

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

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USING DATA FROM OTHER SOURCES

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A CHARGE FROM FSIS: QUESTIONS FOR
CONSIDERATION IN BREAKOUT SESSIONS

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GREEN GROUP BREAKOUT

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10:45 a.m.

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I-N-D-E-X

<u>AGENDA ITEM</u>	<u>PAGE</u>
A Charge from FSIS: Questions for Consideration in Breakout Sessions	
1. What data could third parties provide to FSIS to further enhance protection of public health?	4
2. How can stakeholders assist the Agency in improving collection, validation, analysis and application of data?	17
3. What mechanism(s) can be developed to bring different stakeholders together and share quality data? Task Force? Third party repository? Regularly scheduled stakeholder meetings? Other mechanisms?	28
4. What are the barriers to creating such a mechanism? What incentives could be used to encourage sharing of data?	39

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

2 (10:45 a.m.)

3 DR. VETTER: What worked last time was just
4 going through each individual question and taking
5 comments. This is Danah Vetter, with NAFV, speaking.

6 And we'll start with, "What data could third
7 parties provide to FSIS to further enhance protection
8 of public health?" And one of the benefits of taking
9 on this role is I get to throw in my opinion right off
10 the bat.

11 I think that probably the most important
12 data, particularly when you're talking about any plant
13 data that you can provide to FSIS, which we currently
14 use in plant on a daily basis is microbial testing.

15 I believe it would be a complement to what
16 FSIS already does which is verify what the plants
17 microbial status is, and to no extent do I find that
18 FSIS, the amount of data they obtain or how frequently
19 they test is representative. That's why it's
20 considered verified -- to verify where as we look at
21 in-plant data, it's usually being sampled on a
22 daily -- several times within a day. So it's a more

1 real time and much more representative of what's going
2 on in the plant.

3 MS. GIOGLIO: Anybody else have a thought?

4 MR. CORBO: Tony Corbo, Food and Water
5 Watch. I have a question for Dr. Vetter. So how do
6 you use that in-plant data as, as inspection
7 personnel?

8 DR. VETTER: Danah Vetter again. On a daily
9 basis in-plant, as a veterinarian and IIC in a
10 slaughter plant, we look at several different
11 microbial evidence. We look at *E. coli*, generic *E.*
12 *coli*, to look at process control because it's the
13 indicator organism, you know, of process control. If
14 we start seeing those levels increase, and the plant
15 is doing the very same thing. We simply do it as part
16 of our verification process in-plant as well. And I
17 instruct the supervisors that I supervise to do so
18 also.

19 We've seen a lot of, and I speak to this as
20 a IIC and also as an EAIIO that has seen this in other
21 establishments, slaughter establishments and large
22 processing establishments, where they were doing

1 microbial sampling for *Salmonella* and many larger
2 corporations were even trying to get that on a
3 quantitative basis versus positive versus negative.
4 So that is very, very useful, and they're doing it at
5 multiple places in the process. And typically, you
6 know, we'll see five or six, depending on the plant
7 size and what they're slaughtering, but tests for
8 *Salmonella* is done within a day versus when we do
9 *Salmonella* set for FSIS we do them one per day, 56
10 sample sets. So that's a large part.

11 Also if they have their sanitation programs
12 often incorporate on microbial testing or -- testing,
13 we look at that, and it's really their verification
14 programs that we're looking at.

15 The other thing is I usually have very
16 stringent written protocols for doing this testing,
17 and this is as an IIC and EAIIO, we go in and we read,
18 we're going to do, we're going to sample it this
19 way -- so on and so forth, and we will actually
20 observe them taking those tests to make sure that they
21 are doing it as they said they would. The other side
22 of that is most of the time if they're using --

1 I am in support of this because we do it in
2 plant every day, and to have it be part of our
3 database and for FSIS to determine risk, I think it
4 would be very useful.

5 MS. GIOGLIO: When we were in the room,
6 Robert mentioned third parties being anything non-
7 FSIS. Was there anything else besides microbial data
8 that we think would be useful before we move onto the
9 next question?

10 MR. HENRY: Well, you certainly what to
11 throw up there -- this is Craig Henry with GMA/FPA --
12 certainly want to throw up the allergen verification
13 testing. All the plants certainly have investigated
14 or reviewed that relative to their hazard analysis and
15 would have implemented that within the program. So I
16 guess the question back to Danah, what has been your
17 experience with the acquisition and utilization of
18 that data by the Agency?

19 DR. VETTER: Again, Danah Vetter. We use it
20 in plant every day. If you're in a plant that does
21 allergen testing, then they have an allergen program
22 that they have written and they have certain

1 verification standards for it, and it's very much
2 similar processes that we use is that we look at what
3 they're going to test, how they're going to do it, and
4 then we go back and we look at that implementation of
5 it and that data ourselves to verify that you're
6 looking for any trends or indicators in that like I
7 think Dan Engeljohn references that if you're acting
8 appropriately when you do find something, and so it's
9 just very much the same thing, and I think it would
10 just be an added value to FSIS data because it's going
11 on at a much more frequent basis and quantitatively
12 than FSIS does. Did that answer your question?

13 Currently the plant that I'm in, there's not
14 any allergens. So I primarily have that when I go in
15 as an EAIIO, who I've seen as an EAIIO, and I've even
16 seen it in two cases with plants that we call R&D,
17 research and development plants. Products and
18 allergens, it's very hard to put them on a matrix, an
19 allergen matrix, and so there's a lot of that testing
20 that's going on for the allergens in those types of
21 facilities.

1 MR. HENRY: I believe -- Danah, this is
2 Craig Henry again. The microbial testing that you
3 spoke of and the allergen testing are pretty much
4 operational verification protocols that are being used
5 for previously described or required methods such as
6 SSOPs or sanitation practices or whatever. Certainly
7 there is a concern from the Agency and a focus by
8 industry to look at the inbound load on raw products.
9 And I think certainly that needs to be considered
10 outside of the scope of the existing regulatory
11 practice, because the testing that we've spoken of so
12 far would be supporting of that which is laid out but,
13 of course, industry has not really embraced that
14 probably as fully as it could be but that would be
15 useful information if we were going to develop new
16 interventions or even verify current ones.

17 MS. GIOGLIO: Inbound.

18 MR. HENRY: Yeah, inbound microbial load
19 testing.

20 DR. VETTER: Danah Vetter again. You
21 mentioned outside of regulatory controls, and by that,
22 what do you mean exactly?

1 MR. HENRY: Well, right now there's, there's
2 no mandate for poultry to come in with a given load.

3 DR. VETTER: Right. Okay. This is Danah
4 again. I would agree with that, that there shouldn't
5 be necessarily a standard for incoming load. What I
6 think it could be use to industry and FSIS as well, is
7 how does that compare to what your -- how are your
8 interventions decreasing that incoming load so to
9 speak or when you talk about good safety hazard,
10 preventing, reducing, eliminating. And so I think you
11 could use incoming load absolutely to -- in addition
12 to the ongoing verification processes but not
13 necessarily FSIS developing, oh, you've got to have
14 this.

15 MR. HENRY: Again Craig Henry. And the
16 reason I bring that to bear as example, compared to
17 what we've discussed so far, what we discussed so far
18 is effectively spot testing which is operational.
19 Standalone, you really don't know what it means. You
20 only know, the Agency, the inspectors only know the
21 value of the test they just saw being collected
22 because they were there, applied to a specific time

1 for a specific process. If you were to put that on
2 paper and send it in, standalone means very little.

3 However, when you look at something like
4 inbound load testing, that speaks to a well defined,
5 orchestrated research protocol, something that has all
6 of the correct attributes to develop into a standalone
7 potential study, if you will, that could be useful to
8 the plant in evaluating new methodologies and
9 interventions, as well as those interventions may be
10 well outside the plant itself or it could be useful
11 inside the plant if we had a new intervention come to
12 bear such as irradiation of poultry if we decided to
13 go down that road. So I think that that brings to
14 bear, you know, a different type of data acquisition
15 as far as what the purpose is and whether it could be
16 used standalone and how that data would be transferred
17 to the Agency, of course, we kind of kicked that ball
18 around a little bit today. Al, what do you think?

19 DR. YANCY: Al Yancy, U.S. Poultry and Egg
20 Association. I was going to hold my comment on that
21 until we got down to number 4 --

22 MR. HENRY: Uh-huh.

1 DR. YANCY: -- but I'll go ahead and speak
2 limitedly about what Craig has said. I have no
3 problem with inbound load, but I think the caveat that
4 I would put to that is what's the purpose? If the
5 plant has got a problem and a problem in this case
6 defined as difficulty meeting a regulatory compliance
7 for a given microbe, say *Salmonella*, then I would
8 expect that plant on some level to understand what
9 their inbound load is.

10 If their performance is exemplary, and by
11 that I mean very low, single digits perhaps, at the
12 baseline performance standard comparison, then I would
13 ask why do we need to know your inbound load.

14 MR. HENRY: Right.

15 DR. YANCY: It's moderately irrelevant
16 unless you wanted to do some sort of validation for,
17 as Craig has already stated, some other type of
18 inhibition or some other thing you're doing in your
19 process, then it may become an issue. My concern with
20 any of these is that they're all good practices as
21 they sound on paper and out in open air forum, but
22 it's the application of each individual circumstance

1 that has the most bearing. And if we get ourselves
2 into a position where we are forced to do inbound
3 testing, where we are forced to do -- processes and
4 there's no rationale other than it's a mandate, let's
5 do it, then I've got a problem.

6 MS. GIOGLIO: How about just one more
7 comment, your last comment on this, and then we'll go
8 to the next question. We can certainly come back to
9 these to add anything, just to make sure that you have
10 time to respond to each one.

11 MR. CORBO: Tony Corbo, Food and Water
12 Watch. How many companies are voluntarily doing
13 inbound load? The only one that I'm aware of where
14 it's mandated is I think in Scandinavia, one of the
15 Scandinavian countries that does that, as far as an
16 on-farm testing. Are companies actually voluntarily
17 doing inbound testing?

18 DR. YANCY: Yes. Al Yancy, U.S. Poultry and
19 Egg.

20 MR. CORBO: And how frequent is that as a
21 practice?

1 DR. YANCY: Al Yancy, U.S. Poultry and Egg.
2 I will tell you it is -- I can't speak for the
3 frequency of it. I would think it's infrequent. It's
4 predominantly in the area that I just mentioned. If
5 they know they have a bona fide problem, and by
6 problem I mean a compliance problem based on
7 performance numbers, they're doing it. If they're
8 not, they're missing something in my opinion. Does
9 that answer your question, Tony?

10 MR. CORBO: Yes. Thank you.

11 MS. GIOGLIO: Sorry.

12 MR. HENRY: Craig Henry. I think if you
13 would qualify at the bottom there which is developed
14 studies, okay, prescribed studies supporting data
15 collection or for the intent. Okay. Something to
16 that effect because that's a major difference between
17 what was kind of thrown out above.

18 Craig Henry again. I think coming back to
19 Tony's question which is something that's very
20 important that the vast majority of those stakeholders
21 who haven't been there, done that, will not
22 understand. There has to be a certain reality check

1 with what can be done. If you take 6,000 plants --
2 well, let's back up. How many poultry plants we got?

3 DR. YANCY: Just throw out a round number.

4 MR. HENRY: Let's just say we've got 200
5 plants and let's just say each of those plants are
6 accessing 2 million birds. You're looking at
7 potentially 200 farms per plant per week that are
8 going to be accessed, and if we said we want to go in
9 and do inbound loading, we don't have enough money in
10 the entire USDA Agency budget to address --

11 DR. YANCY: You don't have lab capacity.

12 MR. HENRY: Right. To address --

13 DR. YANCY: We're back -- Al Yancy, U.S.
14 Poultry and Egg. We'll back up the issue of money,
15 which is it shouldn't be but it is an hot item issue.
16 Let's just talk about something we can all understand
17 and agree on, and that's lab capacity. There's not
18 enough.

19 MR. HENRY: Yeah, either by industry or by
20 Agency or third parties. So that's why we come back
21 and say -- and this is what we speak to and why we
22 believe it makes very good sense for risk-based

1 inspection because we have to identify risk, in that
2 it's a logical allocation of resources to address an
3 improved intervention or process that results in
4 measurable positives, improvement in public health.

5 Easily said, not easily done. It takes time
6 and everybody has to step forward. All of what we've
7 spoken of so far is occurring today and has occurred
8 for years but now it's a matter of coming back to, as
9 Al said, there is a capacity issue, which ultimately
10 is constrained by dollars.

11 So I think we have the opportunity to move
12 onto number 2, but I think that's the context that we
13 have to look at. And I will comment that, which I
14 think Dan brought up in his presentation, that Mike
15 Taylor who's worked on both -- in both agencies, and I
16 work closely along with a number of other folks in the
17 food safety information infrastructure that he's
18 trying to develop. We've really had our hands on a
19 lot of that and he's had some very good meetings.
20 This is a very, very large issue that is not easily
21 identified with any mandates or otherwise. It's going
22 to take a lot to get things together but if we stay

1 focused on what the first challenge is, why are we
2 going to go get this data because we're looking for
3 this outcome which has to be very, very finite. We're
4 going to get further down the road. I think that's
5 where Mike trying to go, too.

6 MS. GIOGLIO: Okay. How can stakeholders
7 assist FSIS in the collection, validation, analysis,
8 application and improving all of this as far as that?
9 Danah?

10 DR. VETTER: This is Danah Vetter from FSIS
11 and again it speaks to I think more the industry can
12 report that in a more real time aspect at a greater
13 frequency, and they have that capability because
14 they're at the plant at that time, and they are
15 continually -- this is something, like we said, it's
16 already in place as part of their HACCP plan or SSOP
17 plans, and it's been in place for -- since '98,
18 whenever the implementation of HACCP and SSOP. So I
19 think you're going to get more real time data, and I
20 would also say, and I know we haven't started talking
21 about risk-based inspection and slaughter at this
22 point, but I think that this data that industry can

1 provide us will be critical to that when that does --
2 when we do move forward to that.

3 MS. GIOGLIO: What else?

4 MR. HENRY: Let's see here.

5 DR. YANCY: Al Yancy here, U.S. Poultry and
6 Egg. I say this a little bit tongue-in-cheek. We can
7 assist the Agency by helping the Agency formulate the
8 process of every one of those things. We have to
9 understand as an industry, in other words, what the in
10 game strategy is. How is the Agency intending to
11 analyze this data and for what purpose do they intend
12 to apply it. Because until we understand that,
13 there's going to be a hurdle, and that hurdle is if we
14 don't know what road we're going down and what the
15 purpose of that road is, we're not going to be real --
16 anything but reluctant to go down that road. And I
17 think there's probably a more elegant way of saying
18 it, but that has been a fairly consistent problem as I
19 see it, is not understand how the data is going to be
20 applied. And if we can help the Agency, yes, if we
21 can help the Agency formulate what those collection
22 stamps are supposed to be, what the analysis is

1 supposed to be and what the application of that data
2 is supposed to be, then there will be a consensus of
3 opinion, and in doing that, that data will then start
4 flowing I would think a lot easier.

5 MR. HENRY: Yeah, this is Craig Henry. I
6 would concur with Al's observation. This comes back
7 to an orchestrated focused effort to answer a specific
8 question. So by sitting down, not just with the IIC
9 but with Loren Lange and Janet and Don and Dan and
10 everybody else for a given reason, and it may not just
11 be at a given establishment. It may be at multiple
12 establishments.

13 DR. YANCY: Al Yancy here, U.S. Poultry and
14 Egg. It's across the industry.

15 MR. HENRY: Right. To actually say here's
16 where we want to go, here's what we don't really know,
17 well, show me what you've got, and here's how we can
18 get there, and that again is the advantage of dealing
19 with the allocation of resources, both industry as
20 well as a third party, whoever they may be, as well as
21 the Agency's time. So if it needs to be an

1 orchestrated, well thought out, if you will, we'll use
2 the term research process.

3 DR. YANCY: Al Yancy, U.S. Poultry and Egg.
4 An example of that would be going back just one second
5 to the previous conversation. If it's somehow
6 misunderstood or misconstrued and the upper level
7 discussions between industry, consumer groups and the
8 USDA about inbound load, and that one single point is
9 misunderstood --

10 MR. HENRY: Uh-huh.

11 DR. YANCY: -- then it can very easily
12 translate to an in-plant, 200 different plant version
13 of whether or not you should or should not have
14 inbound load in your facility. And if that's not
15 understood, then we're going to have plants that are
16 being held up and questions being asked about why
17 you're not doing inbound load, you should be doing
18 that, the Agency expects it and so forth. I would say
19 that, yes, they should expect it in a plant that has a
20 documented problem. In a plant that doesn't, I'm not
21 sure they need that. And as long as we have these big
22 ticket items understood, as when we go down this road,

1 that information disseminates down to the lowest load
2 and the plants understand it and they can speak
3 educatedly about it to the USDA folks who also
4 understand it.

5 If we don't have those understandings at the
6 highest level, and we don't assist the Agency in
7 agreeing on these things before we roll it out, we're
8 literally going to have these conversations over and
9 over and again in every individual plant.

10 MR. CORBO: Tony Corbo, with Food and Water
11 Watch again. I think what I've heard from both Craig
12 and Mr. Yancy is a problem that the consumer groups
13 have had about the whole RBI process in general, is
14 that the Agency has not fully articulated the public
15 health goals of moving toward a risk-based inspection
16 system. And the thing is that, you know, what I'm
17 hearing the industry saying in terms of the data that
18 -- the additional data that the Agency wants to
19 collect from the industry, what's the ending here?
20 What are we trying to achieve, and I think, you know,
21 we're back to square one in terms of the questions
22 that we've been raising all along. The Agency, you

1 know, says that they're going to put out papers
2 articulating the public health goals and here we are,
3 you know, a couple of months away from implementing
4 this at least in a pilot project, and we still don't
5 know what the ending is here.

6 MR. HENRY: I think that just in response to
7 that, Tony, because what you ask for would be great.
8 However, even taking the Scandinavia study, the New
9 Zealand work, the -- or anybody else, I'm not aware of
10 any goals that lie there either, as far as end game
11 result when we're talking about the public health
12 domain such as attribution data, you know, CDC data,
13 you name it. I'm not aware of that, that you can show
14 a correlation between the two. What is important
15 though to look at is that, you know, in this process,
16 what we just articulated here is a huge difference
17 between saying I want to drop *Salmonella* to .2 of a
18 percent on an annualized basis, I just want to make
19 that happen. As opposed to Danah's challenge or what
20 was Al's challenge as an inspector, to be in the plant
21 to look at daily operational results. And that's the
22 huge difference.

1 You know, there's one thing where you're
2 trying to collect the data that verifies that if I use
3 a green scrubby pad on a food contact surface, as
4 opposed to using a regular sponge, I've improved what
5 would be a leftover microbial load on that stainless
6 steel surface. That's very important for that moment
7 in time for that day which we're getting ready to run.
8 How much that's going to translate into impacting an
9 ideal goal, to say, well, risk-based inspection is
10 going to drop *Salmonella* by 66.2 percent in a given
11 period of time, is outside the scope of any program
12 we're aware of, although these baby steps though can
13 certainly get there.

14 Now let's just suppose we step into
15 irradiation. Let's take irradiation as a sample right
16 now. The application irradiation across the board for
17 those products that we have no interventions for right
18 now, there's a great research project. How much could
19 that improve our risk relative to produce? That's
20 outside FSIS but we certainly have that option
21 relative to ground beef or other products. That's
22 something where you could actually see a huge change

1 but that's a major intervention which requires
2 additional research. Two different concepts here, both
3 have applicability, and I think we have to work them
4 step by step.

5 MS. GIOGLIO: Getting back to this, what are
6 some of the ways that stakeholders can assist?

7 MS. GREEN: The other thing that might help,
8 too, if you sort of look at those notes on validation
9 and analysis. What are some ways stakeholders could
10 help us validate our data or look at our data on
11 analysis? Any ideas? Kim Greene, FSIS.

12 MR. HENRY: Kim, when you say for
13 stakeholders to validate FSIS data?

14 MS. GREEN: It could be third party data.
15 It could be FSIS data. Just the data we're using in
16 our mission. Any thoughts on that? Is this something
17 you could or would want to help us out with? How
18 about how we're analyzing the data? Is it something
19 you want to step in and be a part of with FSIS? Maybe
20 not.

21 MR. HENRY: Craig Henry. I'm just trying to
22 think about -- because again there's a difference

1 between as I'm thinking through the validation, as an
2 example that Danah commented on.

3 MS. GREEN: Right.

4 MR. HENRY: She validated what she saw
5 collected. She's verified that the written protocols
6 are being executed. That's kind of a done deal.

7 MS. GREEN: Right.

8 MR. HENRY: Now that comes back to again
9 when you look at collection validation analysis and
10 application, that speaks of the developed research
11 projects, all the steps that have to occur as opposed
12 to whether we're going to go through and apply that to
13 every one of the operational steps that a plant uses
14 to say they're good to go. That's commensurate with
15 either a quality program or a food safety program,
16 huge, huge difference. I think all of those are
17 completely required when you're looking for a specific
18 goal be achieved, whatever hypothesis it is in the
19 research program for.

20 DR. VETTER: Danah Vetter. So what I
21 understand you to say is that we'll go back to
22 incoming load, the examples that we just talked about,

1 and that definitely when it comes to let's say ODHS
2 wants to know what is a typical incoming load or just
3 like they've done with *Salmonella* where they've done
4 testing, that the Agency, it was a set up standard
5 research project to just retrieve data that they can
6 make decisions about. That's kind of what you're
7 talking about in that?

8 MR. HENRY: Yes. And again, in tandem with
9 what Al said, because you've got to say why am I going
10 to go out and collect this data which is what Tony's
11 asking for, okay. That's an orchestrated plan. We
12 know what the end goal is. To just go out and collect
13 data, oh, wow, poultry has got *Salmonella*, we already
14 know that. So does lettuce? I mean, you know,
15 there's inherence. Now we try to keep them minimized
16 on all of it because --

17 DR. VETTER: Right.

18 MR. HENRY: -- you know, nature gives us
19 those but, yes, I think that's where we're trying to
20 go to in the context of all of those terms.

21 DR. VETTER: Right. And the incentive then
22 would be, you're not going to get negative necessarily

1 repercussions from that but FSIS would have valuable
2 information that they could base certain public health
3 decisions upon.

4 MR. HENRY: Well, I think you're jumping
5 down again to number 4.

6 DR. VETTER: Sorry.

7 MR. HENRY: Yeah, but I think again
8 forgetting about incentives, everybody gets together
9 for understanding the desire and profit.

10 DR. VETTER: Which I think is what we
11 recorded earlier.

12 MR. HENRY: Yeah.

13 MS. GIOGLIO: Can we move onto the next
14 question, and only because we're getting close to --

15 MR. HENRY: Don't we have until 11:45.

16 MS. GIOGLIO: Right, but you're going to
17 maybe take a little five minute break before you get
18 back. We will definitely have time to go back and
19 address these others. Let's at least get something
20 down --

21 DR. YANCY: Al Yancy, U.S. Poultry and Egg.
22 One thing you may want to put there and you'll have

1 more of a complete answer, you must articulate the
2 goals and also must agree upon the path to get to it.
3 And I think if we do those two things, you answered
4 number two.

5 MR. HENRY: Right.

6 DR. YANCY: The bigger question is number 4
7 which we're moving to in my opinion.

8 MS. GIOGLIO: You have to get there --

9 MR. HENRY: Yeah.

10 DR. YANCY: To achieve those goals.

11 MR. HENRY: Yeah. What's the plan?

12 DR. YANCY: And obviously that involves not
13 just the Agency but the industry and the consumer
14 groups as well, I mean all three seats have to be
15 filled.

16 MS. GIOGLIO: Okay.

17 DR. YANCY: I'm sorry for interrupting.

18 MS. GIOGLIO: That's fine. Okay. The next
19 question asks what mechanisms can be developed to
20 bring different stakeholders together and share
21 quality data such as task forces? Do you think that
22 that might be some way to approach this? Should there

1 be a third party repository? Stakeholder meetings,
2 anything else that you can think of.

3 MR. HENRY: Yes, Craig Henry. I would
4 certainly look to take the DAIG as it exists now if
5 you will and certainly enhance that with other
6 stakeholders. You could call it an initial task force
7 but as you go through this process, that the
8 participants on that task force will vary, basis
9 project, industry and maybe even region. So enhance
10 the DAIG so we will include those stakeholders which
11 would bring in industry, academia, consumer groups, et
12 cetera, dependent upon the project or the task at
13 hand.

14 MS. GREEN: Any thoughts on the third party
15 repository?

16 MR. WALDROP: This is Chris Waldrop,
17 Consumer Federation. I would tend to lean toward a
18 third party repository to collect data. There would
19 need to be certain elements in place then and that
20 includes it's one that's independent, and that it sets
21 the, you know, it kind of sets the standards for what
22 data is going to be acceptable, how it's going to be

1 analyzed and kind of going back to the other question,
2 how do we get there. But data can be acceptable, it
3 can be selected, how do we analyze, how it would be
4 presented, who would have access to it, all of those
5 sort of things need to be sort of laid out in very
6 concrete terms I think in order to make it work.

7 MR. HENRY: This is Craig Henry. I think
8 qualifying that a little bit, Chris, because again
9 separating the two contexts here, in that there's a
10 third party repository for a data dump, and then
11 there's a third party repository that's actually going
12 to collect the data for a given research project.

13 If it's a given research project with a
14 specific end goal, it should have the buy in of all of
15 the stakeholders who participate in developing and
16 executing that program, and should have appropriate
17 access to all of those stakeholders that would be
18 engaged. So whether it's a university, whether it's
19 FSIS, whether it's a company, whatever it is, we're
20 going to have to go through all of the qualifications
21 steps for the data.

1 However, certainly when you get back into a
2 data dump process, if that's what it comes down to,
3 and I think that's the gray zone that we have to come
4 back and say, does there make sense in doing that, can
5 you make sense out of any of it when you get it, we
6 can draw right or wrong conclusions from it, concur
7 all of those things would have very fine attributes
8 for a true repository because if you're going to go
9 for a research project that doesn't become a
10 repository, it becomes an accumulation of data for
11 that particular project.

12 MR. CORBO: Tony Corbo, Food and Water
13 Watch. As I recall, when the Meat and Poultry
14 Inspection grappled with this, Dr. Denton was the
15 Chair of the University of Arkansas and the Chair of
16 that subcommittee, and he was recommending and the
17 subcommittee went along with it, in terms of having,
18 you know, a board that would be a screener of any
19 requests for access to the information in the
20 repository, that they would not -- someone coming
21 along wanting to do like a research project, would
22 have to really put together a rigorous, you know,

1 abstract in terms of what they wanted to do. And so
2 it wasn't going to be just open, you know, willy-nilly
3 to anybody. He had a mechanism in place to evaluate
4 how the information was going to leave that
5 repository.

6 And I told him, you know, because at the
7 time there was an Ag Appropriations Bill on the Hill.
8 I said do you want University of Arkansas to get a
9 little earmark and he laughed and said, no, I don't
10 want to go near this. And so the question becomes who
11 wants to do this because this is going to be a big
12 job.

13 MR. HENRY: Oh, yeah, I think you're
14 absolutely right, Tony, and yet James did bring that
15 to bear and it's a problem. Again, I would throw this
16 back only because how far down the road Mike Taylor
17 is. He has got huge input on this already, and I mean
18 it's taken him a year at this point coming up --

19 MR. CORBO: Right.

20 MR. HENRY: -- just to define the scope of
21 the problem among all because it won't be just FSIS --

22 MR. CORBO: Right.

1 MR. HENRY: -- at all. There will be a lot
2 of players when you start trying to get your hands
3 around it because you're going to say, why have I got
4 the repository to start with?

5 MR. CORBO: Uh-huh.

6 MR. HENRY: Which is a huge challenge. It
7 has some merit but, you know, that's like saying, why
8 don't we have better attribution data? Why don't
9 we -- why doesn't the industry, why doesn't the
10 taxpayer pay for 50 staff nurses in a hospital to
11 collect attribution data? Why don't we just go do
12 that? You know, and maybe it has merit, but we have
13 to step through that to make sure we have
14 justification to move forward. Because the worst case
15 would be to spend a lot of time and money and not get
16 anything useable coming out of it.

17 MR. WALDROP: Chris Waldrop, Consumer
18 Federation. And as a recommendation of the Agency,
19 they should work with Mike Taylor and learn from what
20 he's done already.

21 MR. HENRY: Absolutely.

1 MR. CORBO: So I would say to stay in close
2 contact with that at FSII.

3 MR. HENRY: Yeah, I concur with you.
4 There's no reason to reinvent the wheel.

5 MR. WALDROP: That's the Food Safety
6 Information Infrastructure.

7 MS. GIOGLIO: FS --

8 MR. HENRY: FSII.

9 MS. GREEN: And there was also one other
10 thing that Cliff said which was I heard some concern
11 about if you could do the third party repository and
12 not have -- I don't want to put words in your mouth,
13 useful or --

14 MR. HENRY: Right.

15 MS. GIOGLIO: So --

16 MS. GREEN: A concern with -- Cliff, could
17 you restate it for us?

18 UNIDENTIFIED SPEAKER: Craig.

19 MS. GREEN: Craig, sorry.

20 MR. HENRY: That's okay. Just that the
21 approach towards the repository needs to have an

1 understood goal in mind, you know, structure and
2 function.

3 MS. GIOGLIO: And just getting back to this,
4 is to keep -- work more closely with?

5 MR. HENRY: Yeah. Don't reinvent the wheel.

6 DR. VETTER: That was the Food Safety
7 Information --

8 UNIDENTIFIED SPEAKER: Infrastructure.

9 MR. HENRY: And actually, that's an
10 interesting point, too. I'm just throwing that out.
11 Food Safety Information Infrastructure is Mike Taylor
12 who was at the University of Maryland, who is now
13 going to Georgetown.

14 MR. WALDROP: GW.

15 MR. HENRY: GW. So now you're going to say,
16 where was that database? Why was it there? By the
17 way, who's the champion? Another challenge.

18 MS. GREEN: That's your word I was looking
19 for. Challenge.

20 MR. HENRY: Structure, function, challenge.

1 MS. GIOGLIO: What about additional
2 stakeholder meetings or task force? Do you see those
3 as being useful?

4 MR. HENRY: Yes.

5 DR. VETTER: This is Danah Vetter. I think
6 that especially as this process evolves, those will be
7 very useful, maybe not for actually collecting the
8 data and that type of thing, but to evaluate the
9 processes and how useful it is and meaningful. So I
10 think that's where they will come into play is later
11 down the road after implementation has begun, is about
12 to begin.

13 MS. GREEN: I think I heard see more use for
14 it down the road perhaps.

15 MS. GIOGLIO: Evaluation down the road.

16 MR. HENRY: Yeah, and I guess -- this is
17 Craig Henry. I would just push back a little bit on
18 that. That seems like a little after the fact.
19 Evaluation should not be done down the road. We
20 should know where we're going and agree upon how we're
21 going to get there. So again, structure, function,
22 challenge. How do you define the repository? Why is

1 it going to be there? And how are we going to
2 evaluate the data during the process, not after the
3 process?

4 MS. GIOGLIO: But I think what Danah was
5 saying is that you're thinking these types of meetings
6 with these types of groups would be good during the
7 negligent process which is not exactly --

8 DR. VETTER: Once those things that you're
9 talking about have been, then I think more task forces
10 and stakeholder meetings to, I don't know, something
11 that's more defined.

12 MR. HENRY: Yeah.

13 MS. GIOGLIO: Which is slightly different
14 than what you were saying.

15 MR. HENRY: Well, again, the difference --
16 evaluation down the road, you know, I'm saying that's
17 not where we need to be.

18 MS. GIOGLIO: So you want me to cross this
19 out.

20 MR. HENRY: I'm throwing that out to the
21 group but, you know, that's why --

1 DR. YANCY: This Tom Yancy, U.S. Poultry and
2 Egg. I think it's both. I think you've got to bring
3 together this think tank to get you started first of
4 all and then you have either that same think tank or
5 another one, however you want to do it, that evaluates
6 the progress of your performance.

7 MR. HENRY: Of the repository.

8 DR. YANCY: Of all the things, including the
9 repository, of everything that you've agreed upon.

10 MS. GIOGLIO: What if I take out down the
11 road.

12 MR. HENRY: That's fine.

13 DR. VETTER: I would agree with what you
14 just said. You need an analogy to develop what you're
15 talking about and then later --

16 DR. YANCY: The goals and objectives are
17 somewhat different once you get it pushed, you know,
18 once the boat is pushed out into the water. Now
19 you're afloat.

20 MR. HENRY: Oh, yes.

21 DR. YANCY: And stay afloat.

1 MR. HENRY: Ongoing evaluation. That's
2 fine.

3 MS. GIOGLIO: I can't spell up here.

4 MR. HENRY: It's tough when you're that
5 close to it, isn't it?

6 MR. WALDROP: I would just say that FSIS has
7 advisory committees that could be utilizing for this
8 purpose, either stakeholder meetings or task forces or
9 something like that. So if it's possible to use
10 what's already in place, people are already focused on
11 the Agency rather than setting up a brand new thing,
12 that would be valuable.

13 DR. VETTER: Are you referring to like the
14 National Advisory Committee --

15 MR. WALDROP: NACMPI and -- yes.

16 MR. HENRY: Sure.

17 MS. GIOGLIO: All right. Why don't we move
18 onto the last question and then if there's time and
19 you want to add anything, we can do that. The last
20 question kind of has two parts. So maybe it would be
21 best to just focus on the first one and then the
22 second one. So the first one is barriers to creating

1 some of these mechanisms. So this is A which is the
2 barriers.

3 DR. VETTER: Danah Vetter. I think we've
4 spoken a lot to this already, what is the desired
5 outcome? That's our barrier right now. We don't know
6 the desired outcome of the repository or the gathering
7 of this data, how it will be used. So I'll take that
8 as a barrier. If you don't know where you're going,
9 how can you start.

10 UNIDENTIFIED SPEAKER: By that you mean, you
11 know, it's not clear whether -- is better than
12 attribution data, would better information to allocate
13 inspection.

14 DR. VETTER: Exactly.

15 MS. HOVDE: This is Resha Hovde with Hormel
16 Foods. I think if it started out on a police on one
17 certain pathogen, in one certain area, and with the
18 goal in mind, exactly where we're going to go, what
19 we're going to do with this, the end result, is, you
20 know, to decrease public health in this area, it's
21 similar to what we've been doing with our model and
22 risk base, you know, focusing in on one area, you

1 know, to start with, and other type of pilot programs,
2 to start out with.

3 MS. GIOGLIO: So that the variant is --

4 MS. HOVDE: That the scope isn't so large.
5 Focus on each individual, you know, challenge that
6 we're trying to address.

7 MR. HENRY: You've got to put up there --
8 this is Craig Henry. You've got to put up there,
9 certainly we have an infrastructure issue right off
10 the top, and again, just to save us a lot of time, you
11 know, I would refer back to Mike because we've had
12 four meetings with Mike Taylor. This information is
13 very well defined through Mike at this point, and
14 believe me, we don't have enough paper there to cover
15 everything that's been covered in four meetings with
16 50 people. I think Chris, you know, Caroline's been
17 there, there's been a bunch of us there. So just, you
18 know, there's a bunch of stuff or challenges as far as
19 barriers. And then I'm sure Al would lend to this.
20 Some day it certainly can have proprietary issues tied
21 to it, if you have some legal ramifications.

22 MS. GIOGLIO: Okay. Anything else?

1 MR. CORBO: One other thing. I have to go
2 back to what I said in the general session, you know,
3 why is it taking the Agency three and a half years to
4 talk about this again when it charged the Meat and
5 Poultry Advisory Committee with this in November of
6 2003? Respondent

7 MR. HENRY: Well, now is that a barrier or a
8 reflection, Tony?

9 MR. CORBO: I don't know.

10 MR. HENRY: Well, trust me. You will always
11 be here at this point because the data process, the
12 technology for acquiring it and transferring it would
13 continue to evolve. So this is an awkward question.
14 Somebody say hello.

15 MS. GIOGLIO: Okay. Incentives to encourage
16 the sharing of data. What incentives do you see?

17 DR. VETTER: Danah Vetter.

18 MS. GIOGLIO: This is like the phone
19 connection.

20 DR. VETTER: Probably, and you guys can
21 correct me if I'm wrong that at least from my
22 perspective as an IIC and an EAIO, that most industry,

1 plants are eager to share some information that they
2 have. I see somebody shaking their head no. What my
3 personal experience has been as we've gone in, you
4 know, as an EAIO or an IIC, look at what we're doing.
5 It may not be perfect data. It may not be perfect
6 results, but we are trying to get better, and this is
7 what we're doing to show you that. It may not be this
8 beautiful end result that everybody wants to see, but
9 they want to show and provide information that they
10 are making an effort and they are doing a great amount
11 of testing, that they're spending a great deal of
12 money doing that. And so that is -- that public
13 health is a huge priority for them. So that's been my
14 personal experience with that.

15 So as far as incentives go, like I said, at
16 least in my experience, there has been a -- they want
17 to share.

18 MS. GIOGLIO: Industry --

19 DR. VETTER: Data.

20 MR. HENRY: But what's the incentive, Danah?
21 Why do they want to do it? You're there.

1 DR. VETTER: To show that public health is a
2 priority and whether getting questioned and slammed
3 that it's not, they are putting a great deal of time
4 and effort and money into public health and food
5 safety, and that data shows that.

6 MR. WALDROP: Sort of a public relations
7 kind of thing?

8 DR. VETTER: Yes.

9 DR. YANCY: Al Yancy, U.S. Poultry and Egg.
10 You might want to beef up the public relations in the
11 end. It depends on the on the tests, and I'm going to
12 get on my soapbox but for one second, and that is if
13 your decision regarding food safety of the products
14 you product is based on the presence or absence of one
15 cell, you really have to ask yourself whether or not
16 you've got a food safety system that is rational. And
17 we are trying to make decisions based on the presence
18 or absence of one *Salmonella* cell, that is a variant
19 to having more substantive conversations about the
20 serotypes, about the quantity of those serotypes,
21 instead of just basing decisions, process decisions,
22 economic decisions, food safety decisions on whether

1 or not one *Salmonella* cell is present regardless of
2 the serotype, regardless of the amount of cells. So
3 we really have to look at what it is we're really
4 trying to accomplish; is it the mechanism by which
5 we're trying to accomplish, is it truly substantive,
6 or is it just getting ready for doing something that
7 we think hopefully some day will have an effect.

8 DR. VETTER: Danah Vetter, NAFV. And I
9 think that that's probably one aspect of it, is
10 public -- seeing it beneficial to FSIS and to
11 industry. I do think that it can play into risk-based
12 inspection, and I've already referenced this, and
13 we're not here to discuss it, but in poultry slaughter
14 establishments, I think it is going to be a critical
15 component to the risk-based inspection in poultry
16 slaughter establishments, that is going to factor into
17 where they fall within those categories, and again,
18 this is not from what I've been told by FSIS. It's
19 just from what I know being in the plant as an IIC and
20 an EAIO and from discussions I've had with other NAFV
21 members. So I think that -- and again, we're talking
22 about using this further down the road as well, not

1 here in these processing establishments, and I think
2 when you talk about poultry slaughter in particular,
3 it will play into risk-based inspection and where
4 plants rank within that. And so I think that's an
5 incentive because it goes to where you would fall
6 within that matrix.

7 MR. HENRY: The bottom line of what you're
8 saying, Danah, sharing data results in an improved RBI
9 score.

10 DR. VETTER: Yes.

11 UNIDENTIFIED SPEAKER: And ultimately --

12 MR. HENRY: If that goes in -- their
13 allocation.

14 UNIDENTIFIED SPEAKER: Right.

15 DR. VETTER: Danah Vetter. I'll add to
16 that. There may be some other things, and I speak to
17 poultry slaughter because I just see that this is
18 where it's really coming into play, you know, our line
19 speeds, things like that, but if you can maintain some
20 orderly processes and control, that may be something
21 that could be an incentive possibly.

1 DR. YANCY: This is Al Yancy, U.S. Poultry
2 and Egg. I guess where I was going with that, to be
3 more clear, in case I wasn't clear, I would hope that
4 an incentive of this, of sharing data would drive
5 these conversations farther about the true
6 meaningfulness of the data that we're collecting, and
7 it won't be just a public relations issue because I
8 don't want that to be the case. I don't think anybody
9 in industry wants it to be the case.

10 The real public relations that comes from it
11 should be the success of the programs to control the
12 microbes and the improvement in food safety of the
13 products we produce. That's the public relations, not
14 look at how we're testing, look what we're giving you,
15 and I'm not suggesting that's what we're doing and I
16 don't want it to be that way. And I think an
17 incentive to sharing this data is driving these
18 conversations. It will in some cases elicit some of
19 the problems with the validity that we currently --
20 some of us currently believe we have.

21 So to me that's an incentive. We're doing
22 something now that really should be done or shouldn't

1 be done at all. Then that's an incentive to having
2 these conversations.

3 DR. VETTER: Danah Vetter, NAFV. So some of
4 the stuff that you're speaking about, can you give
5 some examples of that, things that might improve or --

6 DR. YANCY: Yeah, I think when we get into
7 the -- Al Yancy, U.S. Poultry and Egg, and I'll make
8 this brief because I don't want to run out of time. I
9 think when we get into the whole idea of sharing,
10 specifically sharing *Salmonella* data, and we're
11 talking about pluses and minuses, in making decisions
12 on food safety to the end consumer, based on a plus or
13 minus test without recognition of serotype, without
14 recognition of the quantity, I think that's a flawed
15 concept. I think we need to and I'm hardened by the
16 fact that the Agency is now speaking more now about
17 serotypes. I want us to take action on those serotype
18 conversations and I want us to look at numbers, not
19 just pluses and minuses, because I think that bears
20 more fruit in the area of food safety, and I think the
21 incentive of having these conversations about sharing
22 this data is it's going to become apparent, when you

1 share hundreds of thousands of *Salmonella* tests that
2 are pluses and minuses, what does that really mean?

3 DR. VETTER: Right.

4 DR. YANCY: And having that conversation
5 will drive that discussion that I would like us to
6 have. We're already acting on some of it, and I think
7 we could have more --

8 DR. VETTER: Right. This is Danah Vetter,
9 and I'll just add this as an aside. I think what I've
10 seen in most plants that a barrier to them doing
11 quantitative data right now is costs, and again that's
12 a big issue.

13 DR. YANCY: Cost and availability.

14 MR. HENRY: Right.

15 DR. VETTER: But in doing that, in moving
16 towards that, we potentially -- we talk about research
17 projects and things used as research projects, could
18 make that more available and more efficacious I guess.

19 DR. YANCY: Al Yancy, U.S. Poultry and Egg,
20 and I don't mean to interrupt or belabor the point.

21 DR. VETTER: That's okay.

1 DR. YANCY: But there's a conception. I'm
2 not going to say it's a misconception or a correct
3 conception, but there's a conception right now among a
4 lot of folks that says why do I care? What does it
5 matter how much I'm bringing in on my bird, when the
6 pluses and minuses are all that's being weighed on me?
7 What does it matter what the serotype is when all of
8 them are going to count in the end? And I think we
9 need to have discussion about the validity of the way
10 we're looking at it right now, not to criticize what
11 we've done up to this point. It's not about that.
12 It's about HACCP and evolution. What we thought
13 before may not necessarily be as valid now as it was
14 in '97 and '98.

15 MR. HENRY: Uh-huh.

16 DR. YANCY: Maybe we need to reconfigure our
17 thought process and look at this a different way in
18 doing that, doing inbound loads, doing serotyping,
19 doing quantitation, may then bring more value to the
20 discussions so that more people are incentivized for
21 lack of a better term, to do it. If that comes from

1 sharing data, then I'm all for it because it drives
2 the conversation and gets us better places.

3 MR. GRIFFITH: Bill Griffith, Perdue Farms.
4 You said at the end that we might be able to go back
5 and just talk about some of the questions again.

6 MS. GIOGLIO: Yes.

7 MR. GRIFFITH: And if I could throw out a
8 couple of things as far as what third parties could
9 provide FSIS, I speak to a couple of these.

10 MS. GIOGLIO: Okay. Number 1.

11 MR. GRIFFITH: Yeah, number 1. I just want
12 to make clear that everything that's in there, that we
13 have listed up there is speaking towards programs at
14 the plant level that already in -- that are part of
15 really the HACCP plan or being verified by the
16 establishment, by the IIC, the inspectors.

17 A couple of other things that could go to
18 this are an approach I guess to speak to, there was a
19 question about scope, that this thing is so big and
20 can be overwhelming, but these go to the specific
21 types of hazard analysis being performed at facilities
22 today and lists at least a compromised priority of

1 information in each one of the hazard categories from
2 a chemical, a biological and physical basis for that
3 type of processing facility. So you would provide --
4 the third party data being provided to FSIS would be
5 driven by the hazards that are most reasonably likely
6 to occur in that facility.

7 Some of the things that we don't have up
8 there are residue analysis, that every company does
9 thousands of analyses on incoming meats to make sure
10 residues aren't present before processing, and there's
11 a lot of data out there that can be generated and
12 provided to the Agency through that.

13 So really to go back and take a look at the
14 hazard analysis for the type of processing
15 establishment, because there is such a vast difference
16 between a slaughter facility versus a further process
17 or a fully cooked facility, and reduce that scope that
18 we're talking about. Pick the highest priority as you
19 go back to your goals, that we've all said we need to
20 know what the goal of this is, and prioritize that.

21 One other things with regard to question 2,
22 as far as how can stakeholders assist the Agency in

1 improving collection, validation and analysis, would
2 be this group of stakeholders that comes together
3 could really help, in identifying certification
4 programs for that data, because one thing that we've
5 been talking about is everyone or all the companies
6 out there are basically assembling reams and reams of
7 data but I would throw out that not all data is
8 created equal and there has to be some way to verify
9 that those results are valid. And in doing that, part
10 of the validation, there are several certification
11 programs, as with residue, there's already programs
12 out there that FSIS laboratory verify that the
13 sampling is correct. Stakeholders can help point out
14 what all avenues are there. I mean we start talking
15 about accreditation bodies, you've got ISO, you have
16 the residue program. There's *Salmonella* programs that
17 are already in existence and I think we need to
18 identify all those and use any of those that are
19 already out there instead of trying to recreate the
20 wheel.

21 MS. GIOGLIO: Danah.

1 DR. VETTER: Danah Vetter. The other
2 outside source we have that I would suggest they might
3 look at is APHIS data, especially there's the National
4 Poultry Improvement Program and there's *Salmonella*
5 testing that goes along with that as well. And so if
6 FSIS could use that data.

7 MS. GREEN: Danah, could you say that one
8 more time in terms of the agency?

9 DR. VETTER: It's National Poultry
10 Improvement Program, APHIS.

11 MR. HENRY: Yeah.

12 MS. GIOGLIO: Okay. We have time for one
13 more comment.

14 MR. WALDROP: Chris Waldrop, Consumer
15 Federation. I agree that we need some mechanism for
16 validating and verifying that the data is complete and
17 it's quality data in regards to this -- and make sure
18 that, you know, we're getting a complete picture and
19 not just one aspect of whatever the data says.

20 DR. YANCY: Al Yancy, U.S. Poultry and Egg.
21 You said one more comment and I have violated that but
22 I think this is very important and that is I know

1 there's one service provider, antimicrobial service
2 provider company that's here today. I think we need
3 to, all of us, need to attempt to reach out more to
4 those groups and have them involve themselves or
5 encourage them to involve themselves more in these
6 processes because our industry leans heavily on the
7 antimicrobial service industry to help us reach these
8 goals. And it's a little after thought for them to
9 come in after we've already agreed to the standards
10 and then say help us meet them. I think it's
11 imperative for them to come in early, from the outset,
12 and I'm not suggesting anybody's excluding them, but
13 I'm suggesting that they may be excluding themselves
14 because they don't know the importance of having them
15 here. And they've got a lot of data, too.

16 MR. GRIFFITH: Possibly, if we could get one
17 more in there, inclusion of state --

18 MS. GIOGLIO: Here, for this one?

19 MR. GRIFFITH: I'm not sure where it would
20 go but I think we need to recognize that there are
21 several state agencies out there that perform testing
22 and I don't think there is a single data repository

1 that would capture all the state data, the FSIS or
2 federal data and industry data. So I don't know where
3 that would go but --

4 MR. CORBO: Does AMS also do testing?

5 MR. HENRY: Oh, yeah. We've got bunches of
6 agencies. We don't have enough paper here right now.
7 Trust me. Trust me. That again, ditto Mike Taylor.

8 MS. GIOGLIO: Okay. Great. Well, thank
9 you.

10 MR. HENRY: Danah, you did great.

11 (Whereupon, at 11:43 a.m., the meeting was
12 concluded.)

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C E R T I F I C A T E

This is to certify that the attached proceedings
in the matter of:

USING DATA FROM OTHER SOURCES

A CHARGE FROM FSIS: QUESTIONS FOR

CONSIDERATION IN BREAKOUT SESSIONS

GREEN GROUP BREAKOUT

Arlington, Virginia

April 30, 2007

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

Victoria Gudeman, Reporter

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