

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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RED GROUP BREAKOUT

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April 30, 2007
10:45 a.m.

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I-N-D-E-X

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

2 (10:45 a.m.)

3 MS. BLUMBERG: Let's get started by
4 identifying somebody who would like to kind of be our
5 leader and help us get through these four questions.
6 Do we have any volunteers? I'll be here to kind of
7 help you stay on time and take any notes if you want
8 me to.

9 UNIDENTIFIED SPEAKER: Last person to walk
10 in the door.

11 UNIDENTIFIED SPEAKER: Sorry.

12 UNIDENTIFIED SPEAKER: We're looking for
13 somebody to facilitate and so the last person to walk
14 in.

15 MS. BLUMBERG: We need a spokesperson.

16 DR. RYBOLT: I did it last time.

17 MS. BLUMBERG: Somebody can volunteer to be
18 the facilitator. Another person could do the
19 presenting. We can share those functions.

20 MR. REINHARD: I'll facilitate.

21 MS. BLUMBERG: Okay. There we go. We've
22 got a facilitator.

1 MR. REINHARD: Why don't I facilitate and
2 you present it.

3 DR. RYBOLT: I've already presented, so
4 somebody else probably should.

5 MS. BLUMBERG: Okay. Well, Facilitator, why
6 don't you come up?

7 MR. REINHARD: Can't I facilitate from here?

8 MS. BLUMBERG: Do you want to facilitate
9 from there?

10 MR. REINHARD: Is that all right? I'd
11 rather facilitate from here.

12 MS. BLUMBERG: Okay. When anybody is
13 talking, if you wouldn't mind saying your name and
14 your affiliation for the Court Reporter. We are going
15 to have this taped.

16 MR. REINHARD: I'm Bob Reinhard of Sara Lee
17 Corporation. I guess we'll go ahead and get started,
18 and the question that is here is "What data could
19 third parties provide to FSIS to further enhance
20 protection of public health?"

21 DR. RYBOLT: And by third party, we're
22 talking about non-FSIS data.

1 MR. REINHARD: Right.

2 DR. RYBOLT: In-plant pathogen testing.

3 MS. BLUMBERG: In-plant pathogen testing.

4 Anybody else have any other ideas?

5 MR. REINHARD: Plant process control data.

6 UNIDENTIFIED SPEAKER: Intervention
7 validation data.

8 MS. BLUMBERG: I'm sorry. You said
9 validation?

10 UNIDENTIFIED SPEAKER: Intervention
11 validation data.

12 MS. BLUMBERG: I'm sorry.

13 UNIDENTIFIED SPEAKER: And even though it
14 was a subject of last week's meeting, volume
15 information, production information.

16 MS. BLUMBERG: Okay. I'll try and get out
17 of your way. So right now we have in-plant pathogen
18 testing, plant processing control data, intervention
19 validation data and volume production information.

20 MR. REINHARD: Anybody have any other data
21 that they think could be provided to improve public
22 health? All plant data.

1 MS. CHEN: Maybe the testing of process,
2 like indicator organisms to test process control.
3 It's kind of underneath process control data. Like in
4 addition to pathogen control.

5 DR. RYBOLT: Process control data/indicator
6 organism.

7 MS. CHEN: Indicator organisms, yeah.

8 MS. BLUMBERG: Just indicator data or I'm
9 sorry.

10 MS. CHEN: Testing of indicator organisms
11 for process control.

12 COURT REPORTER: Could you state your name
13 for the record? Your name?

14 UNIDENTIFIED SPEAKER: This is Yuan Chen
15 (ph.) from GMA/FPA.

16 MR. REINHARD: Okay. Is there any other
17 data that anyone else thinks FSIS could use to improve
18 public health?

19 MS. CHEN: And I also think that sometimes
20 companies who have testing data on raw materials. So
21 if there is a mechanism in place for company to share
22 those data, you know, it could be useful for

1 establishing -- process on production and -- so raw
2 material testing.

3 DR. RYBOLT: Lot information, lot
4 descriptions.

5 MR. REINHARD: How about audit information?
6 Any other data?

7 DR. BATZ: This is Mike Batz with University
8 of Maryland, Food Safety Research Division. I think
9 there's a lot of data that, you know, industrywide
10 data that FSIS can't collect due to the Paperwork
11 Reduction Act, sort of things such as what percentage
12 of facilities are doing X versus Y, that aren't maybe
13 necessarily useful for risk-based inspection but are
14 the kinds of information that might be useful for
15 public health. I'm just thinking -- I just think that
16 the data that can be used is pretty much limitless.
17 It's kind of dependent upon the question, you know.
18 For risk-based inspection, this set of data gets used
19 for maybe different purposes.

20 MR. REINHARD: Intended use of finished
21 goods would be something that FSIS could get from
22 industry data, if it's going into food service or

1 retail or if it's going to be processed into another
2 product.

3 DR. RYBOLT: Are there any other state or
4 government agency data, you know, at the attribution
5 meeting, you know, we talked about that some but CDC
6 information. Michael Rybolt.

7 MS. BLUMBERG: So do you want me to just
8 add state or do you want me to --

9 MS. ATWOOD: State or CDC public health
10 information.

11 MR. REINHARD: Michelle Atwood (ph.).

12 MS. ATWOOD: Thank you.

13 MR. REINHARD: FSIS. Okay. Any other third
14 party data?

15 DR. BATZ: Any data from academic research I
16 guess would be third party.

17 MS. CHEN: And to add to that, I think there
18 has been some database established in terms of trying
19 to make academic data, data from the literature more
20 available to industry to use in validation and
21 especially in pathogen control database such as the --
22 or the PMP.

1 MS. BLUMBERG: Okay. Should I review the
2 list? We have in-plant pathogen testing, plant
3 processing control data or an indicator organism
4 process control, the intervention validation data,
5 volume production information, testing on raw
6 materials, lot descriptions, audit information, the
7 comment that the data is limitless, intended use for a
8 product, the state and CDC public health information
9 and academic research data and data from literature.
10 Did I misrepresent anything or do I need to add
11 anything?

12 MR. REINHARD: Okay. Then we'll go onto the
13 next question, and the next question is "How can
14 stakeholders assist the Agency in improving
15 collection, validation, analysis and application of
16 data?"

17 DR. RYBOLT: That question almost blends in
18 with question number 3 though.

19 UNIDENTIFIED SPEAKER: Yeah.

20 DR. RYBOLT: What mechanism(s) can be
21 developed to bring in stakeholders? If you bring them
22 in, what can they do to help improve the collection?

1 MR. REINHARD: Bob Reinhard. I just have a
2 comment related to the Agency using data especially
3 plant data and the current model and establishment
4 would be that FSIS continually reviews plant data and
5 decisions. It's important regulatory compliance in a
6 field operation setting. So decisions, academic
7 research that supports interventions, decisions for
8 process control, any of those type things, FSIS
9 currently already reviews and uses in its inspection
10 model, I think it's important. But the question at
11 hand is how could that information be further used in
12 a risk-based model or some other model for inspection
13 more than decision making in a Headquarters type
14 scenario. I think that's really where we are but this
15 data is already used.

16 MS. BLUMBERG: And I think the distinction
17 between number 2 and number 3, is in number 2 we're
18 talking about Agency data and how it can be used, by
19 what mechanism, what formalized mechanism can we
20 engage you in validating the way we collect our data,
21 the way we validate, the analysis we're performing.
22 So we're trying to invite you into our process in

1 that. Whereas 3 is really getting at the data that
2 you have that you could share with us.

3 MR. REINHARD: So with that, does anybody
4 have a comment on number 2, on how the Agency can
5 improve their data collection?

6 MR. HONTZ: This discussion this morning,
7 I'm Lloyd Hontz from GMA/FPA, and maybe some of this
8 was covered but personally we could use more
9 information about exactly how it's collected and
10 validated and analyzed and applied at this point in
11 time.

12 CAROLE: And that actually came out in the
13 meeting, I think the comment was that we need to have
14 a formalized mechanism by which we show you what we're
15 doing, what we're analyzing and invite input. What
16 that mechanism is may be something you might want to
17 comment on how.

18 MS. CHEN: Yeah, remember this morning it
19 was mentioned that eventually there might be synco
20 (ph.) data warehouse. So it would be helpful if we
21 somehow, you know, industry can view the components of
22 that warehouse and not necessarily modify it but have

1 a chance to see what's in there and that's consistent
2 with the idea of being transparent. So I guess first
3 of all, being able to see some of these components,
4 the data itself or like the RBI algorithm to see
5 exactly how it worked.

6 CAROLE: What about things like quarterly
7 meetings? Could it be the result of our analysis and,
8 I don't know, Federal Register and peer review papers.

9 MS. BLUMBERG: Peer review papers.

10 MR. REINHARD: Just so we get it on the
11 record, a data warehouse that's available for people
12 to get the information and review the Agency
13 information and data. And then Carole I believe said
14 then a rapid quarterly release of data. Is that --

15 CAROLE: Some kind of release of the data
16 where there might be input.

17 MR. HONTZ: And I'm just really thinking out
18 loud here because I think a lot of times that -- said,
19 if it's laid out what the data is, how it's collected
20 and so forth, and you take some of the mystery away,
21 and I think it will be more clear to everybody
22 involved, you know, how the Agency works with the

1 data. So I think quarterly meetings and things like
2 that, you know, further discussion on it is a good
3 thing.

4 And I don't mean to jump ahead, but that's
5 what I was thinking in number 3, you know, that might
6 be the third party repository. Whatever that would
7 be, could be a way for, even within the industry or
8 industry and academia to share data across, you know,
9 some of you all remember that we had some of those
10 discussions back years ago when we were first talking
11 about HACCP implementation and so forth, and we had
12 some of those discussions. So that's what --

13 MR. REINHARD: The comment I have, Bob
14 Reinhard again, is that when it comes to approving the
15 collection of data, FSIS has mechanisms which it
16 current works in to collect data and then gives out
17 that information on a quarterly basis or whatever
18 method it is. But one thing that FSIS has struggled
19 with, that they go back and they change the way they
20 actually collect data, how they decide to collect that
21 data. It then changes how the reports come out the
22 next quarter, and FSIS has been very resistant to make

1 improvements in their methodology because no one is
2 willing to take the step and say, well, we used to
3 analyze the data this way and we got result A. We're
4 now collecting and analyzing data this way, and it's
5 XYZ. And they can't necessarily be just directly
6 compared and, I've seen FSIS, if they can't be
7 directly compared, well, they're very unwilling to
8 make improvements in the data because they want to
9 show how the inspector's involved, how the Agency
10 collects their verification data, what the results
11 have come to be. And I think some movement to
12 improving the reporting of the data and saying, well,
13 today data is not different. We don't analyze it that
14 way anymore. We now have a new method. It's
15 something the Agency should look at in a lot of places
16 where they can make improvements and make it of more
17 value.

18 DR. RYBOLT: This question also being at --
19 I think Dr. Engeljohn's presentation talked about it.
20 I'll say validation, analysis and application, similar
21 to the RAMs and RM questionnaire or shakedown,
22 validate your systems that you have in place -- I

1 don't remember the form number but it was the form
2 that the inspectors have --

3 UNIDENTIFIED SPEAKER: 10240-1?

4 DR. RYBOLT: Yeah.

5 CAROLE: You know, that's the -- how can we
6 renew into what -- data that we have and we're getting
7 a little bit off the third party now, because overall
8 the Agency's mechanisms of analyzing data --

9 DR. RYBOLT: Well, that's what I was getting
10 at, this form would be a way for the Agency to
11 validate some of the data.

12 DR. BATZ: It seems to me that as the Agency
13 moves towards more sort of risk-based activities, it
14 gets more engaged with the principles of risk analysis
15 which involve a very, you know, protocols for risk
16 communication that start with the finding of a risk
17 management question up front and have stakeholder
18 involvement throughout. You know, those guidelines,
19 as risk assessment, the risk analysis becomes sort of
20 more the way, in which I think the food safety system
21 is moving. I think that's, you know, it's more
22 appropriate to sort of engage on that risk

1 communication.

2 CAROLE: Right. And I think that is part of
3 why we want to tie ourselves so close to policy
4 because we want to be able for them to say these are
5 the kinds of analysis we need to inform our decision-
6 making. And it helps to prioritize our work, and just
7 like we do with risk assessors and risk managers, you
8 could actually publicize your risk assessment agenda
9 or your, you know, analysis agenda, whatever you want
10 to call it, risk analysis agenda and "comments."
11 People are always coming down the pike and --

12 DR. BATZ: Well, I think it helps you in the
13 end, too, because by the time you get to the end stage
14 where you're releasing the results --

15 UNIDENTIFIED SPEAKER: Yes.

16 DR. BATZ: -- people have had a chance to
17 comment on the methodology as it's going it's going
18 through.

19 CAROLE: So what we're saying is a process
20 by which you go from the beginning to the end in which
21 you're engaging stakeholders.

22 DR. BATZ: Yeah.

1 MR. REINHARD: Bob Reinhard, Sara Lee. Just
2 one more thing on this, and I don't want to confuse it
3 with number 3. But the Agency could actually bring
4 together a task force to look at this specific
5 question in and of itself, not the next question which
6 is share quality data, of how can the Agency improve
7 their internal way they analyze validating and using
8 their data to run their systems. So a task force that
9 included all the stakeholders, a group of people that
10 continuously look at this forward thinking, flows into
11 a risk-based system where everybody has one voice or a
12 way to analyze the data, and it also leads to positive
13 output related to public health.

14 MS. CHEN: And I think one thing that is
15 useful to industry is the guidance documents that are
16 out there. So maybe continuous update of those
17 guidance documents especially putting in information
18 on validation of control, like the *Lm* guidance
19 document. That has been very helpful in terms of, you
20 know, what kind of control measure can be used, is it
21 considered validated, what else is missing, and the
22 people they work for large process as opposed to small

1 plants as well. And that is --

2 DR. RYBOLT: Is DAIG responsible for
3 anything or do they have any responsibility?

4 CAROLE: The Agency is responsible number 2,
5 yeah, and if we were provided it in industry data, we
6 would be responsible for number 3.

7 DR. RYBOLT: Yeah. I'm wondering how can --
8 if the DAIG is responsible for looking at the Agency's
9 data collection and analysis --

10 CAROLE: And making it worth our while.

11 DR. RYBOLT: -- how can the stakeholder help
12 that? Is there a way for representatives from the
13 stakeholder groups to be on the DAIG, be part of, and
14 this kind of goes back to what somebody asked. I
15 don't remember her name now, but was given a list of
16 those names. But also had industry and consumer group
17 rep and an academic rep as part of that.

18 CAROLE: I don't know necessarily --

19 DR. RYBOLT: Or necessarily have the -- but
20 somebody who would have a broad based understanding of
21 all the areas.

22 CAROLE: Right. And I'm not so sure they

1 would be part of the DAIG because that's an internal
2 staff, but I believe it was suggested that we set up a
3 task force and you were part of that interacting with
4 the DAIG, that would be a way to obtain data unless
5 you want to come work for us.

6 MR. REINHARD: Other inputs on number 2?

7 (No response.)

8 MR. REINHARD: We'll then go onto number 3.
9 What mechanisms can be developed to bring different
10 stakeholders together to share quality data? And this
11 relates to a task force, a third party repository,
12 stakeholders meeting or other.

13 DR. RYBOLT: I think that -- there was a
14 recommendation that has a lot of bearing on creating a
15 task force -- creating that task force, that there
16 would be stakeholders on there that set up guidelines
17 and, you know, get by and share, et cetera, et cetera,
18 -- I don't know what framework that has --

19 UNIDENTIFIED SPEAKER: It's a very formal
20 framework.

21 DR. RYBOLT: I was going to say, I think it
22 is and that's following that same EPA model.

1 MR. REINHARD: Right. Bob Reinhard, Sara
2 Lee. I think it's great that FSIS has looked at
3 benchmarking with other agencies. I think there are
4 other agencies besides EPA that use other data from
5 stakeholders. So there may be some other benchmarking
6 there. As I tried to mention and maybe not very well
7 last time, I just want to -- everyone to think about
8 this and this data is already shared with FSIS in the
9 regulatory model, and it is not way outside the box,
10 that we would say, okay, how would we formally use
11 that in a risk-based inspection model and some of
12 these things bring up very, very structured and
13 difficult things to work with, to try to get something
14 incorporated that I really think is already
15 incorporated. And it's just a question of how do you
16 make it more formal. How do you make the data more
17 standardized such that FSIS could evaluate it on a
18 playing field across all their establishments. And I
19 would encourage FSIS to look at the process that's
20 already there and standardize how information could be
21 put into a database, a simple database of, if a plant
22 wants to share how many food contact services they

1 analyze for *Listeria* and 9 C.F.R. 430, then FSIS could
2 enter that somehow into a database that had that data
3 and use that then in whatever mechanisms and models
4 that would be appropriate because that data has
5 already been reviewed by FSIS. It's already collected
6 under a, you know, a standard format by the *Lm*, you
7 know, risk assessment form or the *Lm* form that you
8 fill out when EAIOS visit the plant.

9 So I think the best way to move this
10 forward, is to take the simple information that's
11 already there, it's fairly formalized because there is
12 a process for that, and then we just incorporate that
13 into the model. That's in essence an optional --
14 that's how I want to share that I do "X" number of
15 samples and then take that data and move forward and
16 not make it so complicated that nothing gets through.

17 DR. BATZ: Well, how different, I mean how
18 different are those requirements say between *Lm* which
19 seems to be quite different than, you know, for
20 *Salmonella* or *Campylobacter* in poultry or something
21 which is kind of a different story or O157 in beef? I
22 mean I'm not that familiar with the *Lm* requirements.

1 What are the standardization issues that you're
2 talking about there?

3 And, you know, because it seems like you're
4 right. There's two levels of data. There's the data
5 that you're collecting to sort of satisfy regulatory
6 requirements possibly. You have other data that
7 you're collecting to satisfy audit requirements. You
8 can have other data that you're using to collect
9 internally. And, you know, with all the different
10 testing methodologies out there proliferated by fourth
11 parties or additional parties that are trying to
12 compete on price, all these things that have different
13 sensitivities and specificities and, you know,
14 obviously the standardization issues there are much
15 more complicated than the simpler the data is, you
16 know.

17 Aggregating across plants that are using
18 different testing methodology and different sample
19 protocols seems to me tremendously difficult and
20 that's to me a far bigger problem than just, you know,
21 how can we use this data? You almost need to have
22 volume from everybody who's participating in the

1 program, that they're following this standardized
2 protocol which I would think FSIS would have to sort
3 of validate and publish and everything and everybody
4 would have to use that.

5 But for the simpler data, how similar are
6 the OMB, to have sort of standardization reporting
7 issues to do sort of public pathogens on other
8 products?

9 MR. REINHARD: Bob Reinhard, Sara Lee. I
10 think one thing, FSIS has a tremendous amount of
11 guidance documents on data the plants should collect
12 to make decisions on process control. And simply if
13 we started there with plants that used that guidance
14 and material, collected samples and analyzed samples
15 as that guidance material says, it could easily be
16 rolled up and incorporated and would be standard. It
17 would be straightforward and if FSIS has guidance
18 material on aerobic plate counts and cooked water
19 reuse, then everyone that has that information would
20 want to use that information to show they had control,
21 I think that's one that we were interested in, would
22 be there.

1 The same, I believe there's guidance
2 material on the control of *Salmonella*. I don't know
3 of anything for *Campylobacter*, necessarily from FSIS
4 but, yes, there are places where -- but through that
5 mechanism of FSIS developing and putting out guidance
6 materials, they could define out common and standard
7 ways to collect information thereby then making the
8 data uniform through the microbe process.

9 MS. CHEN: And think although with the
10 pathogens to control these different things on the
11 product, either ready-to-eat or raw, poultry or beef
12 product, but I think one thing the plants have in
13 common is that they all have RBI rating. And so the
14 data that go into the rating include your usual HACCP
15 SSOP implementation data, your validation data and
16 volume data and other relevant data. So they could,
17 you know, use the one that are relevant for their
18 product and put into this algorithm. And one thing
19 they need to do is to show that the rating they get,
20 to verify the rating and also if they believe that
21 their data show that they should be on a different
22 rating that by using those data, you can actually

1 verify the rating and even change that if you can
2 support that. So that would be a common point would
3 be the RBI algorithm, would be a focal point
4 supporting that data.

5 MR. REINHARD: So other mechanisms? I guess
6 we have a task force which was the first option. Then
7 what? Look at current processes --

8 MS. BLUMBERG: I'm sorry, yeah. My
9 handwriting's horrible. Look at current process of
10 looking at data and enter into the database and
11 incorporate into a model. I think I was trying to
12 kind of get what you were saying. Is that not right?

13 MR. REINHARD: I think using, right, simple
14 current processes with the guidance documents to take
15 standardized data that's out there already and just
16 roll it into a system is a good start.

17 MS. BLUMBERG: This is second party data.

18 MR. REINHARD: This is second party data.
19 But there's third party data that are, too, accepted,
20 validation for decision, that may be rolled up, too.
21 I think Michael said formalize the process and make
22 sure everybody's doing the common protocol and

1 methodology. Do we have any other comments on this?
2 It's pretty straightforward.

3 DR. BATZ: Yeah, to me there's the front end
4 stuff which is the guidance documents and then on the
5 back end, you know, maybe, yeah, there's different
6 sort of, you know, a routine collection is different
7 than starting a process like RBI and you're changing
8 it I guess, but the formalized process I think is on
9 the guidance documents as well as on the stakeholder
10 end, you know, there can be a, you know, whenever
11 you're doing something, you have to sort of set in
12 stone. You know, it has transparency in it, has
13 openness, that you know, there's all these protocols
14 out there that exist.

15 MR. REINHARD: Any other comments on number
16 3? As the facilitator, I'd like to try keep you
17 moving.

18 (No response.)

19 MR. REINHARD: Okay. Then number 4 is "What
20 are the barriers to creating such a mechanism? What
21 incentives could be used to encourage sharing of
22 data?"

1 I don't know what would be a barrier to do
2 this. I think creating a task force --

3 MR. GIOGLIO: This is Charlie Gioglio from
4 FSIS. Let me really just ask the questions to get you
5 thinking. The type of data that you all have been
6 talking about is mostly generated by individual
7 establishments but there is some third party data
8 coming from other sources, maybe even academia or
9 whatever, or different studies that are being done.
10 But what are the barriers from establishments or the
11 industry, in particular, for sharing that type of in-
12 plant data with the Agency?

13 CAROLE: I mean does it appear that
14 regulation and --

15 MR. GIOGLIO: Yes, I mean that's I think is
16 a question that, you know, we'd like to get at and
17 then think through what are some ways we can mitigate
18 those barriers, those problems.

19 MR. REINHARD: I think in that regard, what
20 are some of the barriers, the first would be the
21 information that plants shared needs to be protected,
22 needs to be information that is not subject to FOIA,

1 thereby being proprietary information, you know,
2 validation studies and things like that. A lot of
3 that is proprietary.

4 MR. GIOGLIO: The point that Bob made
5 earlier is very true, FSIS in-plant has access to --
6 if need be based on what findings we have in the
7 plants. I think we're looking to get a step beyond
8 that for broader decision making, not focused on one
9 individual establishment. We need broader decision
10 making here, and that's what we want to try and get
11 to.

12 MR. REINHARD: So a barrier to sharing such
13 information in the second part of the data would be
14 everyone understands how that would be analyzed? That
15 would be key, and that's transparent and they
16 understood how it would be used, as to what's going to
17 drive people to participating. Knowing that it
18 improves public health would drive people to
19 participating. It's the third thing I can think of.

20 For other data, state data or academic data,
21 and even industry data, if you're a small
22 establishment, I think probably resources are probably

1 a challenge to this. And I can't speak on what states
2 do related to meat and poultry, but when I was in
3 graduate school, I did research on seafood and states
4 did extensive sampling and testing on seafood, that I
5 did my graduate work in, and that information could be
6 made available to the Federal Government per se. But
7 the resource question would arise, how would the state
8 get that information and give that to the Government
9 and, you know, those type questions. So I think
10 resources is a question mark, not that it isn't --
11 there are resources available, it's just whether or
12 not you use them for what.

13 MS. CHEN: So limitation in resource in
14 plant --

15 MR. REINHARD: Right.

16 MS. CHEN: -- could be a variant. And I
17 agree with what you said earlier about the
18 confidentiality issues and also the regulatory action.
19 That -- that is zero tolerance. So what would be the
20 incentive for industry to go out and do more extensive
21 testing beyond the minimum requirement.

22 MR. REINHARD: On the resources issue up

1 there, it's in-plant, it's in Government, it's in
2 academia. Everyone has resource limitations I think.
3 You know, the state government really for that matter,
4 too.

5 MS. BROWN: Well, I think also along the
6 lines of the resource issue -- this is Andrea Brown
7 with the American Association of Meat Processors. Our
8 association deals with mainly small plants. So the
9 resource issue is something, and also understanding
10 the standardization of process data. If they provide
11 data, it's the data that can be used, you know, in the
12 format because a lot of them aren't maybe computer
13 literate or those kind of technical issues as far as
14 the, you know, whatever compliance guidelines would be
15 out there would be very important to making sure that
16 the data that they were able to provide would be
17 something that would be useful.

18 MS. OSTFELD: This is Jackie Ostfeld from
19 the Government Accountability Project. I just have a
20 comment. Since this information is not public and
21 it's not subject to FOIA which is fine, I just want to
22 make sure that FSIS has some kind of system to

1 evaluate and make sure that the data coming in is
2 objective and it's all of the data. It can't be
3 cherry picked data I mean since it is completely
4 voluntary. There needs to be a mechanism in place

5 MR. REINHARD: That's probably one of the
6 task force challenges, it would be used to establish
7 criteria for evaluating the data that's shared and
8 where it came from, inspector verified the data, et
9 cetera, et cetera. I agree completely.

10 UNIDENTIFIED SPEAKER: I don't know, but we
11 did say necessarily that it was voluntary but I think
12 that probably is a barrier. It needs to be voluntary.
13 It would probably be a way to get people to
14 participate.

15 MR. HONTZ: If I can just follow up a little
16 bit on what about what -- said, that it would be very
17 important that as far as not having barriers. If you
18 don't discourage people from doing microbiological
19 testing, there's potential repercussions from --
20 enforcement actions, if the company -- takes the
21 appropriate steps to eliminate hazard. So I think it
22 would be pertinent on this theory and it would need to

1 be applied across the board, that we want to encourage
2 industry to test as much as they can to try and --

3 CAROLE: It seems like this is a really
4 fruitful idea to try to cash in the second party data.
5 Would that be worth trying to do maybe on a smaller
6 scale, like a pilot or something, like somebody would
7 stand up and, you know, -- a guinea pig to do that and
8 then start to work through some the issues and
9 problems.

10 MR. REINHARD: So a barrier, a way to break
11 down that barrier would be to set up a pilot, I don't
12 know if you're allowed to use that word, a pilot to
13 show all stakeholders how the system would work.

14 CAROLE: Yeah.

15 DR. RYBOLT: I don't know if --

16 CAROLE: I guess -- why wouldn't we be able
17 to --

18 DR. RYBOLT: Well, I understand --

19 MR. REINHARD: There would be concern about
20 data being identified with an establishment or not.
21 That's an establishment question, not necessarily --

22 CAROLE: A particular company rather than an

1 industry there would be one --

2 DR. BATZ: I mean, could you use second
3 party data that went through a third party source? I
4 think that's kind of what happened with *Listeria*.

5 CAROLE: A third party repository or
6 Michelle just pointed out an interesting idea lining
7 the data so you can't really associate it with a
8 particular establishment.

9 DR. BATZ: I mean, you know, when you're
10 talking about a data repository and stuff, I mean the
11 JIFSAN food risk guide work, you know, I mean that --
12 I think one of the reasons, one of the benefits from
13 JIFSAN has been that to get it out of the regulatory
14 office so that this data repository and this sort of
15 system of aggravation can be used to deal with some of
16 these I think FOIA issues and confidentiality issues
17 but, you know, I don't know if the USDA has any
18 similar kind of thing that is part of the Agency but,
19 you know, not affiliated --

20 CAROLE: No, we don't have anything like
21 that now. That's part of the reason for asking the
22 questions. He was saying let's borrow to the extent

1 possible from what other agencies have done. Maybe we
2 need to more closely study the JIFSAN model --

3 DR. BATZ: I mean they put their risk
4 assessments up there. They put up -- I mean I think
5 it was for the temperature control study that they did
6 as part of the *Listeria* stuff and all of that data is
7 up there and available. I don't know. I think it's
8 that kind of process where the data repository has
9 been using it, you know, all along with different sort
10 of risk engagement, you know, PAD, -- you know, to get
11 volume from sort of both sides. The data isn't going
12 to result in punitive action and also finding from
13 consumers, you could say, well, this isn't biased data
14 or it's not cherry picked or anything like that.

15 MR. REINHARD: Other comments on the
16 barriers?

17 (No response.)

18 MR. REINHARD: So I guess that --

19 MS. BLUMBERG: Did you want me to read --

20 MR. REINHARD: -- I've facilitated us
21 through all four questions, and we need to assign
22 who's going to speak.

1 MS. BLUMBERG: You have the second half of
2 the question about incentives.

3 MR. REINHARD: Oh. What could be used to
4 encourage sharing of data? So what are the
5 incentives? Sorry. Incentives to sharing data?

6 MR. HONTZ: Some credit in the algorithm for
7 -- if they were willing to share their data, and give
8 some credit and some positive points in the algorithm.

9 CAROLE: This is Carole. Say you wanted to
10 give positive points for sharing the data, even if
11 it's bad data, like -- I mean like say you're not
12 performing very well, you're sharing --

13 MR. HONTZ: If you're not performing well,
14 the equation should take care of that but the fact
15 that you're actually willing to share information
16 voluntarily with the Agency, I think some type of
17 incentive or some sort of credit, whatever that might
18 be, but the fact that you're giving data, you should
19 get something for that. That would encourage sharing
20 data. The algorithm should take care of if you're not
21 performing well.

22 MS. KLEIN: This is Sarah Klein from CSPI.

1 I just wanted to kind of second that the consumers
2 definitely have a concern that there is no logical
3 correlation which means getting points for sharing
4 data, like we're having trouble figuring out what --
5 where the logical connect is between sharing data and
6 removing a NR or some similar points for a data
7 system, and that's something that we'd like to hear a
8 lot more about before we kind of say, that sounds
9 fair. It just doesn't seem right, you know.

10 MS. CHEN: But if the industry is willing to
11 share more data and data beyond what's required, would
12 the Agency be interested in knowing what their
13 justification for a different rating may be, if they
14 had the justification for it, not necessarily say bad
15 data to use to justify a good rating but do they
16 actually have data to show that the controls are valid
17 and that -- required, we give people an opportunity
18 for discussion on this. That would be a question.
19 And also sometimes industry will have difficulty in
20 validating their controls. So I wonder if they could
21 also share their questions or need for assistance as
22 well and would there be any incentive to help them to

1 address their need, especially in the area of
2 validation processes.

3 CAROLE: I don't know the answers to that,
4 but I think that's a question we definitely could put
5 up. I think one of the points though today is that we
6 want to share data that somebody could take regulatory
7 action to consider on this point, that maybe the
8 establishment actually did something in response to
9 that negative result. I think it's getting back to
10 what you're saying is then you open that dialog, you
11 know, I have this bad data, this is what I've got.

12 MS. CHEN: And they may have good data to
13 share as well. Maybe that's the case and that may be
14 justifiable to say you can get a better rating on the
15 RBI score because of the actual data they have and if
16 they see they are sharing the data, they actually
17 demonstrate their case of getting a better rating that
18 could be an incentive.

19 DR. BATZ: And maybe it's a protocol for,
20 you know, maybe it's not you get inspected less, but
21 if you show, you know, after you've had this bad
22 thing, that you put something in place that warrants a

1 re-evaluation of what your score should be, you know,
2 that if these -- I don't know how often these things
3 are going to be determined, you know, if they're on an
4 annual basis or something like that, where, you know,
5 the concern might be that you have a spike in bad
6 data, you take a lot of action and yet your RBI rating
7 is, you know, considered at the same time you get --
8 if you get points for the score, you have consumer
9 concern. You know, maybe there's a point at which you
10 can't remove that, you know, if you have -- if you're
11 showing bad things, you know, you can't sort of ignore
12 that but maybe you can have some opportunity to change
13 what the score is after you do something to reduce it.

14 MR. REINHARD: Other incentives that could
15 be used?

16 MS. OSTFELD: What about just improving
17 public health and knowing that you're contributing to
18 that by providing data.

19 MR. REINHARD: Other incentives? I was way
20 outside the box and I thought maybe FSIS could provide
21 data. But maybe it could assist with state and
22 academic expenses for that data.

1 CAROLE: Grants to universities or --

2 MR. REINHARD: Yeah, or whatever that
3 mechanism is, however that works.

4 UNIDENTIFIED SPEAKER: I don't think you
5 want to put buy data on there.

6 MS. BLUMBERG: What do you want me to put?

7 MR. HONTZ: Alternate expense, I don't know
8 how the state and academic share.

9 MS. BLUMBERG: Share.

10 MS. CHEN: I think on the point you
11 mentioned earlier about improving public health, a
12 certain segment of the industry could have data
13 collectivity to show that they changed the overall
14 attribution. That would reflect very well on either
15 the poultry side or fruits and vegetables or -- we're
16 talking about meat and poultry, but I can see that can
17 be done under a broader umbrella to have more industry
18 -- data to show that they actually have low levels of
19 pathogens, that could potentially influence the
20 attribution, you know, whatever the attribution is.
21 And that that would be an indication of protecting
22 public health or at least you're not contributing to

1 illnesses as much as before.

2 MS. BURGESS: So are you saying analyzing
3 data and conducting the analysis to demonstrate how
4 the actions that that we're taking in the Agency is
5 protecting public health --

6 MS. CHEN: Yeah, for example --

7 MS. BURGESS: -- more data -- providing data
8 to show that?

9 MS. CHEN: Yeah, to show -- a role public
10 health protection for example, 0157:H7, you know,
11 problems found by -- related to the decrease in the
12 cases from 0157, but I can see that that can only be
13 done through like a collected effort, is that we think
14 that industry segment rather than an individual
15 company. And maybe that's where, you know, the
16 association, we could facilitate them, a collective
17 effort.

18 MS. BLUMBERG: Show how data is protecting
19 public health.

20 MS. CHEN: Collective.

21 MS. BLUMBERG: Collective.

22 MS. CHEN: Yeah.

1 MR. REINHARD: So my facilitating is
2 finished. I'll turn it over to you to find somebody
3 to present it.

4 MS. BLUMBERG: We have about five more
5 minutes if anybody else has something to say. Nobody
6 wants to do the presenting, huh?

7 MS. BURGESS: It's not so bad. Someone has
8 to want to do it.

9 MR. REINHARD: I think Michael can do the
10 presenting. He's presented --

11 DR. BATZ: Yeah, sure.

12 UNIDENTIFIED SPEAKER: Sorry, Michael.

13 DR. BATZ: That's all right.

14 MS. BLUMBERG: Well, thank you all for your
15 contributions, and we'll meet back in the main room in
16 about five minutes.

17 (Whereupon, at 11:40 a.m., the meeting was
18 concluded.)

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C E R T I F I C A T E

This is to certify that the attached proceedings
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USING DATA FROM OTHER SOURCES

A CHARGE FROM FSIS: QUESTIONS FOR
CONSIDERATION IN BREAKOUT SESSIONS

RED GROUP BREAKOUT

Arlington, Virginia

April 30, 2007

were held as herein appears, and that this is the
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Timothy J. Atkinson, Jr., Reporter
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