you're dealing with when
8 you're looking at the percentage of noncompliance.
9 Plants that run seasons versus those plants that run
10 seven days a week, you know, how long they produce,
11 when they produce, those types of things that can
12 cause the data to be different and at least know and
13 understand those variables and how it's going to
14 affect the noncompliance rate when you're looking
15 it.

16 DR. JONES: Just for the time, we have
17 about 42, 43 minutes now. So I could ask the last
18 two comments to be as brief as possible so that we
19 can go back and wrap up all of the questions.

20 MS. GAPUD: I just want to make a comment
21 on B. The differences in inspection, noncompliance
22 rates between establishments, circuits and

1 districts, and again this is where training of the
2 inspectors coming into the establishment will play a
3 critical role, okay. These inspectors coming into
4 establishments should be calibrated because I can
5 tell you if they don't understand what they're
6 asking for, this thing that we are looking at, to
7 help the public, it's not going to work. Training
8 is one of the most important factors here for the
9 success of this project. So hopefully FSIS is going
10 to help us, give us all the support and, you know,
11 address this with the state that they are trained
12 and calibrated properly. Thank you.

13 MS. FOREMAN-TUCKER: I have a question
14 about the question. You're going to collect your
15 data regardless. Are you asking in B what policy
16 steps FSIS should take to try to get a more
17 consistent level of compliance?

18 MR. ALVARES: Not policy. I think what we
19 would like to get some feedback on is what the
20 strengths and weaknesses of, or really what the
21 strengths would be to design a program that could be
22 more suitable towards prevalence. We've heard some

1 of the weaknesses certainly with the *Salmonella*
2 program. We know of some of the issues around
3 biases and selection issues, but I think what would
4 really help us is to get some further input from the
5 Committee on what we should really be considering as
6 far as design of these programs. That may require
7 policy changes to implement, but I think really our
8 focus has been, as a starting point, what do we need
9 to consider to collect the right kind of data, and
10 then how do we get to that point is sort of a
11 downstream question.

12 MS. TUCKER-FOREMAN: Well, I think one
13 thing you might do is just take all the data, you've
14 got this PHIS system coming in, why not just take
15 all of the data from the PHIS system and put it on
16 the website with the establishment number. You're
17 not interpreting anything. You're just putting data
18 out there, and that would make the Agency very,
19 very, very transparent, and then we could make
20 judgments between establishments and circuits and
21 districts.

22 MR. REINHARD: Cheryl, I have a question

1 because you wanted to move to summarize. But we
2 haven't address 5B, and I'd like to address 5B, so
3 I'm ready to talk about it. I didn't know if you
4 thought those were the last two comments and we're
5 going to go on without 5B or how do you want to do
6 it?

7 DR. JONES: No, actually I was asked to go
8 ahead and summarize 1 through 5 so that we can have
9 something to present out at 1:30, and if we don't
10 get to 5B, then we will have to have some kind, I
11 think we spoke, referenced a teleconference or some
12 other way for the group to come together to finish
13 what we don't finish, but what we need to do is
14 actually summarize the answers that we have so far.

15 My recommendation, if you don't mind, is
16 that we begin to summarize 5 first, and make that
17 the answer to 5 and add in something, anything that
18 we haven't gotten from you yet. Will that work? So
19 we'll start the summary answering, actually
20 providing the answer that we're going to report out,
21 with number 5 and go backwards so that we cover
22 everybody's comments, and so is that good for you?

1 Okay.

2 So I guess what I have so far for the
3 summary for number 5 which would be, if the
4 transcriber doesn't mind, we're going to work on the
5 answers now.

6 So for 5, the summary that I have for 5A so
7 far is that given that the data is -- well, I guess
8 there were a couple of concerns. First, that the
9 data's a snapshot in time, and also a question as to
10 whether or not the data that FSIS is presently
11 collecting is actually prevalence data, and I guess
12 Mr. Reinhard said if you take it in aggregate, it
13 might be considered prevalence data, but the
14 recommendation sounds like from the Committee is
15 that FSIS needs to look at prevalence, use the data
16 that you have right now to provide in information in
17 the short term, but in the medium to long term,
18 actually look at the data, define it, whether or not
19 it is prevalence, actually prevalence data, develop
20 some form of position paper to share with another
21 advisory board that you thought was more --

22 MR. REINHARD: NACMCF.

1 DR. JONES: NACMCF.

2 MR. TYNAN: NACMCF, National Advisory
3 Committee on Microbiological Criteria for Food.

4 DR. JONES: Okay. To share with the
5 National Advisory Committee on Microbiological
6 Criteria for Food.

7 MR. REINHARD: I'd like to summarize what I
8 thought we said --

9 DR. JONES: Okay.

10 MR. REINHARD: -- and it's really short and
11 easy I think.

12 DR. JONES: All right.

13 MR. REINHARD: I think everyone said they
14 don't believe performance standard analysis that the
15 Agency currently does for *Salmonella* leads to the
16 ability to make estimates on prevalence in any
17 manner that's appropriate. I think that was the
18 first thing. The second thing I thought that
19 everyone agreed to, and correct me if I'm wrong, is
20 I had asked FSIS if you look at your data as a
21 whole, what confidence or what level does it give
22 you where you potentially, for other pathogens,

1 *Listeria monocytogenes* specifically I talked to, and
2 its prevalence, and does that get you to a point
3 where you need to do more and you need to augment
4 that data with other programs or you're going to
5 accept that for that now.

6 And then the final thing was that this
7 really needs to be passed on to the National
8 Advisory Committee on Microbiological Criteria for
9 Food for them to look at what truly would be a
10 verification sampling program for prevalence.

11 DR. JONES: Okay.

12 DR. TILDEN: And I think just to say it
13 another way is we all agreed that it's appropriate
14 to keep calling it a proportion positive until they
15 run it through that other group.

16 DR. JONES: Okay.

17 DR. TILDEN: And not use the word
18 prevalence.

19 DR. JONES: So it's called proportion
20 positive until it goes through the Advisory -- okay.

21 So that was our answer for A, correct?
22 Okay.

1 So then 5B, we were working on, and one of
2 the first issues with 5B was the differences in
3 sizes of the establishments and the need for the
4 potential to look at different variables based on
5 size and other factors, and I think that's when you
6 wanted to comment and make a comment.

7 MR. REINHARD: Yeah, I think from the
8 question that is put together here with
9 noncompliance rates, currently FSIS has been since
10 February of 2010, looking at noncompliance rates and
11 they looked at establishments that were two standard
12 deviations greater than the mean or the median, I
13 don't remember which one, and scheduling those
14 establishments for FSAs, food safety assessments,
15 because something may be different because they were
16 higher. I think that we could talk for a very long
17 time about whether higher is good or bad. I think
18 that's maybe potentially an inspector writing more
19 NRs is leading to the production of less product
20 meeting the regulatory standards versus one that's
21 zero, but that being said, I think what FSIS did in
22 that timeframe over about six or seven months, there

1 were a large number of establishments that fell two
2 standard deviations outside the mean, several
3 hundred, and they performed FSAs in about two-thirds
4 of those establishment because they had in place to
5 do FSAs for establishments whose NRs were greater
6 than two standard deviations. What I think that
7 leads to is this question can be answered by them
8 analyzing those FSAs and saying, when we went in
9 with extra resources because an establishment was
10 two standard deviations above the mean, what did we
11 find? Were there food safety system issues that
12 were identified that correlated to that higher rate
13 of NR, and what were those likely to be so they can
14 make decisions on how to assign resources in the
15 future.

16 The fact of that matter is, I know they
17 know in circuits and in districts, rates of NRs are
18 very different. In types of plants, rates of NRs
19 are very different, and you guys tried to address
20 that by saying common types of processing, but
21 there's a little bit of data that sits out here now.
22 There were some that were higher. They got FSAs.

1 There's the result of a FSA. What did that FSA say?
2 Did it matter that their NR rates went up, or maybe
3 it mattered that certain NR rates went up that were
4 in that number that led to a finding in the FSA.

5 That would be my recommendation in then
6 trying to figure this out is starting with what data
7 they already have that's out there available to you
8 to make a determination of what do these differences
9 really mean? Are they significant? Should they be
10 used in a public health inspection system? You
11 know, maybe you reward the inspector that wrote many
12 NRs. I'm kidding, but you just have to look at what
13 you have now, I think, and try to figure out did
14 that correlate? There were a lot at two standard
15 deviations. So now in PHIS you want to look at
16 three standard deviations because, you know, and
17 that number's picked, you know. I don't know how to
18 say that it's an arbitrary number, whether it's 2 or
19 whether it's 3 or whether it's 5 or 1. The Agency
20 picks it, and I understand you have to, and you can
21 put reasons behind it statistically when you pick
22 the standard deviation level, but I think going back

1 and say, okay, we picked it, what did it mean when
2 we picked it? Now you're going to pick another one
3 at 3, okay. Fine, that's your decision, but then
4 how did it change? Did it make a difference? Are
5 we really using those resources where they need to
6 be done?

7 MR. REED: Just to make one comment really
8 quick to clarify. Whether or not it's in PHIS is
9 immaterial. So we're doing this now before PHIS and
10 the IT system does not affect whether or not this
11 will be done. I just don't want to get those
12 confused. So it is a real issue to discuss this, I
13 agree with that, but please, it is independent of
14 the IT system.

15 DR. VETTER: I'd just like to say, I think
16 what you said is exactly on the dot or on the spot,
17 but the other thing I think you need to consider is
18 the bottom end of the spectrum, and you can also
19 look at FSAs and what the results of those were when
20 you have a zero or a very low noncompliance rate.
21 I'll probably get shot for saying that, but that can
22 also be an alert or something that you need to

1 consider as well. It's not just those that are
2 above the standard deviation but those that are
3 below or much, sort of out of the norm so to speak.

4 MS. TUCKER-FOREMAN: I have a question
5 about the answer there. Do you mean there are no
6 present plans for the Agency to take the PHIS data
7 and compare inspection results and compliance rates
8 between districts and circuits and establishments?

9 MR. REED: No, ma'am, that's not at all
10 what I was trying to say.

11 MS. TUCKER-FOREMAN: Oh, good. You shook
12 your head, and I thought you were going to say that
13 you meant yes.

14 MR. REED: No, what I was trying to say is
15 that at present, we use the public health decision
16 criteria to help determine FSA scheduling, and when
17 we transition to the other IT system, that's not
18 correlated or related at all those criteria that
19 we're discussing.

20 MS. TUCKER-FOREMAN: Thank you. But you
21 might use PHIS data, or you will use it to
22 determine --

1 MR. REED: Oh, yes.

2 MS. TUCKER-FOREMAN: -- when to schedule
3 FSAs.

4 MR. REED: Absolutely. We will be using
5 all data that we have available both historical and
6 new data.

7 DR. TILDEN: So could we recycle some of
8 the content that we had before where we would put
9 most of our effort on trying to achieve compliance
10 on those regulatory variables that are most directly
11 linked to public health outcomes? Would it be
12 appropriate to restate that here for this one, you
13 know, noncompliance? And it sounds like you already
14 have a process in place to try to standardize, to
15 address intra-inspector variability. So it might be
16 helpful as you're looking at variability within
17 inspectional data to say these are the processes
18 that FSIS has already put in place to try to address
19 the part of this that might be due to variability
20 between inspectors and make that explicit, and then
21 you can move towards and what are we doing to
22 address variability that might be due to the in-

1 plant conditions? Separate them out into two
2 components.

3 DR. MURINDA: I just wanted to ask FSIS if
4 they currently consider the different sizes of
5 operation and types of operations, say whether
6 they're slaughter, processing and also the volume of
7 operation, into their considerations for the NRs or
8 noncompliances.

9 MR. ALVARES: We have considered all of the
10 factors that you mentioned, and to different extents
11 they seem to have different impacts. So certainly
12 we see, especially with certain types of inspection
13 tasks, differences between meat and poultry
14 establishments. To a less extent, we see
15 differences according to plant size. In some cases,
16 we don't see differences at all in relation to plant
17 size. So those are some of the factors we've looked
18 at, but I think that's where we're sort of looking
19 for some further guidance from the Committee as to
20 maybe what they think are other factors that would
21 drive differences in NR rates between
22 establishments, between districts, because times of

1 the year, things like that.

2 MS. TUCKER-FOREMAN: I have -- do you --

3 DR. JONES: Can we -- I'm sorry.

4 MS. TUCKER-FOREMAN: I just have a quick
5 question for him. Do you schedule FSAs, not for
6 cause, but what are called the routine ones, more
7 often in large plants than small plants? Do you
8 consider volume in making the determination for the
9 routines?

10 MR. ALVARES: The answer is yes and no. So
11 we do consider volume in the FSA scheduling process,
12 but our policy, our goal is to conduct a FSA at
13 every plant --

14 MS. TUCKER-FOREMAN: That's right.

15 MR. ALVARES: -- within a four-year cycle.
16 And so to that extent for routine FSAs, really all
17 plants have the same frequency of one every four
18 years at a minimum.

19 MS. TUCKER-FOREMAN: Thank you.

20 MR. ALVARES: Certain for cause FSAs can
21 affect that.

22 MS. TUCKER-FOREMAN: Thank you. Do you

1 think that's -- I mean I really am asking now out of
2 ignorance here, is that statistically defensible to
3 have a set that are scheduled solely on getting to
4 every plant once every four years and with no
5 relationship to volume?

6 MR. ALVARES: I guess I wouldn't say that
7 the four year cycle or the four year period is a
8 statistically determined cycle of frequency.
9 Whether we should be doing FSAs more frequently at
10 larger establishments, certainly I think it's
11 something to consider and maybe a recommendation for
12 the Committee, but it's not current policy of FSIS.

13 MS. TUCKER-FOREMAN: If the goal is to
14 improve public health, and in the absence of data
15 that would say small plants are more dangerous, it
16 would seem that you should base your money where the
17 bulk of the food is produced, and I believe that
18 that's the case with regard to *LM* testing, isn't it?

19 DR. JONES: I guess my only comment there
20 is that I think we recognize there's a tremendous
21 amount of data and data analysis that needs to be
22 done with FSAs to help inform that process better.

1 DR. JONES: Okay. Since we have 20 minutes
2 left, 25 minutes, I would like to suggest that we go
3 through the notes that we have and identify the
4 recommendations that we have that we would like to
5 submit from the Committee and present those
6 recommendations at 1:30 to the full Committee, and
7 then at some short period of time after that, we'll
8 actually write up the official report that will be
9 submitted. Does that sound good?

10 Okay. So if we go back to number 1, the
11 question was who are the likely audiences or
12 customers that FSIS should consider?

13 We broke it out into two different groups,
14 internal and external, and in internal, we had
15 listed USDA, FSIS, and under FSIS, we had a number
16 of specifics which were inspectors, EIOs,
17 supervisors, and actually executives from FSIS.
18 Then we had external where we had some of the other
19 governmental agencies, FDA, CDC, OIG, Congress. We
20 also had establishments, industry, and humane
21 handlers. That was the main answer that we had for
22 question number 1.

1 We had a number of other issues. We also
2 said that -- okay. Also health groups, other health
3 groups may also need the data.

4 We also said that the main thing that we
5 had to keep in consideration was that the goals of
6 FSIS and this data collection project have to keep
7 the public's health as their priority, and in
8 developing those goals, there needed to be measures
9 and metrics that were associated with those goals,
10 and those measures and metrics would then define
11 this expert group or expert team that would come
12 together to help us to address the rest of questions
13 2, 3 and 4. And so those experts would be
14 representatives of the stakeholders that we just
15 listed.

16 The experts would not be responsible for
17 developing policy. They would just be responsible
18 for identifying what information or data is needed
19 from the system, from the data system.

20 Did I cover all of that?

21 UNIDENTIFIED SPEAKER: Identifying what?

22 DR. JONES: Sorry.

1 UNIDENTIFIED SPEAKER: Identifying what?

2 DR. JONES: Identify what data, what
3 information. They wouldn't be responsible for
4 policy or decision making. They would just be
5 representative of the end users and who would use
6 the information and what information they would
7 need.

8 MS. TUCKER-FOREMAN: For what purpose?

9 DR. JONES: For what purpose?

10 MS. TUCKER-FOREMAN: Yes, sir. In order to
11 have an effective public health program?

12 DR. JONES: Right, that's the main
13 objective for everything.

14 MS. TUCKER-FOREMAN: Okay. Thank you.

15 DR. JONES: I'm sorry. I thought you meant
16 something else.

17 MS. TUCKER-FOREMAN: No, no, and you had
18 already said it. I just lost the connection.

19 DR. JONES: Okay. All right.

20 MS. BUCK: And included in that would be to
21 address transparency, the stakeholders should be
22 included in the design process. So we're going to

1 mention something about the transparency?

2 DR. JONES: Yes, and to ensure
3 transparency, the stakeholders are included in the
4 design process, and to ensure that training happens
5 appropriately, and I think that came up in question
6 3 or 4, but I think it's relevant to state it in the
7 beginning.

8 MS. BUCK: Thank you.

9 DR. JONES: So did you get the comment
10 about ensuring transparency.

11 UNIDENTIFIED SPEAKER: Yes.

12 DR. JONES: Okay. So that was number 1.
13 Question number 2 dealt with the sampling results,
14 and the question was does the Committee consider the
15 right priority -- well, first of all, FSIS is
16 considering posting more detailed sampling results,
17 and the question was should it be both microbial
18 and -- should it be inspection results as well as
19 the microbial results, and we said both.

20 The Committee also said that, or the
21 Subcommittee, I'm sorry, also said that this group
22 of experts representing all of the stakeholders

1 would be more knowledgeable or be able to provide
2 the kind of data to define what those datasets
3 should look like.

4 MS. TUCKER-FOREMAN: A minor, minor issue.
5 I kind of think of experts and stakeholders as
6 separate categories of people.

7 DR. JONES: Okay.

8 MS. TUCKER-FOREMAN: The people are being
9 chosen because they represent stakeholders, not
10 necessarily because they're expert, or they may be
11 both.

12 DR. JONES: Okay.

13 MS. TUCKER-FOREMAN: So we may just want to
14 fiddle with, we don't need to do it now, but we may
15 fiddle with that language so that the emphasis here
16 is on the stakeholders rather than on experts.

17 DR. JONES: Okay.

18 MS. TUCKER-FOREMAN: I think that's what we
19 intended.

20 DR. JONES: Okay.

21 MS. BUCK: I think what I want to clarify,
22 we want to identify the public health objectives,

1 but as John pointed out, we're not only looking at
2 the public health objectives, we're also looking at
3 inspection, you know, so do we under this question
4 want to identify both the public health and
5 inspection objectives?

6 DR. JONES: I think the group said we
7 wanted to see both.

8 MS. BUCK: Well, yeah. I just want to
9 clarify that both are in there.

10 DR. JONES: Okay.

11 MS. BUCK: Public health and inspection
12 objectives.

13 DR. JONES: Okay. So the public health and
14 the inspection objectives.

15 MR. REINHARD: But I think what we also
16 said is so that we affirm that the two key datasets
17 are sampling and then inspectional data, but within
18 inspectional data, the emphasis should be on making
19 sure we have the highest quality information on
20 those parts that are relevant to public health.

21 DR. JONES: Okay.

22 MR. REINHARD: And I think FSIS is already

1 moving in that direction. So it's just affirming
2 that, and then the idea of bringing in an ongoing,
3 another group was to validate whatever you talk
4 about. FSIS has a process in place where they've
5 already determined some of those most key
6 indicators, to have them weigh in on what FSIS has
7 already got in process. So I thought our discussion
8 was not that they're going to reinvent and create
9 something all new. It's just get a group to look at
10 that because it's beyond the scope of what we could
11 do here today.

12 DR. JONES: Right, and we looked at, and I
13 think you also mentioned that at that point, that we
14 should look at it from a perspective of that's when
15 the short, medium, and long-term goals came in, so
16 that the short term is to look at exactly what we
17 have today, what FSIS has today, and to have that
18 expert group to actually look at that, see what they
19 can do with it today, what they need in a medium
20 time as well as the long term, and then have
21 something in that process that ensures that there is
22 reevaluation that goes on so that as things change,

1 as the medium term becomes the short term and the
2 long term becomes the medium term, it's a continual
3 reevaluation.

4 MS. TUCKER-FOREMAN: And it was my
5 understanding that that was because we didn't want
6 to get in and tell them they couldn't do anything
7 until this group was formed but that the group might
8 have suggestions in the medium and the long term for
9 areas that they haven't thought of yet.

10 MR. REINHARD: So it's just building it
11 into a process improvement program that they've
12 already got in place.

13 DR. JONES: Okay. Is that good for
14 number 2?

15 Question number 3 was when reporting
16 sampling data and results, A, what criteria should
17 FSIS use to evaluate what information to release to
18 the public? B, should FSIS consider posting
19 establishment-specific data in the manner the
20 establishment has identified, and then what should
21 be considered -- should we consider posting what we
22 don't now post or in what frequency?

1 Once again, I think we suggested that this
2 expert team would more clearly define the answers to
3 that question. We decided that this committee would
4 not answer or could not answer question number B,
5 but as far as what criteria we consider, we said
6 would kind of be developed from that expert group
7 and -- go ahead.

8 MS. TUCKER-FOREMAN: Yeah, I think as I go
9 back and look at this now, that we're really only
10 answering A because C presumes we had an answer to
11 B.

12 UNIDENTIFIED SPEAKER: We didn't do C.

13 MS. TUCKER-FOREMAN: Well, no, but she said
14 we decided we couldn't come up with an answer -- we
15 couldn't agree on an answer to B. I think we're
16 probably going to have to say for B and C because B
17 asks the question should you ever post
18 establishments, and if we can't agree no that, then
19 we can't agree on what we should consider posting
20 that we don't now and at what frequency.

21 DR. JONES: I thought that C was actually
22 talking about what kinds of things that are posted

1 now.

2 DR. VETTER: We talked about specificity
3 and being able to drill down those types of things
4 that they could increase that and also how it's
5 published, in the format that it's published, that
6 it could be formatted in a more useable manner
7 versus, you know, Excel versus PDF.

8 DR. TILDEN: So maybe the solution is to
9 say B and C, we didn't really address but under A,
10 we can tuck in a couple of things. I think we
11 discussed that non-proprietary information shouldn't
12 be shared, or proprietary information should not be
13 shared. Whatever the information should be, it
14 should be clearly communicated so people understand
15 the limitations and the constraints on how it could
16 be interpreted, you know, so this is where this data
17 came from, this is, you know, just some statements
18 of the limitations of the data, and then we also
19 said that's where we can go with what Danah was
20 talking about, as specific information as possible.

21 MS. BUCK: One thing we didn't discuss,
22 which I'm glad you brought up, John, is that

1 proprietary information, I'd like to know if FSIS
2 has a concrete definition of what is contained in
3 proprietary information.

4 DR. JONES: I'm sorry. But just for the
5 FSIS time, when we come back to answer that
6 question, can we put it in the notes that that needs
7 to be answered, summarize 4 and 5 and come back to
8 answer your question.

9 MS. BUCK: Yes, that would be fine.

10 DR. JONES: Thank you.

11 MS. BUCK: Thank you.

12 DR. JONES: So we need a clear definition
13 of what proprietary information is also. So I think
14 we have it for number 3.

15 Number 4, question number 4 -- yes, ma'am.

16 DR. NEGRON-BRAVO: I'm not sure at that
17 point that she was mentioning that there should be
18 some procedures to standardize the form that the
19 data was in. She mentioned about the SOP, for
20 entering data. So there should be a print procedure
21 and standard forms.

22 DR. JONES: You're talking about mentioning

1 the SOPs to ensure the data is entered correctly?

2 DR. NEGRON-BRAVO: Yes, yes.

3 DR. JONES: I think we have that in
4 number 5. You want to put it up earlier?

5 DR. NEGRON-BRAVO: It was said before, but
6 maybe it might be better the other one, right?

7 DR. JONES: Okay.

8 DR. NEGRON-BRAVO: It's important.

9 MR. REINHARD: So I guess one of the things
10 that we can address in number 1 when we talk about
11 the expert team that comes together entire, that the
12 expert team also addresses training of the
13 utilization of the system once it's developed, but
14 we'll also make sure that -- I'll also mention that
15 it's relevant throughout all of these issues that
16 training has to be done appropriately so that the
17 data can be accurate, we can ensure that that's one
18 level of ensuring data accuracy.

19 UNIDENTIFIED SPEAKER: I would not limit it just to
20 training but like specific SOPs for entering data
21 for consistency, so that it's something that can be
22 referred to and it will be entered consistently.

1 DR. JONES: So that there are specific SOPs
2 for entering data.

3 MS. BUCK: And another thing that you
4 didn't mention, but I know we talked about was we
5 have to have standardization of forms if we're going
6 to get these datasets to work together. So
7 somewhere in there, and I don't know if -- how
8 should FSIS determine which forms to use or which,
9 you know, because I think that's going to take some
10 investigation by the various agencies that collect
11 data and you're probably going to want to see
12 guidance from NAS or NACMCF on that as opposed to
13 this body.

14 DR. JONES: Okay. So in addition to the
15 SOPs, we also need the standardization of forms --

16 MS. BUCK: Yes, sir.

17 DR. JONES: -- and we need that
18 standardization approved by one of the external
19 agencies --

20 MS. BUCK: Yes, wouldn't you say so, John?

21 DR. JONES: And you're doing that to ensure
22 that the information can be used across agencies,

1 the standardization of forms or are you just looking
2 at the standardization of forms for --

3 MR. ANDREASSI: Excuse me. Anthony
4 Andreassi of FSIS. I think you mean formats --

5 MS. BUCK: Formats.

6 MR. ANDREASSI: -- so the files could be
7 transferred the different --

8 MS. BUCK: I'm sorry.

9 MR. ANDREASSI: -- entities. Formats.

10 MS. BUCK: No, no, no. I'm sorry.

11 DR. JONES: Okay.

12 MS. BUCK: I'm so sorry.

13 DR. JONES: Right. So standardization of
14 the format of the data so that it can be used
15 between agencies or between systems?

16 MS. BUCK: Yes, precisely.

17 DR. JONES: Okay.

18 DR. TILDEN: I think we've just got to be
19 careful of not making it sound like everything has
20 to run through an external party for FSIS to do
21 their job.

22 MS. BUCK: Yes.

1 DR. TILDEN: I mean they have to be allowed
2 to keep moving forward.

3 MS. BUCK: Well, maybe there's some other
4 way of doing that like with a MOU or MOI, an
5 arrangement between the agencies where they would
6 investigate that.

7 MR. ANDREASSI: Currently we do. Yeah, we
8 have many memoranda of understanding with the
9 different agencies that we share data with, and in
10 that memorandum of understanding, we do have defined
11 formats on how the information is going to be
12 exchanged, not only from the physical but as well as
13 on the technology side, exactly how it's going to be
14 exchanged.

15 MS. BUCK: Yeah. I think --

16 MR. ANDREASSI: We cover that pretty
17 clearly in those MOUs.

18 MS. BUCK: So I don't know as if it has to
19 be this expert panel, but they have got to seek some
20 way of having an integrated approach to this
21 problem. Otherwise, we're going to end up with
22 silos again, and that's not particularly good for

1 the purposes of what we're trying to do.

2 DR. JONES: Okay. So that issue of
3 standardizing the data format is included.

4 MS. BUCK: And the other thing that should
5 be standardized and that probably doesn't come here
6 but, you know, there should be some language,
7 structured language or standard language that FSIS
8 is using in its inspection procedures so that
9 everybody knows what everybody's talking about when
10 you do your inspection.

11 DR. JONES: Okay. So --

12 MS. BUCK: And those are things that they
13 can probably do internally easier.

14 DR. JONES: Sharing of the language that's
15 used in inspection.

16 MS. BUCK: Yeah, I mean they have some
17 language already in their dropdown menus that you've
18 developed. I think everybody needs to know what
19 that language means. So publishing just like a
20 little glossary so that we are all on the same page.

21 DR. JONES: Okay. So that was number 3.

22 Okay. So number 4, how should FSIS

1 determine --

2 MR. REINHARD: I have to look. I believe
3 you.

4 I think on question 4, the group talked
5 about the experts getting together and talking about
6 it, and I don't know that we specifically went into
7 giving it to the other Advisory Committee, but it
8 fits there if that's everyone's preference also.

9 MS. TUCKER-FOREMAN: I thought that we had
10 talked about it going over to NACMCF because it's
11 which variables are higher priorities, what time
12 intervals would be most useful, what levels of
13 aggregation are most useful. I don't think our
14 stakeholder group that talks about transparency of
15 information would necessarily be equipped to do
16 that. It struck me as being something that we ought
17 to turn over to the statisticians.

18 MR. REINHARD: Yeah, I think the whole
19 Subcommittee agreed that it needed to go to a
20 different group to look at it. I think from a
21 timing standpoint, I don't know that FSIS can give
22 it to NACMCF and give them enough time to

1 necessarily go without some sort of information
2 being compiled and put in a format of what they need
3 to review, as far as the variables that you're
4 looking at and what timeframes you think, initially
5 think should be, so they can come back, and I think
6 John said so they could say, yes, we agree or, no,
7 we don't with what's been recommended, that FSIS is
8 putting together.

9 DR. TILDEN: But I do think we agreed with
10 the general direction that FSIS is heading and they
11 had pulled out and they gave us examples of tier 1
12 and tier 2 and they said here's what our current
13 thinking is, and we said that seems appropriate, but
14 as part of this ongoing process, you should hook in
15 with the heavy hitters on the science side.

16 MS. TUCKER-FOREMAN: That sounds like a
17 terrific answer.

18 MR. REINHARD: I agree. So, John, you want
19 to summarize it again in two sentences.

20 DR. TILDEN: In two sentences it was we
21 agreed with the general approach that the FSIS is
22 taking but we suggested for long-term sustainability

1 they have it reviewed by NACMCF.

2 Yeah, no problem. So we agreed with the
3 general approach of focusing on public health
4 outcomes that FSIS is using, but we suggested that
5 they run it by NACMCF for the mid and long-term
6 sustainability.

7 MS. BUCK: Are we also including inspection
8 on those public health and inspection?

9 Just 4.

10 DR. TILDEN: Yeah, that's probably the
11 wrong word, that they have the strategy evaluated by
12 NACMCF.

13 MS. TUCKER-FOREMAN: Yeah, that's good
14 language.

15 DR. JONES: Once again, this was another
16 item that was where we suggested -- is there where
17 we suggested the position paper be presented to
18 NACMCF? So another item where we suggested FSIS
19 continue with what they were doing, develop a
20 position paper and run it by NACMCF.

21 DR. TILDEN: Right. So we agreed with FSIS
22 using the term proportion positive, not prevalence,

1 and that for a more detailed analysis, have it
2 assessed by NACMCF.

3 MS. TUCKER-FOREMAN: I think there that we
4 ought to say the annual proportion positive
5 because --

6 DR. JONES: Annual proportion positive?

7 MS. TUCKER-FOREMAN: Yeah. There's not
8 much basis for year-to-year comparisons here.

9 DR. KASSENBERG: Do you mean to say annual,
10 using the term annual proportion positive instead of
11 the term prevalence?

12 MS. TUCKER-FOREMAN: Yes.

13 DR. KASSENBERG: Okay. So you might want
14 to clarify that on there then, on the text.

15 MR. REINHARD: And then I thought in this
16 one that we did agree that potentially they could
17 look at some of the verification programs in rolling
18 them all together and have their scientists and
19 statisticians determine if then they can get a
20 prevalence number from the combined verification
21 sampling programs, for example, *LM*.

22 MS. TUCKER-FOREMAN: I think this is

1 something that has to get beyond the Agency, Bob.

2 So --

3 MR. REINHARD: I think that, too, but I
4 thought then they would take that with what their
5 rationale was behind combining the verification
6 sampling to the other Advisory Committee.

7 MS. TUCKER-FOREMAN: Okay. All right.

8 MR. REINHARD: And then maybe that's what's
9 meant by develop your position paper and that may be
10 enough because the record will speak for the rest.

11 MS. TUCKER-FOREMAN: Okay.

12 DR. JONES: That's what I think. So how do
13 we feel about the five. Are we good with the five
14 responses for now?

15 So do we have time to define proprietary?
16 You had a question about proprietary, Ms. Buck.

17 MS. TUCKER-FOREMAN: I'm confident that
18 this is defined legally either in the law or the
19 regulations, proprietary is already defined. I know
20 that it's defined under FOIA law, and I'm confident
21 that it's defined here as well. I just don't know
22 what it is.

1 MS. BUCK: The only thing that I did not
2 hear in the summary was we had talked about the
3 transfer of data from the old system to the new and
4 the importance of keeping the historical integrity
5 going. Are we reflecting that in some part in our
6 summary there?

7 MS. TUCKER-FOREMAN: What Pat's referencing
8 was our discussion yesterday, that because we're
9 switching from PBIS to PHIS, and they don't speak to
10 each other, that there has to be some mechanism for
11 not losing the historical data about each plant that
12 exists in PHIS, and I thought the Agency was very
13 reassuring about that yesterday but were you?

14 MR. REED: I think we were, yes. No, we
15 are definitely keeping all historical data as well
16 as all future data. No data is being lost or
17 destroyed or not used.

18 MS. TUCKER-FOREMAN: But how does the
19 computer, if you ask the computer, does it stop at
20 the beginning of PHIS? Am I going to look in a
21 couple of years and see that FSIS is giving me a
22 report, giving the public a report about what's

1 happening, and it's nothing except since the
2 beginning of PHIS?

3 MR. REED: All of the historical data is
4 being kept on the data warehouse. Nothing's to be
5 destroyed, so that when we create reports, we will
6 use the historical data as well as the new data.

7 MS. GAPUD: I just want to say again in
8 number 5, the critical importance of training
9 because that can give us differences in inspection
10 and compliance and everything. So we need to
11 emphasize the importance of training these
12 inspectors who will be going to the facilities in
13 calibration. Thank you.

14 (Whereupon, at 1:46 p.m., the subcommittee
15 meeting was 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

SUBCOMMITTEE 1

DATA COLLECTION, ANALYSIS, AND TRANSPARENCY

Washington, D.C.

September 30, 2010

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

TIMOTHY J. ATKINSON, JR., Reporter
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