

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON MEAT AND POULTRY
INSPECTION

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FALL MEETING

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WEDNESDAY,
NOVEMBER 16, 2005

The meeting was called to order at 9:00 a.m., in the South Building Cafeteria Conference Room, United States Department of Agriculture, 14th and Independence Ave., S.W., Washington, D.C., Barbara Masters, Chair, presiding.

PRESENT:

- BARBARA MASTERS, Food Safety and Inspection Service
- DAVID CARPENTER, Southern Illinois University School of Medicine
- JAMES DENTON, University of Arkansas
- KEVIN ELFERING, Minnesota Department of Agriculture
- SANDRA ESKIN, Public Policy Consultant
- MIKE FINNEGAN, Montana Department of Livestock
- MICHAEL GOVRO, Oregon Department of Agriculture
- ANDREA GRONDAHL, North Dakota Department of Agriculture
- JOSEPH J. HARRIS, Southwest Meat Association
- JILL HOLLINGSWORTH, Food Marketing Institute
- MICHAEL KOWALCYK, Safe Tables Our Priority
- IRENE LEECH, Virginia Polytechnic Institute and State
- CHARLES LINK, Cargill Value Added Meats
- MARK SCHADSchad Meats, Inc.

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ALSO PRESENT:

MARY CUTSHALL, Director (SIPO)

PHIL DERFLER, Associate Administrator (OPED)

DAN ENGELJOHN, Assistant Administrator (OPED)

BRYCE QUICK Deputy Administrator (FSIS)

RICHARD RAYMOND, Undersecretary for Food Safety

ROBERT TYNAN, Deputy Director (SIPO)

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

2 9:00 a.m.

3 DEPUTY DIRECTOR TYNAN: We'd like to get
4 started if we could.

5 I think this morning, I think both of the
6 subcommittees worked diligently last night and into
7 the morning, so we should have a couple of very good
8 reports from the two subcommittees.

9 What we'd like to do for the agenda this
10 morning is go back and look at question number five
11 first, then we'll do Subcommittee 1, Subcommittee 2,
12 and try to come to consensus on each one of those
13 individually, and then last but not least we had a
14 couple of three briefing papers from yesterday that we
15 did not complete because of the time constraints we
16 got into, and so we'll do those at the very end, so
17 that in case anyone has flight arrangements or travel
18 plans if you have to miss something it will be
19 probably the lesser important of the topics, not that
20 they aren't all important, those would be the lesser
21 important.

22 So, with that I'm going to open it up to

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1 Dr. Carpenter and Mr. Kowalcyk maybe to talk through
2 number five.

3 DR. CARPENTER: Question: "If the Agency
4 were to form an ongoing working group to look in the
5 Risk Based Inspection System, RBIS, what
6 recommendations would the Committee have on the
7 following."

8 The discussion led to, I'll scroll down to
9 get to the inspection criteria, third party suggestion
10 -- I'm sorry, let's scroll back up, I should have read
11 that, I'm sorry.

12 "Members offer several options with the
13 second stage as to what type of group would facilitate
14 addressing RBIS. Option to selecting a third party to
15 facilitate the separate emerged as the preferred
16 approach."

17 Is that pretty much a consensus of what
18 our discussion encapsulated yesterday? Okay.

19 The third party suggestion is pursued in
20 undertaking needs to occur in two phases. The first
21 stage, third party, the Committee of stakeholder
22 representatives to facilitate addressing these issues.

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1 Third party could be the National Academy of Sciences,
2 the University Consortium, or other appropriate group.

3 Selected organization needs to be unbiased and
4 charged with seeking out information from all
5 stakeholders by a series of public meetings. Does
6 that capture the major points of our discussion?

7 DR. HOLLINGSWORTH: Jill Hollingsworth,
8 FMI. The only thing I would say on that is, and maybe
9 it doesn't imply that that would be the only way to
10 obtain information through public meetings, I think
11 there will be other ways too, like they might want to
12 do a survey or a questionnaire. They may actually
13 want to have a small group go out and visit plants,
14 and do observations.

15 So, I think that the organization, where
16 it says, "needs to be unbiased and charged with
17 seeking out information from all stakeholders . . .," it
18 might be better worded that including a series of
19 public meetings, but not limited to that.

20 DR. CARPENTER: Sandra?

21 MS. ESKIN: I was just saying, Sandra
22 Eskin, I'm not sure grammatically, the organization

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1 needs to be -- it's information from all stakeholders,
2 I would keep the language via a series of public
3 meetings and other approaches.

4 Jill, is that okay?

5 DR. HOLLINGSWORTH: That's fine.

6 MS. ESKIN: Yes, grammatically.

7 DR. HOLLINGSWORTH: That's the only way to
8 get it.

9 MS. ESKIN: I understand.

10 CHAIR MASTERS: This is Barb Masters.

11 Would the Committee recommend including
12 such as adding the e.g., such as surveys, plant
13 visits, just so that it is very clear to the Agency
14 what approaches you are recommending there? I would
15 include as, after the other approaches, put in parens,
16 e.g., surveys, plant visits, just so it's very clear
17 what the Committee had in mind with the other
18 approaches.

19 DR. HOLLINGSWORTH: I'm sure that there's a
20 lot of data that they would want to review, too,
21 science data.

22 MR. LINK: This is Charles. I just want to

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1 jump in up above that a little bit, the third party
2 statement, it reads to me that we are, basically,
3 endorsing the National Academy of Sciences and maybe
4 some other things, it just reads to me that way, that
5 that's the preferred method, just because of the way
6 it is stated. It says National Academy of Sciences or
7 other things.

8 So, just under the other appropriate
9 groups, maybe other appropriate business consulting
10 groups or something, I don't know. It's just the way
11 it reads to me, that we are almost recommending NAS,
12 maybe not.

13 DR. CARPENTER: Do you actually want the
14 wording, other appropriate consulting groups?

15 MR. LINK: Yes, that's fine.

16 DR. CARPENTER: Committee members okay with
17 that? In addition to other appropriate --

18 DR. HOLLINGSWORTH: And, it's National
19 Academy of Sciences, plural.

20 DR. CARPENTER: Right.

21 DEPUTY DIRECTOR TYNAN: Do we have any
22 other comments on number five?

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1 DR. CARPENTER: Phase I.

2 DEPUTY DIRECTOR TYNAN: Phase I, thank you.

3 MS. ESKIN: IU just have one comment.

4 I know the way that it's written it says,
5 inspection issues, and then further in the document it
6 says of data issues. And, I think what we are saying
7 up above, correct me if I'm wrong, is this third party
8 process would address both inspection and data issues.

9 The issues around data that are listed at the end of
10 this document are just issue spotting. So, I would
11 propose taking out the heading that says, "Inspection
12 Issues," so it's clear it applies to everything.

13 DEPUTY DIRECTOR TYNAN: Okay, where is
14 that, Sandra?

15 MS. ESKIN: Go up, please. See,
16 "Inspection Criteria" I meant, the process is supposed
17 to include both that and -- I think, unless --

18 MR. KOWALCYK: This is Michael Kowalcyk. I
19 think to follow up on your point, Sandy, and I think
20 Catherine mentioned it yesterday, you don't want to
21 create another layer to this, where if we have this
22 group would be assigned at looking at inspection

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1 criteria and the data that would support that, because
2 looking at risk based inspection the two are
3 inseparable. So, if the inspection resources are
4 going to be deployed based on data, it is critical
5 that the data is appropriate and that it's evaluated.

6 So, I would agree that this third party group should
7 be charged with looking at the whole picture.

8 DEPUTY DIRECTOR TYNAN: Other comments on
9 five, on the first phase?

10 DR. CARPENTER: You are commenting on the
11 second phase.

12 DEPUTY DIRECTOR TYNAN: Yes, second phase.
13 Dr. Hollingsworth?

14 DR. HOLLINGSWORTH: I'm not sure whether
15 the way it reads, if it sounds like this Committee
16 will actually -- well, I haven't read the rest of it,
17 maybe I should not -- but I was just commenting on the
18 very first sentence, where I don't think the intent
19 was that the Phase I report would then be given to
20 this Committee, and this Committee would then
21 determine how to implement it. I think the idea was
22 that, again, there may be a process that's necessary,

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1 it may just be -- we may just say, yes, we think this
2 is a great report, and now we are requesting the
3 Agency to go forward, and maybe it says that below, so
4 I should read before I talk.

5 DEPUTY DIRECTOR TYNAN: Would you like us
6 to scroll down a little bit?

7 DEPUTY DIRECTOR TYNAN: Sandra, you had a
8 comment?

9 MS. ESKIN: Yeah, I think, Jill, if we
10 added -- if you'd scroll back up, saying the Agency
11 and the Committee, or the Agency consulting with the
12 Committee, ultimately, the Agency is the entity that
13 has to do something with those recommendations. So,
14 you could either just say the Agency or you could also
15 reference the Advisory Committee.

16 DR. HOLLINGSWORTH: I'm not sure what the
17 bullets are, other suggestions that emerged, other
18 suggestions for what, how to implement it?

19 MS. ESKIN: About the process. I think
20 that's about the third party process.

21 MR. KOWALCYK: This is Michael Kowalcyk.
22 Jill, I think the bullets really speak to the

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1 Committee itself addressing what the Committee should
2 be, you know, some more detail on the make-up of the
3 Committee, and what input should be going into the
4 Committee. So, I can see the confusion where the
5 second phase is the report being passed on to either
6 this Committee or the Agency. You know, I certainly
7 think that the Agency would need to be heavily
8 involved, as should committees that are looking at
9 this and looking at inspection issues.

10 So, I think those are just really into the
11 make-up of the Committee. Maybe we can move them
12 around.

13 DEPUTY DIRECTOR TYNAN: Dr. Harris?

14 DR. HARRIS: Yes, kind of back to Jill's
15 original point, I agree with Jill. I don't think we
16 should reference the Committee right there. That
17 report from the third party needs to come back to the
18 Agency, for the Agency then to decide how best to move
19 forward and whether or not they need to come back to
20 this Committee for more advice.

21 DR. HOLLINGSWORTH: I would agree with
22 that.

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1 DR. HARRIS: This Committee won't be the
2 entity that implements a risk-based inspection system,
3 so I don't want to see things being directed to come
4 back to this Committee unless the Agency wants to
5 bring it back to this Committee.

6 DR. RAYMOND: Barbara, may I jump in on
7 that?

8 DEPUTY DIRECTOR TYNAN: Yes, Dr. Raymond.

9 DR. RAYMOND: I think for clarity, perhaps,
10 that should read that NACMPI will look at the findings
11 and recommendations of the third party for
12 recommendations to forward to FSIS. I mean, your job,
13 you are the advisory committee, this is going to be a
14 technical committee, and you are the advisory
15 committee, you represent a lot of different walks of
16 life. I would prefer that the report come to you for
17 your sanitizing of it, your recommending, you can take
18 parts and pieces of it, you can do with that report
19 what you want and then you advise us. But, you don't
20 implement it, you are exactly right there, we
21 implement it, but I would like your advice.

22 And, as long as I've got the floor, I'd go

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1 to the first bullet there, you need to, for
2 clarification, where it says FSIS and other Federal
3 agencies such as, the state agency is not a Federal
4 agency. I think -- you just need to say and other
5 state and Federal agencies, such as CDC, state
6 inspectors, et cetera, remove the state agencies from
7 that third line but put it up there state and Federal.

8 And then, yeah, remove state agencies
9 there so it's not duplicative. That way I think it's
10 inclusive.

11 DEPUTY DIRECTOR TYNAN: Mr. Link?

12 MR. LINK: Thank you.

13 Just above that, when we are talking about
14 implementation and implementation strategies, would it
15 be appropriate to charge this third party, whoever it
16 ends up being, to review -- I guess to report on
17 findings, recommendations, and implementation
18 strategies, and then the Advisory Committee could
19 review all that, and to your point, provide advice, I
20 guess, to the FSIS, findings, recommendations and
21 implementation strategies.

22 DEPUTY DIRECTOR TYNAN: Mr. Elfering?

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1 MR. ELFERING: Kevin Elfering, if I
2 remember our discussions yesterday, I think this
3 Committee was supposed to be pretty involved in
4 providing the guidance to this third party as well. I
5 don't know if that's really captured in here, if that
6 would in Phase I or Phase II, but we should be
7 providing the initial guidance what this third party
8 should actually be doing, so that they are not putting
9 some report that ends up to be rather meaningless.

10 DEPUTY DIRECTOR TYNAN: Mr. Elfering, where
11 do you see language being put?

12 MR. ELFERING: I'm almost wondering if it
13 should go back in the first phase.

14 DR. HOLLINGSWORTH: It seems to me, and I
15 know I'm going to jump right in, if we scroll down,
16 the bullets that are there now under Phase II,
17 actually, when I'm looking at them I think they were
18 Phase I bullets. Those are things that belong up in
19 Phase I, and maybe instead of -- under Phase II, maybe
20 what we need to put -- well, let me go back, if we
21 move those up, then maybe we need to have a little
22 place under Phase I that says role of NACMPI, and we

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1 can identify what our role is. And, our role might be
2 to meet with the third party to discuss the charge and
3 the expected outcomes, and then the other charge for
4 this Committee would be and to review the final report
5 and make recommendations to the Agency on how to use
6 it and what to do with it, which is kind of different
7 than a Phase I/Phase II, it's almost like these are
8 the things that we are responsible for.

9 Does that address your concern, Kevin?

10 MR. ELFERING: Yes.

11 DEPUTY DIRECTOR TYNAN: Dr. Leech?

12 DR. LEECH: I wonder if we ought to address
13 something related to the time line. I think this is
14 reasonable, just knowing that we meet twice a year and
15 so forth, I don't know how that could affect dragging
16 the whole process out or not, but I think we want to
17 try to be sure that we don't make this be something
18 that makes things take forever and ever, years on end,
19 and never really anything get done.

20 DEPUTY DIRECTOR TYNAN: Does the Committee
21 want to add in some time lines as well, or some --
22 address that issue?

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1 DR. LEECH: Maybe put something there
2 related to time in the other suggestions, just a note
3 that it will be important to schedule meetings so that
4 there's timely use of the data or the reports,
5 schedule meetings so there is -- well, you don't want
6 to let months and months go in between when something
7 is ready and when the Committee meets, and you don't
8 want to give the Committee too much time, so that
9 things are done in an appropriate time, would that --
10 because it's hard to put exact time lines on it at
11 this stage.

12 DEPUTY DIRECTOR TYNAN: Sandra, do you have
13 a comment?

14 MS. ESKIN: Sandra Eskin, you know,
15 schedule meetings to make sure that a report is
16 completed within, again, an appropriate reasonable,
17 I'm not sure that's even more or as specific as we
18 want to get.

19 I'm not sure if there's an average length
20 of time that it's taken a group in this kind of a
21 process to complete a report. I assume it depends on
22 the nature of the charge, but the report is completed

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1 as expeditiously as possible?

2 DEPUTY DIRECTOR TYNAN: Dr. Logue?

3 DR. LOGUE: How about putting in some
4 wording along the lines of that they would have
5 progress reports every time that NACMPI meets, so
6 that's every six months we would know something. You
7 know, why not put in something along that line, and if
8 it goes longer than a year well at least we'd know by
9 18 months where it stood.

10 DEPUTY DIRECTOR TYNAN: Dr. Denton?

11 DR. DENTON: Going back to the comments
12 that Kevin and Jill made earlier, and some of the
13 comments that were made yesterday, with regard to how
14 we might approach providing the oversight and guidance
15 that's given in the charge to that third party.

16 We talked a bit yesterday about whether or
17 not it should be the Committee as a whole or whether
18 it should be a subcommittee of the National Advisory
19 Committee that would be charged with that.

20 Just an opinion, I think, perhaps, a
21 subcommittee of this Committee working in very close
22 collaboration with Barb and others within the Agency,

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1 probably would be an appropriate vehicle to address
2 some of these things with regard to what we expect
3 that third party to do, what we expect the time line
4 to be, so that that works within the context of what
5 the Agency actually hopes to get done.

6 I think the guidance provided here in a
7 general sense is appropriate, but I really think that
8 it's going to fall back to that smaller group that
9 provides the charge to the third party, and sets up
10 the original project that would be a more effective
11 way to deal with those particular issues. Just a
12 thought.

13 DEPUTY DIRECTOR TYNAN: Does the Committee
14 agree, or are there other comments on that?

15 Mr. Kowalcyk?

16 MR. KOWALCYK: To follow up that point,
17 with defining the charge to this third party, being
18 that this is such a big issue, and the scope is very
19 broad, and we're looking at time lines now, I don't
20 know if we are in a position right now to look at
21 solid time lines. And, I think the idea of updates to
22 this Committee allows for a public forum, so to speak,

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1 for status reports on how this is proceeding.

2 One concern I have is in the charge of
3 this third party. Will that be -- shouldn't that be
4 the Agency with input from all stakeholders, as to how
5 this would be approached? So, do we want to work some
6 language into the recommendation on how this third
7 party would be charged?

8 I'm assuming that FSIS would drive this
9 process and giving this third party the responsibility
10 of addressing these issues. However, I feel that FSIS
11 should have input, either from this Committee, or
12 through a series of roundtable discussions done in a
13 public forum. That way, all stakeholders would have
14 an opportunity to be heard, and provide
15 recommendations as to how the process should go.

16 DEPUTY DIRECTOR TYNAN: Okay. Is that
17 consistent with what Dr. Denton was suggesting, a
18 smaller committee?

19 MR. KOWALCYK: Either that or a series of
20 public meetings to address what this third party is
21 going to be asked to do, not necessarily a formal
22 subcommittee of this Committee. I don't know if there

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1 is resources from this Committee that would be able to
2 address that effectively.

3 DEPUTY DIRECTOR TYNAN: Okay.

4 Well, as I understand it then, I think Dr.
5 Denton was suggesting a smaller subgroup of this
6 Committee, to help with the specifications for what we
7 ask the third party to do.

8 Mr. Kowalcyk, if I understand you
9 correctly, you are talking about, perhaps, a series of
10 a broader group of people --

11 MR. KOWALCYK: Yes.

12 DEPUTY DIRECTOR TYNAN: -- assisting in
13 that process.

14 MR. KOWALCYK: Yes.

15 DEPUTY DIRECTOR TYNAN: So, we have two
16 different options for approaching that.

17 Dr. Denton?

18 DR. DENTON: I guess implicit in what I was
19 recommending is that the smaller subcommittee of this
20 Committee help frame this with regard to what the
21 expectations are of what the charge would be, then
22 report back to the full Committee so that the full

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1 Committee has some input into that, to make sure that
2 it's consistent with what we talked about doing.

3 I'm not saying that the subcommittee would
4 become the ultimate authority with that, before it
5 goes to the Agency as a way to jump start this,
6 because I really think that we are probably not going
7 to be able to agree on all the details until we have
8 something that we can react to.

9 DEPUTY DIRECTOR TYNAN: Okay.

10 Mr. Kowalcyk, is that still -- is that
11 consistent? Yours sounded it was broader than the
12 Advisory Committee as a whole, so you were suggesting,
13 perhaps, even public meetings to get to some of the
14 details of this?

15 MR. KOWALCYK: Yes. I still think at this
16 stage it should receive input from all parties that
17 would ultimately be affected, industry, consumers,
18 people doing the research, and academics.

19 DEPUTY DIRECTOR TYNAN: Okay.

20 MR. KOWALCYK: I think that would be
21 important.

22 DEPUTY DIRECTOR TYNAN: Ms. Eskin?

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1 MS. ESKIN: I think that looking at Dr.
2 Denton's approach, my concern with having a
3 subcommittee and then coming back to the Committee of
4 the whole is timing, and we only meet twice a year.
5 So, it would be very unfortunate if we would have to
6 wait that period of time.

7 And, I think in terms of determining what
8 this third party process is going to look at, I think
9 if there was a subcommittee that worked with FSIS,
10 obviously, culling their ideas from lots of sources,
11 that might be a more workable way to move forward.

12 DEPUTY DIRECTOR TYNAN: A subcommittee --

13 MS. ESKIN: A subcommittee from this
14 Committee that works with FSIS in developing the
15 charge and working with --

16 DEPUTY DIRECTOR TYNAN: Without Phase II of
17 coming back to the full Committee?

18 MS. ESKIN: Phase II it would come back to
19 the full Committee.

20 DEPUTY DIRECTOR TYNAN: Okay.

21 MS. ESKIN: This is just Phase I.

22 DEPUTY DIRECTOR TYNAN: No, but I used the

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1 wrong term, but what Dr. Denton was suggesting, a
2 smaller subcommittee, then it would come back to this
3 full Advisory Committee, and you are suggesting?

4 MS. ESKIN: I'm saying I'm concerned that,
5 just from --

6 DEPUTY DIRECTOR TYNAN: Timing question.

7 MS. ESKIN: -- yes, a timing issue, it's
8 easier for a subcommittee to do the work and,
9 basically, be delegated the responsibility, working
10 with the Agency. You add that other layer, that other
11 step of a full committee, we might run into timing
12 issues.

13 DEPUTY DIRECTOR TYNAN: Okay.

14 We'll have to try and come to some
15 consensus with this.

16 Dr. Denton?

17 DR. DENTON: I think that's okay, as long
18 as the rest of the Committee is comfortable with the
19 subcommittee having that responsibility. I think that
20 would be fine.

21 DEPUTY DIRECTOR TYNAN: I saw another --
22 Mr. Link, you had a comment before and changed your

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1 mind, did you want to revisit that? You are thinking
2 it over, okay.

3 Mr. Schad?

4 MR. SCHAD: Yes, this is Mark Schad. I
5 just want to say that I think the idea of a
6 subcommittee is a good one. I think there's a lot to
7 be gained by having a smaller group, and to me that
8 does not mean you have to exclude anybody or any of
9 the stakeholders. You can still get input from all
10 the parties involved.

11 DEPUTY DIRECTOR TYNAN: Okay.

12 So, is there sort of a general agreement
13 that a subcommittee -- oh, I'm sorry, I apologize, Dr.
14 Leech?

15 DR. LEECH: I think you could do it through
16 some communication, it doesn't have to happen just at
17 the formal meetings, and there could be some work in
18 between and some communication related to that.

19 And, I don't know whether it's
20 appropriate, but I wondered if we'd like to say with
21 the progress reports it may be in the scheduling of
22 that we could make the reports due two months before

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1 the Committee meets or whatever, but it would be nice
2 if we knew what was coming and could look at things
3 and have some time to work with it before we came to
4 these meetings, not just see them when we arrive or a
5 week before.

6 And so, maybe as we set this up, we
7 schedule them to have something due with a time line
8 that takes that in consideration, that would be
9 helpful.

10 DEPUTY DIRECTOR TYNAN: You've revisited
11 your thought, Mr. Link?

12 MR. LINK: Yes, I just want to say, I'm in
13 favor of the subcommittee piece. I mean, one of the
14 things we talked about yesterday was this ought to be
15 a kind of small group or we'll never get anything
16 done.

17 So, I like the subcommittee idea, to kind
18 of come back to maybe to the full Committee, or just
19 working with FSIS, to kind of come up with the charge
20 for this third party.

21 But, I think, ultimately, back to
22 Michael's point, I mean, we probably ought to have a

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1 public meeting to talk about, hey, this is where we
2 are going, this is what we think, before we charge
3 them to go too far I guess, and make sure everybody
4 has a chance to get their two cents worth in.

5 But, initially, I think a subcommittee
6 would be a good way to go, and kind of get this thing
7 off the ground and moving.

8 DEPUTY DIRECTOR TYNAN: You could be Mr.
9 Govro if you like.

10 DR. HARRIS: We could attribute these
11 comments to Michael instead of myself.

12 Sounds to me like we are about to put an
13 extra layer in there, because as I read what we had --
14 the instructions to the third party was going to be to
15 get that input from all stakeholders. So, it seems
16 like we are sort of, I don't know, adding a layer if
17 we have a series of public meetings, or, you know,
18 solicit a lot of public input to even develop what the
19 third party is going to be asked, then the third party
20 will be instructed to go find all the stakeholders and
21 ask them what they think again. And, it seems like we
22 are adding an extra layer that's just going to slow

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1 the process down unduly.

2 DEPUTY DIRECTOR TYNAN: Yes, Ms. Eskin?

3 MS. ESKIN: Sandra Eskin.

4 Perhaps one way to satisfy everyone here,
5 we'd go with the subcommittee idea, and rather than
6 have a public meeting to get input on whatever it is
7 the subcommittee and FSIS come up with as the scope of
8 the research, could even put it out for comment, I
9 know it's done, it's not a regulation, all it is is
10 simply public, this is what we are going to ask this
11 third party to do, we'd appreciate your input
12 logistically, and time-wise, and otherwise, using that
13 method to communicate is probably more timely.

14 So again, it would be the subcommittee
15 working with FSIS, and then whatever they come up with
16 is put out for public comment for people to give their
17 input.

18 DEPUTY DIRECTOR TYNAN: Is that agreeable
19 to the Committee as a whole?

20 CHAIR MASTERS: Do you have some language
21 for bullet one there, Ms. Eskin?

22 MS. ESKIN: Sure. An NACMPI subcommittee

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1 would work with FSIS to define the scope of the third
2 party report, and this proposal would be open to
3 public comment.

4 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk, does
5 that work for you? I think you had a somewhat
6 different approach, but is that a workable compromise
7 for you?

8 MR. KOWALCYK: Yeah, I think it does
9 clearly state that, you know, the public comment
10 component I think is very critical, because the scope
11 is, like I said before, very broad.

12 I guess one question I would have to the
13 agency, and I don't know if we need to address that
14 here, is the frequency about which this committee
15 would have to meet. I mean, being that this is a big
16 issue, I'm not -- I'm seeing that one meeting every
17 six months would not be sufficient. So, I don't know
18 if we need to, at this time, put some definitions to
19 that, how often should they meet, and the composition
20 of the Committee. So, I'm still unclear as to how
21 that would effectively work.

22 CHAIR MASTERS: This is Barb Masters, and

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1 again, there is no -- while this Committee as a whole,
2 by Charter, meets twice a year, there is nothing that
3 precludes the Agency from hosting this Committee for
4 meeting more than twice a year, and certainly a
5 subcommittee can meet as frequently as deemed
6 appropriate.

7 So, that's where I think we were looking
8 for your suggestions on how frequently we would see a
9 subcommittee meeting, whether that would be
10 telephonically, in person, so that's the kind of
11 suggestions we are looking for from this Committee.

12 MR. KOWALCYK: It would be the, actually,
13 subcommittee of this Committee communicating, you
14 know, developing then a proposal for the third party.

15 CHAIR MASTERS: And, please provide your
16 suggestions on what you believe would be appropriate,
17 because that is what we are looking for. And, I think
18 I was hearing the Committee suggest, that's why a
19 subcommittee would be more effective, because some of
20 you have more flexibility on how frequently you can
21 meet than others, since all of you, as I understand
22 it, have real lives and real jobs.

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1 And so, while we appreciate all the work
2 that you do, the feasibility of getting all of you
3 together on that frequency is less likely. And so, we
4 are very open to as frequently as you are willing to
5 come together, and so that's why we are looking for
6 your suggestions on how frequently we would see this
7 group meeting.

8 DEPUTY DIRECTOR TYNAN: Dr. Hollingsworth?

9 DR. HOLLINGSWORTH: That second bullet
10 there about scheduling meetings and progress reports
11 when we convene, what if we change that bullet to say,
12 NACMPI, and it could be either -- I'm even thinking
13 the subcommittee, working with FSIS will establish a
14 time line which will include regularly scheduled
15 updates or progress reports. They could even be done
16 by conference call, if we couldn't get together.

17 So, I think -- and again, I don't know
18 that we can set a time line until we know the scope of
19 the work. We may give them a very narrow charge, we
20 give them a very big charge, so I would almost prefer
21 to have that subcommittee as part of their work with
22 FSIS identify what will be the time line and what kind

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1 of updates and progress reports would we expect, and
2 just build that into the whole scope of the work.

3 DEPUTY DIRECTOR TYNAN: Ms. Eskin, I'm
4 sorry.

5 MS. ESKIN: LaVonne is typing, it's both
6 the subcommittee and FSIS together are going to
7 identify the time line, right, and frequency of the
8 meetings?

9 DEPUTY DIRECTOR TYNAN: Dr. Leech?

10 DR. LEECH: Would you want to say something
11 to the fact of, and some meetings may take place by
12 teleconference and be in between the regularly
13 scheduled meetings, to actually say that we are
14 expecting that there's going to be some work outside
15 of our every six months meetings?

16 DEPUTY DIRECTOR TYNAN: Dr. Logue, you had
17 a comment, I think?

18 DR. LOGUE: I don't think we need to get
19 that detailed at this point. I think just that we
20 would set some kind of a time frame.

21 DEPUTY DIRECTOR TYNAN: Okay.

22 Are there other comments on this first

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1 part of the report?

2 CHAIR MASTERS: This is Barb Masters. I
3 think you all had something for the role of NACMPI as
4 far as the actual review of the report and providing
5 advice and guidance back to the Agency, and I think
6 we've lost that bullet somewhere.

7 MS. ESKIN: It's right there, it's Phase
8 II.

9 CHAIR MASTERS: Okay, great. Okay. So, we
10 could -- that stays under the role of NACMPI, great,
11 okay. Don't want to lose that one.

12 DEPUTY DIRECTOR TYNAN: Dr. Hollingsworth,
13 you had a comment?

14 DR. HOLLINGSWORTH: Yes, just kind of lots
15 of recommendations in that sentence. I was just
16 thinking maybe something like NACMPI will review the
17 findings and recommendations in the third party
18 report, and provide guidance to the Agency on how to
19 proceed. I mean, the report may be we don't think
20 this is a good idea, we don't want you to implement
21 it. I mean, let's hope that's not it for all that
22 money and effort, I hope we will have something great,

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1 but I think it would just be that, you know, our role
2 then would be to review that report and then give
3 guidance back to FSIS on how we think they should use
4 it.

5 DEPUTY DIRECTOR TYNAN: Okay.

6 DR. HOLLINGSWORTH: Next steps, what should
7 be the Agency's next steps now that we have this
8 report in our hand.

9 DEPUTY DIRECTOR TYNAN: Is there language
10 that you would propose?

11 DR. HOLLINGSWORTH: Yes, NACMPI will review
12 the findings and recommendations of the third party
13 report and provide guidance to FSIS on next steps.

14 And, you know, because we've already said
15 in Phase I, depending on who the third party is and
16 what charge we give them, they may actually provide
17 the implementation plan, and we like it so much we
18 say, go for it.

19 DEPUTY DIRECTOR TYNAN: Mr. Link, you had a
20 comment?

21 MR. LINK: No.

22 DEPUTY DIRECTOR TYNAN: We spoke about the

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1 data issue earlier, how did you decide you wanted to
2 portray that as part of the report? Was it just
3 simply taking out the headings?

4 MR. KOWALCYK: I think the thought was that
5 the data issues would be part of this.

6 DEPUTY DIRECTOR TYNAN: Okay.

7 MR. KOWALCYK: I mean, the bullet recalls
8 have to be a significant source of assessment data, I
9 mean, that's actually kind of -- that could be
10 actually something that's looked at in the report. I
11 don't know if that needs to be specifically stated
12 here, but, you know, scrolling down some more general
13 points as far as the make-up of the working group that
14 would take on this task, we would certainly want to
15 see experts in data systems and data analysis,
16 statisticians so to speak, not only to protect the
17 integrity of the data, because if the data -- if
18 there's problems with the data that go into a system
19 like this there will be problems in implementation,
20 and to identify the limitations of the data, because
21 part of their recommendation may be changes to how
22 sampling is done. I don't know. But, I think that's

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1 something that should be part of this recommendation,
2 as to what this Committee should -- what this group
3 should comprise of, not only people that are in the
4 food safety world, or in academics, but from that
5 arena that have expertise in data analysis and data
6 management.

7 DEPUTY DIRECTOR TYNAN: So, these bullets
8 would be part of what you would propose to be the
9 charge to the third party, whoever that may be. So,
10 our subcommittee that we've talked about would use
11 these to help frame the --

12 MR. KOWALCYK: Yes.

13 DEPUTY DIRECTOR TYNAN: -- specifics.
14 Okay.

15 Ms. Eskin?

16 MS. ESKIN: In terms of the language that's
17 there, what I would propose is, actually, collapsing
18 it into one bullet, because the first one is just --
19 let me just try some language, perhaps, the third
20 party report would address all of the data issues in
21 an RBIS. And then, we could do a list, including
22 recall data, see if that works, and what was the

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1 second bullet? I think that second bullet is really
2 one that deals with work groups should be formed with
3 experts, I think at the very top we do have a list of
4 who that third party should be -- who should be
5 involved in the process. I don't know if we can add
6 to the list of state agencies, Federal agencies,
7 consumer groups, something to capture that second
8 bullet, perhaps. There we go, we have relevant
9 experts, that may not be specific enough, Mike,
10 including those.

11 And then back to the bottom, that third
12 bullet under data, let's see if we can reference at
13 the very bottom, scroll to what we are working on
14 language-wise, all data issues including recall data
15 and use of technology, is that what that third bullet
16 said? Yeah.

17 DR. LOGUE: Go back up to the other part
18 and put for assimilation and whatever the last part of
19 that other sentence was, for assimilation on analysis
20 of the crude data.

21 DEPUTY DIRECTOR TYNAN: Does that capture
22 what you were looking for, Dr. Logue? Okay.

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1 I'm sorry, Dr. Hollingsworth, how could I
2 overlook you?

3 DR. HOLLINGSWORTH: How could you possibly
4 think a sentence could go by without my commenting?

5 In that one I'm almost wondering, because
6 we've specifically taken -- you know, put in recall,
7 I'm wondering if we should make it more generic and
8 just say all of the data issues in an RBIS including
9 sources of the data, collection of the data, quality
10 of the data, and the use of technology, in other
11 words, just all the issues, even data management, you
12 know, where is it all going to be housed and how is it
13 going to be collated.

14 So, I would be very broad in the scope,
15 and sources of the data quality, data management, and
16 the use of technology, and then take out recall data.

17 DEPUTY DIRECTOR TYNAN: I just wanted to
18 let Lyvonne catch up a little bit before we got too
19 far. We don't want her to leave us right after this
20 meeting.

21 Mr. Kowalcyk?

22 MR. KOWALCYK: I think another addition

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1 that should be made, it came up quite a bit yesterday
2 morning, is the legal and regulatory aspect of the
3 risk-based inspection system, issues that have come up
4 under assets, enforcement issues, and I would
5 recommend that this third party also include people
6 that are expert in regulatory issues that this would
7 address.

8 My concern is, and I think it was raised
9 several times yesterday, that this system could be
10 established but not fall properly within the
11 regulatory framework, and should be looked at.

12 So, maybe if we can add data risk and
13 legal experts.

14 DEPUTY DIRECTOR TYNAN: Thank you, Michael.

15 Other comments? Are we to a point where
16 we can reach consensus on number five, the report?
17 Are there other issues that come to mind?

18 While Lyvonne is trying to figure out how
19 bullets work, I always have the same problem, so I can
20 appreciate the difficulty, could we come to some
21 consensus, just a show of hands, or something that we
22 are all in agreement, yes, on this report as is?

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1 Okay.

2 Are there any nos?

3 MR. LINK: Is there any chance we could
4 just go back to the top and go through it one time?

5 DEPUTY DIRECTOR TYNAN: Sure.

6 MR. LINK: I had a question. Back up on
7 the front page, right there in the last sentence it
8 says the Agency is going to define this charge, I
9 thought we had discussed that this subcommittee would
10 do that, in conjunction with the Agency.

11 DEPUTY DIRECTOR TYNAN: Mr. Link.

12 MR. LINK: In the interest of transparency
13 and openness, whatever we come up with on the
14 subcommittee I guess we need to make sure that
15 everybody has had a chance to sit in, or listen, or
16 whatever.

17 DEPUTY DIRECTOR TYNAN: On the --

18 MR. LINK: I don't know if we need to say
19 that.

20 DEPUTY DIRECTOR TYNAN: -- on the NACMPI
21 Committee as a whole?

22 MR. LINK: Yes.

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1 DEPUTY DIRECTOR TYNAN: Okay.

2 Dr. Hollingsworth, you had another
3 comment?

4 DR. HOLLINGSWORTH: Two places, could we go
5 way back up to the top, to right there. I think it's a
6 little confusing the way it says a third party will
7 form a committee, I think we are not looking at
8 setting up a third party and then another committee.
9 I just think the way it's worded it's unclear there.

10 Well, the third party is the committee,
11 right?

12 MS. ESKIN: Right.

13 DEPUTY DIRECTOR TYNAN: Ms. Eskin?

14 MS. ESKIN: How about just language saying,
15 a third party will be selected to address these
16 issues, or appointed, I don't really care.

17 DEPUTY DIRECTOR TYNAN: And then, we delete
18 the rest of that sentence, is that correct? Okay.

19 MS. ESKIN: Or, a third party -- there's
20 two issues, one is the make-up of that entity, that's
21 the third party, right, and then the second issue,
22 which is also included below, is who that third party

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1 entity will hear from.

2 So, the question is, do we need that
3 second part -- do we need the remainder of that
4 original first sentence? I would propose that we just
5 delete that remaining, form a committee of
6 stakeholders, because we do address those issues in
7 the rest of that section.

8 CHAIR MASTERS: This is Barb Masters.

9 Charles, Mr. Link, did you want to address
10 how you want to form your subcommittee, or do you want
11 to just assume that that will be a transparent process
12 through the Committee?

13 MR. LINK: That's a real good question, how
14 do we select a subcommittee? Volunteers?

15 I think it is appropriate that it talk
16 about that, we need to, I guess, resolve that.

17 DR. HOLLINGSWORTH: Can I add one other
18 thing for Lyvonne?

19 I'm still not, I don't understand that
20 bullet that says a core group. What is that group?
21 That's not the NACMPI subcommittee, it's not the third
22 party, I don't think, I don't know what that is.

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1 DEPUTY DIRECTOR TYNAN: What is the small
2 core group.

3 DR. HOLLINGSWORTH: I would say it needs to
4 come out then probably.

5 DEPUTY DIRECTOR TYNAN: It needs to come
6 out.

7 DR. HOLLINGSWORTH: Because we've already
8 identified the subcommittee, and that just looks like
9 -- I don't know what that's hanging there for.

10 CHAIR MASTERS: This is Barb Masters again.
11 I think it would be helpful to hear some ideas on how
12 you all would propose getting your subcommittee while
13 you are here.

14 MR. KOWALCYK: This is Michael Kowalcyk. I
15 think to follow up with that point, along the line of
16 Charles' comment, I think whatever the composition of
17 this subcommittee is, I think it's important that that
18 subcommittee report -- be required to report back to
19 this Committee, members of this Committee are able to
20 either, if it's a teleconference, to be able to sit in
21 on these meetings, just so that, I mean, this
22 Committee is representative of stakeholders, and I

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1 think the Agency needs to put in place a way to assure
2 that all parties involved are represented at some
3 level in this subcommittee, so that way it's
4 transparent to everybody involved.

5 I don't know if we need to put specific
6 language around that now, or if the Agency would do
7 that and then come back to this Committee for our
8 approval. I don't know what would be the best way to
9 approach it at this point.

10 DEPUTY DIRECTOR TYNAN: Dr. Denton, you had
11 a comment?

12 DR. DENTON: I tend to agree with Mike, but
13 I also want to flip that coin over on the other side
14 and say that I would hope that whoever the
15 subcommittee is has access to anyone else on the
16 Committee to receive additional input as we work
17 through this process.

18 I understand that the subcommittee is
19 going to be charged with the bulk of the work, but I
20 think that we should have that committee feeling very
21 free to talk to everyone else on the committee as we
22 move through this process, because it's going to take

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1 all of us working together, I think, to get this done.

2 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk, does
3 that respond to your comment?

4 MR. KOWALCYK: I think so. You know, I
5 think that maybe we need to have language in here to
6 say subcommittee will report to the full Committee.
7 The full Committee can be included in the subcommittee
8 meetings.

9 As far as the regularity of when they
10 meet, I don't know, maybe I would look to the Agency
11 to spell that out, to set some type of initial time
12 line, and then to see if that would work for the
13 subcommittee members, whoever they may be.

14 DEPUTY DIRECTOR TYNAN: I think that's the
15 question we have on the table, is sort of the options
16 for organizing that subcommittee.

17 Ms. Eskin, you had a comment?

18 MS. ESKIN: Or, maybe it's a proposed
19 language to get to one issue, which is in terms of the
20 make-up of the subcommittee, that first bullet, an
21 NACMPI subcommittee representing all stakeholder
22 groups, I mean, again, the way the full Committee is

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1 organized it's supposed to represent all stakeholder
2 groups.

3 DEPUTY DIRECTOR TYNAN: Yes.

4 MS. ESKIN: So, that is -- that captures at
5 least the idea that it be representative. I don't
6 know if we want to be more specific. I don't think we
7 should be, should it be six people, should it be ten
8 people? I mean, the group as a whole is 16, so but I
9 think that may at least get us part of the way.

10 DEPUTY DIRECTOR TYNAN: Mr. Schad?

11 MR. SCHAD: Yeah, this doesn't get to
12 actually naming names on the subcommittee, but in the
13 opening remarks yesterday there was analogies as far
14 as legs on a milk stool, or pillars of buildings, and
15 those consisted of three stakeholder groups,
16 consumers, and industry, and FSIS, and I think that
17 would be a good starting point, as far as the make-up
18 of the committee, and I believe it has to be
19 definitely smaller than this Committee to get anything
20 done.

21 DEPUTY DIRECTOR TYNAN: Dr. Leech?

22 DR. LEECH: I was going to suggest that you

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1 could start with volunteers who are interested, but
2 make sure that each of the major groups that compose
3 this committee have a chance to -- are represented,
4 and then that as the group works, you know, through e-
5 mail, or regular updates, that people are aware of
6 what's going on, so that not just the people who are
7 on the subcommittee consult folks, but that people who
8 have concerns have an idea of what's going on on an
9 ongoing basis and can submit things if they want to do
10 that to the group.

11 DEPUTY DIRECTOR TYNAN: Just asking a
12 process question, if we had volunteers, and going back
13 to the idea of having equal sort of a representative
14 group, but a small group, if we had four volunteers
15 from the academic side and no volunteers from other
16 places, how would you propose the Agency --

17 DR. LEECH: I think what we'd need to do
18 then is try to seek some others, but start with
19 volunteers.

20 DEPUTY DIRECTOR TYNAN: Okay.

21 DR. LEECH: And then, go and seek to make
22 sure, but do make sure that all the groups are.

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1 DEPUTY DIRECTOR TYNAN: So, initially, it
2 would be volunteers, and the Agency would be making
3 its selections from the volunteers, is that agreeable?

4 Is that what we are suggesting?

5 DR. LEECH: Or, we could suggest someone
6 from this group to work with the Agency to help make
7 sure, since we don't have a chair or anything like
8 that, you know, maybe the two chairs of our subgroups
9 for this time could do it or something, I don't know,
10 but so that there was some input from this group.

11 DEPUTY DIRECTOR TYNAN: Dr. Hollingsworth?

12 DR. HOLLINGSWORTH: I think Mark had a good
13 idea, as far as the three major kinds of groups we
14 need to cover. However, since the subcommittee is
15 working with FSIS, that piece of it is already taken
16 care of.

17 So, I think what the subcommittee needs to
18 have is representation of the consumer group and the
19 industry.

20 The other thing I would throw out, just
21 for a thought, is does the person who is on the
22 subcommittee have to be a member of this Committee or

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1 could they be a designate? In other words, people
2 like, say, Charles and Mark, may not have the time and
3 the wherewithal because of their real jobs to be the
4 subcommittee representative of the industry, but,
5 perhaps, they would want to designate someone, say,
6 from their trade association or someone who represents
7 them.

8 I don't know if that's going to create
9 discomfort on the Committee, but I think we also have
10 to be realistic that it's going to be a lot easier for
11 somebody who is here in D.C., able to come over and
12 meet with the Agency on a regular basis, and have the
13 time to put into it to do a good job.

14 So, I fear that maybe if we limit
15 ourselves we may end up having a committee that's
16 somewhat dysfunctional, because of other commitments
17 and distance.

18 Just a thought.

19 DEPUTY DIRECTOR TYNAN: Mr. Elfering, I saw
20 you reaching for your card, and you changed your mind.

21 MR. ELFERING: I think that, really, FSIS
22 should look at this group, and they should at least

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1 identify who they would feel would be most appropriate
2 first, and then offer that position, and you are going
3 to have to just go through the process of elimination,
4 to make sure that every group is represented.

5 I think you are going to have to identify
6 who you think is going to be the most appropriate as
7 well.

8 DR. HOLLINGSWORTH: Can I just --

9 DEPUTY DIRECTOR TYNAN: Yes, Dr.
10 Hollingsworth.

11 DR. HOLLINGSWORTH: -- I just want to
12 correct something I said, I made a big blunder, I just
13 realized, when I said that the Committee only needs to
14 contribute industry and consumers, that's not true.
15 We also need the state. I guess what I was thinking
16 is, we don't need to appoint Federal FSIS
17 representatives, because we'll be working with FSIS,
18 but I didn't mean to exclude the state representation.

19 DEPUTY DIRECTOR TYNAN: And, we also have
20 the scientific and the academic community as well, so
21 we need to not forget Dr. Denton. I can see him sort
22 of fidgeting in his seat.

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1 Dr. Leech?

2 DR. LEECH: I guess I would think that it
3 doesn't have to be someone who could physically be in
4 Washington, because with the technology we have today
5 it may even be more useful for everybody to do
6 teleconferencing instead of even traveling across town
7 here.

8 So, I'm not sure that it needs to be
9 someone who is physically located here, just someone
10 who has the time and interest, and I would think we
11 ought to start with this group anyway.

12 DEPUTY DIRECTOR TYNAN: Okay.

13 Mr. Elfering?

14 MR. ELFERING: I would just like to offer
15 that we certainly could meet in Minneapolis in
16 January. That surely will make it a small group.

17 DEPUTY DIRECTOR TYNAN: Dr. Carpenter?

18 DR. CARPENTER: Help me out, gang. If you
19 look at the role of the Advisory Committee, as it's
20 listed here, and then you talk about the subcommittee
21 and FSIS, I'm wondering if we should have specific
22 language that says there's a need for mutual assent

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1 from the full Committee. Am I missing something
2 that's already stated, because, you know, we talk
3 about the subcommittee, and then FSIS, but I think the
4 members of the Committee want to make sure that --
5 it's understood?

6 DEPUTY DIRECTOR TYNAN: Yeah, I got the
7 impression from all the conversation that regardless
8 of how we configure the subcommittee that the full
9 Committee would have an opportunity to comment, to
10 weigh in, as the subcommittee proceeds.

11 Mr. Kowalcyk?

12 MR. KOWALCYK: I initially wanted to follow
13 up on Dr. Hollingsworth's comment about the idea of a
14 designate to take a place on this subcommittee.
15 Knowing from resources, time is limited, resources,
16 people running small businesses, people in their
17 careers, so it may be difficult to meet that
18 commitment, whatever that is, and I think we should
19 get that guidance from FSIS as to what your
20 expectations would be of this subcommittee, and then
21 possibly opening up the designates to maybe past
22 committee members who would be eligible, because to

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1 Jill's point, if the meetings were going to be on,
2 say, Washington, D.C., that could become an issue for
3 several Committee members to come here more than twice
4 or three times a year.

5 And then to Kevin's point about FSIS
6 selecting the initial make-up of the committee, maybe
7 that should go to the full Committee, so that
8 everybody here is comfortable with what the make-up of
9 that membership is, so that we don't want to get too
10 far down the road where a particular group feels that
11 they are getting the short end of the stick in this
12 process.

13 DEPUTY DIRECTOR TYNAN: Okay.

14 Could I propose this? I think I heard
15 actually two options maybe that could work together.
16 If we initially after the meeting sent out a note to
17 everyone and suggested volunteers, then if we get an
18 over abundance of academicians, perhaps, then we'll
19 make those final selections.

20 If by good fortune we have one person
21 volunteer from each group, then we are covered, so
22 there won't be any further selection, but then,

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1 ultimately, the Agency will make the final selections
2 from the volunteers.

3 Is that satisfactory, and we will come
4 back and let everybody know how we decide, is that
5 satisfactory?

6 DR. HOLLINGSWORTH: Jill Hollingsworth.
7 Will the volunteers have to be current members of this
8 Committee, or will you be looking to the Committee to
9 recommend other names of people who we think would be
10 well to work on this project?

11 I mean, I'm also wondering if we are
12 looking at NACMPI will designate or nominate a
13 subcommittee versus actually becoming a subcommittee.

14 DEPUTY DIRECTOR TYNAN: My only -- oh, I'm
15 sorry.

16 CHAIR MASTERS: This is Barb Masters.

17 Because of our Advisory Committee laws, I
18 think that if we are dealing with a subcommittee we
19 need to deal with a subcommittee of this Advisory
20 Committee to keep from having to deal with the
21 Advisory Committee laws.

22 And so, I think we'd like to start with a

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1 subcommittee of this Advisory Committee to allow us to
2 move forward very quickly.

3 To answer Mr. Kowalcyk's question, I
4 believe Dr. Leech has got a good idea, and I think we
5 can make a lot of progress working through the
6 technology that we have, web casting,
7 teleconferencing, those sorts of things, and only
8 having to bring folks together when it's absolutely
9 necessary.

10 You know, I think if we met in Minneapolis
11 and did it in January, that would weed out who is
12 really interested in the topic, but I think there's a
13 lot of ways that we could move forward and have
14 progress through E-meetings, teleconferences, those
15 sorts of things, and only getting together when it's
16 absolutely essential.

17 But, not that I'm opposed to having others
18 involved, but you get into advisory committee laws and
19 those sorts of things, when you've moved beyond this
20 actual Committee.

21 DEPUTY DIRECTOR TYNAN: We have several
22 people from that northern tier, so we may get

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1 volunteers out of, you know, North Dakota, it snows in
2 all those areas, as I recall.

3 Okay, so we'll -- just to clarify -- I'm
4 sorry, Dr. Harris.

5 DR. HARRIS: Just one question about the
6 process. How many are we anticipating on the
7 subcommittee? We should probably define how big the
8 subcommittee should be. And, it doesn't have to be a
9 specific number, maybe a range even, you know.

10 DEPUTY DIRECTOR TYNAN: Dr. Raymond, you
11 had a comment?

12 DR. HARRIS: I'll offer four to six as a
13 suggestion, or four to eight. Eight would be more than
14 half of the Committee at eight, and four is almost too
15 small to do anything.

16 DEPUTY DIRECTOR TYNAN: Is that agreeable,
17 four to six? Okay. Then we'll send a note out asking
18 for four to six volunteers for the Committee, and then
19 we'll make decisions based on the volunteers. Is that
20 agreeable to everybody?

21 And then, as I say, we'll come back to the
22 full Committee and let everybody know what the

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1 decisions are.

2 So, do we need to include that in the
3 recommendations that we have here in the report?

4 Fine, then I think let's go back to the
5 report again, is there any last comments regarding --
6 are there any last comments regarding the report, or
7 are we at a point where we have full consensus? Is
8 there an agreement, yes? Okay, fine.

9 Number five is done.

10 I would propose, after all that hard work,
11 that we take a break, and we'll make it, I have 11
12 after, could we come back by 25 after, promptly?

13 Thank you.

14 DR. RAYMOND: Robert, I have to leave at
15 10:30 to go give a talk, so in the two minutes before
16 you adjourn I just want to thank the Committee for
17 your hard work last night, this morning, it was really
18 refreshing coming in early this morning and seeing a
19 group out there working. I know you worked at the
20 hotel.

21 I may or may not make it back, I probably
22 won't make it back today, so not that I don't care,

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1 but I've just got some other issues, but I do thank
2 you. This was a very -- this helped me a lot, this
3 conversation today helped me a lot, and it gives me a
4 lot of good stuff.

5 And, Barb, I know, feels exactly the same
6 way, it gives us some direction, and I think hopes
7 bring it up front that we are going to be as inclusive
8 and transparent as we can be. There's already an
9 article that was written by a reporter yesterday that
10 I would take some disagreement with, it says we are
11 going to move towards a risk-based system, we have to
12 have that done in three years. And, I tell you, we
13 are already doing risk-based, we want -- as I said
14 three times yesterday in my speech, a more robust
15 risk-based system, and there is not an end point. It
16 is a journey, I don't know where the end is. I'll be
17 done some day, I'll be leaving, Barb, hopefully, will
18 still be here, but there will be -- there will still
19 be work for this Committee to do on risk-based. I
20 don't think it ever ends, things change, and the
21 issues change, and we are going to continue to need
22 your help and advice.

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1 So, for this two days thank you, I'm sorry
2 I have to leave, but thank you for your work. It
3 really has been helpful.

4 DR. HOLLINGSWORTH: I wonder if I could ask
5 you a question, Dr. Raymond.

6 Yesterday you commented that you had some
7 thoughts on the different kind of groups that we
8 consider for who potentially should be the third
9 party, including the NAS. I'm wondering if you would
10 be interested in sharing any of your thoughts on that,
11 so that this group has your input on how you see a
12 third party, or what you would like to see a third
13 party do.

14 DR. RAYMOND: Help me with the definition
15 of the third party, I'm sorry.

16 DR. HOLLINGSWORTH: It would be the group
17 that's either the NAS, the National Academy of
18 Sciences --

19 DR. RAYMOND: Oh, I'm sorry, yes, okay,
20 well, the NAS was something I had not thought about,
21 quite frankly. I mean, that was another thing that
22 just opened up a whole lot, so I don't know. I'm

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1 going to have to go home and digest all this.

2 NAS, seriously, I was in the back of the
3 room most of that time listening, and NAS,
4 historically, I think a lot of the comments that were
5 made were right on, they are an excellent
6 organization. They are almost beyond reproach, but
7 they sometimes do not give you the stuff you need to
8 move forward. It's a great fact-finding,
9 scientifically-driven, and there are people who work
10 with them a lot more than I have that I won't forget,
11 I'll have to listen to some people, and I'm sure there
12 are some private for profit entities out there that do
13 wonderful work, and that the Agency has probably
14 worked with in the past, maybe some of you. And
15 again, I don't know who those entities are. A
16 university consortium, I think, is a wonderful idea.

17 You know, there's some things that Barb
18 mentioned, I think she explained it very clearly to
19 you, there's some -- and I'm not sure the Federal
20 Government as compared to the state government, but
21 when I was working for the state if we did any
22 intergovernmental transfer of funds we could do it in

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1 a heart beat, but if we went to an outside entity it
2 took three to six months because of the RFP process.

3 And so, that's, obviously, an issue also
4 that I think we do need to look at as an agency,
5 because I don't want to wait six months for an RFP, 18
6 months for a report, six months for this Advisory
7 Committee, I'm back in Nebraska. I mean, so we will
8 take all those things into consideration. I do not
9 know what the third party will look like, and I'm not
10 going to lean one way or the other today. I think it
11 was a good conversation, and there's a lot of things
12 we need to follow up, probably very quickly.

13 DEPUTY DIRECTOR TYNAN: I've changed my
14 times, let's make it 10:30, and thank you, Dr.
15 Raymond.

16 (Whereupon, at 10:13 a.m., a recess until
17 10:43 a.m.)

18 DEPUTY DIRECTOR TYNAN: Do we have a
19 quorum? We are still missing a few.

20 Okay, we'll get started, they'll just miss
21 the discussion.

22 We have Subcommittee 1, and we are going

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1 to do that next, and I believe a couple of the
2 Committee members have plane flights, so I'm going to,
3 as Dr. Raymond did, thank everybody at this point, so
4 in case anybody gets up and leaves in the middle at
5 least I will have told them how much we appreciate the
6 work and the effort for this meeting. So, I
7 appreciate it very much, and with that, I'm going to
8 turn it over to the Chairperson for Committee No. 1,
9 which I believe is Mr. Kowalczyk.

10 MR. KOWALCYK: Yes, thank you.

11 This subcommittee, I feel, worked quite
12 diligently addressing these issues, pertaining to the
13 table and Mr. Derfler's presentation yesterday, and
14 beginning to address the eight aspects of the
15 inspection that were listed in the briefing papers,
16 and how they specifically pertain to inspection.

17 We had a lively discussion, a lot of good
18 ideas were shared. We were assisted by FSIS
19 personnel, Casey recorded our minutes, and Bee took
20 notes during our meeting. They did a great job.

21 Dr. Masters and Dr. Raymond also
22 participated in this meeting, as did John Engeljohn

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1 and Mary Cutshall, and their input was greatly
2 appreciated.

3 The first aspect is the deployment of
4 resources, and the questions we were given were, what
5 do we think of the four factors that were highlighted
6 in the using risk-based approach table, and I'm sure
7 everybody has a copy of that. I'll go through those
8 four aspects quickly, so that everybody can see where
9 they are, and that it's on the record.

10 The hazards presented by type of product
11 and production process, consideration of how likely it
12 is that hazard will be manifested in a plant,
13 significance of effects of hazard if realized, and
14 ongoing assessment of establishments, food safety
15 system, including interventions and testing.

16 In our report, and in looking over these
17 aspects, the subcommittee agrees that these four
18 issues are appropriate elements to consider in the
19 deployment of resources in a risk-based system.

20 However, FSIS should evaluate each
21 proposed element to specifically address how each
22 would be incorporated in a resource deployment plan.

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1 We felt that, generally, these were very good elements
2 to include, but specifically how could they be applied
3 to a risk-based system.

4 The primary focus of resource deployment
5 should be on the reduction or elimination of public
6 health threats that are most likely to occur. So, we
7 felt that that should be the primary focus of resource
8 deployment.

9 The second point led to our comments in
10 the second paragraph, that consideration of the
11 likelihood of various hazards to occur is an important
12 factor in determining resource deployment. While this
13 seems to capture the intent of a risk-based approach,
14 this element appears to be too broad. FSIS should
15 conduct analysis to specifically determine what data
16 would best support the determination of the likelihood
17 of a hazard to occur. In other words, we are asking
18 the Agency to conduct analysis in order to determine
19 what data, and I know this may step into the other
20 subcommittee's turf, but what data would best support
21 that determination.

22 Through that, gaps in data need to be

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1 identified, as well as an evaluation of currently
2 available data, and the appropriate use of this data
3 in allocating resources.

4 Getting back to the stated elements, we
5 felt that the Agency should undertake the following.
6 The Agency should review the impact of various
7 processes and technology have on risk. There was a
8 discussion among us about different types of plants
9 have different risks, and a good example was brought
10 up is a very manually intensive plant, where it's a
11 small operation where maybe they slaughter one animal
12 and a week and it's all done by hand, versus a large,
13 highly-automated plant. We felt that the Agency
14 should keep an eye on those processes to determine
15 what differences there are pertaining to hazards.

16 FSIS should evaluate current research
17 regarding the likelihood of various hazards to occur,
18 and how variables such as product, processing,
19 species, historical plant performance, as well as
20 seasonality, impact risk. An example would be higher
21 prevalence of E. Coli 0157h7 during summer months.

22 And, we felt that an evaluation -- there

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1 is quite a bit of research that has been done in those
2 fields, so an evaluation of the current research would
3 be useful.

4 Also, do evaluate which hazards would have
5 the most significant impact on public health.
6 Basically, put resources towards the hazards that are
7 most detrimental to the public safety and health.
8 Obviously, severity of effect should be considered.

9 The final element, which would be the
10 ongoing assessment of establishment's good safety
11 system could help FSIS focus resources where they are
12 needed. Through testing and continuous evaluation of
13 intervention processes, FSIS may be able to more
14 effectively allocate resources to address food safety
15 problems proactively.

16 The Agency should review its data and
17 processes as they relate to resource allocation and
18 current HACCP system.

19 Again, there was discussion among the
20 subcommittee about industry adopting HACCP, and the
21 Agency evaluating those processes, and how resource
22 allocation with respect to an inspection can be best

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1 adapted to monitor under the environment of HACCP.

2 I guess that's issue one, if the Committee
3 has comments or other subcommittee members have
4 comments they'd like to add, that would be great, and
5 then we can address those and then move on to question
6 2.

7 Anybody from the subcommittee have
8 anything to add?

9 Mark?

10 MR. SCHAD: Yeah, I just wanted to comment,
11 we were talking about the small -- very small plants
12 being manually, versus the large automated plants,
13 that's not necessarily meant that manually intensive
14 was a bad thing, it can in very many cases be a good
15 thing, less chances of hazards occurring.

16 MR. KOWALCYK: Right, I think that comment
17 is well taken. I don't think -- I think in the spirit
18 of our meeting was, there's just different needs. I
19 mean, your plant, versus a large plant in Indiana
20 somewhere, I mean, your issues, your day-to-day issues
21 are much different than theirs. You know your
22 employees very well, you are almost like family,

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1 whereas, some of the larger plants have higher
2 turnover. So, there's different issues, so I think
3 it's not more that one is riskier than the other, I
4 would argue that it's just different needs.

5 Dr. Harris?

6 DR. HARRIS: I guess very similarly, I had
7 sort of focused on a little different sentence, but it
8 is almost a similar issue. Look in the last paragraph
9 where it talked about continuous evaluation of
10 intervention processes, I would be more interested, I
11 think, in outcomes than processes. You know, is the
12 product that comes out the other end safe or less safe
13 or whatever, so I guess I was a little curious as to
14 what was specifically meant by continuous evaluation
15 of intervention processes, when you guys were talking
16 about it, what were you referring to in that?

17 MR. KOWALCYK: Well, I think that we did
18 focus pretty much on processes, as to where, looking
19 at different plants, and their activities, and where
20 the Agency may benefit from a reallocation of
21 resources based on what interventions are there.

22 I would agree that maybe the addition of

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1 also outcomes, based on testing, would be another
2 thing that is important and should be looked at. So,
3 I would have no problems with adding that to the
4 language.

5 MR. LINK: I think -- this is Charles, just
6 real quick, we also addressed in the work to be done,
7 and actually talking about interventions and sharing
8 best practices, the focus was really on the outcome,
9 not so much the what are you doing, what's happening
10 with it. So, maybe we do need to change some of the
11 language there.

12 MR. FINNEGAN: Our thought process here was
13 even FSIS actually use the HACCP analysis to determine
14 the hazards, where plants are using HACCP hazard
15 analysis, that we as an agency would use that same
16 thought process to determine the true hazards, and
17 keeping in mind the very small plants, like Michael
18 had reiterated, that the hazards are different, not
19 talking about that they are riskier, but it's just a
20 different process.

21 We have small plants that make everything,
22 I mean, they slaughter, they grind, they beef jerky,

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1 they have to do it all.

2 MR. KOWALCYK: Is there a language change
3 that we are proposing?

4 Mr. Govro?

5 MR. GOVRO: Would it suit both your needs
6 to say through testing and continuous evaluation of
7 the effectiveness of interventions, that gets to to
8 outcome.

9 MR. FINNEGAN: Yeah, I would be
10 comfortable with that.

11 DEPUTY DIRECTOR TYNAN: Does that work for
12 the group?

13 MR. KOWALCYK: Are we comfortable with the
14 last sentence?

15 MR. LINK: To get to -- I'm drawing a
16 blank, I apologize, that last statement, maybe --

17 DEPUTY DIRECTOR TYNAN: Shall we go back
18 around the room and introduce ourselves?

19 MR. LINK: -- just having a moment here.
20 The Agency should review its data and processes as
21 they relate to resource allocation, utilizing the
22 HACCP approach. Is that what we are trying to get to?

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1 MR. KOWALCYK: Mr. Elfering?

2 MR. ELFERING: Just to maybe add a little
3 bit to that is, using the HACCP approach, we could
4 actually conduct a hazard analysis, based on -- and
5 that would be establishing the risk of the facilities,
6 you would establish your critical control points, and
7 then that would be intensified inspection. The
8 critical limits would be making sure that those
9 inspections are met on a higher frequency or on a
10 higher priority. Providing corrective action is by
11 reassigning inspection responsibilities, if you have
12 to have corrective action. Record keeping you have
13 already with PBIS, and validation could be reduction
14 of food-borne illness.

15 So, in other words, we would have FSIS
16 embrace HACCP, as they would want the industry to
17 embrace it.

18 MR. KOWALCYK: Would you recommend that we
19 add that to our recommendation? How did you want to
20 word that in here, or do you think this is sufficient?

21 MR. ELFERING: I think it's sufficient,
22 otherwise it will get rather wordy. I think just

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1 using the HACCP approach to do risk analysis.

2 DEPUTY DIRECTOR TYNAN: You were simply
3 explaining the implications of that statement.

4 MR. ELFERING: Yes.

5 DEPUTY DIRECTOR TYNAN: Dr. Harris?

6 DR. HARRIS: Just to nitpick a little bit,
7 would you guys be opposed to using the word, the term
8 HACCP-like approach? I mean, I don't usually think of
9 HACCP for resource allocation. I mean, it's sort of
10 semantic, but at the same time HACCP really is
11 designed to control specific hazards, and I think the
12 resource allocation, if we called it a HACCP-like
13 approach, we would sort of convey the message, but
14 it's really not HACCP.

15 MR. ELFERING: We could maybe even just put
16 using the concepts of HACCP, something that we kind of
17 do already with the livestock industry, they really
18 can't apply HACCP, but they can apply those
19 principles.

20 MR. KOWALCYK: So, we would want to change
21 that to utilizing a HACCP-like approach.

22 DEPUTY DIRECTOR TYNAN: Or, concepts of

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1 HACCP.

2 MR. KOWALCYK: HACCP concepts, okay.

3 DEPUTY DIRECTOR TYNAN: And, Mr. Finnegan,
4 you had a comment?

5 MR. FINNEGAN: Yeah, just to back up what
6 Kevin said, to me that's a fair way to do something,
7 using the HACCP principles, HACCP approach, it would
8 be more fair between the very small and the large
9 plants.

10 DEPUTY DIRECTOR TYNAN: Dr. Hollingsworth?

11 DR. HOLLINGSWORTH: The only thing I was
12 going to add there is that, actually, HACCP is a risk-
13 based approach, and maybe taking HACCP out and going
14 back to a risk approach is more inclusive. If it said
15 that, you know, use the -- review data and process as
16 they relate resource allocation, and use basic risk --
17 or, use risk principles, a risk-based approach.

18 I think that there are other risk-based
19 approaches, particularly in areas like food defense
20 and all, that are used that are not HACCP. So, maybe
21 it's almost too confining to exclusively limit it to
22 HACCP, as opposed to the whole spectrum of risk

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1 approaches.

2 MR. KOWALCYK: So, that would lead us to
3 changing the wording to utilizing a risk-based
4 approach.

5 DR. HOLLINGSWORTH: Yes.

6 MR. KOWALCYK: Risk analysis.

7 Okay, any other comments on the first
8 issue?

9 CHAIR MASTERS: This is Barb Masters.

10 If you go back up, I have a question for
11 the subcommittee on at the top of your -- going back
12 up, going down a little bit, on the data part. You
13 say gaps in data need to be identified as well as the
14 evaluation of currently available data and the
15 appropriate use of this data, and allocating
16 resources. Are you being all inclusive of data,
17 including FSIS data, as well as industry data, as well
18 as research data, or was that intended to be specific
19 to a certain type of data?

20 MR. KOWALCYK: I would say initially it
21 would be FSIS data, that, you know, what data does
22 FSIS have that can guide this approach, and then by

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1 identifying those gaps then the Agency could find,
2 okay, well maybe there is some level of data outside
3 of what the Agency is currently collecting, either
4 another entity is collecting, or the Agency would make
5 the case for collecting that data to fill in those
6 gaps.

7 DR. CARPENTER: Dr. Masters, Subcommittee 2
8 is looking at data, we will elaborate on that further.

9 CHAIR MASTERS: Is there any changes we
10 could make, I think it's important to identify that in
11 your report so we understand what the intent of that
12 bullet was. Does that capture what you are looking
13 at, Michael, or is there anything you could say, say
14 once we've identified our own gaps that we would look
15 to other sources of data, or -- I just want to be
16 really clear on what the recommendation is here.

17 MR. KOWALCYK: Well, basically, the second
18 sentence to say, determine additional data needs to
19 meet -- to fulfill the goal of a risk-based inspection
20 system.

21 CHAIR MASTERS: Thank you.

22 MR. KOWALCYK: To determine additional data

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1 needs that would enable the Agency to implement a
2 risk-based inspection system.

3 Any other comments on issue one?

4 DEPUTY DIRECTOR TYNAN: Mr. Finnegan?

5 MR. FINNEGAN: Mike Finnegan.

6 Yeah, we had a lot of discussion, part of
7 the data would be the plants' data too that Dr.
8 Raymond was talking about collaborating with the plant
9 on a positive attitude, that they are willing to share
10 their data of sampling and so forth, that that would
11 also be included in our data there. We had quite a
12 discussion on that.

13 DEPUTY DIRECTOR TYNAN: There's no language
14 change, though, does this capture the ideas that you
15 have?

16 MR. FINNEGAN: I believe so. You know,
17 there's a lot of Parts 2 data, but that's one of them
18 that we discussed in detail.

19 DEPUTY DIRECTOR TYNAN: Okay.

20 MR. KOWALCYK: Okay, moving on to issue
21 two, work to be done. In Mr. Derfler's presentation,
22 work to be done under a risk-based approach, from the

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1 presentation it states, "Work will vary based on
2 evidence of risk. While there are basic procedures
3 that will need to be done with some regularity, the
4 system will be designed to be responsive to
5 inspectional findings through the use of the decision
6 criteria that will be designed to help inspectors."

7 The first question asked us by the
8 Committee, or by the Agency was, do you believe that
9 there are ways other than decision criteria to guide
10 inspectors as they perform their activities?

11 Our recommendation is to establish an
12 inspection system that is responsive to inspection
13 findings. The Agency seeks to apply decision
14 criteria, decision criteria for inspectors are
15 currently in the field for the one directive we
16 discussed with Dr. Engeljohn. The Agency states that
17 this methodology has been well received by inspection
18 personnel and believes it has been an effective tool.

19 The Committee recommends additional evaluation
20 regarding the effectiveness of the current decision
21 criteria process.

22 One thing that was discussed in our

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1 meetings was the flexibility, and we feel that this
2 process also needs to be flexible enough to
3 efficiently address changes in inspection
4 procedures/best practices. Some example of how
5 evaluation can be done through a review of the PBIS
6 system, that was brought up among the subcommittee.

7 There was some questions about better ways
8 to do so, and opportunities to investigate as part of
9 our recommendation. One would be to evaluate basic
10 inspection procedures and to define inspection in
11 today's environment, what is currently being done is
12 the essence of that.

13 To understand the industry's top food
14 safety practices, to identify current standards and
15 how inspection can improve upon those standards, and
16 we talked in our meeting about the top things that a
17 producer needs to do every day to assure that they are
18 producing safe product. What do they see as the top
19 priority, and we felt that the Agency needs to develop
20 a very firm understanding of what those are, and then
21 it could possibly help guide inspection activities to
22 focus on those things where maybe some plants are

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1 failing along those priorities.

2 Evaluation of current HACCP. HACCP work
3 assignments split to determine if efficiencies can be
4 gained in non-food safety procedures. This gets to
5 the traditional approach of the presentation, where
6 under HACCP assignments 70 percent of assigned
7 procedures are devoted to food safety, while the other
8 30 percent to other procedures designed to protect
9 consumers, OCP, other consumer protection.

10 We recommend evaluating that current split
11 to see if efficiencies can be gained with respect to
12 the non-food safety procedures.

13 Now, we talked about does it split 90/10,
14 or 85/15, we don't -- it doesn't seem like we have
15 enough information to make that determination, and
16 maybe that's something the Agency, through its
17 evaluations, could do.

18 Evaluate current practices to identify
19 opportunities to improve plant and inspector
20 collaboration, and that goes to the point discussions
21 of looking at the big picture of what is the plant
22 doing to assure safe product, and then some of the

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1 minor procedural things, such as whether it's a
2 signature on a document or initials on a document, you
3 know, where should the inspectors prioritize their
4 focus when in a plant.

5 And then finally, capture industry success
6 regarding food safety intervention. This is to
7 identify those in the Agency that are doing a good job
8 at inroad processes to prevent food that can be
9 contaminated from going into the food supply, and
10 helping engage with them in the development of best
11 practices aimed at improving public health.

12 Now, those were the two topics that we
13 were able to address in our time yesterday. We were
14 actually booted out of the room. So, the other issues
15 stated in Mr. Derfler's presentation are, obviously,
16 very important, and I'm not going to speak for the
17 subcommittee, but for myself, you know, should
18 probably come back in this forum or a forum like this
19 to be addressed at a later date.

20 Does anybody on the subcommittee have
21 anything to add?

22 Charles?

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1 MR. LINK: Yeah, thanks.

2 We were kind of word smithing this thing
3 at the very last minute, and a couple of the notes
4 I've got didn't necessarily get transferred up here,
5 so I want to go back up to the second bullet point. I
6 think what we discussed there was to change that, to
7 understand the industry's top food safety practices to
8 identify current standards utilized to improve public
9 health. The intent behind that I think was for the
10 Agency to understand that we had discussions, what are
11 the top ten or top 20 things that we do as an industry
12 to ensure that we are producing safe food, that, you
13 know, if we had to choose what are the five things we
14 wouldn't do today, from the ten that we would do, to
15 make sure we don't have a problem. So, that was the
16 intent behind that, understanding what our top food
17 safety practices are, but to brief public health.

18 Is that fair to say?

19 And then the other comment I had down was,
20 in the next bullet point where we are talking about
21 gained in non-food, was to really spell out, I guess,
22 in food safety versus other consumer protection

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1 concerns, issues, as opposed to non-food safety.

2 DEPUTY DIRECTOR TYNAN: Charles, how would
3 you propose then to change that?

4 MR. LINK: Split determining efficiencies
5 to be gained in Agency focus on food safety versus
6 other consumer protection concerns, issues.

7 DEPUTY DIRECTOR TYNAN: You want it to say
8 on food safety versus other consumer protection
9 concerns?

10 MR. LINK: That's what we were talking
11 about trying to identify that currently 70/30, should
12 it be 90/10 or whatever, I guess that was what we were
13 trying to get to. And right above that it says --
14 just take out that word other, just before food. No,
15 the other other.

16 DEPUTY DIRECTOR TYNAN: Too many others.

17 Does that capture your thinking, Charles?

18 MR. LINK: I think so. I think it
19 clarifies that bullet even more.

20 DEPUTY DIRECTOR TYNAN: Mr. Finnegan?

21 MR. FINNEGAN: I wonder if we should even
22 clarify it farther, so somebody that is reading this

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1 knows that we are talking about the word safety split,
2 what we are talking there is the 70 percent food
3 safety and 30 percent other procedures.

4 MR. KOWALCYK: Do you want to put that in
5 parentheses after split?

6 MR. FINNEGAN: In parentheses after split,
7 just to define so that anybody who reads this knows
8 what we are talking about, after split, 30 percent --
9 or, 70 percent food safety, 30 percent other
10 procedures.

11 MR. KOWALCYK: Okay.

12 Dr. Harris?

13 DR. HARRIS: A couple of questions. One of
14 them is already on the screen so I'll start with that
15 one, back to that second bullet point again. What do
16 we know about the linkage between food safety
17 practices and improvement in public health? That's
18 one we got into, talking about in our data session
19 last night, is the difficulty we have in tying a
20 specific practice to a specific improvement in public
21 health. So, I guess my question there is, how do we
22 get to where we understand how those particular food

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1 safety practices are impacting public health. I don't
2 really have a suggested improved language, or, you
3 know, change in the language here, I just question if
4 that's really, you know, how we get there.

5 And, the other one I had, and we can talk
6 about that one first if you want and then I'll point
7 out the other one, or just -- we need to look at
8 another section, since I don't have a copy of that in
9 front of me, but as we went over it I wanted to look
10 back.

11 DEPUTY DIRECTOR TYNAN: Your issue there
12 is, is there a linkage between best practices and food
13 safety gains, is that -- do I understand?

14 DR. HARRIS: Well, my point is, I'm not
15 sure that we know the linkage between any particular
16 food safety practices and how they impact public
17 health. Intuitively, obviously, we think they do, and
18 believe they do. My question there is, how is the
19 Agency going to understand that? We are recommending
20 that the Agency try to understand it, how would they
21 go about that?

22 DEPUTY DIRECTOR TYNAN: All right.

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1 MR. KOWALCYK: I think that gets to the
2 heart of the matter, actually, is being able to
3 identify, through food attribution and data of the
4 like, to identify, these interventions are ultimately
5 effective, and that is a gigantic data issue.

6 DR. HARRIS: I guess the point is, I don't
7 want to just imply that because a particular entity, a
8 particular company, has a lot of cool practices that
9 automatically that's an improvement in public health.

10 MR. KOWALCYK: Sure.

11 DR. HARRIS: Without data to support that.

12 MR. LINK: Can we -- this is Charles -- can
13 we change it to say something along the lines of,
14 current standards utilized to ensure the production of
15 safe food?

16 DR. HARRIS: That I think would be a more
17 direct approach.

18 DEPUTY DIRECTOR TYNAN: Could you say that
19 again, Charles?

20 MR. LINK: To ensure the production of safe
21 food, safe food.

22 DEPUTY DIRECTOR TYNAN: Is that consistent

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1 with your thinking, Michael?

2 MR. KOWALCYK: I believe so.

3 DR. HARRIS: The other one I just wanted to
4 look at again, because I may have a question about it,
5 scroll up to the little section where it made
6 reference to PBIS -- there it is, evaluation, I just
7 want to reread that sentence.

8 Is the subcommittee suggesting that the
9 Agency evaluate their PBIS system and how it could be
10 improved, or is it suggesting that it should mine the
11 current system for data? When I see the word review,
12 I'm curious as to whether you meant review whether or
13 not the PBIS system should be changed on what data it
14 collects, or are you just suggesting that the data be
15 pulled out of the PBIS system?

16 MR. KOWALCYK: I think we were suggesting
17 the second, where utilizing that information to
18 determine if the decision criteria process was
19 effective, put some structure around, okay, the
20 decision criteria process has been received well so
21 far, is there other evidence to support that? So, it
22 was more of like mining into that data, rather than

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1 changing that system.

2 DR. HARRIS: Is that -- when we get into
3 the data discussion, we did have some discussion about
4 what data are available through the PBIS system, and
5 are those data capable of providing the kind of
6 information that would be useful.

7 DEPUTY DIRECTOR TYNAN: Is there a language
8 change, though, am I hearing the group say that there
9 is a language change for this particular sentence to
10 clarify that?

11 DR. HARRIS: I don't have any direct -- I
12 mean, I was just trying to get clarification on the
13 bullet.

14 MR. LINK: I'll recommend one, since I've
15 got to choose the word smithing.

16 DEPUTY DIRECTOR TYNAN: Mr. Link, would you
17 recommend one?

18 MR. LINK: Because we actually did use the
19 exact term "mining data," but maybe we should say
20 evaluation could be done to thoroughly understand the
21 data provided by the PBIS system, or should be done.

22 DEPUTY DIRECTOR TYNAN: Could you repeat

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1 that again for us?

2 MR. LINK: Evaluation could be done to
3 thoroughly understand the data provided through the
4 PBIS system, or a thorough review of the data, maybe
5 that's a better way to say it.

6 DEPUTY DIRECTOR TYNAN: Thorough review of
7 the data?

8 MR. LINK: Provided by or through the PBIS
9 system.

10 DEPUTY DIRECTOR TYNAN: Okay, thorough
11 review of the data, okay.

12 MR. LINK: Provided by the PBIS system.

13 DEPUTY DIRECTOR TYNAN: Of the data,
14 provided by the PBIS system.

15 MR. LINK: Just say, the evaluation could
16 include a thorough review of data, I would say, could
17 include.

18 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk, that
19 works for you?

20 MR. KOWALCYK: Yes.

21 DEPUTY DIRECTOR TYNAN: Okay.

22 MR. KOWALCYK: Any other comments from the

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1 subcommittee?

2 Mike?

3 MR. FINNEGAN: Mike Finnegan.

4 I'm just throwing you a saw here. I wonder
5 if we should clarify what we mean by data. You know,
6 data, you know, could include NRs, positive samples,
7 negative samples, the PBIS, the establishment's
8 records that they are willing to share with us on a
9 good faith basis. I'm just throwing that out, if we
10 need to clarify what we mean by data. It's a long
11 list.

12 DEPUTY DIRECTOR TYNAN: Perhaps we could
13 hold that thought until Dr. Carpenter's report. Would
14 that be something you'd want to address there? Okay.

15 Okay, so hold the thought. Good thought, just
16 timing. Timing is everything.

17 Any other questions?

18 Mr. Link, are you -- you know how we
19 respond to those things.

20 Are there other questions or thoughts?
21 So, we have consensus on the report as it is written?

22 Yes? Cool. Okay.

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1 CHAIR MASTERS: This is Barb Masters. I do
2 want to ask one question.

3 Mr. Kowalcyk raised the point that the
4 subcommittee felt it important for the rest of the
5 subcategories to be addressed, and does the
6 subcommittee want to capture that thought in their
7 report?

8 DEPUTY DIRECTOR TYNAN: Could you repeat
9 that?

10 CHAIR MASTERS: Mr. Kowalcyk raised the
11 point that the rest of the categories in the chart
12 should be addressed in some format. Does the
13 subcommittee want to address at least re bullets at
14 the bottom of the report that they would like the
15 opportunity in some format that the rest of those
16 questions should be addressed? Would they like that
17 in their report?

18 MR. KOWALCYK: I think it could be added.
19 I think we could also add that added with some more
20 specific examples and questions behind them. These
21 are very general questions.

22 So, I think if we had a little more

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1 structure we could tackle more of these within a
2 meeting, say the subcommittee feels that the
3 additional aspects should be addressed at a future
4 date -- feels the additional aspects of an inspection
5 need to be addressed at a later date, and that --
6 well, and that additional background information
7 should be provided by the Agency.

8 DEPUTY DIRECTOR TYNAN: So, will the
9 Committee put that to a vote? I think we still have
10 consensus, even with that addition. Okay.

11 Could I suggest before we begin
12 Subcommittee 2, in the interest -- I know it's warm in
13 here, seriously, we'll take no more than a ten-minute
14 break, that would put us at 25 til, and that will
15 allow some of the folks that may have to get to the
16 airport to successfully do that, and we'll come back,
17 that will give us time to get the next report up and
18 be ready for the Committee.

19 So, ten minutes max, please.

20 (Whereupon, at 11:25 a.m., a recess until
21 11:37 a.m.)

22 DEPUTY DIRECTOR TYNAN: We're going to

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1 address Subcommittee 2, and we are going to try and
2 get a copy for you so you'll have something before you
3 leave.

4 So, we are going to have Subcommittee No.
5 2, and I'm going to let Dr. Carpenter lead the
6 discussion now.

7 DR. CARPENTER: Thank you, Robert.

8 At the outset, I want to point out the
9 diligent efforts of the Committee members, which
10 included Andrea, Jill and Sandra, Gladys, Joe and
11 Michael. You notice first names aren't repeated much
12 until we get to Michael, and we have three on the
13 Committee, three Michaels. You know, we definitely
14 have our leader Barbara, only one Barbara, and, of
15 course, we have Robert, who is sure to implement and
16 enforce the FSIS addition of Robert's Rules of Order.

17 Thank you, Robert.

18 I think at the very outset, as we
19 initiated our discussion of risk-based data, and we
20 are going to have it on the screen eventually, right,
21 okay -- well, I should also point out that our
22 technical consultants included Philip Derfler and

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1 Bobby Palesano, I'm sorry, I'm going to crucify his
2 name, and also Dr. Arrington and Bryce Quick, and
3 members of the public also had comment.

4 At the outset, the committee concluded,
5 not with consensus, but unanimity, that the scope of
6 the challenge was well beyond our capabilities in the
7 time frame allocated to deal with it. The issues of
8 data for feeding into risk-based inspections is,
9 obviously, critical, very large, very complex, and
10 rather than addressing each of the issues that Mr.
11 Derfler outlined in the table we decided to address
12 the data universe, if you will, in a very concise,
13 succinct manner. Okay?

14 So, if we look at what is on the screen,
15 the subcommittee was charged with addressing a three-
16 part question, questions and answers are as follows.

17 Will data be appropriate for designing and
18 implementing RBIS? The asterisk is there at the
19 insistence of Jill, who made some significant inputs
20 just a little while ago to the edition that you see
21 before you, and so it's for the Committee members to
22 either embrace or to reject as we look at this

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1 expanded version.

2 Data needs cannot be identified exclusive
3 from the development of the RBIS. The design of the
4 RBIS will define data needs.

5 Going on with the three-part question,
6 part A, how should the Agency obtain the data? Agency
7 needs to consult with the relevant experts in order to
8 identify from within the universe of possible data the
9 data needed for a risk-based inspection system that
10 would improve public health. Emphasis on public
11 health data.

12 Once necessary data is identified through
13 the process set out in No. 1, the Agency then needs to
14 determine if any of the data that it already collects
15 falls within the identified data need. Agency should
16 consider posing questions, are there ways to make the
17 data collected by in plant inspectors more specific?
18 And, this particular one we are looking at reports
19 from inspectors that are codes associated with NRs et
20 cetera, and there just isn't enough specificity
21 associated with that.

22 The second bullet point, are there ways to

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1 correlate the various data sets that already exist?
2 In the discussion we talked about Dr. Masters'
3 referral to stove pipes, this being agriculture. Some
4 suggested really silos, but, you know, you know what I
5 mean, we need to integrate those data.

6 Point No. 3 under Part A, the Agency
7 should work with the industry to determine what data
8 is needed, what data is already available, and the
9 ways to collect and share the data. Proper assessment
10 should be done to ensure accuracy, consistency,
11 reliability.

12 Let's address just A, suggestions,
13 consensus, improvements. Silence is golden or what?

14 Michael?

15 MR. KOWALCYK: Michael Kowalcyk. Was there
16 any discussion regarding public health data? I think
17 one of the problems is, is that in a lot of cases the
18 food-borne illness victims don't know what made them
19 sick. There's really no good way to trace that to its
20 source. I mean, personally, I have a case where I
21 fall in one of those, and my family falls in one of
22 those, where we have evidence but we don't ultimately

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1 know.

2 As to discussion, was there any discussion
3 within the subcommittee about public health data, also
4 trace back, animal ID, things like that, was that
5 discussed in the subcommittee as a possible means for
6 developing data that would guide a risk-based system?

7 DR. CARPENTER: We discussed attribution
8 and the data -- go ahead, Sandy.

9 MS. ESKIN: I was going to say the same
10 thing, we discussed attribution and talked about
11 different types of data, but I think we intentionally
12 kept the description very general, in fear of,
13 perhaps, by specifically mentioning something,
14 perhaps, making people think other things weren't
15 there. I mean, if you think we need to be more
16 specific, then we can certainly look at more specific
17 language.

18 DR. CARPENTER: I think we didn't use the
19 word attribution, when you coin the phrase, the
20 universe of possible data, which would include public
21 health data that we would have to go to in order to
22 generate that which would answer those questions.

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1 MR. KOWALCYK: If we could add that
2 language, call that out public health data as an
3 example, including public health data.

4 MS. ESKIN: I think what Mike is saying,
5 under one it says, again, the Agency needs to consult
6 with the relevant experts in order to identify from
7 within the universe of possible data, we could put in
8 parentheses, including public health data.

9 MR. KOWALCYK: I think that's fine. I
10 think it should be in there just because it's a
11 separate source of data, so, I mean, ultimately, since
12 improving public health is the goal, okay, it's
13 different than actual data about public health.

14 DEPUTY DIRECTOR TYNAN: Other comments?

15 Michael, you had some comments on data
16 earlier that we asked you to sort of hold.

17 MR. FINNEGAN: Right, and I think Mike and
18 Sandra covered it, I just wonder if we should be more
19 specific what data is. You know, it is, it's the
20 universe of data, so that's satisfied.

21 DEPUTY DIRECTOR TYNAN: Okay, so you are
22 satisfied.

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1 DR. CARPENTER: All right, moving on to --
2 you are okay with No. 2, and 3 as stated here.

3 All right, scroll up to -- demonstrate all
4 of B -- thank you, is the Committee aware of the type
5 of data the establishments or other customers use to
6 identify emerging problems in an operation? How can
7 FSIS get access to this data, if it does not presently
8 have it?

9 The subcommittee is not familiar with data
10 used by establishments and other customers, and their
11 customers, to identify emerging food safety problems.

12 We urge the Agency to communicate directly with
13 industry representatives to learn about this data.
14 The Agency and industry should collaborate on
15 identifying data needs, data gaps, and best methods
16 for collecting and analyzing the data.

17 Response to B.

18 Mr. Elfering?

19 MR. ELFERING: I'm just wondering if you
20 would even want to consider putting something in there
21 encouraging FSIS to reach out to the state agencies
22 that have data, that they are not already getting. We

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1 do sampling all the time in retail establishments that
2 may or may not have -- most of them are going to have
3 some association with meat and poultry, and I think
4 that we would be very willing to share that data, even
5 with the PFGEs that we are doing Listeria and E. Coli
6 that may be of some value to the Agency.

7 DR. CARPENTER: So, the recommendation is
8 to insert to urge the Agency to communicate directly
9 with industry representatives and state
10 representatives? Oh, okay, thank you, and state
11 agencies, okay. Should stage agencies be repeated in
12 the next sentence? Is there a need there for that?

13 Sandra, yes, no? Is this satisfactory?

14 Mr. Elfering, does that capture the
15 essence?

16 DR. LOGUE: Just so I can clarify Kevin's
17 point, what kind of state data are you thinking of,
18 because I'm concerned about if you say something like
19 retail establishment meats, but how do you know that
20 contamination of whatever the hazard is didn't occur
21 there, as opposed to something back to a plant. So,
22 we have to be careful how we define that, I think.

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1 MR. ELFERING: I think one of the things
2 that we've really found valuable is, using molecular
3 subtyping, so that even if we would find a particular
4 species -- well, let's use *Listeria monocytogenes*, if
5 we find a particular subtype with that molecular
6 subtype in a delicatessen doing environmental samples,
7 and FSIS has the same molecular subtype that they have
8 obtained in a sample of product that they've maybe
9 sampled at a facility, it might be of some value to
10 just, what is actually what we are finding out there
11 as far as the different types of subtypes of *Listeria*,
12 similar to what's already being done on pulsenet.

13 DR. CARPENTER: And, to the question,
14 should greater specificity be outlined in this
15 response, recommendation?

16 DR. LOGUE: That's up to you, but I just
17 needed -- I just needed to clarify the type of data,
18 be careful how we use it, because maybe we end up
19 tracing something that didn't come from a plant, that
20 came from at the retail level. So, we just need to be
21 careful that we do that.

22 If we are trying to build an RBIS at the

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1 production level, my logic here, I'm just trying to
2 figure a way that we make sure that we don't end up
3 building it the wrong way.

4 MR. ELFERING: And, I think whenever we do
5 the surveys like this, if we are taking product
6 samples, we are always making, you know, we are
7 identifying whether they are considered to be an in-
8 tact or a non-in-tact sample, but let's just say that
9 we're finding persistent in an environment in a deli a
10 particular molecular subtype of Listeria, and they
11 have products that are coming from 20 different
12 facilities, and all of a sudden they have the same
13 molecular subtype on a particular product that they've
14 sampled, we might be able to correlate where that
15 contamination actually occurred. Did it come in from
16 a product into the retail establishment, or is it
17 something that's persistent in their environment?

18 MR. ELFERING: Well, as the characteristics
19 of the risk-based inspection process evolves, won't
20 that direct the kinds of data that would enhance the
21 development of that, so it will probably fall out as
22 we get more specificity in that process. Okay.

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1 Jill?

2 DR. HOLLINGSWORTH: I think, though, in
3 this particular section, Part B, the question was
4 specific to accessing industry data. I think, though,
5 Kevin's point is a good one, and maybe above it at the
6 end of point number -- where we had No. 3 right above
7 this.

8 DR. CARPENTER: It's part of A.

9 DR. HOLLINGSWORTH: Yeah, maybe there,
10 where No. 3 is there, we should add a 4 and say, other
11 sources of data including state agencies, federal
12 agencies, because that will capture the CDC thing, and
13 research data, published research data, should all be
14 taken into consideration, and then that sort of covers
15 everything.

16 DEPUTY DIRECTOR TYNAN: Dr. Denton?

17 DR. DENTON: Jill just stole my thunder.

18 DR. HOLLINGSWORTH: Thanks for the idea.

19 DR. DENTON: Include research institutions,
20 including academic, as well as other types of research
21 laboratories, there's a wealth of information out
22 there in the published literature.

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1 DR. CARPENTER: Okay, please give us
2 assurances that No. 4 captures all of those items.

3 Okay, members concur, that's No. 4, part
4 of A, that's appropriate?

5 MS. ESKIN: Sorry, if we put it up there,
6 are we going to take it out of the question?

7 DR. CARPENTER: We have to take it out of
8 the --

9 MS. ESKIN: We just put it -- state
10 agencies is in that recommendation in two places.

11 DR. CARPENTER: In the line above right
12 there.

13 MR. ELFERING: Just a point. You may want
14 to keep it in there, I mean, not exclusive to FSIS,
15 but state agencies are doing those work as well, and
16 they should be collaborating with the industry too, to
17 be getting information. So, I would say leave it in
18 there.

19 DEPUTY DIRECTOR TYNAN: On LaVonne's
20 behalf, how do we want to do that? Is the Committee
21 comfortable putting it back in? Okay. WE have a
22 winner on that one? All right. Moving right along.

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1 DR. CARPENTER: Moving on to C. If the
2 industry data is used, how does FSIS ensure data
3 quality? Recommendation, how to ensure the quality of
4 data will vary depending upon the type of data that is
5 at issue. The Agency can begin by looking at how it
6 ensures the quality of industry data that it currently
7 reviews.

8 Does it need to expand beyond this? Is
9 there a need to be more specific, prior data?

10 DEPUTY DIRECTOR TYNAN: Dr. Leech, you had
11 a comment?

12 DR. LEECH: Are there any ways to set some
13 standards for what needs to be done, left to the
14 scientists to make data be considered reliable, and
15 that you could say that you are looking at those? I
16 mean, I don't -- I know that you are saying look at
17 what you are doing now, but it sounds like we don't
18 have any idea of what encompasses what we would call
19 quality data. So, is there a way to -- and I don't
20 mean today, because I don't think there's any way to
21 do that at this point, but because that's something
22 that needs to be done in order to deal with this.

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1 We've sort of tried before, I think.

2 DEPUTY DIRECTOR TYNAN: Let me understand,
3 to give --

4 DR. LEECH: Maybe set some criteria for
5 what we'd like to know something is quality, in terms
6 of data.

7 DEPUTY DIRECTOR TYNAN: I'm sorry, comments
8 on that comment?

9 DR. LEECH: Yes.

10 DEPUTY DIRECTOR TYNAN: Okay, we'll start
11 with Mr. Govro.

12 MR. GOVRO: My feeling is that our answer
13 to the question is that we really can't answer the
14 question unless it's made more specifically. So, to go
15 into that subject now I think is premature.

16 DEPUTY DIRECTOR TYNAN: Ms. Eskin?

17 MS. ESKIN: And, building on what Mike just
18 said, again, I think the threshold response of the
19 subcommittee was, we are not the right people to be
20 able to set these criteria, but here's how we think
21 this should go. So, I think the intention down the
22 road is that certainly will be part of this whole

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1 process.

2 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk?

3 MR. KOWALCYK: Just to pile on that issue.

4 It was addressed in question 5 also, is people that
5 are data experts should be part of that group to
6 address that specific question.

7 DEPUTY DIRECTOR TYNAN: Mr. Link, you've
8 decided not to pile on?

9 MR. LINK: I think Michael covered it. I
10 guess the question is, who is really qualified, and we
11 ought to make sure we've got experts in the field to
12 make those calls.

13 DR. CARPENTER: All right, consensus on C
14 and its recommendations? Thank you.

15 That concludes Subcommittee 2's reports.

16 DEPUTY DIRECTOR TYNAN: Final chance for
17 comments before we go to the vote?

18 MR. LINK: I do have a question.

19 DEPUTY DIRECTOR TYNAN: Oh, I'm sorry.

20 MR. LINK: If we are going to go down the
21 road of maybe we ought to be relying on expert data --
22 experts, should we make that statement in here, that

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1 instead of the Agency needs to look at it, maybe the
2 Agency ought to defer to data analysis experts,
3 potentially, this third party that we talked about in
4 the Question 5.

5 DR. CARPENTER: Charles, how do you want to
6 word smith it?

7 MR. LINK: I don't know, I was just asking
8 the question, should we. So, if you agree that we
9 should review it, then we'll come up with language for
10 it.

11 DR. LOGUE: I'm inclined to agree with
12 Charles that we should say something here.

13 DEPUTY DIRECTOR TYNAN: Dr. Logue, I'm
14 sorry, I'm having trouble hearing.

15 DR. LOGUE: I'm inclined to agree that we
16 should say something here, because we've got to have a
17 criteria on what do we call quality data, and are you
18 anymore qualified as the Agency to select it versus
19 somebody else? So, we need to set that standard up,
20 if that's what you want.

21 DEPUTY DIRECTOR TYNAN: So, the
22 recommendation then would be to have someone develop

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1 that criteria that's qualified?

2 MS. ESKIN: Maybe we can answer that by
3 scrolling up maybe to the top of the second -- maybe
4 in that recommendation, the subcommittee is not
5 familiar with the data used, and if we scroll down,
6 maybe we could include some reference to that third
7 party study as being part of the process.

8 Again, I think our understanding is that
9 this third party process would give us recommendation
10 as far as designing a risk-based inspection system and
11 the data that's necessary. So, maybe we can say that
12 in fewer words right where the cursor is now. We
13 could say the subcommittee assumes that the third
14 party report would identify this data, and then maybe
15 add based on the report recommendations we would urge,
16 and then continue with it the way it is. Does that
17 capture what you are looking for?

18 MR. LINK: And then, maybe the very last
19 one would just refer back to the third party report to
20 help clarify the validity of the data, industry data,
21 quality of the data.

22 MS. ESKIN: So, the next recommendation,

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1 and you could just add at the end there, and can
2 consider the recommendations in the third party report
3 that address data quality issues or data assurance. I
4 don't know what the proper terminology is for the
5 quality.

6 DEPUTY DIRECTOR TYNAN: I'm sorry, Mr.
7 Kowalcyk, do you have another comment?

8 MR. KOWALCYK: Yeah, maybe a possible
9 addition to No. 4 up above, looking at sources of
10 data. Other countries that have implemented risk-
11 based systems, should we advise the Agency to look
12 into what data those countries utilized to facilitate
13 their risk-based system? I think New Zealand and
14 Canada come to mind. Maybe that data would be of some
15 use.

16 Now applying what they do versus how our
17 system works may be difficult, but just as another
18 source of information.

19 DR. CARPENTER: International.

20 MS. ESKIN: I don't think I'd use the
21 international, it really is comparative, in other
22 words, you are not looking at some international body,

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1 you are looking at other countries' systems. So,
2 rather than using that, and maybe data collected by
3 food safety agencies in other countries.

4 DEPUTY DIRECTOR TYNAN: Does that get to
5 your issue?

6 MR. KOWALCYK: Yeah, I think that's a good
7 addition.

8 DEPUTY DIRECTOR TYNAN: Dr. Leech, does
9 that sort of get to your issue as well? Okay.

10 MR. Finnegan?

11 MR. FINNEGAN: I just wanted to make one
12 comment. I like the word state agencies, because it's
13 all encompassing, because the local health departments
14 are also sampling, and I know they have available
15 data, and I just wanted to make that comment.

16 DEPUTY DIRECTOR TYNAN: Is there some
17 change that we need to make?

18 MR. FINNEGAN: No, no, I want to leave
19 state agencies, which includes also the local health
20 departments and they are sampling more and more of the
21 retail, which was Question 5 on our list.

22 DEPUTY DIRECTOR TYNAN: Okay.

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1 MR. FINNEGAN: So, I wanted to leave state
2 agencies.

3 DEPUTY DIRECTOR TYNAN: We want to be sure
4 that we get all your comments on the record. So, we
5 have a winner on No. 2, consensus yes?

6 Oh, I'm sorry.

7 CHAIR MASTERS: This is Barb Masters. Do
8 we want to put a comment at the bottom of this report
9 about being inclusive to the other sections of the
10 chart that are not considered, as we did with the
11 other reports? That would be a question to the
12 subcommittee chair.

13 DR. CARPENTER: Excellent suggestion. I
14 think we definitely have to address it to a base
15 inspection, cut and paste.

16 DEPUTY DIRECTOR TYNAN: We'll do that.

17 DR. CARPENTER: Okay.

18 DEPUTY DIRECTOR TYNAN: So, with that
19 addition, we have a winner, is that correct? Okay,
20 perfect. Okay.

21 I think we are done with the reports.
22 What I will propose to do is, we'll take these back,

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1 maybe do just a touch of editing, in terms of
2 grammatical, spelling, all that good stuff, no changes
3 in content or substance, and then I'll send that back
4 out to you when I send out the note regarding
5 volunteers, so that you can take one more look so if
6 there's any issues that we somehow may -- I don't
7 think we did, but if we put something in the wrong
8 place you can speak now or forever hold your peace.
9 So, I'll do that as well, give you one more
10 opportunity to take a look at it.

11 And, with that, I think I'll turn it back
12 over to Dr. Masters, maybe for the closing. We have a
13 couple of briefing papers.

14 CHAIR MASTERS: Okay, we have a couple
15 briefing papers and public comment.

16 So, as more of you make planes, I want to
17 thank everyone for their hard work. I think we've got
18 a lot of input. I know, particularly, we had a lot of
19 interest around Question 5, and I think we got a great
20 -- lot of substantive input there, and I think you
21 made a lot of progress on even the questions. So, I
22 appreciate all the work of the subcommittees and the

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1 Committee.

2 So, we will move to the updates and the
3 public comment, so we want to make sure we get to
4 those.

5 MS. ESKIN: May I ask that we do the public
6 comment first, because, obviously, I think it is
7 between the two people that need to be here.

8 CHAIR MASTERS: Absolutely, we will do
9 that, and then we'll get to the final briefings. So,
10 we will do that.

11 I just wanted to make sure I got the thank
12 you in for those of you that are running for the door
13 so I don't chase each of you to the door.

14 We will do that.

15 DEPUTY DIRECTOR TYNAN: So, should we do
16 the public comment?

17 CHAIR MASTERS: Yes.

18 DEPUTY DIRECTOR TYNAN: I don't have the
19 sign-up sheet with me, did anyone sign up for public
20 comment this morning?

21 Can I ask you to come up to the microphone
22 here, and please identify yourself and your

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1 organization. You can use that microphone right
2 there.

3 MS. NESTOR: Hi, I'm Felicia Nestor, and
4 I'm with Food and Water Watch. I just wanted to make
5 a comment about, there's been a lot of talk about
6 approaching a third party to assist with the work of
7 the Committee, and I wanted to talk about this report,
8 "Scientific Criteria To Ensure Safe Food," which is
9 the most recent report by NAS on these issues, and
10 point out, you know, there's quite a significant
11 mistake in this report, which I think provides a
12 cautionary note to how the procedure is going to
13 continue here.

14 In a chapter on FSIS, USDA inspection, and
15 in a section called, "Review of Current Standards for
16 Meat and Poultry," the section is talking about the
17 sampling frequency under the Agency's two cornerstone
18 scientific programs, generic E. coli sampling, and the
19 pathogen reduction salmonella sampling. Those two
20 programs are extremely different.

21 The generic E. coli is based on the volume
22 of production, the salmonella sampling is based on

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1 sample sets that are randomly assigned. Possibly a
2 plant will have a sample set each year.

3 So, in the report it says the sampling
4 frequency for the pathogen reduction standard for
5 salmonella is identical to that for the process
6 control indicator, which would be generic E. coli.

7 If you were in a large young cattle kill,
8 they would probably be doing about 80 generic E. coli
9 tests per week, whereas, if that plant was selected
10 for a random sampling on salmonella, it would get 80
11 salmonella tests per year.

12 So, as I said yesterday, I'm not a
13 scientist, but to me 80 per year is a lot different
14 frequency than 80 per week, and I think that, you
15 know, that discrepancy calls into question the
16 comments, the evaluations that were made, the
17 recommendations that were made by this Committee.

18 I'm not sure how many of those evaluations
19 or recommendations were based on that miscalculation,
20 but to the extent that they were, they might be
21 affected by it.

22 I think it also points out, this report

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1 was reviewed by -- it was contributed to by people in
2 this Agency, it was reviewed by, I think, at least
3 former members of this Agency, by many university
4 professors, by members of the industry, and nobody
5 caught that. This is not an obscure topic. These were
6 the two, the only two, routine, scientific testing
7 programs under HACCP, and they got it wrong, very
8 wrong.

9 So, I hope that as you are thinking about
10 how to set up this procedure, you factor in a lot of
11 review and accountability. Had FSIS put this report
12 out itself, it would have gotten dinged, very strongly
13 by the public, but the fact that it was NAS, you know,
14 I don't know, maybe people figure, you know, good
15 enough for government work, what do they know?

16 But, you know, had I put this out, I'm
17 sure I would have -- you know, it would have been
18 criticized very strongly by the Agency. It's
19 substandard work. It's not good enough. You know,
20 public health depends on this.

21 Thank you.

22 DEPUTY DIRECTOR TYNAN: Thank you.

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1 Do we have any other public comment?

2 Yes, ma'am, if you'd come up to the
3 microphone, please identify yourself and your
4 organization.

5 MS. HEBEBRAND: Good afternoon.

6 My name is Charlotte Hebebrand, and I'm
7 here from the European Commission Delegation of the
8 European Union.

9 Thank you for the opportunity to provide
10 comment. First of all, I would like to commend you
11 for all your hard work, and also for the transparency
12 with which you have undertaken these discussions. I
13 think that's very commendable.

14 The EU is very much in favor of a risk-
15 based inspection approach. We have been, and continue
16 to move in that direction. And, this is clearly an
17 important issue for the U.S. It necessitates a lot of
18 domestic discussion.

19 I would like to maybe just remind you that
20 it could be useful also to think of this from an
21 international perspective, and I was very glad to see
22 that in the last subcommittee you referred to data

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1 collected by food safety agencies of foreign
2 countries.

3 It might be helpful to think also about
4 what criteria foreign countries, the U.S. trading
5 partners, including the EU, are using.

6 And lastly, I would like to just highlight
7 a related issue, which is the question of inspections
8 abroad, and that the EU, for one, would also be very
9 much in favor of a risk-based approach there to FSIS
10 inspections abroad.

11 And, on that note, I will be happy to
12 leave some more detailed comments with you for your
13 consideration.

14 Thank you.

15 DEPUTY DIRECTOR TYNAN: Okay, thank you.

16 Any other commenters?

17 Okay, we have one item -- well, two small
18 items left on the agenda, which relates to going
19 through our briefing papers.

20 And, yesterday we abbreviated that
21 discussion in order to get into the substance of the
22 meeting. So, we thought we might just spend one

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1 moment to go back to the briefing papers for a moment.

2 And, I think where we ended up, under Tab
3 11 I think was the next briefing paper that we
4 provided to you in your notebooks. We wanted to be
5 sure if there were any comments that we got those, and
6 for the members that have left we'll try and get some
7 e-mails and see if there is any comments from them as
8 well.

9 Mr. Link, you had a comment on this one,
10 and I'm going to ask Dr. Thaler to come up.

11 MR. LINK: I guess I have a question, and
12 then maybe I need some clarification, but in the
13 background, you talk about salmonella in 2002 and 2003
14 rolled or ground turkey and ground chicken. Is there
15 2004 data to go along with this?

16 DR. THALER: We are working to get up the
17 more current data up on the web. For this meeting we
18 used the most current data that we had publicly
19 available.

20 MR. LINK: All right.

21 And, the other point is on the second page
22 where you are talking about promising interventions

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1 identified. Down, I guess, in bullet point No. 4,
2 undefined competitive exclusion products. I'm not a
3 veterinarian, and I don't really get involved in that
4 so much, but it is my understanding that there is some
5 real difficulty in getting these things approved for
6 use, because they are considered as feed additives.
7 Is that -- I mean, it may be out there, but we can't
8 use it?

9 DR. THALER: Right, they are not as feed
10 additives, but FDA is looking at them as a new animal
11 drug, and they have had difficulties working through
12 that process. So, we weren't saying promising as if
13 they are really out there and available for you to
14 use, for what's currently being developed and what's
15 currently trying to be produced. So, keep an eye on
16 what might be available in the future.

17 MR. LINK: Well, I guess then that taken,
18 the next one, the autogenous vaccines, which we also
19 apparently can't use because of some APHIS regulatory
20 requirements or prohibitions, so while they may be
21 promising we can't use them, so I just want to be
22 clear so nobody goes away thinking, hey, there's all

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1 these things out there that they don't know why we are
2 not using them.

3 DR. THALER: Right, and at the public
4 meeting that point was brought up very clearly to our
5 Undersecretary for Food Safety, and I think there will
6 be discussions to look further into that issue.

7 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk?

8 MR. KOWALCYK: Yes, thank you.

9 In the research gaps identified, there are
10 some studies that are listed, namely, the studies to
11 identify best management practices to reduce
12 salmonella. Does the Agency have a time line for when
13 those studies would be initiated and then completed?

14 DR. THALER: You have to recall that FSIS
15 is not the research agency and we have to work through
16 Agricultural Research Service and whatever we can
17 finagle out of academia and other research partners.
18 So, we don't have really a time line for that.

19 DEPUTY DIRECTOR TYNAN: Are we done with
20 pre-harvest? Other comments? Okay.

21 Thank you, Ellen.

22 CHAIR MASTERS: This is Barb Masters, and I

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1 would just add to that, to bring it to a little bit
2 more closure, as we hoped by having a pre-harvest
3 meeting that it would be a robust discussion with the
4 researchers at the table, as well as the processors
5 and those in academia, to put on the table some of the
6 good ideas that might be available and to at least
7 generate interest in the research community on some of
8 the needs that were there for the processors. And, I
9 think there was a very good discussion to help the
10 researchers understand what the needs were of the
11 processors. So, we were hoping to at least generate
12 that interest in the research community, and I think
13 there was a great interest and a good showing, we had
14 over 200 participants in that meeting.

15 DEPUTY DIRECTOR TYNAN: I think under Tab
16 No. 12 we were supposed to have our legislative
17 update, and that was passed out at the beginning of
18 the meeting yesterday.

19 Keith, I saw Keith her earlier, and Lisa,
20 and they must have had a conflict because they are not
21 here now.

22 If there are any questions regarding --

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1 I'm sorry -- oh, I'm sorry, I apologize, if there was
2 any questions regarding that then maybe we can ask
3 Terry to field those for you.

4 No questions I guess. Perfect.

5 Okay, last but not least is the National
6 Advisory Committee on Microbiological Criteria for
7 Foods, and that's under Tab 13 in your book, number
8 one in your hearts, I'm sure.

9 And, we have Gerry Ransom with us who
10 could respond to any questions you have regarding the
11 NACMF.

12 DR. RANSOM: No questions for NACMF?

13 Dr. Elfering?

14 MR. ELFERING: I was going to ask about the
15 safe cooking of poultry products. Will that report be
16 available to us as well?

17 DR. RANSOM: Yes, it will. As I
18 understand, that project, the consumer guidelines for
19 the safe cooking of poultry products, they have pretty
20 much finished their work, and at our next meeting in
21 March, we anticipate it to be March, 2006 in
22 Washington, D.C., we expect that that document will be

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1 brought to the full Committee for deliberation, and we
2 hope that it will be adopted at that time.

3 And, I wanted to thank Dr. Elfering also
4 for coming to present to that subcommittee, for
5 bringing us data from a couple of -- from an outbreak
6 related to a poultry product in Minnesota and
7 Michigan. That was very helpful to the committee.
8 This was a product that appeared cooked but wasn't,
9 and had caused some problems, and it really gave the
10 subcommittee some good data to work with. So, that was
11 greatly appreciated and greatly helped the work of the
12 subcommittee. So, we thank you.

13 DEPUTY DIRECTOR TYNAN: Dr. Logue, you had
14 a comment?

15 DR. LOGUE: I had one quick question for
16 you.

17 The methods that you are proposing for a
18 broiler rinsing, what about turkeys, because they are
19 bigger birds?

20 DR. RANSOM: Okay. The focus of the
21 camplovacter subcommittee was to get recommendations
22 for FSIS on a method to be used for an upcoming

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1 broiler baseline, which we anticipate to start in
2 early 2006. The NACMF did make a reference to turkeys
3 and that additional work would have to be done,
4 particularly, because there are sampling difficulties
5 due to the size of those birds. So, they do make
6 mention of turkey in particular, but there was no
7 focus at that time.

8 DEPUTY DIRECTOR TYNAN: Ms. Eskin?

9 MS. ESKIN: Just a quick question.

10 Again, you note there's a subcommittee
11 that's working on the safe cooking of poultry
12 products, and then there's one on cooking parameters
13 for seafood. I just thought that was interesting,
14 because isn't NACMF an FSIS -- is it an Agriculture
15 Department thing, is there some sort of -- because --
16 I'm asking the question because FDA is the agency that
17 regulates seafood.

18 DR. RANSOM: Okay, right.

19 NACMF is sponsored by FDA, FSIS and FDA,
20 they are co-sponsors.

21 MS. ESKIN: Oh, okay.

22 DR. RANSOM: We also have sponsorship by

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1 the Department of Commerce, and also the Department of
2 Defense, and CDC also sponsors NACMF.

3 MS. ESKIN: That answers my question, thank
4 you.

5 DEPUTY DIRECTOR TYNAN: Any other questions
6 on the other Advisory Committee, or colleagues on the
7 other committee? No.

8 Okay, well, thank you, Gerry, very much.

9 I have an apology to make. I misspoke. I
10 went to the wrong tab, I think we have one other
11 briefing paper that related to the Technical Service
12 Center, which is our group in Omaha, Nebraska, and
13 it's under Tab 8. I don't think we did that
14 yesterday, and the only reason that it occurred to me
15 is because I looked out and saw Lynvel sitting out
16 there and he's been patiently waiting to answer any
17 questions you have.

18 Ms. Eskin?

19 Come on up, Lynvel.

20 MS. ESKIN: Again, the Technical Service
21 Center, the clients, so to speak, are inspectors,
22 right? It's FSIS staff, or is there a large pool that

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1 uses the services of the Technical Service Center?

2 MR. JOHNSON: Our predominant client is
3 probably going to be Infection in Industry, but we get
4 some calls from consumers, state directors for state
5 inspection programs, so anybody that really wants to
6 call us they can.

7 MS. ESKIN: Do you have a process whereby
8 you periodically, as part of your self-assessment and
9 improvements, do you get feedback in any sort of
10 formal survey kind of way from the inspectors and
11 other people who use your service to help improve it?

12 In other words, is there anything sort of systematic?

13 MR. JOHNSON: Yes, we are working with
14 OPEER right now to do a survey of the inspectors, also
15 they are going to do an evaluation of some of our
16 management controls, we call them, within the Tech
17 Center, just for our consistency.

18 So, we are working with OPEER right now to
19 do some of that.

20 MS. ESKIN: Thank you.

21 DEPUTY DIRECTOR TYNAN: Mr. Kowalcyk?

22 MR. KOWALCYK: With respect to the Agency

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1 town hall meetings, will feedback from those meetings
2 be made available to this Committee? I know several
3 subcommittees over the past few meetings have
4 discussed using the Technical Service Center as a form
5 of outreach, and just to give us a sense for how that
6 is working. Are these public meetings also, these
7 town hall meetings, from the Technical Service Center?

8 MR. JOHNSON: I'm not familiar with what
9 town hall meetings you are specifically talking about.

10 The Tech Center hasn't had any public or any town
11 hall meetings.

12 CHAIR MASTERS: The Agency is hosting town
13 hall meetings, and we do that both with our inspection
14 personnel and with the industry, and they are open
15 meetings. They are considered public meetings. They
16 are not opposed to bringing feedback to this
17 Committee, and I guess I would ask, when you are
18 asking for feedback, what specific sort of feedback
19 would you be interested in, because we are certainly
20 not opposed to bringing you that feedback, but I'd be
21 interested in what sort of feedback you'd want, so I'd
22 know and be prepared to know what sort of feedback

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1 you'd be interested in receiving.

2 MR. KOWALCYK: I guess regarding the eight
3 field personnel perception of what's expected of them,
4 and consistency. I know a few meetings ago,
5 consistency was a big issue, consistency of message
6 from Headquarters.

7 DEPUTY DIRECTOR TYNAN: Other questions
8 regarding the Tech Service Center?

9 Did I miss any other briefing papers? I
10 don't think we've missed anything in the past day and
11 a half, so I think we are done, and I'm going to turn
12 it back to Dr. Masters again.

13 CHAIR MASTERS: Again, I want to thank you
14 for your outstanding work. I'm always impressed with
15 the work that you do. You work all day. You work
16 well into the evening.

17 I often get teased about the work habits
18 that I keep, and so they tell me that I rub off on
19 folks, so I appreciate your work ethics and the work
20 that you brought to this Committee, and I want to
21 thank the public that came, and the comments. I think
22 we got some good feedback from the public as well, and

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1 I think it's useful to hear your perspectives, and I
2 think we heard some very good perspectives, and some
3 different perspectives. And so, I want to thank the
4 public and your input that you provided to the
5 Committee as well. And so, I think it was a very
6 useful meeting from that perspective as well.

7 And, I hope that everyone felt like they
8 had the opportunity to be heard, because I think that
9 is something that is very useful as we move through
10 this. And so, I'm very optimistic that we got input,
11 again, I think that we spent a lot of time on Question
12 5, and I think that was what we had hoped to gain from
13 this, because Dr. Raymond and myself both said in the
14 very beginning that the transparency is going to be
15 what makes this a valuable effort as we move forward.

16 And again, we are moving forward, we recognize that
17 we've taken some steps, and we need to continue to
18 take steps, and to take those steps we need input
19 from all of our stakeholders. And, we identified
20 three large groups, which is our employees, including
21 our state employees, we think of you as some of our
22 own, our consumers, and the industry.

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1 And so, to do that we needed some means to
2 continue to have a sounding board to move forward.
3 So, I think that was the most important process that
4 we went through.

5 And, the feedback you gave us, even in the
6 form of answering a couple of the questions, I think
7 is useful to us, and it gives us some ideas of whether
8 or not some of the initial work that we are doing is
9 heading in the right direction or not the right
10 direction.

11 And, as we move toward getting toward a
12 sounding board, I think it gains us the input that we
13 needed to at least continue down some of that initial
14 work that we are doing.

15 And so again, I appreciate the work of
16 this Committee, as well as the public. There's a
17 large group of you that stuck with us the entire two
18 days, so thanks to all of you, and we'll look forward
19 to ongoing opportunities, not only in putting the
20 infrastructure together, but ultimately on putting all
21 the steps in place.

22 So again, thanks to all of you for your

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1 hard work over the last couple of days.

2 Thank you.

3 DEPUTY DIRECTOR TYNAN: Thank you very
4 much.

5 (Whereupon, the above-entitled matter was
6 concluded at 12:29 p.m.)

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