

UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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VALIDATION
BREAKOUT SESSION

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THURSDAY
SEPTEMBER 22, 2011

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The Advisory Committee met in the Georgetown Room in the Savoy Suites, 2505 Wisconsin Avenue, N.W., Washington, D.C., at 1:00 p.m., Cheryl Jones and Patricia Buck, Co-Chairs, presiding.

MEMBERS PRESENT:

CATHERINE N. CUTTER, Co-Chair, Pennsylvania State University

CHERYL JONES, Co-Chair, Morehouse School of Medicine

PATRICIA K. BUCK, Center for Foodborne Illness Research and Prevention

FUR-CHI CHEN, Tennessee State University

SHELTON E. MURINDA, California State Polytechnic University

JOHN D. TILDEN, Michigan Department of Agriculture

CAROL TUCKER-FOREMAN, Consumer Federation of America

STEVEN E. WARSHAWER, Mesa Top Farm

J. BYRON WILLIAMS, Mississippi State University

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ALSO PRESENT:

SCOTT GOLTRY
AMBER HEALY
JANICE SCHECHTER
BILL SHAW
MERYL SILVER
JAY WENTHER

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

1:33 p.m.

CO-CHAIR JONES: So, in the essence of time, okay. I guess one of the first things that I kind of wanted to put on the table was to ask, since we've had some changes in this meeting, I'm sorry.

I wanted to pose the question if we wanted to go forward and have me as the Chair, or we can change that, which would be okay with me.

I didn't know how the Subcommittee Members felt about, we have some new committee members with a lot of experience with validation and have someone else be the Chair.

(No response.)

CO-CHAIR JONES: No comments?

MS. BUCK: I liked you as Chair last time.

(Laughter.)

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1 DR. WILLIAMS: We love you.

2 MS. BUCK: So, maybe you don't want
3 to be Chair. I thought you were just
4 marvelous.

5 CO-CHAIR JONES: Well, I didn't
6 know if Dr. Cutter wanted to.

7 MS. BUCK: Dr. Cutter, would you
8 like it?

9 CO-CHAIR JONES: We could be,
10 whatever the Committee wants.

11 DR. MURINDA: Well, you ran away
12 from that committee so you wouldn't be Chair,
13 right?

14 (Laughter.)

15 CO-CHAIR JONES: Well, no, no, it
16 wasn't that. It's just I had more experience
17 with validation.

18 MS. BUCK: Well, I would think the
19 two of you would perhaps --

20 CO-CHAIR JONES: We'll probably
21 work closely together, anyway.

22 MS. BUCK: Well, why don't we have

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1 Co-Chairs, okay?

2 DR. MURINDA: Splendid idea.

3 MS. BUCK: That's a splendid idea,
4 then Co-Chairs. Does anybody object?

5 DR. WILLIAMS: Totally endorse.

6 MS. BUCK: Totally endorse, Co-
7 Chairs.

8 DR. WILLIAMS: By acclamation.

9 MS. BUCK: And Carol says, yes, I
10 heard her.

11 (Laughter.)

12 CO-CHAIR JONES: Okay, so I guess
13 we have, what, the three questions to address
14 and we have a little under three hours. So
15 let me, 50 minutes a question, just to make
16 sure that we get to all of them. Sound good?

17 MR. WARSHAWER: So, do we have to
18 do what we were asked to do?

19 (Laughter.)

20 MS. BUCK: Yes. We can do more,
21 but we have to do what we were asked to do.

22 MR. WARSHAWER: So let, maybe we,

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1 if there's a way to work those three questions
2 a little quicker, then we could get to some of
3 the other interesting questions that have been
4 boiling around the topic.

5 And we might, they might be
6 illuminated through addressing those three.

7 MS. BUCK: In conversations,
8 exactly, no, you're right, we have to do these
9 three. So, the Chairs were asking that we
10 limit the discussion to a half hour, maybe?

11 CO-CHAIR JONES: Per question?

12 MR. WARSHAWER: Let's try it.

13 MS. BUCK: Do I have to put that in
14 a motion? We don't have to go through all
15 that?

16 MR. WARSHAWER: We don't have to do
17 Robert's Rules?

18 MS. BUCK: Okay, I didn't know.

19 MR. WARSHAWER: Only if we, if we
20 begin to misbehave, then we'll revert to
21 Rules, how's that?

22 CO-CHAIR JONES: All right, so the

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1 first question, has everybody read the first
2 question?

3 During the HACCP system validation
4 guidance development has become clear that
5 many stakeholders, including FSIS personnel,
6 have difficulty reading and assessing
7 scientific literature to be able to adequately
8 translate information into a HACCP system
9 design.

10 What innovative strategies can the
11 Agency utilize to help establishment personnel
12 identify critical operating parameters and
13 then determine where in the HACCP system it is
14 appropriate to ensure implementation.

15 DR. TILDEN: And a couple of us had
16 questions that we ran out of time and we
17 didn't have time to ask. So, it might be a
18 good thing to just start with some of those.
19 Since Dr. Shaw is here.

20 It's just, I had one. So, and it
21 goes, it's kind of a basic question, but it
22 would help me understand. So the problem that

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1 this guidance is supposed to address,
2 principally is exactly what this question is.

3 Is that what you're seeing is that
4 establishments are having problems identifying
5 the critical parameters and then appropriately
6 integrating them into their HACCP plan.
7 That's the central problem.

8 MR. LIANG: Can I add to that a
9 little bit. And this, as I understand, I
10 thought it's largely about, or maybe not,
11 maybe I'm wrong, tell me about smaller plans,
12 is that right? Or not necessarily?

13 MR. SHAW: It's not, okay. So,
14 generally, the issue is not relegated to only
15 small establishments. They're generally, when
16 we write a guideline, because of what
17 guidelines were designed to do, brief small
18 business, we generally write guidance
19 documents targeted to small and very small
20 establishments.

21 We see this issue happen in larger
22 establishments, too. And they typically read

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1 these documents also. But our audience, when
2 we write these documents, is primarily small
3 and very small establishments. And so, then
4 to also answer your question --

5 DR. TILDEN: Okay.

6 MR. SHAW: Generally that is,
7 that's where, when we read these various
8 examples and we've lived through these
9 experiences, the common sort of thread that
10 draws most of, almost all of them together is
11 this, looking at the scientific documentation
12 that they have in file cabinets or in binders
13 and reading through that.

14 And then when you look at their
15 process itself, or walk out on the floor, and
16 you're looking, in various degrees you will
17 see them not matching.

18 DR. TILDEN: Okay.

19 MR. SHAW: And so, and so, at that,
20 so our concerns are, at that, if you're
21 already at that point, therefore then the,
22 it's unsure whether this step or intervention

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1 or whatever, is at its maximum effectiveness
2 as adopted. What they're basing their system
3 on. I mean the scientific says, oh, we get a
4 five log reduction. But then if you, see
5 their process and see that certain, you know,
6 parameters are not being either measured or
7 implemented in a similar way, are they really
8 getting five log that they're documenting that
9 they're saying they're getting.

10 DR. TILDEN: Okay, and a related
11 question is, is this a generalized problem or
12 do you have evidence that it could be, you
13 could characterize where the non-compliance
14 is, so that efforts could be more targeted
15 towards where the problem is, rather than a
16 generalized solution.

17 MR. SHAW: Well, I guess, there are
18 sectors of the, I guess we could say that
19 there are sectors in the industry where it's
20 more pervasive than other sectors.

21 And sometimes that's the nature of
22 the process or product and also, like

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1 historical situation. But, we can find them,
2 I mean we find them almost everywhere.

3 DR. WILLIAMS: So you're species
4 oriented with that?

5 MR. SHAW: Typically, what I would
6 say is we're like going to go a hierarchy,
7 slaughter is where it begins. Because
8 typically when you look at the ready-to-eat
9 products, the predominant ready-to-eat
10 products are typically fully cooked.

11 They're using Appendix A, they're
12 cooking, it's thermal. I mean, and they're
13 cooking the product and typically that's a
14 fairly consistent and understood sort of
15 process.

16 And there are typically not as much
17 issues that go along with that. When you get
18 into the RTE products where cooking is not the
19 primary process, it may be a contributor, it
20 may be a hurdle process where there's a number
21 of issues that accumulate into a full
22 validation and heating may be a small part of

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1 it. We get issues there. We tend to, but
2 then, back at slaughter, we tend to get a lot
3 of issues that really move our way around
4 slaughter.

5 And it comes to the various
6 interventions that are taking place and that,
7 and then in the further processing, we can get
8 into issues of cooking instructions, you know,
9 not ready-to-eat products that are, what we
10 would call the 03H variety, partially heat
11 treated but not fully cooked.

12 And so the consumer is, you know,
13 responsible for finishing it off, per se. And
14 so we get some cooking instruction validation
15 issues, and that sort of thing.

16 CO-CHAIR CUTTER: I'd like to kind
17 of weigh in on this because there's two
18 things. Where are they getting the papers
19 from and why did they choose that one paper?

20 They'll go online, they'll find a
21 paper, they think it matches the units. More
22 likely or not I get a call from the plant

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1 after FSA, or they're in the middle of an FSA,
2 EIO says call me, try to get the paper. They
3 problem is, is that they give you this little
4 snapshot of what they're asking for.

5 I need a carcass intervention. So
6 you pull out papers and you send them, PDFs
7 usually along those lines. And, without me
8 stepping in the plant and knowing anything
9 about it.

10 You know, I always have the caveat.

11 You must make sure that this, this paper
12 matches what you guys are doing in your plant.

13 If it doesn't, then it's worthless.

14 So I'll send it to you, but you
15 have to read the paper and understand what
16 you're looking for. So I try to ask as many
17 questions as possible when they ask those kind
18 of, ask for those papers.

19 But it's very difficult without
20 being in the plant. And with 400 plants in
21 Pennsylvania, I can't do it. It's just, it's
22 cost prohibitive.

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1 So sometimes it's, you know, you're
2 shooting in the dark. You don't know what
3 you're dealing with. If I've been in the
4 plant, it's one thing.

5 But, if I haven't, it's a cold call
6 and I have no idea. And it's hard, and I
7 know, Byron, same thing.

8 DR. WILLIAMS: Same thing.

9 CO-CHAIR JONES: We don't know.
10 They'll say our EIO says get this paper, so
11 we'll get the paper for them and sometimes
12 it's wrong, because the EIO maybe doesn't know
13 either.

14 So, I wouldn't say it's just plant
15 issues, but there are some other things here
16 too.

17 MR. SHAW: Oh, there's many things.
18 I mean there's many things floating around
19 this situation and over the last like couple
20 of years we're constantly trying to sort of
21 look at it holistically of the various, you
22 know, players that play a role.

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1 All the players that play a role.
2 Because it's not one, it's not one stakeholder
3 or one entity in the process, it includes
4 everyone.

5 MS. BUCK: Yes. Would it be
6 helpful, I mean I don't know, I've not been in
7 the plants, I don't know all of the
8 interventions that are in place.

9 It would seem to me that the
10 variety is huge. Would it be helpful if FSIS
11 would come up like a, with a chunk of
12 categories?

13 CO-CHAIR CUTTER: They have done
14 that.

15 MS. BUCK: They've already done
16 that?

17 CO-CHAIR CUTTER: Yes, Ohio State
18 has a document where you have all the
19 different types of papers that you can use for
20 all the different types of parameters.

21 And FSIS has shared it with, you
22 know, it's on their website.

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1 DR. WILLIAMS: It's printed binders
2 out, supplementary --

3 MS. BUCK: I know, but that's way
4 to big. I mean we're talking, I'm talking
5 about boil it down so that it's --

6 CO-CHAIR CUTTER: Well I've always
7 asked FSIS, just tell me what papers you guys
8 accept. Put them into PDFs, get the approval
9 to copyright and put them on the website.
10 That would be so much easier that way.

11 MS. BUCK: Yes, I mean, because I
12 think a lot of the problem is there's just too
13 much information for --

14 CO-CHAIR CUTTER: And, Jay, I think
15 --

16 DR. WENTHER: It's ironic, the
17 issues come full circle. Because back in the
18 day we've asked for White Papers that
19 University Professors have gone through and
20 bullet pointed, you have to have this point
21 and this point and this point, in the
22 parameters there.

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1 Kind of identified in this document
2 are saying now we have to identify these
3 parameters. And then there was such a push,
4 three or four years back, that these plants
5 had to have scientific papers.

6 So nothing else is any better but
7 this paper is good. So now we're coming back
8 to let's identify the parameters. And White
9 Papers to identify those with professionals
10 that can sit back and education and academic
11 level that everybody can accept. USDA and
12 Plants, would be very, very helpful.

13 DR. WILLIAMS: The issue comes down
14 to interpretation at the plant level, both
15 from Inspector's perspective as well as the
16 plant personnel. And there's only so many of
17 the state people, you know, that are
18 supposedly professionals to go around.

19 And Cathy's swamped and I'm
20 swamped.

21 MR. SHAW: And I completely agree
22 with you. Because some of the issues that we

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1 have arisen, I mean they can be fairly
2 nuanced. I mean we had an establishment that
3 it was a beef slaughter establishment. They
4 were doing a hot water carcass, for instance,
5 in antimicrobial. And something as what could
6 appear to the untrained eye of, they were
7 measuring the temperature of the water back at
8 the holding tank.

9 But then when it went through all
10 the lines in the slaughter plant, came out the
11 nozzle, and the temperature of the water
12 hitting the carcass was about 15 to 20 degrees
13 lower, and actually it was, like there were
14 nozzles along the carcass, and the top was
15 closer to the temperature and then the bottom
16 was the coldest.

17 And so it can, and that's a
18 validation issue of like, of, because the
19 paper, you know, clearly said the temperature
20 of the water at point of contact with the
21 carcass.

22 CO-CHAIR CUTTER: But how did they

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1 not understand that?

2 MR. SHAW: And they didn't fully,
3 you know, the establishment didn't fully look
4 at that. They just saw, you know, the title
5 of the paper was, you know, a hundred and some
6 degree water, antimicrobial. But then in
7 materials and methods you that was --

8 MS. TUCKER-FOREMAN: Can I back up
9 a minute, I came in a few minutes late and I
10 know we want to talk about specifics today.
11 But I think it's important to know from the
12 beginning that we have these problems, because
13 of some decisions that were made historically.

14 And there, some of that may have
15 some relevance to what we're talking about
16 today. For example, one of the decisions that
17 was made early on, was that USDA would not
18 approve HACCP plans.

19 And that might have made, would
20 have made some different problems, but it
21 might have made fewer problems. The other
22 one, I just have to say something about it,

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1 because it's very basic to many of us.

2 If you look at the slides, Slide
3 Number 5, for example says, initial practical
4 in-plant demonstration proving the HACCP
5 system can perform as inspected.

6 And then Number 7 is, initial in-
7 plant measures as written in the HACCP system
8 can be implemented within a particular
9 establishment to achieve the intended food
10 safety goal, objective.

11 When the consumer groups began to
12 formulate a position on HACCP, we had a very
13 simple requirement. We wanted it to be able
14 to demonstrate the food coming off the end of
15 the line was cleaner, safer, less
16 contaminated, less likely to cause food borne
17 illness.

18 That was what we wanted. What we
19 got was a system that says if everything is
20 done exactly the right way, you get that to
21 happen, maybe, with a maximum amount of
22 confusion.

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1 Validation rests at the plant level
2 on measurement and some on microbial testing.

3 It seems to me, and I've spent a lot of time
4 looking at modern regulatory systems, FSIS is
5 very unusual in the fact that the whole system
6 is prescriptive. It would have been possible
7 to start off and say with HACCP, you will have
8 to perform your own measurements and your own
9 microbial testing to show that your HACCP plan
10 isn't just capable of achieving these goals,
11 but does on a day-to-day basis.

12 And when the inspector checks, the
13 inspector will test to see, take measurements
14 to see and test to microbial testing, to see
15 if your system is meeting the goals.

16 And then if you are not doing it by
17 some prescriptive manner, what difference does
18 it make, you are producing a product that is,
19 that meets safety requirements.

20 And then you would have a modern
21 regulatory system. Most of those, clean air
22 for example, are based on, EPA says to you,

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1 this is the level of particulate that you can
2 have as your steam, your material comes out of
3 the smokestack, as your smoke comes out of the
4 stack.

5 They don't go in and tell them how
6 to get there, they just say they have to meet
7 this standard. And then we quibble about the
8 standard.

9 But not about what the plant does.

10 And with 6,000 meat and poultry plants,
11 you're going to have endless quibbling because
12 each one of them is different.

13 And so it pains me each time I see
14 us go further down this path of
15 particularizing the system that really
16 reinforces an archaic food safety system,
17 which is one that relies on constant oversight
18 by federal employees.

19 A more effective, rigorous,
20 science-based oversight for most of the
21 industry, I still wouldn't let you slaughter
22 animals without having somebody there all the

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1 time.

2 But most of it, you could have
3 regular plant visits and not the constant
4 oversight that we have. So, thank you for
5 letting me make my speech. It will influence
6 what I say about the rest of these things.
7 Because I'm really troubled that we're going
8 to sit here and spend all afternoon talking
9 about, and that the Agency is forced to spend
10 endless amounts of time thinking about what I
11 consider not to be the basic issues.

12 And that companies are burdened by
13 having to deal with uncertainty that I don't
14 think is necessary in a large number of cases.

15 Thank you.

16 MS. BUCK: Does that take us into
17 the performance standards?

18 MS. TUCKER-FOREMAN: Sure it does.

19 MS. BUCK: Well, I mean, I think
20 she's right. I mean we don't, we have
21 performance standards set out in HACCP but
22 they're not enforceable and that's the system

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1 we've been working with for quite a while now.

2 So we have an alternative system.
3 And, the alternative system we have to maybe
4 start saying to ourselves, is not working
5 appropriately. Or, if you want to make
6 modifications to it, we're going to have to
7 make it, like Cathy and you've suggested that
8 it has to be more accessible to all those
9 plants out there.

10 Those 6,000 plants. And if that
11 means we have to go back to a system where we
12 use White Papers, so it can be translated for
13 these people, more explicitly.

14 I mean some of it is explicit.
15 They do not understand. It's not that they
16 don't want to understand, they cannot make the
17 transfer of knowledge from where, what the
18 paper is saying and how that's going to work
19 in their real plant life situation.

20 They don't have the critical
21 thinking skills to do that.

22 DR. WILLIAMS: The papers are

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1 written for that, number one. For that --

2 MS. BUCK: That's not written.
3 That's why we need the White Paper, I think
4 that's a good idea.

5 MS. TUCKER-FOREMAN: That courses
6 down to the Agency being very prescriptive and
7 the Agency doesn't want that and companies
8 don't want that.

9 DR. TILDEN: Well, the big
10 companies don't want that. But I can tell you
11 then, as I read through this, a lot of our
12 operators in Michigan are not research
13 scientists.

14 And it sounds like the position
15 description that's coming out of this, is that
16 you have to be a research scientist.

17 MS. BUCK: Exactly, that's what I'm
18 saying, this is too much for them.

19 MS. TUCKER-FOREMAN: Let me tell
20 you, being a research scientist doesn't mean
21 that when it happens and in this plant on this
22 day, that it's meeting the standard of the

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1 research scientist.

2 DR. TILDEN: One thing I just
3 wanted to throw out there. So, I'm a
4 veterinarian and when I was in veterinary
5 school we had reading scientific literature
6 classes.

7 And I can tell you that the people
8 going through vet school, some are good at
9 reading scientific papers and some of them
10 would say, shoot me now, so I don't have to do
11 this over and over again.

12 And it's not like one is smarter or
13 dumber than the other, it's a complex skill
14 and some people's brains work that way, and
15 some people's don't.

16 And so we make the distinction
17 between researchers and practitioners. We
18 have some meat processors who are excellent
19 practitioners. Don't try to make them into a
20 researcher and don't take the time and energy
21 that they do excellent practice of making meat
22 and divert them from that, trying to be

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1 something that they're not.

2 And so I think that's what we try
3 to do, is figure out how do you help them use
4 the skills that they have, so that they can do
5 what they're supposed to do for their job.

6 MS. TUCKER-FOREMAN: And how do you
7 test, how do you ascertain that at the end of
8 the line, the product is safe to eat? That's
9 all we want, is just some assurance that it's
10 safe at the end of the line, and somebody has
11 to check that.

12 I don't care if you're the best
13 research scientist alive.

14 MR. WARSHAWER: I'm afraid I'm
15 going to stumble over trying to explain this,
16 because I've got all these little shooting
17 ideas in my brain that are trying to thread
18 together.

19 I was trying to prepare for this
20 meeting, I was looking at a little bit of the
21 history since the final House approval. And
22 stuff that's gone on to try to understand the

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1 functional differences at very small and small
2 and large and stuff that was supposed to
3 happen and may or may not have happened, to
4 make HACCP workable and not one size fits all.

5 It's not nice to hear people say
6 this is not a one size fits all solution, it's
7 not going to happen. And what it, what I'm,
8 coming mostly from the small operator side and
9 very small even, I sit there and I think,
10 okay, how many dollars a year in gross sales
11 would I have to have to hire my own scientist?

12 Because that's what I need, I need
13 a scientist who knows the papers, knows the
14 literature, knows the research, and can then
15 interpret it in a way that I can practice
16 with.

17 Okay, that's, the 300 largest
18 enterprises probably have that. They probably
19 have their own scientist. Somewhere down in
20 that category of small, is about as, I can't
21 do much with it, because it's too broad.

22 But somewhere in the small is where

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1 enterprises stop being able to afford their
2 own science and interpretive skills.

3 And I think there's a distinct
4 difference in how an enterprise operates where
5 they have in-house science and how one
6 operates where they don't, in terms of how
7 HACCP can be expected to perform.

8 And so what it seems to me, if I
9 take a step back to the level like what Carol
10 was, having not been in this discussion like
11 most of you have for 15 years, the challenge
12 is how to get the, if we're going to say it's
13 science-based, how do we get science
14 interpreted into practice for enterprises who
15 can't hire their own science?

16 Maybe that's grossly
17 oversimplifying it, but that's what it looks
18 like. Because it's not, we acknowledge
19 certain things. Every plant is different.

20 It's not one size fits all. It's,
21 but, and science is what it is. It's evolving
22 and producing new information and it's

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1 supposed to be.

2 The facts change. The knowledge
3 changes. The interventions change. That's
4 supposed to be what's happening. So how does
5 that information translate through to the
6 largest number of plants who don't have anyone
7 hired and can't afford to have anyone hired to
8 provide that service in-house. So back to the
9 beginning of HACCP in '96, the final rule. At
10 the same time there was a comment about
11 needing a user group for small and very small,
12 modeled after NACMPI, or maybe that came out
13 in 2005 and 6, when there was a review of how
14 HACCP works for small and very small.

15 And it was guided by something from
16 the International HACCP Association, and
17 that's when it maybe came up that they needed
18 a user group.

19 Well, that's great. That's kind of
20 what we're functioning as, but we're not the
21 users. So we're speaking for them. But, and
22 we're doing the best we can.

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1 But without another layer, there's
2 a missing layer. If we're going to use HACCP
3 systems to get to the point where we can
4 predict the outcomes that Carol and others are
5 saying we need.

6 We have to have a way to get
7 science interpreted into practical matters
8 that's accessible to operations that can't
9 afford to hire their own.

10 And that's why so many plants went
11 out of business. That's why in New Mexico, we
12 lost most of our capacity when HACCP rule was
13 promulgated.

14 And now we're seeing this
15 resurgence of small and very small plants.
16 And demand from markets that are being
17 positioned to receive product from those kinds
18 of enterprises.

19 But we don't have a system, we
20 haven't addressed the core problem that made
21 the system inadequate for that particular
22 segment.

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1 And so maybe I've just spent way
2 too many words to say what everybody already
3 knew and so I apologize. These other pieces
4 are answered by a mechanism for delivery.

5 If we had science, the science
6 available in the right form, to all of the
7 plants of different scales and all the
8 processes of different scales, and the
9 interpretation was happening in a timely
10 fashion and in an updated fashion, with new
11 information.

12 These pieces that you guys are
13 struggling with wouldn't be happening this
14 way. And we'd be able to talk about
15 measurement, because we would have some, we'd
16 be developing benchmarks that could be
17 consistently applied, regardless of scale and
18 regardless of process.

19 So I think you've got the right,
20 it's like are we dealing with symptom or
21 cause. You brought us the symptoms. These
22 are the things that happen to us out in the

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1 field.

2 The cause is what we're trying to
3 get at here already. And that's why I say,
4 you know, do we have to answer the questions
5 we were asked to answer, because I think
6 there's something we've got to deal with
7 first.

8 CO-CHAIR JONES: I think that, just
9 to, go ahead.

10 MR. SHAW: Well, I guess I would
11 say I agree with you and some of the things
12 that we struggle constantly is, I mean this is
13 anecdotal and private to us, is that we often
14 feel that researchers many times write for
15 each other and not for the person who's going
16 to use the research.

17 And so you read articles where it's
18 not, there, I believe there are ways to write
19 research articles where it's a lot more clear
20 cut to the end user of that research and how
21 to apply it better.

22 There are researchers that do it

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1 well and sit and say, you know, I know who is
2 going to use this research after me and I
3 know, like, and they'll sort of lay it out.

4 In even a HACCP environment.
5 They'll like lay it out, this is how I would
6 expect this to get, you know, translated. But
7 quite often our research articles don't --

8 CO-CHAIR CUTTER: And I'll tell
9 you, I just submitted a paper, it's like, I
10 was telling Jay, page proofs. When we're
11 going through the review process they said,
12 who is this written for?

13 Why is it written for the
14 scientific community when we're trying to
15 address the small plant interventions. And I
16 got hammered on that in the reviews.

17 And we argued and counter-argued
18 and we went through a second review.
19 Thankfully, I got the page proof this week,
20 it's going to be published.

21 But it specifically says for small
22 plant. We put everything in PSI we don't put

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1 it in metric so that the small plant will
2 understand it.

3 DR. WILLIAMS: I'll let go of that
4 because we get hammered by reviewers.

5 CO-CHAIR CUTTER: That's the
6 scientific community doing that.

7 MR. SHAW: Because they work for
8 them.

9 DR. WILLIAMS: But that's what we --

10 CO-CHAIR CUTTER: But that general
11 food protection is --

12 (Simultaneous speaking.)

13 MS. TUCKER-FOREMAN: I have a
14 proposal then to address this issue, and it
15 goes back to, somebody suggested already, why
16 doesn't FSIS acknowledge the reality of this
17 problem, both of the problems.

18 The inability to get the scientific
19 papers to be on point for small operators and
20 their problems with the system. And contract
21 for a series of very specific papers that,
22 John did you suggest that to tell people how

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1 to --

2 DR. TILDEN: No, somebody must
3 have.

4 MS. TUCKER-FOREMAN: -- how to meet
5 the HACCP requirements. And put it out and
6 say this is the rule. Now, under some
7 circumstances I would argue against that
8 because I want you to be less prescriptive.

9 On the other hand, if we're going
10 to deal with the reality, you've got the
11 reality of a situation that's not working for
12 large numbers.

13 MS. BUCK: And that's your problem,
14 it's not working.

15 MS. TUCKER-FOREMAN: And so --

16 DR. WENTHER: The Ohio State
17 document is very, very good. But you throw
18 that at a meat plant, you're throwing a bible
19 at them.

20 MS. TUCKER-FOREMAN: Exactly.

21 DR. WENTHER: There's some very
22 limited number of, I mean especially with the

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1 small and very small. It seems like there's a
2 very limited number of papers per CCP, per
3 HACCP plant.

4 You can identify a few
5 professionals that look through those and
6 everybody comes to some group discussion and
7 agreement and it's accepted by USDA and they
8 have the papers on hand, but they don't have
9 the exact anecdotes to follow.

10 You'll move this ball, I mean Dr.
11 Shaw and his group and USDA, they've taken the
12 validation document and really revised it a
13 lot, since where it was. And if that's what
14 they're asking for and that's going to achieve
15 the goal of, here's my paper and I have it on
16 file and here's the criteria and here's how I
17 monitor it.

18 And I've accomplished what you
19 think I'm going to accomplish to put it in
20 place, and it should make an impact.

21 MS. TUCKER-FOREMAN: And then
22 you've got to have the measurement that says

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1 it really does work, because you have to take
2 into consideration on the ground. That the
3 temperature of the water wasn't at the point
4 of application what it was where it was being
5 measured.

6 Now, part of that, obviously is the
7 inspector's responsibility to come in and say,
8 oh, yes, you know, you're not doing this.
9 Maybe it's the Food Safety Review Team.

10 But it does seem to me that, it's
11 not just one paper, because clearly one paper
12 is not going to do it. It's probably 25
13 papers or how many other.

14 CO-CHAIR JONES: Well, one of the
15 things that I'm hearing and tell me if I'm
16 kind of synthesizing this properly. One of
17 the things I'm hearing is that there needs to
18 be like the Cliff Notes or cheat sheet type of
19 thing taken from the scientific papers or
20 white papers that is understandable for the
21 layperson or the person who, the practical
22 person who is actually at the plant level.

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1 Whether it be the processor or the
2 inspector who actually can look at these
3 things that are considered acceptable or
4 proven criteria. And it be a cheat sheet.

5 Whether it be in PDF format, I
6 think somebody mentioned that on a website.
7 And that it be continually evaluated and
8 refined as things change.

9 Based on the needs of the plant,
10 the needs of, based on size, and what have
11 you. And, in addition to having that type of
12 information accessible or at hand, also it
13 sounds like some of the plants need
14 consultants, if you will or scientific
15 consultants or, that can come and actually
16 evaluate their specific needs on some kind of
17 periodic basis.

18 And I'm saying all that because
19 when I look and kind of past 30 minutes, the
20 first 30 minutes and we can reevaluate whether
21 we want to keep pushing the 30 minute thing.

22 But we're talking about innovative

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1 strategies. That means things that haven't
2 necessarily been approved yet, so put
3 something out there that, you know, is not
4 being done but needs to be done.

5 So it doesn't have to fit perfectly
6 into what's already happening. So, that's
7 kind of what I'm hearing.

8 MS. EWING: What is a good
9 progression? Because we keep talking about
10 using and as a Processor I have lots of papers
11 and I have my HACCP programs. No, not a
12 single one of those papers fits my processes
13 in all my different plants. What I go back to
14 isn't my in-plant validation what supports my
15 using that piece of research?

16 If not? Then what's the point of
17 me doing in-plant validation? So I'm
18 confused.

19 MS. TUCKER-FOREMAN: Well, I think
20 that's a terrific point, because we've only
21 talked about the scientific papers and not the
22 in-plant validation.

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1 DR. WENTHER: Are you talking
2 validation or in-plant monitoring?

3 MS. EWING: I'm talking about
4 validation, making sure it works. I mean I
5 can guarantee the processing water is not
6 always the same temperature.

7 MR. LIANG: At this risk of saying
8 something stupid, because I don't know
9 anything, it seems to me there are, there's,
10 it depends. If you're talking about a process
11 validation, that's not necessarily going to
12 tell you whether your process works from any
13 outcome point of view, which is I think what -
14 -

15 MS. TUCKER-FOREMAN: Yes, exactly.

16 MS. EWING: Well, we've got very
17 simple processes in our operation, it's
18 simple. Now if we, you know, furthering
19 processing gets more complex, then we go to
20 Appendix A and Appendix B, and then we look
21 for results.

22 Did we meet that point? So it's

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1 really pretty simple. But then when you drag
2 in all this research and trying to fit the
3 parameters of this certain persons, and
4 they're doing the research for producing
5 interventions and microbial producers,
6 equipment people, that's what this research
7 is.

8 Very often funded by, so they want
9 to show that their piece of equipment works as
10 opposed to somebody else's. And so you're
11 constantly, depending on who's research you're
12 using, you're constantly in the middle.

13 And somebody is going to always
14 say, well what about over here?

15 CO-CHAIR CUTTER: Well, that even
16 gets at the point of what's acceptable for
17 supporting documentation. I've had plants
18 who've gone outside, had a challenge that he's
19 done with a micro testing lab, not through an
20 academic institution, and then they get
21 hammered because it's not peer reviewed. Then
22 what?

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1 I mean they paid the money to go
2 have a challenge study done, but it's not peer
3 reviewed, so is it not valid then? So, these
4 are the questions.

5 MS. EWING: Well, I get hammered
6 for not doing that. For having, you know,
7 not, well, it all depends on which --

8 CO-CHAIR CUTTER: And it's
9 expensive. I mean anybody who's doing this
10 you want to say that this is acceptable.

11 You know, you're paying the money
12 to have this done and just because it doesn't
13 end up in a peer review journal, does it mean
14 it's not worth, as if it's worthless.

15 And, to me, I don't, if the science
16 is done correctly and it's outlined and
17 somebody can read that and understand that,
18 then there shouldn't be a problem.

19 But that begs the question, now are
20 you going to get people who are just going to
21 whip something together and push it forward as
22 fake. And that's a real possibility, and then

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1 what?

2 So, there's so many of these things
3 trying to --

4 DR. WILLIAMS: There are no 100
5 percent, in all cases scientific articles to
6 back up all the processes that are out there,
7 let's face that fact.

8 They're not there, period. And
9 they won't be because they're too expensive to
10 do, or they may not be practical to do,
11 because I've run into the same thing.

12 It gets back to using sound
13 judgment, and bear in mind this, that the
14 burden of all the responsibility in an
15 overlying theme in all of this, and I think
16 it's gotten away and I'm going to get some
17 disagreement.

18 But the production plant has a
19 responsibility to produce as safe a product as
20 possible. That does not relieve the consumer
21 responsibility completely.

22 And my point being taken into the

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1 fact of labeling.

2 MS. BUCK: Yes, I would agree with
3 that. We have a problem with labeling. And
4 until we, I mean there's some things that just
5 have to be done.

6 We're not charged with looking at
7 that right this minute. We could have an
8 offline discussion about that. But you're
9 right, there are other things. The one thing
10 I would like to know, you have an educational
11 outreach program for small businesses, small
12 and very small, the training is separate.

13 Has there been any idea of
14 expanding into that very good program that
15 you've started? Something where they can get
16 the counseling type of information that they
17 need for their validation processes.

18 I mean is that something we can
19 suggest to them, that you have, you have a
20 little nugget of something there. I mean the
21 best thing to do is to sort of adopt really
22 what HACCP was about.

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1 And that is to look at the end
2 product testing, but Scott and I don't want to
3 get in an argument this afternoon about
4 performance standards.

5 (Laughter.)

6 MS. BUCK: But I'm just saying,
7 that would probably be the best thing to
8 resolve the situation. But we're not going to
9 do that.

10 MR. SHAW: I mean I think that
11 suggestion speaks to Question 3 and not, I
12 mean you are the Committee and you're the
13 intelligence in this room so --

14 MS. BUCK: We're the people in the
15 room.

16 (Laughter.)

17 MR. SHAW: I mean we're, if that's
18 something that you all think is valuable, I
19 mean, that's the sort of things we want to
20 hear.

21 We want to hear those ideas if,
22 because I know on our level, I mean to a

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1 certain extent askFSIS, day in and day out we
2 provide that, that guidance, you know, to both
3 establishment and inspection personnel who
4 come to us.

5 We're not part of that group that
6 you're referring to. We're in, you know,
7 we're in the Office of Policy.

8 MS. BUCK: Yes.

9 MR. SHAW: And we do that. And,
10 but I do agree with you there's not a
11 systematic place for that. There's not, it's
12 not structured or it's not --

13 MS. BUCK: It's not advertised.

14 MR. SHAW: Right, it's not
15 codified, it's not a --

16 MS. BUCK: People don't know about
17 it.

18 DR. WENTHER: The Office of
19 Outreach, the askFSIS is very -- the Office of
20 Outreach is more the office of dissemination.
21 Because if I want something I call them up
22 and they give me a brochure.

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1 If I ask them what that brochure
2 means and how they interpret it and put it in
3 place, no way.

4 MS. BUCK: Well then you need to
5 marry it with somebody else.

6 DR. TILDEN: Exactly. And I think
7 that goes back to, we all know the 80/20 rule?
8 Solve 80 percent of the problems with 20
9 percent of the first effort and you spend the
10 next 80 percent of your time trying to get
11 that last 20 percent?

12 Well, ten years into this HACCP
13 thing, you know it's our telling thing that
14 we're still swirling on this issue.

15 MS. BUCK: That's right.

16 MR. SHAW: And so, I think what
17 we've got to do is figure out how to get it so
18 the core is rock solid. You know, basic
19 processes that are done commonly.

20 You don't have to sweat it. If
21 you're doing these things, don't worry about
22 it. Because what happens on too many of these

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1 discussions is we hopscotch from issue to
2 issue to issue to issue, and we don't get the
3 core rock solid.

4 So as I talk to practitioners, you
5 know, EIOs and front line supervisors and
6 processors, what they say, oh, it's not that
7 complicated.

8 You know, and after, they've
9 figured it out how to communicate and say yes,
10 fully cooked lethality, you know that's not
11 that complicated.

12 You know, there's this, this and
13 this. And then you hear someone else talking,
14 oh, yes, that's not, I know how to explain
15 that. If you could get the practitioners with
16 the scientist to come together and say, here's
17 the science and then the practitioners tell
18 you, this is how you communicate the science,
19 in the right kind of questions that will
20 illustrate how to apply the science, you can
21 do it.

22 But what it is, is I don't think we

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1 should be sitting here talking about it two
2 years from now, that somebody somewhere should
3 do something.

4 You know, it's like what does it
5 take to get the extension kind of people and
6 then the association type people, the folks
7 that actually have the practical experience on
8 how to implement problems and problem solving,
9 get them to work together to create a tool
10 box.

11 MS. TUCKER-FOREMAN: Yes, but Carol
12 is so right. I lived in Pittsburgh when they
13 went through that big deal with the air
14 quality. I'm old enough to remember that,
15 okay.

16 And they set the standard. And
17 when you set the standard and you measure to
18 make sure the standard has been met, then
19 companies will improvise and meet that
20 standard.

21 DR. TILDEN: I disagree. I
22 disagree.

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1 MS. TUCKER-FOREMAN: Well, it's been
2 proved, and it is the modern way to regulate -
3 -

4 DR. TILDEN: No.

5 MS. TUCKER-FOREMAN: -- instead of
6 having the government stand over you and say -
7 -

8 DR. TILDEN: All I can tell you is
9 those of us who work with small and very small
10 plants, you can tell them that they've got to
11 get the endpoint to that.

12 And if they don't know what's
13 coming in the front door and they don't know
14 why it changes in the middle, you can put them
15 out of business, but you can't tell them how
16 to --

17 MS. TUCKER-FOREMAN: Well, John,
18 you know what? It strikes me that many of
19 them know exactly what to do to get the
20 desired result in the end, but it doesn't fit
21 a pattern in a scientific paper. And I've
22 written all the way through the slide show,

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1 were there violations to show where you did
2 your examples.

3 Were there violations? Did they
4 have contaminations in these cases? Did they?

5 In all of these cases? Did they every day or
6 on some days? You gave us --

7 DR. TILDEN: Four examples.

8 MS. SILVER: Yes, the reason those
9 examples started was through investigations
10 following issues through positive samples.

11 MR. SHAW: Following positive
12 samples or outbreaks or how we got back to
13 that. And through the investigation we, I
14 mean through the investigation we sort of walk
15 ourselves back and try and figure out, okay,
16 what caused this issue?

17 And so, and those were our
18 conclusions as to what happened that led to
19 why we were there to begin with.

20 MS. TUCKER-FOREMAN: But in some
21 plants, basically I think if you don't know
22 what you're getting in the front door and you

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1 can't control your temperature, you're going
2 to have a problem.

3 But there are a lot of things
4 beyond that that are really detailed issues
5 and it strikes me that some people know how to
6 do it and are having good results every day.

7 And they can't tell you how they
8 got there. Or maybe you would look at their
9 requirements of their suppliers and say it's
10 not adequate.

11 But, in fact, it's working for
12 them, because they're buying from the same
13 people every time and I know that that person
14 does these things.

15 So, it seems, you know, like I
16 continue to advocate that you have some
17 mechanism for showing that they're meeting the
18 standard, the desirable standard at the end of
19 the line and you don't tell people how to do
20 it.

21 But there ought to be a mechanism
22 for offering assistance where people need it.

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1 But the offering of assistance or the request
2 for assistance and the offering of assistance
3 and the acceptance of assistance, can't be
4 equated with a, you're home safe, that you've
5 complied.

6 MS. SILVER: It's not a recipe.

7 MR. WARSHAWER: Do this and
8 everything will be okay, no. Do this because
9 it's what's indicated. Monitor it and report
10 on it so we know if it's okay.

11 There's, back in that same '96,
12 period, I came across this thing that I didn't
13 get to dig into, called the Small Business
14 Regulatory Enforcement Fairness Act.

15 MS. TUCKER-FOREMAN: I remember
16 that.

17 MR. WARSHAWER: Okay. When you
18 said, yes, you just tell them what, how clean
19 you want the air to be, and they'll figure out
20 how to do it.

21 That method of regulation creates
22 concentration. It creates bigger and bigger

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1 enterprises, because that's who's got the
2 resources to solve the problem.

3 And if this Small Business
4 Regulatory Enforcement Fairness Act is an
5 antidote to that approach. They can't, there
6 has to be more than here's the outcome, you
7 figure it out.

8 Because otherwise we'll only have
9 bigger and bigger businesses because that's
10 who can afford within house, the resources
11 necessary to create solutions.

12 MS. BUCK: Well, we have to back in
13 to this problem is what you're saying.

14 MR. WARSHAWER: So we're back to
15 this sort of bifurcated approach, where at a
16 certain scale they can, the businesses can
17 problem solve, should problem solve and a
18 certain kind of innovation will come out of
19 those businesses.

20 But we've got a whole other range
21 of enterprises who are not met by that
22 approach.

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1 DR. TILDEN: Right, and then what
2 happens is if you create an unworkable system,
3 you know, you say okay, here's a number, make
4 your numbers and then I'm not going to tell
5 you how to get there.

6 And you say, one to 400, you know,
7 you want to work with 400 people and tell them
8 how to meet the numbers? It's the same in
9 Michigan.

10 Our guy, when he retired he said,
11 whew, I'm free. But --

12 MS. TUCKER-FOREMAN: You know, I'm
13 sorry, I'm a capitalist and I believe that
14 large or small, if you can't meet the
15 standards then you can't be in business.

16 DR. TILDEN: Well, this is where --

17 MS. TUCKER-FOREMAN: Now, having
18 said that, I've got my asterisk which says
19 that it's reasonable to offer the kind of
20 information that USDA has not wanted to take
21 responsibility for offering because, as Steve
22 and I were discussing at lunch, there are the

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1 HACCP fundamentalists who say HACCP belongs to
2 the company, it doesn't belong to the
3 government.

4 And the government shouldn't tell
5 people. But these are people who are saying,
6 tell me, tell me.

7 DR. TILDEN: And maybe there's an
8 alternative so it doesn't have to be FSIS that
9 develops it. It's a, you know, university and
10 industry consortium or whatever.

11 You know, there's ways you can work
12 it, so that you get the best science and the
13 best practical information crystallized down.
14 Whosever's logos are on top of it.

15 MS. TUCKER-FOREMAN: But FSIS has
16 to sign off on it.

17 CO-CHAIR CUTTER: Just so you know,
18 I am part of a consortium that developed this
19 summer with academic and ARS researchers to do
20 exactly this with validation.

21 So we are making steps in that
22 direction.

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1 DR. TILDEN: Oh, cool, okay we're
2 done.

3 (Laughter.)

4 MS. TUCKER-FOREMAN: Okay, all
5 right.

6 CO-CHAIR CUTTER: Texas A&M,
7 Colorado State, Eastern Regional in
8 Philadelphia, Iowa State, people who have been
9 doing validation work for years, my colleagues
10 over the years.

11 So we are working on this and I
12 bring this to your attention now because this
13 is exactly what we want to propose.

14 MS. BUCK: What is the name of the
15 consortium?

16 CO-CHAIR CUTTER: I'm sorry, do you
17 have it there, Jay? It's a consortium for
18 process validation expertise, like CPE
19 something, CPVE. I had a copy of it and I
20 left in my other notebook.

21 MS. BUCK: That's okay, we can get
22 it later.

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1 DR. MURINDA: So what's the profile
2 of expertise on that panel?

3 CO-CHAIR CUTTER: People who have
4 been doing validation for industry purposes
5 for a number of years.

6 DR. WENTHER: Consortium of Food
7 Process Validation Experts.

8 DR. MURINDA: Actually it's
9 microbiologies.

10 CO-CHAIR CUTTER: Go ahead and read
11 the list on there.

12 DR. WENTHER: Out of the 12
13 individuals, 11 of them have a background in
14 microbiology. Gary Acuff of Texas A&M, Mindy
15 Brashears of Texas Tech, Jim Dixon out of Iowa
16 State, Cathy Cutter, Penn State University,
17 John Luchansky out of ARS, Peter Muriana from
18 Oklahoma State.

19 Randy Phebus, Kansas State
20 University, Steven Ricke, University of
21 Arkansas, Jeff Sindelar out of the University
22 of Wisconsin, Manpreet Singh of Auburn

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1 University, John Sofos, Colorado State
2 University, and Dr. Thippareddi out of
3 University of Nebraska.

4 MS. TUCKER-FOREMAN: Other than
5 you, who in that group works extensively with
6 small companies? Because all, the first five
7 names I heard work for the biggest five
8 companies I know.

9 CO-CHAIR CUTTER: Yes, and that was
10 a question that came up earlier today. Jeff
11 Sindelar from Wisconsin does. I'm trying to
12 think. I mean most of them we would say would
13 work, and I would say John Luchansky has
14 worked with small plants, he has worked with
15 them in Pennsylvania.

16 Probably not as extensively as me,
17 but he has. I can't think of anybody else,
18 but that's a very valid point, and we talked
19 about this.

20 And there's even discussion about
21 bringing some industry folks on who have
22 expertise to support us. And, I don't know,

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1 we could make copies of that or I can send it
2 out to the Committee later on.

3 We just drafted this about a week
4 and a half ago, well, I was asked to present
5 this at the meeting, so here's my opportunity.

6 DR. WENTHER: And that's why I went
7 through the websites and looked at everybody
8 who is on here and everybody has a
9 microbiology background, with the exception of
10 Dr. Sindelar, who is about 60 percent
11 extension, 40 percent research.

12 MS. TUCKER-FOREMAN: My reluctance
13 about that kind of consortium putting
14 together, I, you know, it's terrific to have
15 them put it together. FSIS has to accept it
16 as meeting the public health need.

17 It wouldn't be in fair of an
18 assumption that FSIS has to adopt whatever
19 comes out of such a group, because what we
20 want is not can it work, but does it work?

21 We want the measurement and the
22 microbial assessment to show that the plant is

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1 able to make it work and on the ground, in
2 their circumstances, not at the level of
3 several people meeting in a room saying this
4 should work.

5 CO-CHAIR CUTTER: No, I mean we
6 realize that there are limitations and I'll
7 pass this around, I don't know, Jay, if you
8 want to pass your copy around? Just so
9 everybody can look at it, just so they have an
10 idea.

11 We realize that there are pitfalls
12 with everything we do. There's even the way
13 we do challenge studies, the way we
14 disseminate the information.

15 Right now this group wants to get
16 together and do a one-day workshop on the best
17 practices for validation that we can
18 disseminate in our particular states.

19 So, I mean, it's a step in the
20 right direction.

21 MS. TUCKER-FOREMAN: It is.

22 CO-CHAIR CUTTER: Is it perfect?

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1 No, we've got still work to do, this is, we've
2 only had two meetings to discuss this all and
3 put this together in a lot of emails, so it's
4 just a step.

5 MS. TUCKER-FOREMAN: It will be,
6 actually, the research that comes out of, how
7 it's applied in the various states will be
8 really important.

9 CO-CHAIR CUTTER: We even addressed
10 the White Paper, the White Paper issue, it's
11 listed there as a way to take this information
12 and present it to FSA. But we realize that
13 there is -- we need to do something and this
14 is why we put this all together.

15 MS. BUCK: Yes, I think, I think
16 you are absolutely right, Cathy, we need to do
17 something because we've been sort of just
18 treading water for ten years, and that has got
19 to stop.

20 CO-CHAIR JONES: So can you put
21 some words to --

22 MS. TUCKER-FOREMAN: Well, that's

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1 one of the innovative ways.

2 (Laughter.)

3 MS. BUCK: That's an innovative way
4 of saying we want to stop this swirling mess.

5 MR. WARSHAWER: Well, what I'm
6 hearing is, let's look at what happened
7 between last meeting and this meeting and we
8 made, the Committee made some recommendations.

9 All through the presentations this
10 morning, they were saying you recommended
11 this, we're following up on it. So what
12 we're, it looks like there's a, if we use that
13 as an example, we need some kind of a body who
14 presents the process verification material.

15 The USDA approves it. Maybe it has
16 to go to lawyers, who knows who has to look at
17 it to decide if it's acceptable. And once
18 it's approved, then it's disseminated through
19 Office of Outreach and people in the field
20 start using it.

21 So what we're trying to do is
22 design a mechanism so that the right people

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1 are producing the information. It's going
2 through FSIS and then out to the stakeholder
3 community.

4 And so that would be an innovative
5 strategy, I suppose. Is that, and there may
6 be several different categories in which this
7 kind of subject matter expert body needs to be
8 formed.

9 Maybe there's only the one, but
10 there may be others where this style of
11 approach, so FSIS is getting, perhaps
12 participating in, but is getting outside
13 authority, expertise, outside expertise to
14 produce the information that it needs, so that
15 it can get it out to the stakeholders so that
16 then the regulation process works more
17 effectively.

18 MR. SHAW: I mean, I just, and I
19 don't want to be giving you ideas, but it is
20 something that we did discuss, I think it was
21 Meryl's idea, is that at one point we were
22 discussing.

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1 We had discussed about a situation
2 where we would actually go through some of the
3 large, the papers that we see from up, time
4 and time again as supporting documentation.
5 And we would actually diagram them. Like we
6 would actually diagram them and then, you
7 know, highlight and underline and very, like
8 where, where the critical operating planners
9 were in that document.

10 We do have, there were questions
11 about copyright, questions about, oh, if those
12 ten are the ones chosen, are we promoting
13 them. And we're a regulatory agency so we
14 have difficulty doing that.

15 CO-CHAIR JONES: We understand.

16 MR. SHAW: We still think it's a
17 great idea, it's just we go back and forth and
18 whether we're the right body to do that or,
19 without the other ramifications that comes
20 along with it?

21 DR. WENTHER: Just accept it, you
22 don't have to do it.

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1 CO-CHAIR JONES: So if another body
2 moves in and that type of document, for your
3 review.

4 MR. SHAW: I mean we would give
5 comment on it, we would make comment on that
6 review. But it does become, it's a difficult
7 position for us.

8 Like we, it's an ethical question.

9 DR. TILDEN: It seems like it would
10 be a lot quicker if you had the extension
11 types who are already doing this day-to-day.
12 They kind of know what their short lists are.

13
14 And then if you had some way of
15 combining that scientific expertise and then
16 leverage the practical expertises of industry
17 folks and match it up.

18 So one of the things that typically
19 gets thrown out to me is I've got 90 different
20 products, there's no way I can make this work.

21 Well, then when I talk to the
22 people who actually do this quite a bit, they

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1 said, well, yes, those 90 products, they
2 always fall into a couple different
3 categories, so you can pretty quickly get it
4 down into categories.

5 And the other is one or two oddball
6 things, but those are oddballs, so let's just
7 help them see how they can get 80 percent of
8 their problems solved with 20 percent of their
9 effort and then move forward.

10 And I think most of the people who
11 work on these things, have all the shortcuts
12 already worked out. But it just seems like it
13 hasn't been distilled down into a single
14 place.

15 So it seems like everybody is
16 reinventing and stumbling through this over
17 and over again.

18 DR. WILLIAMS: In conjunction with
19 that, John, and then as the information system
20 was disseminated this morning and the pitfalls
21 that it's got, would it not be part of the
22 innovative strategy that we put forth to not

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1 try to encompass everything all at one time,
2 through the agency?

3 Do a segment whether that be specie
4 or type product or process, do that and see
5 how it works. Learn from that and then expand
6 it into the others, rather than all at one
7 time.

8 Because I'm afraid that in the way
9 the guide is written, if it's thrown out there
10 and enforced it is going to be absolute
11 chaos.

12 DR. TILDEN: Right, so if you do
13 the low hanging fruit thing, what are the most
14 stable processes that are best, easiest to do
15 and get, cover the biggest footprint in the
16 meat industry? Get those first.

17 MS. TUCKER-FOREMAN: Do you have in
18 your mind the ten biggest, the ten most
19 frequent problems?

20 CO-CHAIR CUTTER: That was my
21 question about prioritizing. Which CCPs need
22 to be addressed, right now, need the most

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1 attention?

2 MS. TUCKER-FOREMAN: I think part
3 of our answer ought to be exactly that,
4 identifying, prioritizing so you identify the
5 top ten or 12 that whatever works at this.

6 MR. SHAW: I mean bet we, I mean I
7 bet if we sat down and thought about it for an
8 hour or so, I mean we can come up with where,
9 and we always get new ones all the time, but I
10 think we have, we can come up with bigger
11 categories of like where issues arise.

12 I mean, you know, with
13 interventions around the antimicrobial and the
14 chemistry around them, that's, you know,
15 that's a big issue for us, we find.

16 And that's the chemistry of things
17 come out where you have establishments with
18 antimicrobial in dips or whatever and the PH
19 is the important part of that antimicrobial
20 and an establishment doesn't really realize
21 that and doesn't monitor it.

22 So, therefore, they're not getting

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1 the most out of their, because you know PH is
2 such an important part of that. So that's,
3 and there are scenarios around that.

4 I mean there's scenarios around
5 some of the non-traditional, ready-to-eat
6 products that sort of hit, you know, cooking
7 instructions type thing, developing cooking
8 instructions. I mean we could come up with
9 like a large --

10 MS. BUCK: You could talk even to
11 your strategic planning team to get some
12 insights from them on to set some of the
13 categories or priorities, whatever you want to
14 call them.

15 I mean you have a big problem.
16 When you have a big problem, one of the best
17 things you can do is break it down into
18 smaller parts, that are manageable.

19 So you have a big problem, and it's
20 not been resolved for at least the past 12
21 years. So you're going to have to, you're
22 going to have to reapproach it and not be like

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1 the fly that keeps trying to go out the window
2 when the door is three feet away.

3 MR. SHAW: Well, the other thing I
4 would say, it is an issue for the past 12
5 years, and I would say, you know, not
6 everything is an issue and I think not
7 everyone learned HACCP on Day 1, 12 years ago.

8 And I think, you know, people,
9 there are parts of HACCP as one of those, I
10 think, earlier academics of HACCP or whatever,
11 fundamentalist, HACCP fundamentalist, that
12 would be me.

13 In that there are aspects of HACCP
14 that are easier to understand than others.
15 This happens to be one of the, probably the
16 most complex part of HACCP.

17 And so, you know, early on over the
18 12 years, and I think you were 80 percent and
19 the 20 percent and we learned the things that
20 are more understandable first and then as we,
21 I mean we have had food safety success over
22 the years.

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1 And now we're getting to the next
2 issue that we need to, you know, educate
3 about. Not everyone, as a former teacher, you
4 can't teach everything all at once.

5 MS. BUCK: Yes.

6 MR. SHAW: You've got to move.

7 MS. BUCK: That's it.

8 MR. WARSHAWER: The other piece is
9 that not everyone learns the same way. And I
10 will take a little, I mean I'm not sure that
11 folks who can't interpret a scientific paper
12 lack critical thinking skill.

13 I think they may learn a different
14 way. And so the idea of taking a paper and
15 diagramming it or turning it into a picture
16 book or a photo series.

17 There's all kinds of different
18 media. Now, I'm thinking about how Global Gap
19 teaches good agricultural practice in Africa.

20 They don't hand them a three-ring
21 binder, they have pictures. And, you know,
22 there's nothing wrong with operate, key

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1 personnel in meat plants learning through
2 imagery rather than through text.

3 And not necessary that they have to
4 go online and be Googlers in order to learn
5 the latest. If we're going to pursue the
6 desired outcome of safer food, we have to get
7 the material into a form that a very broad
8 range of learners and a very broad range of
9 people wishing to apply those, can access
10 them.

11 That's a, could be a USDA FSIS
12 task. The material comes from these newly
13 created subject matter expert sources. But
14 how to present it and how to, you know, that's
15 the outreach and education part that, and
16 you're concern, the concern that was raised
17 that we're a regulatory body, we're not
18 supposed to do that.

19 And I get there's a firewall
20 between the Inspector and everything else.
21 But a regulatory body that can't educate it's
22 stakeholders, can't inspect them.

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1 And that's kind of the quandary
2 that we're in, where you can say we don't
3 approve your HACCP plan, but we're sure going
4 to rate you and rank you and report on it,
5 once you've got one.

6 MR. SHAW: I agree with you. And
7 one thing I don't want to lose sight of when
8 we're talking about the scientists, because I
9 do think the scientists have a role to play,
10 because instead of me critiquing someone
11 else's work, I think they should speak for
12 their own work.

13 And I do agree that the scientific
14 community has this issue around writing
15 themselves. But I do think the scientists
16 have also a responsibility when they're
17 putting this research out, to also put it out
18 in a way that the ultimate user can understand
19 it.

20 MR. WARSHAWER: I'm not sure I
21 agree. That's not fair. I mean that's
22 telling the scientists how to do their

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1 science. Let's let scientists be scientists.

2 Let's let regulators figure out how
3 to disseminate the information in a form that
4 the user community can benefit from.

5 CO-CHAIR JONES: I don't mean to cut
6 you off, but with, for the essence of time --

7 MR. WARSHAWER: Go ahead, sorry.

8 CO-CHAIR JONES: -- I wanted to
9 kind of have an answer for Number 1. And
10 that's identify the top ten or so issues.
11 This is what I heard, identify the top ten or
12 so issues, whether they be species type
13 product process related, to develop a body
14 which would include those scientists, which
15 would include practitioners, who would review
16 the existing research that's been done by the
17 scientists and take into consideration the
18 various learning styles that we have produced,
19 various products that could help the end user
20 or the person who's actually inspector,
21 processor.

22 Identify the key points that should

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1 be addressed. Have FSIS review these products
2 and then disseminate them to, starting with
3 the top whatever number of issues we start out
4 with.

5 Whether it be three or ten. That
6 be something that they identify based on
7 complexity of the issues, I guess, and
8 implementation. And then just address them.
9 And have it be something that has that
10 continual --

11 MR. WARSHAWER: Iterations.

12 CO-CHAIR JONES: Yes.

13 DR. WILLIAMS: Would it also not be
14 appropriate that FSIS put out to every single
15 plant, to all its personnel, the optimum
16 explanation of the differences of validation
17 versus verification?

18 Because I get that and I know Cathy
19 does every time I do a HACCP class. What's
20 the real difference? In a means that a
21 layperson could understand.

22 DR. TILDEN: One of the things that

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1 we found is that us regulators in Michigan,
2 had to humble ourselves a bit and recognize
3 that how we, when we explain things and we
4 wrote up fact sheets for the industry.

5 And we said, oh, here, we got it
6 for you. It was just like Greek. And so we
7 ended up doing a collaborative process, where
8 we got the scientists to say here's the
9 content. And then we get the industry folks
10 and others to say, how do you put the content
11 into something that makes sense to others.

12 So it's got to be a collaboration
13 between multiple parties. But if we can
14 respect those rules, then I think we'll do
15 well.

16 CO-CHAIR JONES: So the
17 collaboration between multiple parties --

18 DR. TILDEN: Well, you've already
19 got the scientists getting together.

20 CO-CHAIR JONES: In the group
21 between them and the practitioner.

22 DR. TILDEN: But then just loop in

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1 industry people so they can say, yes, that
2 resonates, yes, that works. Or there's better
3 examples. And then you funnel in the right
4 examples, case studies, whatever, and then you
5 get something that industry associations can
6 push at their annual meetings.

7 Extension people can do at their
8 workshops and you start building on each
9 other's efforts.

10 MS. TUCKER-FOREMAN: But how do you
11 get the FSIS to say, if you're doing that
12 you've met at least a threshold for an
13 effective HACCP plan? Where does FSIS, FSIS
14 obviously has to bless this.

15 DR. TILDEN: Let Dr. Shaw do all
16 that for us.

17 (Laughter.)

18 MS. TUCKER-FOREMAN: We can't say
19 that we suggest that FSIS turns over their
20 responsibility for this to an outside group.

21 CO-CHAIR JONES: No, I think the
22 leak in the process was that they, FSIS does

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1 have to review. And, when I say review, I
2 don't mean just look at it. I mean actually
3 be involved.

4 But just not necessarily be the
5 sole, have the sole responsibility of creating
6 it.

7 Because you miss the end user or
8 the practitioner.

9 MS. TUCKER-FOREMAN: I accept that,
10 but I don't want to say in the process that
11 FSIS is relinquishing their responsibility for
12 setting what is an acceptable HACCP program.

13 So, somewhere along the line, it
14 has to be, it will in reality have to be what
15 FSIS thinks meets their responsibility. So
16 that they can say to companies, yes, if you're
17 following that, you're probably doing the
18 right thing.

19 CO-CHAIR JONES: Would FSIS be
20 responsible for identifying the key, the ten
21 issues?

22 DR. WILLIAMS: Absolutely.

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1 MS. TUCKER-FOREMAN: Oh, I believe
2 so.

3 CO-CHAIR JONES: They would be
4 responsible for that.

5 DR. MURINDA: Is it ten issues or
6 ten problem areas?

7 CO-CHAIR JONES: I just used the
8 word issue.

9 DR. TILDEN: Whatever, it's just,
10 priorities, that's what they're doing, they're
11 setting priorities.

12 MS. TUCKER-FOREMAN: And then they
13 can set another ten and ten and ten, but there
14 ought to be the A Number 1 list. People won't
15 do it unless FSIS, after the first group we'll
16 say, either this works for us or you need to
17 change two or three things, before it works
18 for us.

19 So I don't know exactly how to
20 phrase that. You don't want, you don't want
21 to use terms like veto, but you need some sort
22 of endorsement from FSIS that this meets their

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1 --

2 DR. TILDEN: Sometimes we call that
3 vetting it with our stakeholders.

4 MS. TUCKER-FOREMAN: Oh, that's,
5 well except the stakeholder. FSIS isn't the
6 stakeholder.

7 DR. TILDEN: I know, but FSIS will
8 run it through and get it reviewed by others,
9 to get input from others and then they --

10 MS. TUCKER-FOREMAN: That's good,
11 that's good. Put it out for public comment.

12 DR. TILDEN: Yes, and that way it's
13 transparent.

14 MS. TUCKER-FOREMAN: Yes.

15 DR. TILDEN: But the thing is, none
16 of us wants to change the science for
17 politics, you know, so I think we just have to
18 recognize that input is good but we've got to
19 recognize everybody has their own
20 perspectives.

21 And I was just looking at the
22 strategic plan, this all folds in pretty

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1 nicely. You know, they say talk about
2 strength and collaboration between internal
3 and external stakeholders to prevent food
4 borne illnesses.

5 So what we're proposing is not
6 outside of what they want to do.

7 MS. TUCKER-FOREMAN: No, no, it
8 just, I think I'm good with how we're talking
9 about it.

10 MS. BUCK: I would just suggest to
11 you that you put in there, besides
12 practitioners, you put other NGOs.

13 CO-CHAIR JONES: Okay.

14 MS. BUCK: Because I think there
15 are other groups that could possibly give some
16 --

17 CO-CHAIR JONES: So in the place of
18 practitioners?

19 MS. BUCK: Oh, I'd say
20 practitioners.

21 CO-CHAIR JONES: Practitioners and
22 other NGOs.

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1 MS. BUCK: Yes.

2 MR. WARSHAWER: There's one piece
3 that I'm not sure we've captured.

4 (Off-the-record comments.)

5 CO-CHAIR JONES: Okay, real quick,
6 there are refreshments and drinks next door,
7 and snacks if we need to take a break. But I
8 wanted to get the wording for, get the wording
9 down for Number 1, but we also need to move on
10 to Number 2.

11 CO-CHAIR CUTTER: Actually, I think
12 we see a lot of overlap, I think we've already
13 commented on two.

14 CO-CHAIR JONES: So we should be
15 good?

16 CO-CHAIR CUTTER: I think so, I
17 mean what do you all think? I mean they're
18 asking does the Committee have additional
19 suggestions as to the Agency can better
20 describe this important concept?

21 And I think we need a collective
22 group to go through this.

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1 MS. BUCK: Where is Page 14 of the
2 Guidance?

3 DR. TILDEN: It's kind of cryptic.

4 MS. BUCK: What does it say?

5 CO-CHAIR CUTTER: It says what
6 types of processes and products need to be
7 validated and they make like a little synopsis
8 along the lines, if you're doing pork and beef
9 then you should do in-plant data for both
10 species.

11 But if you're making a product that
12 has, just a change in spice blend, then you
13 wouldn't have to validate both those, you just
14 pick one and do that.

15 You're going to do small diameter,
16 large diameter sausage, only just do the large
17 diameter, at the time and then do it later
18 when you can do the other. In a nutshell.

19 MS. BUCK: Wait, go over that
20 nutshell again?

21 CO-CHAIR CUTTER: It's the last
22 four bullets there.

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1 MS. BUCK: Those last four bullets.

2 CO-CHAIR CUTTER: That's all
3 they're saying that they, plants can
4 prioritize their validation steps or
5 validation in the plant based on some of these
6 things.

7 So if you're processing or
8 slaughtering a pig, the process is inherently
9 different because of the steps. Therefore,
10 you should be validating the CCPs for that, as
11 well as beef, if you do beef in the plant.

12 And then if you do any of the
13 ready-to-eat, for the process products, they
14 want you to consider doing, maybe one product
15 if the only change is just a spice blend,
16 instead of doing both of them, just to save on
17 resources and things like that.

18 And then if you make small and
19 large diameter sausage, do the large diameter
20 because that's the worst case scenario.

21 MS. BUCK: Yes, because you'll
22 capture both.

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1 DR. TILDEN: The only thing I, you
2 know, as I was looking at that Page 14, the
3 first sentence under the, what types of
4 processes and products need to be validated.

5 The first time I read that I just
6 said to myself, oofta.

7 (Laughter.)

8 DR. TILDEN: And it was just like
9 all CCPs, interventions, prerequisite
10 programs, equipment. And I thought, well that
11 means I'm responsible for documenting
12 everything in all ways.

13 And I just, for, I think the whole
14 thing of prioritizing and focusing where it
15 needs to be, I think especially the small and
16 very small, they need some breathing space to
17 know some things don't have to be measured all
18 the time. One of the things we don in our
19 government, is we say, if we're measuring
20 everything all the time, nothing is getting
21 done.

22 And so we've got to figure out how

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1 to focus the measurements where they need to
2 be.

3 MR. WARSHAWER: Areas of greatest
4 risk, it's supposed to be, right?

5 DR. TILDEN: Yes.

6 MR. WARSHAWER: You keep trying to
7 --

8 MR. GOLTRY: I've got a comment on
9 this whole prerequisites and all that, because
10 if you look at the original preliminary draft
11 Compliance Guide, they were specifically
12 talking about prerequisite programs.

13 And the comments that we submitted
14 to AMI was if their validation be for CCPs and
15 prerequisite programs were there is not a CPP
16 that follows the prerequisite program.

17 In other words, if you have half a
18 program just based totally on prerequisite
19 programs, then those prerequisite programs
20 should be validated as if they were CCPs.

21 Yes, because, I mean, like you
22 said, the definition of prerequisite, what's

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1 that? But it can get very laborious and FSAs
2 could go on for six months.

3 MR. WARSHAWER: I was thinking that
4 when you guys were describing how this model
5 would play out and then you say getting in,
6 we've got the scientists and they do, and then
7 we get the industry involved and that's all
8 good.

9 The piece that's missing it's the
10 same scale thing, and I hate to be the
11 complainer about the larger enterprises can
12 afford to participate, the smaller can't.

13 And so in the example that I'm real
14 familiar with, with Global Gap, which is a
15 worldwide partnership, non-profit, on good
16 agriculture practice.

17 They have small holdings, you know,
18 special resources dedicated to small holding
19 involvement and small holding problems. And
20 this is pre-farm-gate production of mostly on,
21 and I'm thinking about the produce and fruit
22 and vegetable sector.

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1 So how, in a process like this, how
2 do we assure that the small and very small
3 plant, practical knowledge comes into this
4 interpretive process.

5 The scientists, you know, FSIS has
6 said here's the top ten, the scientists have
7 developed a body of response. We're trying to
8 turn that into a form that can be used.

9 We know that the larger enterprises
10 can afford to send their interpretive staff.
11 The smaller enterprises can't.

12 How does this mechanism work to
13 assure that the greatest number of
14 stakeholders who have the problem with this,
15 are present for the interpretive process and
16 we're making sure that it works for them.

17 DR. TILDEN: In Michigan, we have a
18 group called the Michigan Meat Association,
19 which by and large tends to be the, not the
20 multi-state kind of folks.

21 They tend to be the mid-size, small
22 or very small kinds of places. So, by working

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1 with them, and they get cranky with us from
2 time-to-time, as Jay knows.

3 But they're not shy about telling
4 us where we're screwing up. So we would
5 typically ask them, to involve some of them.
6 So I imagine other states have associations as
7 well.

8 DR. WILLIAMS: Not active.

9 MS. BUCK: I mean you have 50
10 different states and not all the states are, I
11 think we're close to being in uniformity.

12 MR. WARSHAWER: Not in New Mexico.

13 DR. MURINDA: National Meat
14 Association.

15 MR. WARSHAWER: Well, the bigger the
16 Association in geography, the less the smaller
17 enterprises will participate, just because of
18 cost and time constraints.

19 DR. MURINDA: The NMA focuses on
20 the small to medium plants.

21 MR. WARSHAWER: Yes?

22 CO-CHAIR CUTTER: Jay --

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1 DR. WENTHER: Everybody focuses on
2 small, because it's 95 percent of the 6,200
3 plants that's out there, even AMI has got
4 small members.

5 DR. MURINDA: Yes.

6 MR. GOLTRY: And we work on certain
7 things more than you probably realize.

8 MS. BUCK: I think you'd be a really
9 good source for FSIS to discuss those White
10 Papers with.

11 DR. TILDEN: And then maybe what
12 you do is you have some focus groups of
13 different kinds of folks and run the products
14 by them, and see what they think?

15 MR. WARSHAWER: Yes, that's great.
16 Is it possible to have some of this process
17 also go out into the field, where the
18 operators are located? Because that gets the
19 best involvement from people who are otherwise
20 disenfranchised, just due to cost and
21 distance.

22 MS. BUCK: You mean like town hall

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1 meetings?

2 MR. WARSHAWER: No, no, focus group
3 style is more like it.

4 MS. BUCK: Yes, well a focus group.

5 MR. WARSHAWER: I mean, like in New
6 Mexico, we've got folks that I wouldn't bring
7 to the meeting like that, because they'd just
8 raise hell and undo any bit of progress that
9 we've made.

10 But we've got a number there that
11 would be the right people, but they'll never
12 come to a meeting held in Washington or
13 Chicago or Seattle.

14 CO-CHAIR JONES: So you're talking
15 about like after the large group creates these
16 tool kits that are used, whether it be a
17 diagram that you talked about. Actually
18 taking them out to the small --

19 MR. WARSHAWER: Yes, yes.

20 CO-CHAIR JONES: And make sure you
21 --

22 MS. BUCK: Outreach.

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1 MR. WARSHAWER: The outreach has to
2 be done --

3 CO-CHAIR JONES: What if we take
4 them out to the small --

5 DR. WILLIAMS: Send them to select
6 small entities and get their input.

7 MR. WARSHAWER: Right, right.

8 CO-CHAIR JONES: Get their input,
9 say is this relevant, does it --

10 MR. WARSHAWER: It could be one-on-
11 one or it could be groups, it really varies.
12 But there has to be a way, before we accept
13 something as ready-to-use that it's field
14 vetted to the people who are most difficult to
15 get information to and results from.

16 MS. BUCK: Could you do this, even
17 by webinars or teleconferencing?

18 MR. WARSHAWER: They don't even
19 have dial up out there.

20 MS. BUCK: Yes, but telephone
21 conferencing, would that work at all?

22 MR. LIANG: Can your association do

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1 what he's asking for your small membership?

2 DR. WENTHER: We make it available,
3 that's the thing. I mean it comes on almost
4 like a pilot program, if that's what you're
5 asking for is a pilot program to see if this
6 thing actually works.

7 And that's what would be
8 interesting. And we probably could have
9 potential. I mean I've got HACCP plans that
10 we've created just as model HACCP plans.

11 We could essentially create the
12 validation documents surrounding those to see,
13 is this what we emphasize as thinking that
14 would be acceptable?

15 MS. TUCKER-FOREMAN: I like the
16 idea of pilot projects before you get --

17 MR. LIANG: So do I.

18 MS. TUCKER-FOREMAN: -- it's such a
19 big ship we're moving here.

20 MR. LIANG: Can we task FSIS with
21 trying to identify model, you know, for trade
22 associations for guys like you who are worried

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1 about being disenfranchised, who don't, who
2 can't get out of your state or have a local,
3 an active local association. Is that too many
4 words?

5 MR. SHAW: Is there, I mean is
6 there a potential way of bringing together,
7 you know, land grant university extension
8 people under larger group where they're, for
9 lack of a term, deputized.

10 You know, they come together, what
11 you're talking about and they've deputized and
12 can be able to do that sort of information
13 dissemination that they have, that they've
14 come together as a group and the issues have
15 been, and they have a more single message.
16 Like a concerted message.

17 CO-CHAIR CUTTER: Well, that's what
18 this consortium is sort of trying to do. And,
19 you know, we can make it as big as we need to.

20 I mean you guys have already said we need
21 NGOs, we need industry, we need regulatory
22 focus involved in this process. I don't see

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1 why not.

2 DR. TILDEN: But it might be good
3 to segment it a little bit, so you don't throw
4 everybody all at the same, you know, and just
5 sequentially.

6 CO-CHAIR CUTTER: But I'm going to
7 throw this back, being the academic that I am
8 and in the economy that we have, are there
9 funds available to help support this endeavor?

10 We need money to be able to meet
11 and to work together.

12 MS. TUCKER-FOREMAN: Well, FSIS has
13 none and ARS has none.

14 MR. LIANG: So the question is
15 could you do it through membership dues or
16 other --

17 CO-CHAIR CUTTER: I don't think so.

18 MR. LIANG: You're trying to get
19 some, you don't have that kind of scale, you
20 know the small rooms or so. Can you affiliate
21 some way and get that.

22 MR. GOLTRY: Well, one of the ways

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1 is maybe we need to put these kind of
2 discussions more on a number of technical
3 meetings that are held.

4 And like, I don't know if you're
5 going to get the right crowd, you know, like
6 RNC, research conference, various conventions
7 as workshop kind of things.

8 One way that would get it done as
9 the money is at issue. As long as we're all
10 saying the same thing, when you do that.
11 Because I think you're going to have
12 disseminate this thing because I agree that
13 validation, and Bill you said before, we even
14 had some conference calls with some of our
15 members.

16 And it was herding cats on what
17 validation is. Validation, verification, in-
18 plant validation, scientific validation versus
19 HACCP validation. But I think over the last,
20 since the first guide was created, I think,
21 it's caused a firestorm and I think people got
22 their heads around what this really is, and

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1 it's an important part of the whole HACCP.

2 MS. BUCK: One suggestion,
3 somebody, because we're a small, very small
4 non-profit, and somebody suggested to us that
5 we do teleconference calls, go to our local
6 community college.

7 And you can actually, they can link
8 you up so that you, actually people can see
9 each other.

10 Now I realize that just means that,
11 you know, a lot of your people don't have
12 computers or anything, but could there be a
13 system whereby, like you would facilitate
14 bringing, you know, and making that type of
15 thing happen.

16 Because part of it, you're right,
17 you have different style learners. And some
18 of those learners are actually social
19 learners. And they need to feel like they're
20 part of the, a network.

21 And that's why in-person meetings
22 are so very important. So it's just, it may

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1 be something very trivial and small, but I
2 would certainly suggest it as another way to.

3 DR. TILDEN: We're, Michigan, we're
4 experts in being broke, because we've been
5 broke for ten years.

6 (Laughter.)

7 DR. TILDEN: We started way before
8 you came to the party.

9 (Laughter.)

10 DR. TILDEN: But the thing is you
11 always have money to do the most important
12 things. And if --

13 MS. BUCK: But you have to set
14 priorities.

15 DR. TILDEN: Right, and that goes
16 back to priorities. So maybe if we're not
17 looking for a million dollar mega-grant, but
18 we're looking for seed money, you know, to do,
19 for the pilot phase.

20 Because, like in Michigan, if you
21 could say the meat industry is way diverse, so
22 you want to have some from Mississippi, and

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1 some from Pennsylvania and some from Michigan,
2 and see if this thing can work on a wide range
3 of things.

4 We just go down and say we want a
5 pilot and we want it piloted in different
6 diverse kinds of settings, and see if these
7 tools can work in a wide range of hands.

8 And we really would appreciate some
9 seed money from FSIS or someplace so that, you
10 know, if it's going to cost, you know, 50 or
11 100 bucks a head to do something like this,
12 can FSIS pay for a quarter of that.

13 And then the states and the
14 associations, we all have to, we all pitch in.

15 You know, that's a good thing to say, hey,
16 here's a catalyst, come join the party.

17 MS. TUCKER-FOREMAN: I would, I
18 need to be assured, because my members will
19 not like it if I'm not that, we're not
20 endorsing anything that says small plants get
21 to meet different standards for safety.

22 That has to be explicit in this,

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1 that we're looking for ways to explain to them
2 how they can meet the standard, not change the
3 standard to meet the need.

4 MR. WARSHAWER: Well, what I feel
5 like we're trying to do is to take your point,
6 that modern regulatory systems govern outcomes
7 and figure out a way to administer that
8 regulatory system that's fair to enterprises
9 of all scales.

10 The outcomes are not changed.

11 MS. TUCKER-FOREMAN: I'm not in
12 for, I'm not in really for fair, I'm in for
13 meeting the safety standard, because fair is
14 in the eye of the beholder.

15 MR. WARSHAWER: Well, I'm just
16 going back to that small business fairness
17 regulatory blah, blah act.

18 MS. TUCKER-FOREMAN: But I never
19 voted for that.

20 MR. WARSHAWER: But it's the law.

21 (Laughter.)

22 MR. WARSHAWER: Yes, but it's the

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1 law. And it's the law for a reason.

2 MS. TUCKER-FOREMAN: And it is
3 imperfectly applied, I think would be fair to
4 say. I'm not, I'm not, I've got to be assured
5 that we're not, it's got to be in there that
6 we're not endorsing differentiated standards
7 of safety based on some --

8 MR. WARSHAWER: Everyone agrees.

9 MS. TUCKER-FOREMAN: Okay.

10 DR. TILDEN: Now, but that whole
11 thing about fairness, though, is one of my big
12 concerns is that what I see is a lot of people
13 bailing from FSIS.

14 Because as their standards get
15 ratcheted up and up, if people don't think
16 they have a reasonable chance of being able to
17 succeed, they punch the eject button.

18 And they, or they go retail exempt.
19 Which means they go from some form of a
20 regulatory structure to almost no regulatory
21 structure.

22 And so what I think we've got to do

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1 is make sure that, as we're ratcheting things
2 up, and to solve this box, we're not
3 transferring risk to someplace else and
4 creating a problem.

5 MS. TUCKER-FOREMAN: That's
6 absolutely fair. However, the amount of meat
7 and poultry that gets sold that way is de
8 minimis because so few people can buy from
9 somebody who doesn't have to meet some
10 standard.

11 For example, you can't sell to a
12 school district, if you're not inspected.
13 There may be a few you can sell to now, but
14 there won't be two or three years from now.

15 DR. TILDEN: Well, that's a whole
16 area of discussion and that's not one of our
17 three questions.

18 (Laughter.)

19 MR. WARSHAWER: Right, but that
20 doesn't change the fact that if we drive
21 people out of the public system, there will be
22 a bigger underground economy. And that's just

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1 --

2 MS. TUCKER-FOREMAN: There's no
3 sign right now that we have a big underground

4 --

5 MR. WARSHAWER: Oh, my heavens,
6 where do you live?

7 (Laughter.)

8 MS. TUCKER-FOREMAN: Okay, let's
9 talk about as a percentage of the total amount
10 of meat and poultry consumed since about 75 to
11 90 percent is produced by the 360 or the 600,
12 369 very large plants.

13 MR. WARSHAWER: Right, so apply
14 your argument and let's just drop the small
15 and very small because 75 percent of the food
16 comes from those 369. It will save us a bunch
17 of money.

18 MS. TUCKER-FOREMAN: No, no, no,
19 70, yes, 75 to 90 percent.

20 MR. WARSHAWER: Yes, so, but that,
21 there's a cultural reality as well. It's not,
22 you know, that's where the word fairness comes

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1 in. And I understand it's imperfect and I
2 understand it's interpretive, but it's there
3 for a reason.

4 MS. TUCKER-FOREMAN: The people in
5 the hospital with food borne illness don't go
6 by fair, was the meat safe.

7 MR. WARSHAWER: Well, then you, but
8 --

9 MS. TUCKER-FOREMAN: And that's
10 fairly objective standard.

11 MR. WARSHAWER: Then we don't want
12 people to be encouraged to operate outside a
13 system that includes a standard that we're all
14 striving for.

15 MS. TUCKER-FOREMAN: But we're not
16 going to lower the standard to encourage them
17 to stay in.

18 MR. WARSHAWER: Agreed, we all
19 agree on that.

20 MS. TUCKER-FOREMAN: Okay.

21 MR. WARSHAWER: It's the how
22 question that we're discussing.

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1 MS. TUCKER-FOREMAN: I just have to
2 have that made explicit because otherwise I'm
3 going to get, you know, I have a membership I
4 work for.

5 MR. WARSHAWER: That's fine.

6 MS. TUCKER-FOREMAN: They want to
7 know we're not going to say --

8 MR. WARSHAWER: We want them to be
9 --

10 MS. TUCKER-FOREMAN: Then I'm not
11 going to be part of a committee that says it's
12 okay to lower the safety standards.

13 DR. TILDEN: Right, but also --

14 MS. TUCKER-FOREMAN: They want the
15 reverse.

16 DR. TILDEN: But also, in our
17 government, in Michigan State Government, we
18 are held accountable not to create regulations
19 that are unattainable.

20 So it is an issue of, I think a
21 societal issue of you can say, you have to
22 have perfect water. But if there's no way to

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1 get perfect water, that standard is
2 meaningless.

3 So the challenge that we face all
4 the time is trying to come up with standards
5 that people can achieve.

6 MS. TUCKER-FOREMAN: Well, I think
7 that the amount of foodborne illness probably
8 suggests we haven't reached perfection.

9 DR. TILDEN: I'm not, that's why
10 I'm here. We're working on that. But the
11 issue of fairness is not inconsequential,
12 because you have to work collaboratively with
13 people.

14 And if people don't feel like
15 they're being treated fairly, they will not
16 collaborate with you. So, I mean it's that
17 simple.

18 CO-CHAIR JONES: I'm sorry, can we
19 look at the wording for --

20 (Laughter.)

21 DR. TILDEN: You keep coming back
22 to getting the job done.

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1 CO-CHAIR JONES: Can we list the
2 wording for Number 1 and see how we can
3 expound or expand on it to get, include
4 Number 2 and 3.

5 MS. TUCKER-FOREMAN: Can you zoom
6 in a little bit?

7 DR. TILDEN: Yes, please.

8 MS. SCHECHTER: I was trying to,
9 how do you like that.

10 (Off-the-record comments.)

11 CO-CHAIR JONES: Have we made a
12 decision?

13 DR. TILDEN: We made a decision
14 that we're not lowering the standards for
15 anybody. Especially not those small plants.

16 (Whereupon, the above-entitled
17 matter went off the record at 3:06 p.m. and
18 resumed at 3:24 p.m.)

19 CO-CHAIR JONES: I think we have,
20 excuse me, we have about 45 minutes or 51 to
21 be more exact. But we've come up with a quick
22 stab at the wording for our recommendation

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1 for, oh, one of the things that came out was
2 that the Subcommittee recommends that the
3 difference between validation and verification
4 be clearly explained.

5 I put that in as a comment, if
6 that's okay. And then the --

7 DR. WILLIAMS: And made available
8 to all clientele.

9 CO-CHAIR JONES: And made available
10 to all clientele. Clearly explained and made
11 available to all clientele?

12 DR. WILLIAMS: All stakeholders.
13 (Off-the-record comments.)

14 CO-CHAIR JONES: And then the next,
15 okay.

16 MS. TUCKER-FOREMAN: Make it
17 develop the consortium or, you had the purpose
18 first, develop a process to create a tool kit
19 by developing a consortium of scientists and
20 so on.

21 CO-CHAIR CUTTER: To develop a
22 consortium.

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1 MS. TUCKER-FOREMAN: Yes, but the
2 first thing is what, to put in what you want
3 them to do.

4 MS. BUCK: So you need to move the
5 creative tool kit up where your cursor is and
6 then back where develop is, yes.

7 MS. SCHECHTER: Oh, I see.

8 MS. BUCK: Yes.

9 MS. SCHECHTER: Develop a process
10 to create.

11 MS. BUCK: A tool kit, yes. So you
12 just want to copy that whole thing and put it
13 up, until the semicolon, you missed the
14 semicolon.

15 MS. SCHECHTER: Oh, I'm sorry.
16 Down to tool kit?

17 MS. BUCK: Now down to the end of
18 the parentheses.

19 MS. TUCKER-FOREMAN: That should go
20 up above develop.

21 MS. BUCK: Back it up there, back
22 up a little more, there, now you got it. And

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1 put that up after develop a process.

2 MS. TUCKER-FOREMAN: No, that goes
3 after validation, because that's the first
4 thing you want them to do.

5 MS. SCHECHTER: Okay, I'm a little
6 confused, develop a --

7 MS. BUCK: The process.

8 DR. WILLIAMS: Insert what you cut
9 and pasted, cut right after process.

10 MS. BUCK: Right after process.

11 DR. WILLIAMS: Insert it.

12 MS. SCHECHTER: Process.

13 DR. WILLIAMS: To create.

14 MS. BUCK: And then make another
15 bullet after the parentheses.

16 MS. SCHECHTER: Do you want develop
17 a link? Or develop a consortium?

18 MS. TUCKER-FOREMAN: It seems to me
19 that what we want to do is identify the top
20 priorities in which there are particular
21 issues with validation.

22 Where there are problems with

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1 validation.

2 MR. WARSHAWER: Specifically
3 problems which resulted in recalls or positive
4 tests or food, validation issues which,
5 validation problems which resulted in food
6 safety issues.

7 MS. TUCKER-FOREMAN: That's good.
8 Can you say that again.

9 CO-CHAIR CUTTER: Validation
10 problems.

11 MR. WARSHAWER: Problems which
12 resulted in food safety issues.

13 CO-CHAIR CUTTER: That resulted.
14 I'm an English major.

15 MR. WARSHAWER: Okay, fine, I'm
16 not.

17 CO-CHAIR CUTTER: Resulted in food
18 safety issues.

19 MR. WARSHAWER: Yes.

20 DR. TILDEN: So while we're on that,
21 what we're saying is --

22 MS. TUCKER-FOREMAN: No, take that

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1 out now.

2 DR. TILDEN: So are what we're
3 saying is we're not trying to do everything
4 all at once, but we're focusing initially on
5 where there are proven food safety problems?

6 MR. WARSHAWER: Validation issues
7 which are problematic.

8 MS. TUCKER-FOREMAN: And then the
9 second thing would be develop a process to
10 create a tool kit and that provides basic
11 information to address these issues. Right
12 there.

13 DR. TILDEN: Keep going to the word
14 that, three, four more words.

15 MR. WARSHAWER: A tool kit that.

16 MS. TUCKER-FOREMAN: Addresses
17 these issues.

18 MS. BUCK: And basic, you said
19 basic. That addresses basic issues and
20 supports diverse learning styles.

21 MS. TUCKER-FOREMAN: Well, no,
22 including, let's see, that addresses basic

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1 issues for --

2 MS. BUCK: Is it the basic issues
3 or the top --

4 MS. TUCKER-FOREMAN: The priority
5 issues.

6 MS. BUCK: Addresses priority
7 issues.

8 MS. TUCKER-FOREMAN: Experienced,
9 I'll wait until you --

10 CO-CHAIR CUTTER: Addresses these
11 priority issues?

12 MS. TUCKER-FOREMAN: Addresses --

13 MS. BUCK: Priority issues?

14 MS. TUCKER-FOREMAN: These priority
15 issues.

16 DR. WILLIAMS: Addresses identified
17 priority issues.

18 MS. TUCKER-FOREMAN: That's good.

19 CO-CHAIR CUTTER: The identified
20 priority issues. And get rid of basic.

21 MS. TUCKER-FOREMAN: And that --

22 MS. BUCK: And supports --

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1 MS. TUCKER-FOREMAN: And supports,
2 good.

3 MS. BUCK: -- diverse learning
4 styles.

5 MS. TUCKER-FOREMAN: And then we
6 need to say, in the next button -- develop a
7 consortium, except, do we really want FSIS to
8 do that or do we want them to encourage the
9 creation?

10 MS. BUCK: We could encourage the
11 creation of a consortium.

12 MR. WARSHAWER: Well that's kind of
13 a question. There was, is it bad if FSIS has
14 some accountability to it and vice versa?

15 DR. MURINDA: Encourage is support.

16 MS. TUCKER-FOREMAN: Encourage and
17 support.

18 MS. BUCK: Encourage and support
19 the creation.

20 MS. TUCKER-FOREMAN: That's good.

21 MR. WARSHAWER: I mean we wouldn't
22 be here as a committee, except that we're an

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1 FSIS committee. Do we want a consortium that
2 is essentially an FSIS committee?

3 MS. TUCKER-FOREMAN: Well, you'll
4 wait until the end of time to get a committee
5 approved.

6 MR. WARSHAWER: Okay, so we start
7 it as an ad hoc consortium and then try and
8 get it legislated?

9 MS. TUCKER-FOREMAN: Yes.

10 MR. WARSHAWER: Okay.

11 MS. TUCKER-FOREMAN: Or at least
12 endorsed in some way.

13 MR. WARSHAWER: Administratively.

14 MS. TUCKER-FOREMAN: Yes.

15 MR. WARSHAWER: Okay.

16 MS. TUCKER-FOREMAN: Because
17 they're trying to eliminate advisory
18 committees. You notice this one only met
19 twice in the last three years.

20 MR. WARSHAWER: And hadn't met for
21 how many years before that, though?

22 MS. TUCKER-FOREMAN: Oh, no, it met

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1 regularly, three times a year.

2 DR. MURINDA: And in that
3 consortium where do the extension experts
4 belong --

5 MR. WARSHAWER: There was a gap
6 from 2008 to 2010.

7 (Simultaneous speaking.)

8 DR. MURINDA: -- because of the
9 ability to bridge the gap between the research
10 and that for the dissemination.

11 MS. BUCK: Aren't they part of the
12 stakeholders, the extension?

13 DR. MURINDA: It's pretty broad.

14 MS. BUCK: In between so extension
15 --

16 DR. WILLIAMS: Academic is covered.

17 (Simultaneous speaking.)

18 DR. WILLIAMS: Academic/extension.

19 DR. MURINDA: Yes.

20 CO-CHAIR CUTTER: I think the
21 mission is fine.

22 MS. BUCK: Academics I think would,

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1 do we need the public health departments in
2 here at all?

3 CO-CHAIR CUTTER: Probably not,
4 they were just confusing.

5 DR. MURINDA: I think the
6 scientists you cater for that.

7 MS. BUCK: They can fall under the
8 scientists, and they're stakeholders.

9 CO-CHAIR CUTTER: For process --

10 DR. MURINDA: Processors.

11 MS. BUCK: Should we say food
12 practitioners?

13 DR. WILLIAMS: I think that's a
14 given.

15 DR. MURINDA: Food or meat?

16 MR. WARSHAWER: Oh, when you say
17 meat processors.

18 DR. MURINDA: We are focusing on
19 meat.

20 MS. BUCK: Well, they're the
21 practitioners.

22 DR. WILLIAMS: Well, I mean it's --

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1 MS. BUCK: We can put processor.

2 CO-CHAIR CUTTER: The meat and
3 poultry industry personnel?

4 DR. MURINDA: Most of all we're
5 talking about meat.

6 MS. BUCK: Do you want meat and
7 poultry industry personnel? Third bullet,
8 what do you want? Do you want to be called a
9 practitioner or do you want to be called meat
10 and poultry personnel?

11 MS. TUCKER-FOREMAN: Well, that
12 means, actually that means somebody, it might
13 mean somebody who is running a plant instead
14 of somebody who's running a trade association.

15 CO-CHAIR CUTTER: You said food
16 industry --

17 DR. WILLIAMS: You've got
18 stakeholders, that covers it.

19 MS. BUCK: How about processing
20 practitioners?

21 CO-CHAIR CUTTER: Practitioner
22 seems to me, it seems like that's a

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1 Veterinarian.

2 DR. MURINDA: Bovine practitioner.

3 (Laughter.)

4 MS. BUCK: No offense to the
5 Veterinarians.

6 MR. WARSHAWER: That's why we've
7 got a group.

8 (Laughter.)

9 DR. MURINDA: You have bovine
10 practitioner.

11 MR. WARSHAWER: Yes, I was.

12 MS. BUCK: But what do you want to
13 call them because they're practitioners right
14 now?

15 CO-CHAIR CUTTER: I don't call my
16 processors practitioners.

17 MS. BUCK: How about just
18 processor?

19 CO-CHAIR CUTTER: That's what I
20 said earlier.

21 (Simultaneous speaking.)

22 MR. WARSHAWER: Change

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1 practitioners to processors and you've got it.

2 CO-CHAIR JONES: And then the last
3 one is took kit should be part of this.

4 MR. WARSHAWER: Take out the first
5 one.

6 MS. BUCK: No, you can't take out
7 the first one.

8 CO-CHAIR JONES: Oh, no.

9 MR. WARSHAWER: Oh, okay, no, no,
10 I'm wrong, I'm wrong, I'm wrong, sorry, I
11 missed a word.

12 CO-CHAIR CUTTER: I'm just worried
13 that if we mandate that they provide funding
14 for this, it may not go anywhere.

15 DR. TILDEN: How about the
16 committee recommends?

17 DR. WILLIAMS: It still doesn't
18 mean it shouldn't happen.

19 MS. BUCK: We could say that the
20 committee recommends that FSIS provide review
21 and partial, we could say it that way.

22 DR. WILLIAMS: No, we'll provide

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1 review and encourage partial funding.

2 MS. BUCK: Okay.

3 DR. WILLIAMS: Because we do want
4 them to review it.

5 MS. BUCK: Yes, you're right. So
6 the committee recommends that FSIS will
7 provide review and encourage partial funding?

8 MR. WARSHAWER: And consider,
9 consider partial funding?

10 MS. BUCK: No.

11 DR. MURINDA: Must, must.

12 (Laughter.)

13 MS. BUCK: Yes, I would take out
14 partial too.

15 DR. MURINDA: It's up to them to
16 decide.

17 MS. BUCK: We're going to get
18 partial, so take out partial. You don't need
19 partial.

20 MS. TUCKER-FOREMAN: Do you need
21 that verb, will?

22 MS. BUCK: I don't think you need

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1 will. You want them to provide it.

2 MR. WARSHAWER: What's wrong with
3 the committee saying, recommending that FSIS
4 provide funding?

5 MS. TUCKER-FOREMAN: No, we want
6 it, don't want it to say partial, because, say
7 funding.

8 MS. BUCK: That's what we just
9 said.

10 DR. MURINDA: It might provide all
11 of it.

12 MS. BUCK: They won't provide all
13 of it.

14 (Simultaneous speaking.)

15 MS. BUCK: Provide review and
16 funding to support.

17 MR. WARSHAWER: Well, let's be
18 realistic, how much money does it cost for the
19 system to not work?

20 MS. TUCKER-FOREMAN: We're trying
21 to get as much as possible. If you say
22 partial --

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1 MR. WARSHAWER: I know, but what I
2 mean, the idea that FSIS would look at it and
3 say there's no money to do this, FSIS analysis
4 could include savings achieved through
5 successful implementation come from other
6 areas where we're going to cut expenses.

7 So it's not our business to say
8 where it comes from, it's a function that FSIS
9 needs to fund.

10 MS. TUCKER-FOREMAN: To meet the
11 outline of their strategic plan.

12 MR. WARSHAWER: Yes, ma'am, here,
13 here.

14 MS. BUCK: Okay, we have to put
15 something about the strategic plan in there.

16 DR. TILDEN: In accordance with the
17 strategic plan objective Number 4.

18 MR. WARSHAWER: Four and seven.

19 DR. TILDEN: Four and seven, there
20 you go.

21 MS. BUCK: Okay, the committee
22 recommends that FSIS provide, that FSIS, and

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1 then you can put a comma after FSIS and say
2 something like, that FSIS, in accordance with
3 their strategic plan.

4 CO-CHAIR JONES: Why don't we put
5 that first?

6 MS. BUCK: Okay, we could do it
7 first.

8 CO-CHAIR JONES: Up in the top in
9 that first--

10 MS. BUCK: Okay, and we could do it
11 up there, I didn't think of it there.

12 CO-CHAIR JONES: At the very
13 beginning?

14 MS. BUCK: Yes because this, we
15 have to justify it.

16 CO-CHAIR JONES: Like as a comment?

17 MS. BUCK: No.

18 CO-CHAIR JONES: Right in the
19 recommendation?

20 DR. WILLIAMS: No, above the
21 recommendation.

22 CO-CHAIR JONES: Yes, that's what I

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1 was saying. The first comment is to --

2 DR. WILLIAMS: No, above the
3 recommendation.

4 MS. BUCK: Above the
5 recommendation.

6 CO-CHAIR JONES: Oh.

7 MS. BUCK: Yes.

8 CO-CHAIR JONES: And there's a
9 comment up there.

10 MS. BUCK: Right under the comment?

11 DR. WILLIAMS: No.

12 MS. BUCK: No.

13 MR. WARSHAWER: So is this the
14 answer to all three?

15 DR. TILDEN: This is one.

16 MS. BUCK: Well, no, this isn't
17 really a part of the comment, this is preamble
18 to our recommendation.

19 DR. WILLIAMS: Right, as another
20 point, like a preamble.

21 MS. BUCK: A preamble to the
22 recommendation.

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1 CO-CHAIR CUTTER: So it would go in
2 front of identify.

3 MS. BUCK: Yes, well, I mean.

4 CO-CHAIR JONES: Well, this is kind
5 of a preamble too. I took it as defining the
6 difference.

7 DR. WILLIAMS: Well, yes, that's
8 first off. But in accordance to --

9 MS. BUCK: Instead of recommend,
10 just say in accordance with.

11 DR. WILLIAMS: No, you still have
12 to have recommendations there, because that's
13 what we're recommending.

14 (Simultaneous speaking.)

15 MS. BUCK: That's your preamble?

16 DR. WILLIAMS: Yes.

17 CO-CHAIR JONES: I don't think we
18 need to differentiate.

19 MS. BUCK: Preamble to
20 recommendations.

21 CO-CHAIR JONES: Just preamble.

22 DR. WILLIAMS: Preamble, semicolon,

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1 in accordance to or in accordance with
2 strategic, FSIS strategic plan goals.

3 MR. WARSHAWER: Four and seven, I
4 think it's four and seven. But Dr. Shaw, you
5 said you thought what we're talking about was,
6 were relevant to goals four and seven?

7 MR. SHAW: Four and seven.

8 DR. WILLIAMS: I would say four and
9 seven and I believe --

10 MR. WARSHAWER: We got it, thank
11 you.

12 DR. TILDEN: We were listening to
13 the power point presentation this morning.

14 DR. WILLIAMS: And then you come in
15 with recommendations.

16 MS. SCHECHTER: Do you need that?

17 DR. WILLIAMS: You can spell it
18 out.

19 MS. BUCK: Are we done?

20 MR. WARSHAWER: We've got to do
21 two, I think.

22 CO-CHAIR JONES: No, I don't -- I

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1 think, all this is all encompassing for all
2 three of the questions. I don't know if you
3 look at them, if you think that --

4 DR. MURINDA: They're redundant.

5 DR. TILDEN: I thought, well two is
6 still a little iffy, I think.

7 MR. WARSHAWER: Two is more
8 specific.

9 DR. WILLIAMS: Two is specific on,
10 to me, I interpret that as asking, and Dr.
11 Shaw, correct me if I'm wrong, is if you have
12 a category of products, say boneless fully
13 cooked hams and you have XYZ products in
14 there. You've got ten products in there.
15 You're asking how many of those actual,
16 individual products do you need to collect
17 validation data on, for that category. Is
18 that correct in what I'm saying?

19 MR. SHAW: Yes, because it goes to,
20 I think, the comment the good man from
21 Michigan said, that we do have, especially in
22 the red meat world, where they will make like

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1 90 sausages and they all have like a different
2 spice.

3 DR. WILLIAMS: Spice kit or
4 something.

5 MR. SHAW: Spice mix or something.

6 And, in our initial guidance, I think they
7 all panic very quickly. But, to us, we looked
8 at it like, well no, you wouldn't do all 90 of
9 them, you'd pick the thick, if you're cooking
10 them, you'll take the thickest one and do that
11 one and then move on.

12 But it started a panic. And so
13 we've attempted to sort of describe that, what
14 decision tree process or how you would go
15 about, but, you know, more input is always
16 required.

17 DR. WILLIAMS: Well, I think that's
18 going to come back and actually could be
19 covered by this scientific recommendations
20 that are being done here and for those
21 individuals to make those interpretations.

22 DR. TILDEN: So we could add a

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1 bullet to knock off Number 2, by just saying,
2 including categorization and worse case, blah,
3 blah, blah.

4 DR. WILLIAMS: I think it's, just
5 to show that we have addressed that question.

6 MR. SHAW: And then I would make a
7 request and I know you're putting in there the
8 validation versus verification. In addition
9 to that, there is a section in the guidance
10 document that talks about that.

11 So any sort of like specific
12 clarification, recommendation language, things
13 you like in that language, things you don't
14 like, in addition to that recommendation,
15 would be greatly appreciated. It's about a
16 page and a half, actually in the guidance. We
17 would be happy to --

18 DR. WILLIAMS: It's bulleted.

19 DR. TILDEN: Put it on a diet.

20 (Laughter.)

21 CO-CHAIR JONES: Do we do something
22 like, doing the same thing that you're doing

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1 with the White Papers, making it more user-
2 friendly?

3 DR. WILLIAMS: User-friendly, you
4 know, simplified in a very shortened version.

5 CO-CHAIR CUTTER: Do you need an
6 executive summary in there that basically
7 highlights the important points?

8 MS. BUCK: It would seem to me what
9 we need to do is we need the validation and
10 verification needs to address all public
11 health issues with the processing.

12 So I mean if you have a small,
13 skinny patty you're producing, and you have a
14 thick one. If you test the thick one and it's
15 okay and you're using the same process for the
16 thin one, then it should also be okay is what
17 you're saying?

18 CO-CHAIR CUTTER: That's what they
19 say in the guidance, they already say that in
20 there, so I think we're covered under that.

21 I think, I guess the question is,
22 is in the, the very early part of this

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1 document, we need to sort of condense some of
2 the important points into something more
3 easily readable.

4 DR. WILLIAMS: I don't know.

5 CO-CHAIR CUTTER: Is that, that
6 one?

7 DR. WILLIAMS: I think that goes to
8 the comment right there, is what you're
9 asking.

10 CO-CHAIR CUTTER: I like the
11 question approaching this document, I like
12 that, I think that --

13 DR. TILDEN: That's good, going in
14 the right direction. And providing examples
15 is good. But, so you're asking for a little
16 more specifics on this clearly explained part?

17 CO-CHAIR CUTTER: Yes.

18 MR. SHAW: I mean, anything that
19 you can sort of, you know, lift out of the
20 guidance.

21 DR. TILDEN: So what if we were to
22 throw in there clearly and concisely, because

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1 I think clearly doesn't mean more words.

2 CO-CHAIR CUTTER: Clearly and
3 concisely explained.

4 DR. TILDEN: Yes, and then if we
5 could add the thing, providing examples and
6 questions and practical whatever. That's, I
7 think that's where it really helps is you get
8 beyond the general words and you provide
9 concrete examples.

10 DR. WILLIAMS: At the end to
11 include, to include specific examples.

12 DR. TILDEN: Yes.

13 DR. WILLIAMS: Or representative
14 examples, should I say.

15 DR. TILDEN: Yes.

16 MS. BUCK: And made available to
17 include, that's such a hard sentence, wow.
18 Verification be clearly and concisely
19 explained.

20 DR. WILLIAMS: How about we put a
21 period there?

22 MS. BUCK: Move to include after

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1 explain.

2 CO-CHAIR CUTTER: Yes, I would
3 agree. My mother was an English Teacher.

4 DR. TILDEN: There was nobody in my
5 family that talked.

6 (Laughter.)

7 DR. TILDEN: That's why I went into
8 science.

9 MS. TUCKER-FOREMAN: I don't know
10 that you really need to say anything more
11 than, clearly and concisely explained.

12 DR. WILLIAMS: I think you're
13 probably right.

14 MS. BUCK: Yes, sometimes less is
15 more.

16 MS. TUCKER-FOREMAN: It's either
17 this, or we're going to have to have three or
18 four lines. Unless you really need it, I
19 think that we ought to leave it at that.

20 DR. TILDEN: But I do think, one of
21 the things that people said, was the question
22 and answer format was good and that examples

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1 were good.

2 So rather than blocks of text, you
3 know, paragraphs, giving them something
4 specific.

5 DR. WILLIAMS: Okay, let's leave it
6 alone before we screw it up more.

7 MS. BUCK: The Subcommittee
8 recommends that all stakeholders --

9 MS. TUCKER-FOREMAN: That FSIS make
10 available --

11 MS. BUCK: To all stakeholders the
12 difference between validation. Yes, I just
13 moved that all stakeholders up. Subcommittee
14 recommends that, that's going to be too hard?

15 CO-CHAIR CUTTER: I think it's
16 fine.

17 MS. BUCK: That the difference
18 between validation and verification be clearly
19 and concisely explained to include
20 representative samples and made available to
21 all stakeholders, okay.

22 CO-CHAIR CUTTER: Because the most

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1 important part is that --

2 MS. BUCK: Yes, is that up there,
3 yes.

4 DR. WILLIAMS: Then we need to put
5 --

6 CO-CHAIR JONES: We need a bullet
7 for --

8 DR. WILLIAMS: We need a bullet to
9 address Questions 2 and 3.

10 MR. WARSHAWER: I think three is
11 rolled into one.

12 DR. WILLIAMS: But we just need to
13 make a reference to that.

14 DR. TILDEN: The only thing on two,
15 I feel pretty strongly that that first
16 sentence is just huge. Is there a way we can
17 tighten that up?

18 MR. WARSHAWER: On Page 14, you
19 mean?

20 DR. TILDEN: On Page 14.

21 MR. WARSHAWER: The famous Page 14?

22 DR. TILDEN: Because it sounds like

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1 they need to collect execution data on
2 everything in the plant.

3 CO-CHAIR JONES: As time and
4 financial resources permit?

5 MS. BUCK: On any instead of all?
6 Would any work?

7 DR. TILDEN: Well, it really goes
8 back to that thing where we talked about, when
9 you start including all the prerequisite
10 programs, where does that end?

11 So maybe we use that language where
12 as prerequisite programs that are not followed
13 by CCP.

14 MR. WARSHAWER: Hey, we're going to
15 be done with this when we walk out of the
16 room.

17 DR. TILDEN: We're not going to be
18 editing it for the next two months?

19 MR. WARSHAWER: No.

20 (Laughter.)

21 MR. WARSHAWER: I'm going to have
22 to hurt you.

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1 DR. TILDEN: Well, that wasn't
2 totally off, the questions were impossible to
3 report out on.

4 DR. MURINDA: I think that section
5 should come after the second bullet, just push
6 it up.

7 CO-CHAIR JONES: Where, where?

8 DR. MURINDA: About the pilot.

9 CO-CHAIR JONES: Does that read
10 correctly?

11 CO-CHAIR CUTTER: Well, let me ask
12 you, do we need to put in an order, like
13 encourage, I think the scientists --

14 CO-CHAIR JONES: Should come first.

15 CO-CHAIR CUTTER: Should come first
16 before the tool kit, because aren't they going
17 to develop the tool kit?

18 DR. MURINDA: Yes, what I'm talking
19 about is the second one, where it says develop
20 the process to create a tool kit.

21 CO-CHAIR CUTTER: Just develop the
22 tool kit.

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1 DR. MURINDA: And then after that
2 you elaborate on the tool kit.

3 MS. BUCK: Yes, what is the most
4 important thing that we're asking FSIS to do?

5 MR. WARSHAWER: The consortium.

6 MS. BUCK: The consortium, so --

7 MR. WARSHAWER: I think that can be
8 reversed.

9 MS. BUCK: We need to put the
10 consortium second.

11 MS. TUCKER-FOREMAN: Yes, put the
12 consortium second. We've moved it down.

13 MS. BUCK: So we need to take --

14 CO-CHAIR CUTTER: Move encourage
15 and support up to, above develop.

16 MS. TUCKER-FOREMAN: Yes, just take
17 the whole bullet.

18 DR. WILLIAMS: Yes, cut the whole
19 bullet and paste it as the second one.

20 CO-CHAIR JONES: Develop a tool
21 kit.

22 MS. TUCKER-FOREMAN: But we don't

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1 want FSIS to develop the tool kit.

2 CO-CHAIR JONES: Right, the
3 consortium should develop a tool kit, right?

4 DR. WILLIAMS: She had that in
5 there when they put it back in there.

6 CO-CHAIR CUTTER: Yes, but I mean,
7 because you've got a list of things and --

8 CO-CHAIR JONES: How about develop
9 a tool for kit with input from the consortium?

10 (Simultaneous speaking.)

11 CO-CHAIR JONES: Encourage, develop
12 pilot test?

13 CO-CHAIR CUTTER: WE need to
14 develop a tool kit with input from whomever.

15 MS. TUCKER-FOREMAN: Yes.

16 CO-CHAIR CUTTER: The consortium,
17 FSIS, stakeholders.

18 MS. TUCKER-FOREMAN: Except start
19 it with, let them know it's an exception to
20 the, starting with the verb, it reads weird.
21 IF you just say with the input of the
22 consortium, develop a tool kit.

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1 MS. BUCK: Okay, yes.

2 MS. TUCKER-FOREMAN: Sometimes we
3 get too devoted to putting our verbs first.

4 CO-CHAIR CUTTER: So with the input
5 of --

6 MS. TUCKER-FOREMAN: Or work with
7 the consortium to develop a tool kit.

8 CO-CHAIR CUTTER: In collaboration?

9 MS. TUCKER-FOREMAN: That's fine.

10 CO-CHAIR CUTTER: In collaboration
11 with the consortium? Do you want to
12 capitalize consortium?

13 CO-CHAIR JONES: If you do that,
14 they'll make you capitalize extension.

15 MS. BUCK: We don't want to go down
16 that road.

17 CO-CHAIR CUTTER: I know, that's
18 why I said it.

19 CO-CHAIR JONES: What about that
20 question --

21 DR. WILLIAMS: Let's address
22 Question 2 and 3 in this, so this thing in

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1 complete.

2 CO-CHAIR JONES: Well, we were
3 saying three is already --

4 DR. WILLIAMS: Yes, but we need to
5 say that in there, though, so that we have
6 addressed it.

7 CO-CHAIR JONES: Well, we could say
8 that above.

9 MS. BUCK: No, we didn't.

10 CO-CHAIR JONES: I said we can.

11 MS. BUCK: We can, but we didn't.

12 MR. WARSHAWER: Well, then we
13 better.

14 MS. BUCK: We could put it at the
15 bottom and it would seem to me that that would
16 also be a good location. Because, you know,
17 we had three questions. So, I don't care
18 where you want to do it.

19 DR. TILDEN: What if on that tool
20 kit, it's not only doing the prioritization,
21 can we say develop a tool kit that, and just
22 stick in teaches HACCP. What's the three?

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1 CO-CHAIR JONES: Validation,
2 reassessment and verification.

3 DR. TILDEN: Well, what do they
4 want us to do. Understand HACCP systems
5 validation.

6 MS. BUCK: Are you on Page 14,
7 again?

8 DR. TILDEN: No, I'm looking at the
9 Question 3.

10 MR. WARSHAWER: Question 3 on Page
11 6.

12 DR. TILDEN: What's the words we've
13 got to put in there to make it blend with the
14 tool kit?

15 DR. WILLIAMS: Just put the bullet
16 down there say, you know, addressed in, by via
17 tool kit in above recommendation.

18 MR. WARSHAWER: Okay.

19 MS. BUCK: Decision-making
20 processes?

21 MR. WARSHAWER: Are you looking at
22 Number 2 or Number 3?

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1 MS. BUCK: I was looking at two.

2 MR. WARSHAWER: Well, the statement
3 is, for establishments use of a wide variety
4 of products within one category, it may be
5 impractical and unnecessary to gather in-plant
6 data as part of initial validation for all
7 products.

8 CO-CHAIR CUTTER: Well, I think
9 this gets at the point of prioritization. We
10 need to understand what are the issues and
11 then sort of work on those initially and then
12 --

13 MS. BUCK: Criteria, decision-
14 making criteria.

15 MR. WARSHAWER: Right. Question 2
16 is specifically in relation to products who
17 produce a wide variety of products within a
18 HACCP category.

19 So what we need to say is that our
20 prioritization of validation requirements
21 includes this scenario. Right?

22 CO-CHAIR CUTTER: Yes, this is

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1 going to be a recommendation to, remember
2 Question Number 2.

3 MS. BUCK: Well, this is for
4 Question Number 2. Do you have all three
5 questions up there, somewhere?

6 CO-CHAIR CUTTER: No, not yet, but
7 I can put them up.

8 MS. BUCK: Yes, that would be one
9 way, put that as Question 1 and Question 2 and
10 Question 3, and then plug them in.

11 DR. WILLIAMS: Is, Dr. Shaw, is
12 that one of your top ten priority issues
13 that's addressed here in Question 2?

14 MR. SHAW: Oh, it's a huge one.
15 Because, I will tell you when we first put the
16 guidance out for the first go around, we
17 received over 2,000 comments.

18 I would say a vast majority of
19 those 2,000 comments were small processors
20 that panicked when they looked at that and
21 thought that, you know, I --

22 DR. WILLIAMS: Have to do it for

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1 every product.

2 MR. SHAW: And, to be honest with
3 you, I will be, we were shocked by that.
4 Because we're like, why would you do that?
5 Sure you wouldn't, you would not do all 120
6 types of sausages. You don't do that.

7 DR. WENTHER: But then you forced
8 the plants to come up with supporting
9 documentation so you don't have to do all the
10 products.

11 And it also identified in their
12 species processes, equipment and just look at
13 the smoked sausage. The smoked sausage may
14 look the same, but there's an all pork one,
15 all beef one and beef and pork one. I could
16 see an Inspector saying those are all three
17 different.

18 Because of the species that's used
19 and the species was identified and documented
20 and it's still. That's where it came from.

21 CO-CHAIR CUTTER: That's where the
22 education of Inspectors needs to come in.

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1 MR. SHAW: But therein lies our
2 question to you all. That depicts why that
3 issue made it to one of your questions.
4 Because we had to find a way to describe that
5 decision-making.

6 Because in that list and how he
7 said that, I would go for the beef one and the
8 beef and pork one, no, and the pork one, no,
9 if I had my choice.

10 And that scenario --

11 CO-CHAIR CUTTER: Well, because
12 you're --

13 MR. SHAW: In that scenario, but in
14 that scenario. And it's very difficult to
15 explain, to lay out that thought process and
16 not get too in depth about a specific type of
17 product.

18 It's really, I mean we have
19 struggled with that for months and months and
20 months. It's not easy to sort of describe
21 that decision tree with the vast, you know,
22 6,200 plants with --

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1 CO-CHAIR CUTTER: How can you
2 define, you know, something that fits the
3 worst case scenario?

4 MR. SHAW: Inevitably someone came
5 out and said you just need to do one product
6 per category and you can look at the red meat
7 category, I've got guys that are making ham,
8 sausages, roast beef, dried beef, all in the
9 red meat category.

10 And those are all different. And
11 then you start breaking that down even
12 farther, according to the guidance.

13 MS. BUCK: You need a broad way of
14 identifying what's going to be verified.

15 MR. SHAW: Validated.

16 MS. BUCK: Or, excuse me,
17 validated.

18 MR. SHAW: Through the years I have
19 the debate whether a bone-in ham is the same
20 as a boneless ham. And that's how difficult
21 this issue gets.

22 MS. BUCK: Well, it's not the same,

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1 is it?

2 CO-CHAIR CUTTER: No.

3 MS. BUCK: I mean I think that part
4 of it is and it's not the same.

5 DR. WENTHER: It's going to take
6 longer to get that bone at.

7 MR. WARSHAWER: Would that be worst
8 case scenario?

9 MS. BUCK: So, you do the, do you
10 want to use the term worst case scenario.

11 DR. WILLIAMS: But who is going to
12 determine what's the worst case because she's
13 saying that the expertise may not exist out
14 there, on both sides, to determine which is
15 the worst case scenario. If they don't have
16 the scientific model as a basis to determine
17 that.

18 MR. WARSHAWER: They're not supposed
19 to. And this is where we get back to the idea
20 that FSIS can't just say, okay, here's what
21 you got, do this one.

22 The Inspector can't say that

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1 because they're inspecting. That would be a
2 firewall breach between the outreach and
3 inspection.

4 But somebody has got to say bone-in
5 ham is the worst case, do that one and
6 everything else is covered. So how do we get,
7 so, and that's where I was thinking, early in
8 the beginning I was saying we might have more
9 than one consortium.

10 Or can FSIS just decide to do it.

11 DR. WILLIAMS: I don't think you
12 want that.

13 MR. WARSHAWER: Then we need
14 another third party.

15 DR. TILDEN: So maybe what the goal
16 is, is not to have the mother of all lists
17 that you break it down into. Is you have a
18 couple of examples of how you would, the
19 principle, how you would apply the principles
20 creating --

21 DR. WILLIAMS: A worst case
22 scenario.

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1 MR. WARSHAWER: Well, or you start
2 with a typical situation. This guy makes 15
3 products and this is how he would break them
4 down into three, or what.

5 But I think you can figure out how
6 to show them the principles of how to break
7 multiples, when you lump and with you split.
8 And maybe have two or three different
9 examples.

10 DR. WILLIAMS: Provide specific
11 examples.

12 DR. TILDEN: Almost like a
13 frequently asked question. Well, I make these
14 kinds of products, can I lump them or do I
15 need to split them?

16 DR. WILLIAMS: That's right.

17 DR. TILDEN: And then after they
18 see four or five examples and they say, oh,
19 okay, now I can apply these principles
20 someplace else.

21 MR. WARSHAWER: But then we don't
22 want them to go spend a bunch of money

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1 producing it and then have someone come out
2 and say, oh, you did it wrong, this is
3 actually the worst case.

4 DR. TILDEN: But that's why you get
5 this think out there ahead of time and then
6 you train people in it, so when the Inspector
7 comes in and says, you can't do that.

8 Say, well, this is what I was
9 basing it on. And they'll say, oh, I guess
10 you're right.

11 MR. WARSHAWER: But who is the
12 authority that can counter the interpretation
13 of the Inspector?

14 MS. BUCK: Well, is there an
15 authority in existence, today, that does this
16 type of thing?

17 DR. WILLIAMS: Well, that's, well
18 it even comes back to that or sometimes the
19 Cathy Cutters and the Williams of the world
20 get called in and asked their opinion. But
21 the ultimate decision lies with --

22 MS. BUCK: FSIS.

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1 DR. WILLIAMS: -- in FSIS.

2 MS. BUCK: Well, then FSIS has to
3 do it. They're the ones that has to define
4 it.

5 DR. WILLIAMS: That's what I'm
6 saying, they provide the examples --

7 MR. WARSHAWER: Okay, so ask FSIS,
8 as the oracle, and if you've got a date
9 stamped email from ask FSIS saying, with your
10 scenario, here's the worst case.

11 And your Inspector comes and says
12 no, that's not it, then it's an internal issue
13 at FSIS and the processor is done until that
14 gets resolved.

15 MR. SHAW: But I have to say the
16 better that we can explain the decision tree
17 or how you get to that conclusion, the better
18 that we can explain how to do that, the less
19 questions will get.

20 MR. WARSHAWER: Well, over time, as
21 both the processors and the Inspectors become
22 or you should get that question less and a

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1 whole new category of questions.

2 DR. TILDEN: Okay, so you need the
3 guiding principles document for how to
4 categorize.

5 MR. WARSHAWER: Yes.

6 DR. TILDEN: With a bunch of
7 different examples and it's FSIS sanctioned
8 and then you can put it out there and then the
9 exceptions that don't get covered by that,
10 call FSIS.

11 But that way everybody is not
12 making it up every time and you're always have
13 to ask over and over again the same thing.

14 MR. WARSHAWER: What do you think?

15 (Off-the-record comments.)

16 DR. WILLIAMS: Let's go back and
17 summarize what John said, I think that
18 addresses that with the examples.

19 DR. TILDEN: So create a guidance
20 document that identifies guiding principles
21 for lumping and splitting categories, product
22 categories, for the purposes of validation.

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1 CO-CHAIR JONES: That there's a
2 plan create --

3 DR. TILDEN: A guidance document
4 that provides guiding principles.

5 CO-CHAIR JONES: It just seems to
6 me we're going in a different direction to
7 limit the size --

8 DR. TILDEN: And examples, for
9 lumping and splitting product categories.

10 CO-CHAIR JONES: For lumping?

11 DR. TILDEN: We can change the
12 language later. For grouping product
13 categories for the purposes of validation
14 testing. You guys have done that before?

15 (Simultaneous speaking.)

16 CO-CHAIR JONES: And you said
17 something about, where did he go? Oh,
18 something to the effect of, indication of
19 exceptions?

20 DR. WILLIAMS: Extenuating
21 circumstance or exceptions that --

22 CO-CHAIR JONES: That don't fit

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1 into this --

2 DR. WILLIAMS: Extenuating examples
3 will be referred to --

4 CO-CHAIR CUTTER: On a per case
5 basis.

6 DR. WILLIAMS: Per case basis to
7 FSIS.

8 CO-CHAIR CUTTER: Indicating
9 extenuating circumstances.

10 DR. WILLIAMS: FSIS will review
11 validation of product category.

12 (Simultaneous speaking.)

13 CO-CHAIR JONES: Again, always keep
14 in mind these categories and if you have
15 questions, call us.

16 MR. WARSHAWER: So, can we, in that
17 recommendation can we say that if FSIS, if
18 asked, FSIS renders an opinion, then that
19 opinion protects the processor in the event of
20 a disagreement, interpretive disagreement with
21 an Inspector and that FSIS has to then,
22 becomes an internal issue, not a processor

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1 issue, if there's a disagreement.

2 So what we're trying to do is
3 facilitate a smooth transition, where --

4 CO-CHAIR CUTTER: Well, basically
5 anything that's written by *askFSIS*, should
6 serve as adequate --

7 DR. WILLIAMS: That sets precedence
8 anyway.

9 CO-CHAIR CUTTER: That sets
10 precedence for the Inspector.

11 MR. WARSHAWER: Right, so that, and
12 yes the Inspector will defer to an *askFSIS*
13 opinion. Because if we put that out there,
14 then the processor knows if they use that FSIS
15 service, they're getting the protection they
16 need for their practice.

17 I'll bet when we stop by, people
18 probably don't know that. Have never had that
19 successful experience.

20 MS. TUCKER-FOREMAN: Could you
21 lower it so I can read the line that's
22 partially --

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1 DR. WILLIAMS: Category,
2 parentheses S.

3 CO-CHAIR CUTTER: No, category, no,
4 no, no, you're good, go down to the bottom.

5 MS. BUCK: Can we make that larger?

6 MR. WARSHAWER: You want to be able
7 to read it or something?

8 (Off-the-record comments.)

9 DR. WILLIAMS: No, that is correct.

10 CO-CHAIR CUTTER: You just changed
11 the y to ie.

12 DR. WILLIAMS: If you include it in
13 a word. I did have an English class or two,
14 way back when.

15 (Laughter.)

16 CO-CHAIR CUTTER: I've been working
17 on food safety and forgotten all the rest of
18 it.

19 DR. WILLIAMS: Can we just not put
20 them, can we just not make it, you know, as
21 we've done here. Say Question 3 at the end of
22 two here and make the reference that we've

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1 addressed the recommendations?

2 CO-CHAIR CUTTER: So, are we okay
3 with that? Is everybody okay with that?

4 CO-CHAIR JONES: The question on
5 the table is if we, Question Number 3, excuse
6 me, I'm sorry. Question 2, I mean Number 3,
7 can we write out the question and then make a
8 comment, made a comment that it is addressed
9 in Question Number 1?

10 MR. WARSHAWER: Yes.

11 CO-CHAIR JONES: Is that okay?

12 MS. TUCKER-FOREMAN: We're
13 condensing here.

14 MR. WARSHAWER: We're lumping.

15 DR. WILLIAMS: Grouping.

16 MR. WARSHAWER: Whatever.

17 (Laughter.)

18 DR. WILLIAMS: I couldn't resist it
19 John, I had to antagonize.

20 CO-CHAIR CUTTER: Did you say we're
21 dumping?

22 MR. WARSHAWER: Lumping.

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1 DR. WILLIAMS: Now we've got a
2 third one, dumping.

3 (Simultaneous speaking.)

4 MS. TUCKER-FOREMAN: If you have a
5 guidance document you don't need to provide
6 guiding principles, just principles and
7 examples. Drop guiding in the first line.

8 MR. WARSHAWER: Maybe it's the
9 guidance document part that's not right.
10 Because that's a formal process, guidance
11 documents. Public comment and all that blah,
12 blah. So do we just want create a document
13 that provides guiding principles?

14 MS. TUCKER-FOREMAN: That's fine by
15 me.

16 MR. WARSHAWER: It's simpler.

17 MS. TUCKER-FOREMAN: That is less
18 limiting.

19 MR. WARSHAWER: Yes.

20 MS. TUCKER-FOREMAN: It may be a
21 guidance document in the end, but you're
22 right, less limiting.

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1 MR. WARSHAWER: It should start out
2 as an internal document and move towards
3 guidance as it gets proven.

4 MS. TUCKER-FOREMAN: Yes, good.

5 (Whereupon, the above-entitled
6 matter went off the record at 4:15 p.m. and
7 resumed at 4:19 p.m.)

8 CO-CHAIR CUTTER: Do you all want a
9 copy of this before you leave today? We're
10 going to mull it over to the morning, if you
11 have anything. But thank you so much.

12 (Whereupon, the above-entitled
13 matter was concluded at 4:23 p.m.)

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