

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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CONFERENCE CALL BREAKOUT

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April 30, 2007
10:45 a.m.

George Mason University
Arlington Campus
Room 244
3401 Fairfax Drive
Arlington, Virginia 22201

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MS. PATRICIA BUCK
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MS. BARBARA KOWALCYK
MS. FELICIA NESTOR

I-N-D-E-X

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2. How can stakeholders assist the Agency in improving collection, validation, analysis and application of data?	
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?	
4. What are the barriers to creating such a mechanism? What incentives could be used to encourage sharing of data?	

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

2 (10:45 a.m.)

3 MR. TYNAN: For those of you who are on the
4 phone, Operator, if I could ask either Mr. Prins or
5 Mr. Mott to serve as the Chairperson for that group.

6 OPERATOR: Okay. For parties on the phone,
7 do you want me to go ahead and open all of their lines
8 so they can talk amongst themselves?

9 MR. TYNAN: I think you should have the open
10 line to whoever decides to be the chairperson.
11 Mr. Mott, are you on the phone?

12 OPERATOR: Just one moment. Let me open his
13 line.

14 MR. TYNAN: Okay. Mr. Mott? Is Mr. Prins
15 on the phone?

16 OPERATOR: Yes. Mr. Mott has disconnected,
17 and I'm waiting for Mr. Prins.

18 MR. TYNAN: I'm sorry, Operator, I'm having
19 difficulty hearing. There's a lot of --

20 OPERATOR: That's fine. We're just trying
21 to locate Mr. Prins on the line. All right. There
22 you go. Mr. Prins, your line is open.

1 MR. TYNAN: Mr. Prins, could I ask you to be
2 the sort of Chairperson and reporter for the folks
3 that are on the telephone?

4 (No response.)

5 MR. TYNAN: I'm sorry, Operator. I didn't
6 hear an answer.

7 OPERATOR: Okay. His line is open. I'm
8 sorry he's not responding. Do we have Rick Prins? Is
9 your line muted, sir?

10 MR. TYNAN: Well, Operator, if we could, if
11 we could do it this way. If you could open all the
12 lines, and if I could ask for a volunteer to be the
13 Chairperson of that group, I would appreciate it.

14 OPERATOR: Okay. Go ahead, sir. All lines
15 are open.

16 MR. TYNAN: Is there anyone that could
17 perform that role for us for the audio group?

18 OPERATOR: I'm sorry. Once again, all
19 parties on the phone, your lines are open if you could
20 respond.

21 MS. BUCK: I don't think anybody else is on
22 the line. I think I'm it that's on the line.

1 OPERATOR: No, we have several parties on
2 the phone. We have 20 people on the phone at this
3 time.

4 MS. BUCK: Well, good. Are any of them
5 responding?

6 MR. TYNAN: Ms. Buck, would you be willing
7 to do that for us?

8 MS. BUCK: I'm not prepared to do it. I
9 would not be able to, you know, be able to do this for
10 you.

11 MR. TYNAN: Okay.

12 MS. BUCK: Most of the people have left
13 their phones like I was going to do and just leave
14 them laying there and go do some other stuff.

15 MR. SCHAD: This is Mark Schad. I'll do
16 that if nobody else wants to do it.

17 MR. TYNAN: Mark, you're a fine man. I
18 would appreciate that very much. I regret having to
19 ask you to do that a second time for us, but if you
20 would consider doing that, that would be great.

21 Maybe, Operator, if you could leave
22 Mr. Schad's line open and perhaps he could pose the

1 questions and then you could ask for comments from
2 each of the group to go around to whoever has a
3 comment. And, Mark, that's pretty much how you did it
4 the last time. Is that correct?

5 MR. SCHAD: That's correct. And that sounds
6 like a good way of doing it, Robert.

7 MR. TYNAN: Okay. Then we'll leave it up to
8 you to take it from here.

9 MR. SCHAD: Operator, is my line going to be
10 open at all times as long as I put the mute button on?

11 OPERATOR: Yes, it is, sir.

12 MR. SCHAD: Okay. Thank you. Okay. If
13 everybody's ready, I think you know all the questions
14 but I'll repeat it. Just so we all know, the first
15 question, "What data could third parties provide to
16 FSIS to further enhance protection of public health?"

17 I'm not sure, I think Dave Bernard asked a
18 good question, and I didn't quite get the response to
19 that, but I think that third parties, somebody can
20 correct me if I'm wrong, that could include
21 establishment. Or maybe somebody can correct me if
22 I'm wrong on that, but let's just go ahead with

1 comments in response to that question.

2 OPERATOR: Thank you. Barbara Kowalcyk,
3 your line is open. Barbara Kowalcyk, your line is
4 open.

5 MS. KOWALCYK: Hi, this is Barb. I just
6 wanted to comment on this first question is that I
7 find it very difficult to answer it mainly because I'm
8 not really sure what data they have and what's the --

9 OPERATOR: I'm sorry. This is the Operator.
10 Do I have David Goldman or Sally Fernandez?

11 MR. TYNAN: Operator, did you --

12 OPERATOR: Hi, sir. Do you want me to mute
13 it so that you're not able to hear those on the phone
14 or do you want their lines open so you can hear?

15 MR. TYNAN: Well, you can leave them open.
16 We have an audio man here that can probably turn the
17 sound down just a little.

18 OPERATOR: Okay. I just wanted to make
19 sure.

20 MR. TYNAN: Okay. Thank you.

21 OPERATOR: Thank you.

22 MR. SCHAD: Okay. Does somebody else have a

1 comment on that question?

2 OPERATOR: Once again on the phone, press *1
3 for questions or comments.

4 MR. SCHAD: This is Mark, and I'm going to
5 go ahead and kind of respond to what you said, Barb,
6 just owning and operating an establishment, maybe this
7 will kind of -- it's not going to answer what FSIS is
8 looking for necessarily, but I know the kind of data
9 that some establishments might have that FSIS does not
10 require. They may collect micro data on their
11 incoming raw materials. They might data on total
12 aerobic plate count on some of their sanitation
13 equipment. I'm trying to think of data that some
14 plants generate that are not required and they might
15 just keep it as far as their internal quality control
16 system. So I'm not saying that's answering your
17 question. I understand why you're asking the question
18 to the question. How does that help you, Barb?

19 MS. KOWALCYK: Is my line still open?

20 OPERATOR: Yes, it is. Go ahead please.

21 MS. KOWALCYK: Well, it just seems to me --
22 I mean I think that that's good to know but, you know,

1 how much data does FSIS really have, how are they
2 using it? How much are they getting from other
3 government agencies? I mean I think there should be a
4 distinction between, you know, government data and
5 non-government data as opposed to being, you know,
6 data that you might get from CDC or FDA or state and
7 local agencies as opposed to lumping it in together
8 with Agency data which is what it seems like they were
9 talking about, again saying that anything that is non-
10 FSIS data is third party. It just, you know, I think
11 that they really need to outline what they have and
12 better identify the gap there. If we don't know
13 exactly what they have and where the gaps are, it's
14 really hard to say, you know, what data would be good
15 to plug in. I mean I think that the examples that you
16 gave are very good examples, but I don't know how much
17 of that FSIS is collecting and quite frankly why
18 aren't they collecting that data.

19 MR. SCHAD: Okay. I'm going to put a
20 comment in on that. I'm just kind of going back to
21 our discussions on NACMPI and I'm not going to say I'm
22 for or against these things, but I know some people

1 brought up like data from state meat inspection
2 programs, FoodNet, those type of entities.

3 OPERATOR: This is the Operator real quick.
4 Do you want me to open all lines on the phones?

5 MR. SCHAD: Yeah, I think it would be
6 fine --

7 OPERATOR: Okay. Thank you. That way --

8 MR. SCHAD: -- as long as everybody
9 identifies themselves.

10 OPERATOR: All lines will be open. Thank
11 you.

12 MR. ANDREA: Mike Andrea.

13 MR. SCHAD: Yeah, go ahead, Mike.

14 MR. ANDREA: I'm with Cargill. And --

15 UNIDENTIFIED SPEAKER: Operator, this is --
16 We are not able to hear anything. Is there a way to
17 check the line?

18 OPERATOR: This is the operator. I just
19 muted the line so that that way on the phone they can
20 talk amongst each other, all lines open, but I just
21 muted it so you wouldn't hear the background.

22 UNIDENTIFIED SPEAKER: Actually, we do need

1 to be able to hear it.

2 OPERATOR: Did you want to hear it? Okay.
3 I'll just open the line real quick.

4 UNIDENTIFIED SPEAKER: Just so everyone
5 knows, we are recording this and so we do need to be
6 able to hear this over at -- thank you.

7 MR. ANDREA: Okay. I'm Mike Andrea from
8 Cargill. My question was the description of what
9 third party information would be and if we just leave
10 it as the general -- any information that isn't
11 collected by FSIS, then how do we put any credence on
12 that information collected unless the third party
13 information comes from accredited, you know, parties
14 that have certain criteria they follow when they
15 collect the information that we are going to submit
16 and is going to be used to determine anything. So I
17 guess it was a comment more than anything but I mean,
18 even the information I'm collecting in my
19 establishment, it's for my own use and I don't think,
20 you know, that you can take that information and make
21 any judgments or any decisions on that information
22 that you get from FSIS because I'm not an accredited

1 company doing the testing. So that's my comment.

2 MR. SCHAD: Yeah, this is Mark, Mike, and I
3 think that's an excellent point because it kind of
4 gets to question number 2 also. So thanks for that.

5 MS. BUCK: This is Pat Buck, and I don't
6 know a whole lot about collecting data, but I know
7 Barbara does and one of the things she was telling me
8 about is that when FDA requires this, it's a very
9 complicated -- verified data. The FDA, they have all
10 of their data stored offsite in a fireproof setting,
11 and the data must -- and plus anyone of the
12 participating groups have to understand that they
13 could have an FDA audit which are generally extensive
14 to verify the data, and I just think that this is
15 going to be costly. I don't see how we're going to
16 build a verifiable data repository at this point.
17 That's why I asked several of the questions I did.
18 It's not that I'm against it, it's just how are we
19 going to put something like this in place with
20 verified data.

21 MS. NESTOR: Excuse me. Can anyone hear me?

22 MR. SCHAD: Yeah, I can hear you. Go ahead.

1 MS. NESTOR: Okay. Good. This is Felicia
2 Nestor. I was having a lot of trouble. I had to call
3 back in several times because it seems like I hadn't
4 been unmuted. I don't know whether there are other
5 people that are also having that same problem.

6 MR. SCHAD: No, the Operator all has us on
7 the open line now, Felicia, so go ahead.

8 MS. NESTOR: Well, that's what they told me
9 as well. I just wanted to find out whether I was part
10 of the conversation. I don't have a comment at this
11 point. I probably will in a little while, but I just
12 wanted to alert you to a possible problem.

13 MR. SCHAD: Thank you, Felicia. You're
14 good. So anybody else --

15 MS. NESTOR: And you may want to take a roll
16 call and see how many just to make sure. You know,
17 supposedly there are 20 people on this line and if
18 they want to take a roll call to see how many people
19 are actually on this line and can say anything.

20 MR. SCHAD: Yeah, I think the operator will
21 be able to tell us that, and if everybody will just
22 identify themselves when they speak. Thank you,

1 Felicia. Okay. Next comment please. I think we can
2 comment on any four of these questions, and then I'll
3 just kind of put the comments together in some kind of
4 logical manner when I do the report. So just anybody
5 go ahead on any of these questions on the whole
6 subject.

7 MS. NESTOR: Okay. This is Felicia Nestor
8 and unfortunately like I said, I was kind off the call
9 here for a little while. So perhaps I missed
10 something, but have you all discussed the incentive
11 aspects of this yet?

12 MR. SCHAD: No, not yet, Felicia, but you
13 can go ahead with that.

14 MS. NESTOR: Well, I'm just wondering, does
15 anybody have -- what's everybody's idea of -- what are
16 the incentives for? To get the industry to share what
17 kind of data, what is FSIS going to get out of the
18 data that is shared?

19 MR. SCHAD: I think the Agency believes
20 there's a lot of data out there from any third parties
21 that the Agency cannot -- does not have access to at
22 this time, and they think there's some good data out

1 there that could help the Agency. So they're asking
2 us on what is this type of data that's out there
3 that's good data and how can they get to it? That's
4 my understanding.

5 MR. ENGELJOHN: This is Dan Engeljohn. If I
6 can perhaps give you a little insight to that in that
7 this isn't the only consideration but the way the --
8 the way the Agency has used the incentive base in the
9 past and intends to do so in the future, but certainly
10 is open to input but an example would be an *E. coli*
11 O157:H7 testing, where the Agency collects roughly
12 11,000 tests a year, whereas an individual
13 establishment, particularly some of the larger
14 establishments are doing several hundred thousand
15 tests a year in that establishment alone because
16 depending on the process, they are collecting on a 15
17 minute basis production a lot of the information or
18 every single hour of production, they are collecting
19 tests and they're doing that all day long. So they
20 accumulate a significantly higher number of tests than
21 what the Agency would ever be able to develop and put
22 in place.

1 And so the issue would be how could the
2 industry's data supplement FSIS testing such that if
3 the Agency is going to maintain it's 11,000 samples
4 for O157:H7, which we do intend to do, how best to
5 allocate those 11,000 samples because we aren't able
6 to collect enough information in a particular
7 establishment to make statistical decisions about the
8 operation but the establishment alone may, in fact, be
9 collecting a sufficient amount of information to make
10 some greater statistical estimates about the
11 confidence they have that contamination doesn't exceed
12 their ongoing average or in some fashion exceed the
13 variation that they've established over time, over
14 region and over seasonality.

15 And so the Agency has in the past said that
16 it would, in fact, continue to collect the 11,000
17 samples but allocate them differently amongst those
18 establishments that have what we would say would be
19 reputable testing programs such that they should get
20 some credit for that and as a consequence, the Agency
21 reduces but doesn't exempt testing in those
22 establishments and increases its testing in

1 establishments who don't do the level of testing that
2 my be in other establishments.

3 So that's an example of an incentive base
4 where the Agency reduces the frequency of testing.

5 MS. NESTOR: And, Dan, what's the level of
6 confidence required? I read the, you know, *E. coli* --
7 I can't remember what the verbiage is, but there's
8 some standard that FSIS holds a company to, something
9 about reliability. Can you tell us the in statistical
10 terms, you know, how much sampling they have to do?
11 They have to do it to a 95 percent level of confidence
12 that they would find *E. coli*. I mean what is the
13 standard that they must meet.

14 DR. ENGELJOHN: This is Dan Engeljohn again.
15 In the case of 0157, where there isn't a regulation
16 that establishes a minimum standard, the industry
17 practice today amongst the larger producers is that
18 they've designed programs in the manner called N60 in
19 which they are taking a sufficient number of samples
20 on an individual lot basis to give them some
21 confidence that they have a 95 percent confidence that
22 the contamination level doesn't exceed 5 percent.

1 Well, the 5 percent is not a reasonable number from
2 the perspective of levels of contamination for O157 in
3 that we know that the contamination rate is
4 considerably lower than that.

5 And so over time, this would be from one
6 production lot to the next, they can lose their
7 statistical means to make some assessment about the
8 level of confidence that they have, and that's the
9 type of thing that the Agency would be looking at in
10 terms of if certain minimum criteria are met, it may
11 be in one range in terms of consideration versus a
12 lower level of testing that the establishment may use
13 which may encompass more of the small producers who
14 don't have the resources to test as robustly as do
15 those larger establishments who do test every single
16 production line every day.

17 And so we've identified a variety of ranges
18 we look at but we don't have absolute minimums
19 established for any of our testing programs.

20 MR. SCHAD: This is Mark, and I'm going to
21 speak to that from an industry perspective especially
22 from very small plants. And a lot of us do microbe

1 testing and especially for adulterants like O157:H7
2 and -- and one of our concerns is that we generate
3 this data but we don't have a statistician on staff to
4 develop a statistical program, and my input would meet
5 from FSIS is here are some samples, we have this data,
6 we do want to share that with you but we don't know if
7 it's -- or not. You can tell us how to develop a
8 statistical program. We'll do that so it is
9 statistically sound data and we'll share it.

10 DR. ENGELJOHN: And this is Dan Engeljohn.
11 I think that's exactly the kind of input that's
12 helpful to us. We certainly can and have developed
13 compliance guideline information to share with
14 industry to say here are the vulnerabilities that you
15 would accept or you would be operating with, and if
16 you designed a program in one way versus another, and
17 it's those real life examples that would be most
18 helpful to us. So getting in the real life examples
19 that are very small or a small producer would use in
20 relation to the larger operations, which we have more
21 information about, then that could be one way that we
22 could make some discernment about the level of

1 vulnerability that individual establishments may face,
2 and that we could look at those differently in terms
3 of targeting whether or not we conduct an inspection
4 testing request in those establishments. But we
5 certainly could do that.

6 MS. NESTOR: Is Barbara Kowalcyk on the
7 phone?

8 MS. KOWALCYK: Yes, I am.

9 MS. NESTOR: Okay, good, Barb. I just
10 wanted to make sure that you're hearing some of this.

11 Dan, I have another question. I think
12 they're all questions. It sounds like from what
13 you're saying is that what FSIS gets out of the
14 industry data in the *E. coli* situation is it takes --
15 FSIS then does not have to do as much samples, that
16 the industry basically is doing and paying for the
17 sampling. So FSIS' regulatory responsibility to
18 insure that the food is safe, the industry is actually
19 doing that and paying for it. It's not like you're
20 taking -- it's not like you have -- you are taking
21 that industry data and then putting it into a database
22 and using it, you know, for any other thing like, in

1 other words, to assess nationwide percentages or
2 anything like that. It's just a matter of the
3 industry is doing it so therefore FSIS doesn't have to
4 do it. Is that right?

5 MR. ENGELJOHN: This is Engeljohn. I think
6 that's one way to look at it, and I think that's been
7 the traditional way that the Agency has used this in
8 the past, but I would just say that the way we have
9 the risk-based programs designed today is that those
10 that have investigated the greatest resources in
11 testing, as an example, would be sampled differently
12 than and in their own sub-sampling frame than those
13 who don't do as much sampling, so that we're not -- we
14 insure that we're getting data out of all the
15 establishments involved in the program so that you're
16 not exempt from it and that we have some targeted way
17 to test.

18 But I think one of the issues here is that
19 we have used this as a means to allocate our sampling
20 resources, but that isn't the only use that we could
21 find in the data. As an example, the industry does
22 collect a significant amount of manufacturing trim

1 data on a routine basis such that they can discern
2 changes nationwide in the amount of contamination that
3 is potentially in the manufacturing trim operations
4 that are used for raw ground beef. And having a
5 mechanism in place whereby industry would be
6 automatically sharing that information with us and
7 insuring that that information is, in fact, that
8 there's some integrity behind it, would be one way for
9 the Agency to be alert to the fact that perhaps we
10 need to step up our verification testing if we see the
11 trend such that the percent positive is rising, and
12 that usually lets us know that there's perhaps a
13 higher degree of O157 in this case, coming in on
14 cattle that are going into slaughter or that the high
15 prevalent season may, in fact, not be within the
16 constraints that we've traditionally thought it to be.

17 So there are other ways we could use the
18 data. We haven't used it that way in the past.

19 MS. NESTOR: I'm sorry I have to ask this
20 follow up question. But again, I didn't hear the
21 first half of your answer. There's seems to be
22 problems on this phone. So what you said is that

1 basically so far the Agency has not used this data for
2 anything other than, you know, to take the burden off
3 of it on the samples, but conceivably it could under
4 RBI. Is that correct?

5 DR. ENGELJOHN: I think that's a fair way to
6 look at it, Felicia. Traditionally we have used the
7 industry data in a means by which we would reduce
8 testing, but the need would be in the future is to use
9 it to indicate trends, and the example I tried to give
10 was the manufacturing trim as an example.

11 MS. NESTOR: I heard that.

12 DR. ENGELJOHN: Okay.

13 MS. NESTOR: Thank you.

14 MR. FOUCHE: Mark, can I ask Dan a question?

15 MR. SCHAD: Yeah, go ahead, Ron.

16 MR. FOUCHE: When we talk about testing, it
17 depends on what level we're at, where we're doing and
18 who's doing it and so forth. The philosophy has been
19 that when you do testing, particularly when you do it
20 at the pathogenic levels, like *E. coli* or *Salmonella*
21 or *Lm*, that the product is being held. When we start
22 talking about doing all this testing, how -- what

1 criteria, what advice is going to be given in
2 relationship to that type of situation? Some of these
3 tests take, depending on what type of test they are,
4 they take quite sometime. So what advice would you
5 have at that point?

6 DR. ENGELJOHN: This is Engeljohn. Well, it
7 depends on which pathogen we're talking about, but
8 I'll just use O157 as the example, in the sense that
9 oftentimes it's marketed particularly by -- mostly by
10 the very small producers for just in time sales, where
11 they're producing it for a particular contract that
12 day. And so holding the product oftentimes has not
13 been feasible for some operations. And the Agency's
14 recommendations in those cases are that if you're not
15 going to test the ground product that's going out the
16 door for which we would be testing, the industry has
17 the opportunity and should be looking then at
18 modifying their programs and looking at the
19 manufacturing trim that they're bringing in the door
20 perhaps that came in the door the prior week or days
21 earlier, in which they could be doing a sampling
22 program to best find low level contamination on the

1 source materials and then make decisions on that as
2 opposed to just relying upon finished product testing.

3 So there are alternatives that could be
4 considered for operations that really they have to
5 produce product just in time.

6 But I would also identify that for virtually
7 all the pathogens FSIS is interested in, there are a
8 series of screens methodologies that can give back
9 results much, much quicker. They're far more
10 sensitive in the sense that they pick up more markers
11 and might give a false positive but if the particular
12 establishment was intending to react as if those were
13 confirmed positives, then they would have a more
14 effective, more public health oriented protection
15 program.

16 So there are alternatives to be considered
17 for which the industry could, in fact, be considering
18 in the design and development of their programs such
19 that they may share data earlier in the system as
20 opposed to just finished product testing.

21 MR. FOUCHE: It makes some sense, Dan, but
22 if you're going to take raw product coming in and

1 you're going to produce a ready-to-eat product, then
2 you really -- have to form a policy that if it's going
3 to go out the door, it can't have any contamination.
4 And we have to assume that all of the meat that we get
5 from federal establishments have the pathogens to it,
6 so we have to have things in place, lethality factors
7 that are going to eliminate it. It would seem to me
8 that it's very expensive to test incoming products and
9 then know that we're going to finish the product in a
10 proper manner that there would be no contaminants
11 there or adulteration.

12 DR. ENGELJOHN: I think that's where your
13 data that demonstrates your ongoing effectiveness of
14 your system comes into value. If it's a ready-to-eat
15 operation, it is prudent for you to have data to show
16 that when you know what the incoming load is, and you
17 know that you've applied your interventions and your
18 lethality steps properly, and that you have data for
19 that, and you have ongoing historical data, then
20 that's where the value of historical data can come in
21 if you don't have the opportunity to do the testing
22 yourself.

1 MR. SCHAD: Ron, this is Mark. I've been
2 listening to you, and I'm going to put all your
3 questions down there kind of like it's comments or
4 concerns if that's okay with you.

5 MR. FOUCHE: Whatever.

6 MR. SCHAD: Okay. Anything else?

7 MR. FOUCHE: Let me say one more thing, Dan.
8 And that is, you know, we, the people that ship
9 product out in ready-to-eat form have to be very, very
10 good and clean and so forth. How come we can get
11 product in from other suppliers, raw suppliers that
12 they don't have the same situation we have? It
13 becomes a challenge to all of us. I know you don't
14 have an answer and I don't have an answer for it but
15 that's the -- the philosophy is, okay, you test the
16 product coming in. Well, that's like me going to a
17 Safeway and they're going to test our product to make
18 sure it's okay coming in. I think going back here to
19 number 4, on that, Mark, the very first part of it,
20 you know, the whole thing is trust, and quite frankly
21 I think some of us out here are not sure we have as
22 much trust as we'd like to have in all the --

1 MR. SCHAD: Ron, I'm going to agree with you
2 on that because I don't personally feel that way
3 necessarily, but I've just talked to so many other
4 plants that said, well, if I share data, all I do is
5 see a downside to it. How's it going to be protected?
6 If I don't share it, I'm kind of like where I am right
7 now. If I do share it and it's a positive, it can
8 only hurt me. Nothing can happen that sharing it will
9 ever help me.

10 DR. ENGELJOHN: This is Engeljohn. I do
11 just want to -- because I'm very interested in this
12 issue of your trust and the issue of sharing the data
13 and wanting to share it, and I oftentimes hear from
14 stakeholders that they don't want to share the data
15 because they believe FSIS would adversely take an
16 action based on that data, and my response always is,
17 well, please challenge us on that. If the issue is
18 one in which I haven't properly trained the employees
19 on how to interpret that data, then I need to know
20 that and we need to respond to that.

21 But I think that there is a concern being
22 raised here that if you share data with the

1 Government, you're going to be punished for that, and
2 the issue here is that we want to find a way to share
3 the data, not have in place a punitive system that you
4 fear but have in a place a mechanism so that you know
5 and that we know how you are interpreting that data
6 and responding to it in order to protect public
7 health. And so we've got to get in some fashion a
8 means to identify what is it that you have a fear of
9 sharing and why, and then what would be some solutions
10 for fixing that, and if it's a training issue, if it's
11 an example issue of some data that you have that you
12 would like to share but you're afraid to, and you want
13 to work with the Agency on some -- scenarios or other
14 training scenarios such that we can walk through the
15 process of how the inspection force should respond to
16 that data, that's what would be very helpful to me
17 because I do have difficulty understanding why it is
18 you would have data that you are fearful to share with
19 the Agency. Because my concern with that would be
20 that if you're fearful to share it, then perhaps I do
21 need to be more concerned about it. And I would like
22 some more clarity on that.

1 MR. FOUCHE: Dan, let me ask you a question
2 real quick. At what point -- it's my understanding
3 that once we give information to FSIS, that can and
4 is -- can be and would be public information through
5 the Freedom of Information Act. Am I right or wrong?

6 DR. ENGELJOHN: I think generally speaking,
7 unless it's proprietary information, and again there's
8 some distinctions made between what's proprietary or
9 not, but you have the individuals on the phone who are
10 quite skilled at FOIA in terms of requesting
11 information. And so I think it really becomes one of
12 what is the information that's being requested, and
13 whether or not the Agency is able to turn it over in a
14 timely manner. But for the most part, I would say
15 information generally coming into the Agency is
16 releasable through an FOIA. Portions of it may be
17 redacted because it may, in fact, be proprietary but
18 if it's predecisional in the sense that it's helping
19 to form the basis for a decision, there are some
20 exceptions for that.

21 But the general rule I think would be that
22 it's information the Agency is relying upon. It's

1 information -- it's Government information at that
2 point.

3 MR. FOUCHE: Thank you.

4 MS. BUCK: This is Pat Buck, and to respond
5 to questions about this is very interesting because I
6 do understand the industry's -- is to why would they
7 want to give data that is harmful to them, into a
8 repository, that is then going to become governmental,
9 you know, information. And if we set this up in such
10 a fashion, what we're going to actually have is the
11 industry is going to be forced to cherry pick their
12 information, and if they give you only the good data
13 as opposed to all of the data that's, you know, their
14 access, which brings us right back to how are we going
15 to verify all of this which is, you know, the first
16 question. How are we going to, you know, does the
17 cost to verify this information make it really doable
18 which is going to be extremely high. And I really
19 think that the FSIS, and I don't think they're doing
20 it intentionally, but I think in some ways it's
21 putting the industry on the spot of solving the
22 problem that FSIS does not have enough testing for its

1 own regulatory purposes. And, you know, how are we
2 going to -- I mean the think the idea of the
3 repository is probably a very good thing but
4 developing it is going to take a long time. We're
5 trying to put a risk-based inspection system in place.
6 How are we going to do that, I don't, I don't see the
7 role of industry data playing as developing RBI at
8 this particular point in time. Maybe five years from
9 now it might be a possibility but right now, I don't
10 see how it's going to be helpful.

11 DR. ENGELJOHN: If I could, this is
12 Engeljohn, just to respond. Just to go back to where
13 we started today's meeting off with that the Agency
14 has made it known that at the moment, with RBI, the
15 Agency is not crediting or it's not fully crediting
16 industry data in the decisions we're making in terms
17 of allocating inspection resources. And that's true
18 for a general rule, and the issue would be that this
19 is an issue for which we think does need development
20 over time, and we believe that that time is necessary
21 to put in place in order to have a system that has the
22 integrity and security that's necessary.

1 But there are individual risk-based
2 verification testing programs that the Agency has put
3 in place, in which we have mechanisms to at least know
4 more about the industry's practices, and this relates
5 to testing. And so we have those in place today with
6 how we do our general risk-based targeted testing but
7 it's not as a general rule what we're intending to do
8 today with risk-based inspection because we realize
9 there's a need to develop this particular area
10 substantially over time. And so I just want to make
11 clear our goal today is to identify the things to be
12 attended to and so that we can come up with the
13 strategy to get where we need to be, to best utilize
14 this information in the future.

15 MS. BUCK: Well, I appreciate that, but this
16 is what have to determine, is what is the Agency
17 planning to do with the data, the repository, once
18 it's collected. Do you have specific guidelines so we
19 know what they're going to use the data for?

20 MR. SCHAD: Pat, this is Mark. Would you
21 have any ideas on that, that you could comment, so we
22 could give feedback to the Agency on that?

1 MS. BUCK: No, I mean listening to the
2 conversation this morning, it sounds to me like this
3 is a much larger idea, the repository than just risk-
4 based inspection. I mean are we going to take this
5 data and, for example, are we going to give it to
6 FoodNet or to PulseNet or to any of the other agencies
7 so they can make, you know, a better determination.
8 Are we going to use this data with our food security
9 program? You know, where will the data actually be
10 going or what is the value or what are we using it for
11 once we collected might be something important to
12 identify because if you have this really wonderful
13 broad range of ideas, then maybe industry could say,
14 you know, this is going to be part of a larger
15 project, and I will participate in this because I see
16 a -- that's good.

17 DR. ENGELJOHN: This is Engeljohn. If I
18 could, that helps me to better understand the question
19 you're asking, Pat. From the perspective of our
20 intentions, and I think the attribution meeting one in
21 which we identified there is a need to have better
22 information about what products are making people sick

1 and how to share that information more so with CDC and
2 state and local authorities. And I think that to the
3 extent that there is data, and I just use the example,
4 the Agency presently collects *Salmonella* data from raw
5 products, and we do serotype that information and in
6 some cases we subtype it down to see whether or not
7 there's any antimicrobial resistance and other markers
8 that are present there, and that information is shared
9 with CDC.

10 The industry collects substantially more
11 data than what the Agency does with regards to
12 *Salmonella* on a day-to-day basis on the products that
13 they produce, and if there was a mechanism by which
14 that information, serotype information, antimicrobial
15 resistance, all these other intricate pieces of data
16 could, in fact, be shared through FSIS who gives that
17 information directly to CDC or CDC and FSIS are
18 directly looking at those databases to see whether or
19 not there's illnesses associated with particular PFGE
20 patterns and so forth, then perhaps we would have a
21 better system in place to prevent the outbreaks and
22 more importantly to get at the issue of the sporadic

1 ones.

2 But that would be an excellent example of
3 the vast amount of data that the industry does have
4 that they currently don't share with FSIS that FSIS or
5 another third party could be source for which that
6 information could be shared with CDC as an example and
7 then that could be better used in terms of attribution
8 information. I think that would be an absolute
9 wonderful thing to have happen. It isn't something
10 that happens today.

11 MS. KOWALCYK: This is Barbara Kowalcyk.
12 Are you saying that FSIS currently share PFGE pattern
13 *Salmonella* verification testing --

14 DR. ENGELJOHN: I couldn't quite make out
15 the end of that question but I think the question was
16 does FSIS currently share PFGE pattern information
17 with CDC? Was that the question?

18 MS. KOWALCYK: Yes.

19 DR. ENGELJOHN: Yes. Every single data
20 point that FSIS has with regards to PFGE pattern and
21 microbial resistance if we have it, serotype
22 information, it is automatically shared with CDC and

1 we have individuals who work with CDC in trying to
2 interpret that data as well. But, yes, that
3 information has been for sometime shared directly with
4 CDC.

5 And let me make it clear. What we share
6 with CDC is information that's not specific to an
7 establishment. FSIS has that information and is able
8 to go back to it and follow up on it, and we do share
9 the serotype information with the establishment. So
10 the PFGE pattern, in and of itself, the isolate and
11 the pattern that we have, that is, in fact, what is
12 shared in the CDC database.

13 MS. KOWALCYK: Okay. I have several
14 concerns about the use of third party data, and I
15 guess it's probably going into question 4. Can
16 everybody understand me?

17 MR. SCHAD: I can, Barb.

18 MS. KOWALCYK: Okay. I think that, you
19 know, and Pat raised some of these questions earlier
20 at the -- I think one of the big concerns I have is,
21 one, if you're going to kind of give credit to
22 companies that can afford to do their own microbial

1 testing, then you bias it towards larger plants or
2 plants with more resources and it in some way hurts
3 the little guy which I don't really think that's a
4 good thing. So that's one concern.

5 The other concern is how are you going to be
6 able to verify the validity of the data so that
7 another ConAgra situation doesn't happen where FSIS
8 thought ConAgra was doing their own *E. coli* testing
9 on -- largely because of a history for *E. coli*. You
10 know, I will go back to the FDA sample. The FDA on
11 the -- side does rely heavily on this data. They have
12 to. They can't afford to do their own -- files -- now
13 the scrutiny of that data is very high. It's very
14 expensive to maintain that data -- maintain records
15 for so many years, at offsite facilities, in fire save
16 locations because, you know, when the FDA comes
17 calling for an audit, well, if there's a fire or we've
18 misplaced them is not an acceptable response. And if
19 the company cannot produce the data on an audit, there
20 are sizeable fines, and does the Agency -- the Agency
21 doesn't even have the authority currently to enforce
22 its performance standards.

1 If a company is found to be withholding data
2 from the Agency, how are they going to take
3 enforcement action against the company? If you need
4 to protect public health here and the company is
5 cherry picking its concentrations of data, what is the
6 repercussion to FSIS or FSIS is already -- position
7 where they can put the resources necessary into the
8 types of audits. These are time consuming audits.
9 And I'm not so sure -- I'm not sure how much FSIS
10 gains from having industry provided data as opposed to
11 going out and collecting it themselves.

12 These are all things that I see as potential
13 problems because there may be ways to get around it.
14 So right now FSIS has very limited resources and, you
15 know, I don't think they understand that using
16 industry data and then going out and auditing it,
17 that's resource intensive. You have to have people, I
18 mean for a pharmaceutical company, it meant shutting
19 down business for a couple of weeks when they went
20 through the audit with the FDA, and I can't -- shut
21 down an entire company. I can't imagine industry
22 agreeing to shut down, you know, they don't have the

1 staff that some of these companies do to shut down and
2 go through the FDA audit, you know. And there has to
3 be a level of protection there for public health so we
4 don't have another ConAgra, and I understand that most
5 companies aren't going to do that if it only takes
6 one -- thing.

7 MS. NESTOR: Can I make a comment? This is
8 Felicia Nestor. Hello.

9 MR. SCHAD: Go ahead, Felicia.

10 MS. NESTOR: Hello.

11 MS. KOWALCYK: We can hear you, Felicia.

12 MS. NESTOR: Oh, okay. Good. I just want
13 to follow up. I had questions before and now I want
14 to make a comment.

15 It seems pretty clear what FSIS wants out of
16 this cliché, and it seems pretty clear what -- can
17 get. FSIS doesn't have to expend resources on testing
18 and the industry can probably get less -- by the
19 Government. It's not clear what the consumers are
20 going to get out of this, and I think that we need to
21 be clear exactly what benefits there are to the
22 consumer in this. I mean our -- about improving

1 public health protection and so far it's pretty vague
2 what consumers are going to get out of this expected
3 plan.

4 You know, when we look at what the Agency
5 did with ConAgra, you know, that was an extensive plan
6 there and, you know, -- the Agency didn't take any
7 steps even though they knew that ConAgra was getting a
8 lot of positives. Well, the truth of the matter is,
9 that the inspectors -- in that plant on the frontline
10 were jumping up and down for months trying to get the
11 Agency to do something about it, and it was
12 Headquarters, it FSIS policymakers and administrators
13 that didn't do anything and until many people got sick
14 and one person I believe died, you know. And someone
15 from industry that says they don't have much trust in
16 that, you know, the higher up we go, believe me, you
17 know, from a consumer's standpoint, I also -- you
18 know. I think that there is -- industry gets any
19 benefit for sharing data, the Agency has to make it
20 crystal clear what the benefits to consumers are and
21 that it's a real benefit, not that the Agency, you
22 know, not that they might be, you know, but the Agency

1 has something, a backdoor policy, where the consumers
2 are not getting the benefits that the Agency is
3 announcing they are as they did with ConAgra.

4 MR. SCHAD: Felicia, this is Mark, and I'm
5 going to see if I can get you an industry perspective
6 on that, you know, why we would want to share data.

7 MS. NESTOR: Uh-huh.

8 MR. SCHAD: I'm going to see if I can get
9 you an industry perspective of why we would want to
10 share data?

11 MS. NESTOR: Yeah, great.

12 MR. SCHAD: And my own personal point is,
13 okay, as one plant owner, I'm going to qualify that up
14 front. When I want to share data I'm not thinking
15 necessarily less inspector time. That does not bother
16 me one way or the other. But if I'm collecting a lot
17 of data and I'm a ready-to-eat plant, and I've been
18 going years and years and I'm getting negative on
19 my -- both on what the Agency's collecting and what
20 I'm collecting now, right now it's like, okay, Mark,
21 you've done your in-house data but we're not going to
22 accept it because it's not -- and whenever I go to the

1 Agency, and I'm not talking about Dan Engeljohn here,
2 and I'm not talking about people in Washington. I'm
3 talking about local people. They're telling me, well,
4 we can't accept it, and it's like I'm shooting in the
5 dark here. Tell me what is wrong with it. It can't
6 help but make it right. And that's why I made that
7 point earlier on. My viewpoint is the Agency needs to
8 provide us guidelines on how to do it so we can
9 generate this data. What if a plant, especially a
10 very small plant, okay, they're telling me I can't use
11 the data now -- but if I have the guidelines and I can
12 prove the efficacy of my product, that's why I --
13 that's the incentive I see for --

14 MS. NESTOR: Okay. I want to respond to
15 that. Unfortunately, you know, we don't get to have
16 the regulatory authority to clone meat processors like
17 you, Mark. You know, if we did, consumers would not
18 be advocating and expressing so much concern. You
19 know, as Oliver Wendell Holmes said, the law is made
20 to deal with the bad actors, not with the good actors.
21 You know, if everybody was a good actor, we wouldn't
22 have to -- consumers wouldn't have to be here

1 representing ourselves, you know.

2 So I mean I appreciate your input, and I
3 hope you recognize that when we're saying these
4 things, it's not because we think everybody in
5 industry is not trustworthy, you know, that's far from
6 it. But we have to protect ourselves from those that
7 are not trusting.

8 MR. SCHAD: Okay. Thank you, Felicia.

9 MS. BUCK: I have a question. This is Pat
10 Buck.

11 MS. KOWALCYK: This is Barb Kowalcyk.

12 MS. BUCK: Go ahead, Barb.

13 MS. KOWALCYK: And I have a follow up to
14 what Mark said. I think what Mark said is very
15 complete. FSIS needs to do kind of what the FDA does.
16 If you're going to go out and collect data -- you have
17 to supply up front your analysis plan, how you're
18 going to collect, analyze and determine data. Okay.
19 The FDA has to sign off on that -- and, you know, that
20 way if it's -- they can't come back, you know, five
21 years later and say, this is what the FDA turned over,
22 and somebody says I don't like that anymore, I want to

1 do it this way, this is my personal favorite way of
2 analyzing the data. It's -- but what I don't know is
3 if FSIS really understands that the amount of time and
4 energy and resources it takes to go get an approved
5 statistical analysis plan or sampling plan, whatever
6 you want to call it, it actually has to do audits to
7 make sure that you don't have the bad apples trying to
8 get away with it by only submitting their negative
9 test results. You have to have random audit checks on
10 that and I don't think FSIS realizes how much time and
11 energy and expense that is going to take, and it's
12 going to take an entirely different type of workforce
13 than what they currently have in order to do that.
14 They can't -- from what I understand, they can't get
15 FSAs done in a timely manner. I don't know how they
16 would manage to get these sampling analysis plans
17 completed in a timely manner. I think it's a good
18 idea but, you know, is there a benefit -- with the
19 cost of that, which that way, actually be less if FSIS
20 did the sampling themselves --

21 MR. SCHAD: This is Mark, and I think we're
22 all bring up some good points here. But in the

1 interest of time, I think we need to wrap this up. So
2 if anybody has any final comments on -- in about 10
3 minutes.

4 MS. NESTOR: I do have a final comment.
5 This is Felicia Nestor, and this will be quick.
6 Someone said do we have suggestions with what could be
7 done with the data? Yes. Keep the PFGE -- if
8 industry wants credit for its data, it has to turn
9 over the PFGE patterns for the data that it's
10 providing and that has to be in a public repository so
11 that people that get sick from foodborne illness can
12 then go and look and see if they can identify the
13 plant that made them sick.

14 MR. SCHAD: Thank you, Felicia.

15 MS. NESTOR: And I know that's a long shot,
16 but I am not saying that facetiously. I am making
17 that as a recommendation and a comment.

18 MR. SCHAD: Thank you, Felicia. Anybody
19 else? Anybody else with a final comment?

20 MS. BUCK: This is Pat Buck. I just have a
21 question and it's about the PFGE. Dan Engeljohn said
22 that FSIS -- one was information -- but I --

1 MR. SCHAD: Dan, are you still there?

2 MR. TYNAN: Dan is here but, Mark, I'm going
3 to break in for a second and we have about 10 minutes
4 before we're going to reconvene. So if you want to be
5 wrapping it up, that would be great.

6 MR. SCHAD: Okay. Thank you. That's what
7 we're doing here right now.

8 MS. BUCK: I'll find out the answer to that
9 question.

10 MR. SCHAD: Okay. Thank you, Pat. Any
11 final comments?

12 (No response.)

13 MR. SCHAD: If there's no last comments, I
14 guess we'll wrap this up right now. Thank you. I
15 guess he's not there, but thanks to Dan Engeljohn for
16 hanging in there with answering some discussion
17 points. Thank you to everybody. I think we had an
18 excellent conversation. We've raised a lot of
19 concerns and comments for the Agency. Thank you.

20 MS. BUCK: If I may make a comment. I think
21 it was helpful to have all the lines open unlike the
22 last time where we had to press *1.

1 (Whereupon, at 11:40 a.m., the meeting was
2 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

CONFERENCE CALL 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.

ANDY VOGEL, Reporter

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