

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

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RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

GROUP 3

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October 10, 2006
3:55 p.m.

George Mason University School of Public Policy
Arlington Original Building
3401 Fairfax Drive
Arlington, Virginia 22201

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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 (3:55 p.m.)

3 MR. SPANGLER: We're going to try to get
4 done the first paper by approximately 5:00 and go back
5 and see what we've come up with, see how far we've
6 gotten, maybe pick out a few highlights, on these
7 first six questions.

8 So the first question on establishment risk
9 control is, are these six components appropriate and
10 adequate? And hopefully -- I see you're pulling out
11 their PowerPoints. They'll probably be helpful, the
12 six components that are on the graph, that have
13 received a lot of attention. So are they appropriate
14 and adequate will be the question. Anyone is welcome
15 to jump in.

16 MR. REINHARD: Bob Reinhard. I'd like to
17 comment on the appropriateness. We believe that FSIS
18 should look at the six components. We think that's
19 appropriate but we believe that one of the breakouts
20 that were shown in that wheel, the in-commerce
21 finding, should be rolled up under the enforcement
22 action. If you see what was proposed there, FSIS said

1 if there was a significant in-process event or in-
2 commerce event, such as a confirmed illness back to a
3 product. And that's handled currently and that leads
4 to enforcement action. We think it would be more
5 appropriate to take that part of in-commerce and move
6 it under enforcement action because there are a lot of
7 other in-commerce findings, consumer complaints
8 related to quality, which are data that is being
9 proposed I believe not to be used, and it would
10 simplify the model and make it easier to understand.

11 MR. SPANGLER: So roll in-commerce into
12 enforcement.

13 MR. REINHARD: That's correct.

14 MR. SPANGLER: And that would simplify the
15 findings. Is that the idea?

16 MR. REINHARD: That's correct. It would get
17 data, whatever you used --

18 MR. SPANGLER: Honestly, I can only get so
19 many notes down. So anyone that could help me take
20 some more detailed notes. We have the recording going
21 on, but we're going to do a report back to the group
22 tomorrow morning. So I can only get so many notes on

1 the flipchart. So whoever wants to volunteer, a
2 couple of volunteers to help me take a little more
3 detailed notes.

4 MR. REINHARD: I have to make a correction
5 because food defense is in there and I didn't realize
6 that. So seven controls are potentially appropriate
7 but then we had two we would recommend that FSIS
8 consider adding, and one being process intervention,
9 as a spoke to itself and this relates to the idea that
10 an alternative 3, hot dog and deli product, a ready-
11 to-eat product versus an alternative 1 ready-to-eat
12 product, and that the risk to the -- and control which
13 allows them to differentiate those interventions and
14 have it directly affect the model which truly does
15 represent potential for exposure to the public.

16 And then a final category we would be
17 interested in seeing used is intended use of product.

18 MR. SPANGLER: Okay.

19 MR. REINHARD: And I know this was talked
20 about on the other axis, on the Y-axis, but it's
21 probably most appropriate on the X-axis because it's
22 what's decided by the plant. So this example would be

1 if a slaughterer makes ground turkey, which was ranked
2 23rd, that that slaughterer uses 100 percent of their
3 ground turkey to make cook in the bag sausage, that
4 product then in essence is not a risk, as if that
5 producer was making ground turkey to be sold at
6 retail.

7 So we would say there would be seven
8 different categories.

9 MR. SPANGLER: What was the last process
10 thing? Can you identify -- are you willing to take
11 notes?

12 MS. RASOR: Someone pointed at me.

13 MR. SPANGLER: I appreciate it. It'll help
14 us make a good report for tomorrow. So other comments
15 on whether the six components are appropriate and
16 adequate?

17 MR. GOVRO: I just have a question for Bob.
18 Just a clarification.

19 MR. SPANGLER: Okay.

20 MR. GOVRO: On the interventions, would that
21 component be appropriate for all types of products or
22 just the ones where we're talking about *Listeria* 1, 2,

1 3?

2 MR. REINHARD: Well, *Listeria* is the most
3 simple -- but I think it would be appropriate for all
4 types of products. There would be a slaughterer that
5 has steam cabinets to reduce the level of *Salmonella*
6 and then there would be slaughterers that didn't.
7 Those type of interventions could be built into a
8 model and the key would be the ability of the Agency
9 to identify what things are appropriate, the use in
10 the product, but because of HACCP and the way it's set
11 up and the requirement on the producer to validate and
12 show their validation and verification for
13 intervention, we feel like it would be appropriate.
14 And it would really -- it would make it possible to
15 differentiate along the different spokes of the wheel
16 with that added component versus not having that for
17 example.

18 DR. RICE: Well, it was my understanding
19 that slaughter was not going to be separate for risk-
20 based inspection. Is that --

21 DR. MASTERS: FSIS is considering this for
22 processing and off-line slaughter, off-line slaughter.

1 UNIDENTIFIED SPEAKER: So interventions for
2 *Salmonella* in poultry slaughter is not going to be
3 included, right?

4 DR. MASTERS: Intervention in poultry
5 slaughter off-line would be included by your off-line
6 inspection --

7 MR. SPANGLER: Off-line process intervention.
8 Is that a more accurate way to state it? Barbara?

9 DR. MASTERS: I'll -- food safety
10 intervention. Food safety intervention.

11 MR. SPANGLER: Bob?

12 MR. REINHARD: Yes, food safety intervention
13 would be fine.

14 MR. SPANGLER: I don't see any other cards.
15 Do you have any more comments on question 1?

16 MS. BROWN: I have a comment on
17 intervention, representing small plants. I appreciate
18 the configuration of intervention -- but some
19 consideration I think should also be examined for
20 small plants without the financial ability to
21 implement some of the intervention activities versus
22 large facilities. That's what I wanted to comment on.

1 There should be some kind of ability to take that
2 factor into consideration.

3 MR. SPANGLER: Small plants may not be able
4 to --

5 MS. BROWN: Financially.

6 MR. SPANGLER: Carol?

7 MS. TUCKER-FOREMAN: Help me understand this
8 a little more because it comes up and I'm not sure I
9 understand. Would there be a substitute action that
10 could demonstrate the same effectiveness?

11 MS. BROWN: I'm not sure of that answer.
12 We've thought about it and I haven't come up with an
13 answer but the categories of intervention I don't
14 think are necessarily fair to all the different types
15 of plants.

16 MS. TUCKER-FOREMAN: We're going to have
17 issues with the fact that you might suggest that
18 because it's a small plant that it shouldn't have to
19 meet the same safety requirements of big plants. You
20 can define it differently in a way that you can afford
21 but it's going to be the bottom line that says the
22 same result, but every time I hear the small plant

1 thing I get --

2 MS. BROWN: I mean there's a baseline for
3 regular -- and this definitely meets that based on
4 regulatory requirements. Some of the large plants
5 have additional interventions in place that go beyond
6 what the regulations require that the small plants
7 don't have but they still certainly meet all the
8 requirements.

9 MS. TUCKER-FOREMAN: --

10 MR. SPANGLER: So in terms of a suggestion
11 for FSIS about how to deal with this, I think Andrea
12 mentioned -- said some things about a scale or -- can
13 you reiterate that?

14 MS. BROWN: I don't know if it's fair to use
15 a scale in this situation or not, but some type of
16 consideration for intervention on a smaller scale --

17 MR. SPANGLER: So consider scale --

18 MS. BROWN: Research that's been done in
19 smaller plants, maybe there's something there that we
20 can use.

21 MR. SPANGLER: Carol, did you want to add
22 something?

1 MS. TUCKER-FOREMAN: Yeah, just one thing
2 that this plant doesn't qualify for -- if you don't
3 put it in the pool of plants that don't have to do --
4 because the projections are unfair, that one of things
5 that you're raising is these plants just have to meet
6 the most basic regulatory requirements to be able to
7 be given a category of plants that present such a low
8 risk that they don't -- that they get a reduced
9 inspection. I think that's what we're talking about
10 here.

11 MR. SPANGLER: Okay. Without going too far
12 off track of the questions because that's sort of a
13 comment building on the previous addition to the six
14 factors. So now we're sort of diverging from the task
15 at hand. Let's try and stick with the question
16 whether the six factors are appropriate or adequate
17 and certainly --

18 MS. TUCKER-FOREMAN: Well, I think it --
19 because we just had a discussion that --

20 DR. MASTERS: Well, let me point out, they
21 direct as well in questions number 2 and 4. So I
22 think they are, that from an Agency perspective, that

1 question 2 says some should be weighted more than
2 others, and question 4 says other ways besides food
3 safety assessments to evaluate establishment food
4 safety design. The Agency has considered things like
5 interventions and particularly a focus on
6 interventions for *Listeria* and food safety assessment
7 design and so we have looked at it there, and I hear
8 Bob -- Bob's pulling it out and putting question
9 number is separate spokes suggesting he would pull it
10 out of design and make it its own spoke, and I hear
11 Andrea saying maybe even weight it differently. So
12 I'm not trying to put words in people's mouths but I
13 want to suggest that Carol is leading the ball in play
14 and is probably to lay. And as an Agency we welcome
15 conversation and it's useful to us to say, how do
16 others feel about making it its own category of
17 intervention because at one point people are saying
18 maybe food safety assessment is gone and small and
19 very small plants have to go prove it, and that's
20 fine, and if they come out with no enforcement,
21 they're good.

22 Now the next question is if intervention is

1 a separate category, they can either get 0 and get
2 plus marks if they're using it. That's another way of
3 looking at it. So Carol's saying is there a baseline
4 they have to meet? The baseline could be yes, they
5 have to pass the food safety assessment without
6 getting an enforcement action. For them not to be
7 negative to a small or very small plant, some of the
8 thoughts of the Agency is, yes, they have to meet food
9 safety assessment and that they do validated
10 intervention -- keeping the ball in the court.
11 Actually we're working on three questions
12 simultaneously if that helps.

13 MR. SPANGLER: There will be no sort of
14 demerits but starting out at baseline and then --

15 DR. MASTERS: This is just a thought and the
16 Agency is --

17 MR. SPANGLER: Okay. Any other comments on
18 the first question about appropriate and adequate.
19 Pat and then James. I didn't see who went first.

20 DR. DENTON: It doesn't matter.

21 MR. SPANGLER: James and then Pat. Go
22 ahead.

1 DR. DENTON: Okay. I think that Barbara has
2 already discussed this, but on question number 3 where
3 the question is, is there other useful information
4 about establishment risk control that FSIS is not
5 considering, that's where I believe other
6 interventions would be part of what's in play here.
7 So I think we may have questions that are overlapping.
8 We don't know if they're adequate, but -- question
9 number 3.

10 MR. SPANGLER: Does anybody else want to
11 weigh on where intervention would fall?

12 MS. HOVDE: I'm looking at this and the
13 small plant and large plant sitting side by side, that
14 larger plants may have more resources, but I think
15 they all have data and no matter who you are, you know
16 your process. If you have data, that's something that
17 the Agency can look at and weigh it, and do you have
18 this data, do you have the science behind your
19 process, and -- category small or large. The data is
20 very important.

21 MR. SPANGLER: So consider the data a plant
22 has to support the processes being used.

1 MS. HOVDE: Yes.

2 MR. SPANGLER: Pat.

3 MS. BUCK: Actually, she asked the question
4 I was going to ask but the other thing I am curious
5 about and somebody mentioned it downstairs, how do we
6 put food defense in here? And is this an appropriate
7 thing for us to be tackling when we already have so
8 much to tackle, you know, with risk-based inspection.

9 It's not that it's important, I believe it is, but I
10 do think the interventions category is probably more
11 important and encompasses of what we're trying to do
12 which is lower pathogen and contamination as opposed
13 to food defense. I don't know what other people think
14 about that.

15 MR. SPANGLER: So you would say -- you're
16 questioning whether food defense is appropriate and
17 suggesting that perhaps intervention is more
18 important.

19 MS. BUCK: Also the purposes of what we're
20 trying to do with this. I don't want to totally get
21 rid of the idea of food defense --

22 MR. SPANGLER: Okay.

1 MS. BUCK: -- but I think that it doesn't
2 carry as much weight in this discussion.

3 MR. SPANGLER: So for RBI purposes. Okay.
4 Excuse my handwriting if it's getting too sloppy.

5 MS. BUCK: I think risk-based inspection
6 should drive the defense. I don't think we should be
7 driven by the defense.

8 MR. SPANGLER: Okay. Angelo?

9 MR. FILI: I've turned it up a little bit
10 more to a cut and dry picture myself of what FSIS does
11 because I think the fact that vending plants for years
12 and years have been processing tons and tons of meat
13 every day, to meet those of the system relative to
14 safe or unsafe food in our country, and to me I begin
15 to worry if we're going to make risk-based inspection
16 system, and we're going to look at the things that may
17 help limit future outbreaks or lower *E. coli* or lower
18 the risk of someone getting sick, it does make me
19 wonder why look at the inspectors that are currently
20 in the plants, and I am fortunate enough to have seen
21 NRs and seen what inspectors do and what they talk
22 about, and what worries me is that we're talking about

1 branching out into some of these things. I mean for
2 me, inspection, not inspection, but the intervention
3 systems, they're already in. They're looked at every
4 day. You've got to approve them once or twice or
5 every three years, whatever it may be. I guess I look
6 at this at what are we are going to do next. So if we
7 look at food safety, is the plant safe because there's
8 a door that's open constantly to an alleyway in
9 Philadelphia. That happens. And I mean I personally
10 worry how would an inspector who is standing there who
11 has been around food most of his life when you look at
12 a set of shipping receipts for product delivered in
13 Indonesia and make a, you know, I do worry about
14 branching out into areas that are not going to stop
15 somebody from getting either sick or products
16 adulterated but I do think the food defense system,
17 not even part of it, not even the 400 pages or 32
18 pages, it does bring in some things that makes me
19 think why was that door left open every day -- and
20 once you go through that system, I don't know whether
21 it meant -- this system, but it definitely needs to be
22 a once a year -- it needs to be incorporated somewhere

1 but I don't know where the daily responsibility to
2 inspect is because I'm very leary of adding
3 responsibilities to inspectors --

4 DR. RICE: I don't believe it's a
5 responsibility because the 08 task has been changed
6 and allow the task to be performed. Are you aware of
7 that?

8 MR. FILI: I'm not sure what that --

9 DR. RICE: The food defense tasks that are
10 assigned to the USDA, the 08 tasks.

11 MR. SPANGLER: -- data on that.

12 DR. MASTERS: For like other consumer
13 protection. So the PBIS --

14 MR. FILI: No, I wasn't aware of that but I
15 know for us, I like to know my inspectors are --

16 MR. SPANGLER: I --

17 MR. FILI: -- gap in the fence, for me it
18 doesn't make -- it doesn't help us, but some of these
19 things certainly have. I don't want to say -- but it
20 should certainly be on rotating task of once every six
21 months or three months to check that --

22 MR. SPANGLER: It should be included but

1 maybe not on a daily part of the routine?

2 MR. FILI: I know you want to roll it into
3 the mix but in reality, it's really once it's -- six
4 foot fence with guards around, it somewhat begins to
5 solve that task.

6 MR. SPANGLER: Okay. Let me know if this
7 doesn't capture your thoughts, but I think I got it.
8 Rod's been patient. He's got a comment.

9 MR. LEONARD: I've been following the
10 industry for I think now something like 50 years, and
11 to follow up on Angelo's point, there are really two
12 sources of expertise about what problems exist in a
13 meat and poultry processing plant and that is the
14 people who are working for the company and the
15 inspector and, you know, here we sit around this room
16 today, most of you work for the company and you're
17 invited as part of agriculture on how they can somehow
18 miraculously change inspection, so that it really
19 works which they haven't been able to do for the last
20 30 years. But I don't see any information coming into
21 this on these issues from the inspectors.

22 We go out and we try to hire 32 or 33

1 experts and we can only find 23, and those 23 don't
2 seem to be able to agree on very much except that they
3 are experts. So I'm concerned that what we hear, what
4 we've heard today is a system that's based on
5 inadequate data, based on flawed data, based on a
6 system essentially which is a guess and we dress it up
7 by saying this is the view of experts.

8 Clearly, the department is not ready to move
9 into a major revision of the inspection program. The
10 Administrator wants to do it in two years because in
11 two years he's going to be gone. There's going to be
12 a new President. There's going to be a new Secretary
13 of Agriculture. There's going to be a new
14 Administrator, and we're going to do this all over
15 again. So why don't we have some information from the
16 people who really know what the situation is, from the
17 inspectors.

18 MR. SPANGLER: That's one suggestion I have
19 here. We're here with a discrete task. So let's try
20 and get some productive input in the process. So
21 that's one thing I have here. You pointed out there's
22 two sources of expertise, employees, plant employees

1 and inspectors and you said industry's represented
2 here, but we need information from the inspectors.
3 Does that capture your thoughts?

4 MR. LEONARD: My thought is we're no where
5 ready to even move this thing forward --

6 MR. SPANGLER: Okay.

7 MR. REINHARD: I'd like to go back to the
8 question on food defense. I don't know. The only two
9 comments I head were probably that food defense would
10 not be part of the RBI model. It would be moved out
11 and separate. I think everybody agrees on that.
12 That's what it looks like. Does anybody want to say
13 something different? I think we all know it's
14 important. So for the record that should be there,
15 everybody agrees with that, too.

16 MR. SPANGLER: So just generally, do people
17 agree with this? Maybe one or two times per year
18 but --

19 MR. REINHARD: More specifically the food
20 defense would not be part of the RBI model in
21 evaluating establishment risk control. It would be
22 handled under other Agency activity.

1 MS. BUCK: This should drive.

2 MR. SPANGLER: Would you say the second part
3 you said? Should not be part of the RBI model. It
4 should be moved to other Agency activity.

5 DR. RICE: It's being handled right now. We
6 could leave it where it is.

7 MR. REINHARD: That's correct. That's
8 correct. It would be rolled into RBI.

9 MR. SPANGLER: Okay. Does everyone
10 generally agree with that sentiment? We can highlight
11 in our small group report. Does anyone not agree with
12 that idea.

13 (No response.)

14 MR. SPANGLER: Okay. So we can conclude
15 with this piece. Does anyone not agree with this
16 idea?

17 (No response.)

18 MR. SPANGLER: Okay. Then I'll highlight
19 that for your report then.

20 UNIDENTIFIED SPEAKER: This is just a
21 personal observation I think on a comment that was
22 made earlier, and this is just on what we're talking

1 about. The first time I ever seen Washington, and I've
2 been in the 17 years, but the first time I -- some of
3 the ideas were going to become. In my opinion, I
4 think we have industry and all I've ever thought about
5 since I got my first job was the meat industry, and I
6 think like Barb or some people, all they ever thought
7 about was food inspection. I mean this is all they
8 think about, and I think they caught up their system.

9

10 In my opinion, where we are today, HACCP was
11 brought in. It certainly introduced four or five new
12 items such as very long and detailed food system
13 designs, system implementation systems, enforcement
14 actions you still always have to look at, pathogen
15 control. Now I think scientifically we're at a point
16 where it's time, in my opinion, where I see these
17 things today and why I can again this year, because it
18 is time to put the inspection system on a HACCP basis,
19 have them on a program that tells them what we're
20 doing, we're checking these 17 things and if those are
21 right, then go back out there and look at how it's in
22 the plant but check on these orders, because that's

1 what's happened to plants. I think plants were doing
2 these things for 100 years. Now somebody put a GK or
3 a KQ by everything there, and nobody stirs it up
4 anymore because I can see very quickly, okay, in terms
5 of -- when I look at these, it is a method of the
6 HACCP plan. And again I'd like to say myself, when
7 you start asking an inspector to look at what happened
8 out in commerce, when you start asking the inspector
9 to look at food defense ideas, those things that are
10 not part of his day or every day, he's got to go in
11 the office and wait for an hour for somebody to
12 produce all of the consumer complaints, not saying --
13 they're very important I think, but they also have
14 them I think at CDC or at these control centers where
15 someone can see it. Those types of things, I inspect
16 personally somewhere where it's below 35 degrees in my
17 own opinion but I think it's better for us --

18 MR. SPANGLER: So let me clarify a little
19 bit. So put the inspection on a HACCP type system.

20 UNIDENTIFIED SPEAKER: Yeah, we itemize
21 risks, the hazards and then we put a critical control
22 system in place. I think their critical control

1 system is hands on. Put their hands on the problem
2 that they see, and that's kind of what we're talking
3 about today.

4 MR. SPANGLER: Can you say just a little bit
5 more about that?

6 UNIDENTIFIED SPEAKER: What I guess I'm
7 saying is, in a HACCP system, we look at the hazard,
8 and then we put a critical control program together to
9 fight them. I think here what they're saying is, and
10 I know there's been a lot argument in the other room
11 as to what the experts were or what the elicitation
12 was, once they have ascertained what the problems are,
13 and one side may say that that is the expert
14 elicitation placed those in a point system, and the
15 other side may be saying -- but the idea to me is that
16 once that gets identified through whatever means we
17 decide to identify the task, I think it should be
18 putting our people in those areas, and that's what
19 this system suggests.

20 The comment was that I think working on non-
21 plant specifically like food commerce or food defense
22 is probably -- they're best handled in a --

1 UNIDENTIFIED SPEAKER: I wouldn't think the
2 inspectors at the local level was going to be involved
3 with -- I would say --

4 UNIDENTIFIED SPEAKER: I thought maybe they
5 would go into the folder and look at what's been
6 attached to the plant, I guess was the way I
7 envisioned it.

8 MR. SPANGLER: So just to be sure about what
9 you're saying, that you're not so sure about the in-
10 commerce piece.

11 UNIDENTIFIED SPEAKER: My own opinion is
12 that.

13 MR. REINHARD: Well, that's what was already
14 said and I think it was repeated and I guess he said
15 he supported RBI, that in-commerce would be rolled
16 out, and it goes to enforcement if enforcement takes
17 place in the plant.

18 MR. SPANGLER: Okay. I saw Carol and then
19 Barbara.

20 MS. TUCKER-FOREMAN: Let Barbara talk
21 because she may answer your question.

22 DR. MASTERS: Just to answer Angelo's

1 question, the way we've been envisioning the system,
2 in talking about this system, to try and help
3 determine the information that Ann would have, and Dr.
4 Raymond's scenario when he talked about Ann -- . The
5 information she would have in trying to determine
6 inspection levels in the plant, and I talked in my
7 presentation about a mathematical formula or
8 algorithm. That information would be housed in our
9 data warehouse, which is currently at headquarters.
10 And so information on consumer complaints is currently
11 in that data warehouse, for each individual plant that
12 might have consumer complaints. Recalls for each
13 individual plant are currently in that data warehouse.
14 Enforcement actions currently are electronic and we're
15 moving those into the data warehouse. Food safety
16 assessments are electronic and -- information. So we
17 would envision that that information and that for or
18 whatever reason the algorithm would be, provided to
19 the in-plant inspector for each plants on their
20 assignment.

21 So, Angelo, the inspector personnel at your
22 facility, they would be told the information we have

1 on this facility is that their ability to control risk
2 is X based on NRs, based on in-commerce findings, and
3 then questions that are asked later are it's changed
4 over time because last month they had a consumer
5 complaint or last month they had a recall. So they
6 wouldn't go find that information. That would be
7 handled at headquarters through this big data
8 warehouse where the information is.

9 MS. TUCKER-FOREMAN: I have some questions
10 about the consumer complaints. It's referred to in
11 the paper but I didn't see anywhere where there's a
12 detailed list of what the categories, specific
13 categories are of consumer complaints. My guess is
14 that they get written different ways because you get
15 them from a whole variety of -- How do you
16 categorize? How do you decide which one has public
17 health significance? Which one doesn't? Is that
18 built into your database and is something where you
19 could just print out what the categories are?

20 DR. MASTERS: This is Barb. Our Office of
21 Public Health Science currently has officers that do
22 the triaging on our consumer complaints, the workings

1 to make that. Also algorithm as it goes to public
2 health nurse triage, but they are looking at public
3 health illnesses. They are looking at foreign bodies
4 that have caused injury. They are looking at
5 pathogens or things that have caused things such as,
6 something that might be a pathogen and has caused
7 illness. They're looking for either injury or
8 illnesses. That then is turned over to our program
9 evaluation enforcement and review, associated with
10 your establishment who goes out to investigate the
11 complaint and validate whether or not it is from that
12 establishment or whether or not it has been confirmed
13 as a true complaint.

14 And the system as Dr. Goldman was
15 suggesting, the number that he gets, we have been
16 ahead of CDC in confirming such things as E. coli
17 outbreaks. Also in that process we have found mouth
18 injuries. We have found foreign bodies and we are
19 starting to connect our continual complaint system
20 with the states, and Carol sent me an e-mail over
21 lunch to let me know one company is interested in
22 trying to put their consumer complaint list in and

1 match it up to ours. So we are starting to get some
2 interest in --

3 MS. TUCKER-FOREMAN: This is for those cases
4 where, because I've been around for a long time, I
5 have seen this written and referred to on a number of
6 occasions. I have never seen actual documents and I
7 hear you're putting this into an algorithm but I never
8 see that document and, you know, I'm really curious
9 about this because I have questions about the validity
10 of consumer complaints unless they are verified by a
11 public health record or validated by a public health
12 record. And I don't know how you mix physical hazards
13 with microbiological hazards. So those are all things
14 that it would really be helpful if we could see
15 something that describes very precisely.

16 MR. SPANGLER: So seeing like some public
17 information about how the consumer complaints are
18 categorized.

19 MS. TUCKER-FOREMAN: Yeah.

20 DR. MASTERS: I have people downstairs
21 putting -- as to what we have today, and I'll e-mail
22 you a copy of that.

1 MR. SPANGLER: So Carol -- Rod, Bob -- and I
2 need the yellow card from you.

3 MR. LEONARD: I wanted to comment on what
4 Carol said.

5 MR. REINHARD: So being an RBI model, they
6 put that as an in-commerce finding on it, we propose
7 that they move that under the regulatory enforcement,
8 because if there is an illness, there's a regulatory
9 enforcement. So it would be caught through that in-
10 commerce finding. So you would be for that also?

11 MS. TUCKER-FOREMAN: I want to see what in-
12 commerce means before I say I'm in favor. That's the
13 problem I'm running into here.

14 MR. REINHARD: Right.

15 MS. TUCKER-FOREMAN: Because in-commerce
16 also refers to temperature controls that FSIS has no
17 control over.

18 MR. SPANGLER: Rod.

19 MR. LEONARD: I just want to clarify what I
20 was trying to say and come back to what Andrea was
21 commenting on, that we need a HACCP program for
22 inspectors. Inspectors are there to carry out the

1 statute. The statute is explicitly clear. It says we
2 shall examine carcasses and products and we shall
3 remove product that is contaminated or hazardous, and
4 what we are getting into is talking about a whole
5 range of things to be done, that we can do. We can
6 examine consumer complaints and that might lead us to
7 a little bit more understanding of what the system is
8 doing, but the inspector needs the support of the
9 department, FSIS, meat and poultry inspection, to
10 carry out the legislative intent of the Congress which
11 is to examine and remove hazardous product.

12 MR. SPANGLER: Let's pause for a second.
13 We're just past 4:30. We're on the verge of, you
14 know, where we're supposed to be transitioning over to
15 the second paper. So I just want to check in. I'll
16 be happy to continue this conversation if you all are
17 happy with that. So at least for five minutes, I'd
18 like to return back to the questions on the sheet to
19 see if we can get a couple of pieces put up here.

20 I think on question 1, it sounds like we
21 have an agreement that food defense was, you know,
22 important but maybe not part of the RBI model. That's

1 clear feedback on that question I think. And then we
2 sort of touched on question 3, which I'd like to come
3 back to.

4 On the second, about intervention and --
5 actually, why don't we just do that now. Do we want
6 to put -- this is kind of hard to go over. But
7 intervention, you know, to be useful information
8 that's not currently included in the system, that
9 would qualify for that question. Does everybody agree
10 with that? Is that what we said?

11 UNIDENTIFIED SPEAKER: We not agree that
12 intervention would fall in.

13 MR. SPANGLER: Pat.

14 MS. BUCK: This is Pat, and I think
15 intervention is very appropriate. When we talk about
16 intervention, and I'd certainly like to have a
17 consensus or some idea what is included in
18 intervention. I have a very broad term for
19 intervention. I actually consider labeling as
20 intervention.

21 MR. SPANGLER: Okay.

22 MS. BUCK: Whereas people in the industry

1 might say, whoa, we don't want to hear that as an idea
2 of intervention. But to me that would also be
3 something that should be clearly defined of what we
4 mean when we talk about intervention.

5 MR. SPANGLER: So I don't think we're going
6 to reach consensus on that right now on how we define
7 that. We can put --

8 MS. BUCK: A couple of broad categories.

9 MR. SPANGLER: Let's see.

10 MS. RASOR: We need to come up with a
11 definition.

12 UNIDENTIFIED SPEAKER: Or at least some
13 elements that would be included.

14 MS. RASOR: Yeah, what elements are --

15 MR. SPANGLER: Okay. Moving onto question
16 3, we're not going to worry about relating much on
17 this. Everyone is focused on this. So everybody
18 agree that we should use interventions but there's
19 questions on how -- what would interventions be and
20 how we would weigh them.

21 UNIDENTIFIED SPEAKER: Right.

22 MR. SPANGLER: So let's just put

1 interventions. I'm going to put question 3 here,
2 interventions, and then let's grab some ideas about
3 what that would entail. Pat, you just mentioned
4 labels.

5 MS. BUCK: Well, I mentioned labeling
6 because I see that as an intervention for the
7 consumer. Okay. Now I realize you and industry
8 people have a lot more specific interventions that,
9 you know, would timely treat the needs, and the
10 poultry or steps that you can take to reduce the
11 pathogen loads. So I can --

12 DR. RYBOLT: It's --

13 MS. BUCK: I mean there's just --

14 MR. SPANGLER: I know these need to be
15 clearly outlined -- settle down. Settle down now.
16 He's trying to keep track of who's speaking and so am
17 I. Just before, we have Sid and then we have Mike,
18 but I'm just going to -- since there are a lot of
19 questions and different ideas about what intervention
20 involves. So let's just say interventions and needs
21 clear definition, and we'll just leave it as that.

22 MR. CLEMANS: What I heard is define, say

1 how they would be validated and say how they would be
2 weighted.

3 MR. SPANGLER: Defined, validated and
4 weighted?

5 MR. CLEMANS: Right. And what are the --
6 validate that they're really meaningful I guess
7 enforcement or how it would be weighted.

8 MR. SPANGLER: Validated and weighted.

9 UNIDENTIFIED SPEAKER: And I assume there is
10 consensus on this?

11 MR. SPANGLER: Does everyone agree with
12 this?

13 UNIDENTIFIED SPEAKER: I mean in reality,
14 you can't open your plant in the morning without a
15 defined validated intervention. All of them are --
16 day. I mean you can't possibly put them in a
17 higher -- you couldn't put any more risk-based -- you
18 can't put any more pressure, on how much pressure on
19 that -- steam at nine pounds or that the water's
20 running. And you have to stand there every second
21 watching it. They never leave that dial. Never. So
22 I don't know how -- I understand this question but how

1 do you raise intervention up to a level of this
2 when --

3 MR. SPANGLER: Mike and --

4 MS. HOVDE: Resha.

5 MR. SPANGLER: Let's -- Mike's been waiting.
6 So let's do Mike and then Resha.

7 MR. GOVRO: Just going back to the
8 intervention and whether it should be split out or
9 not. I'm not opposed to splitting it out but when I
10 read the paper about control, risk control process,
11 those were the types of things that I thought of that
12 would be part of the system design. That would be one
13 component. Now what I'm hearing is that you're saying
14 that's an important component, maybe so important that
15 it should be split out but I don't necessarily think
16 that it needs to be split out. I think it's a
17 component and you could look at it either inside or
18 outside the controls. You can't even -- without the
19 other one. So --

20 MR. REINHARD: Mike, I'll follow up for you
21 because on food safety assessment, they're looking at
22 your support and your ability to meet the regulatory

1 requirements, not whether or not you have extra things
2 that go above and beyond that would reduce the
3 likelihood of an illness, if something in the system
4 would get through, if that makes sense. So when we as
5 industry think of -- for me, I guess I'll speak for
6 me, if I were to think of food safety design, and what
7 the Agency has done to come into our establishment and
8 look at that, what they look at is that you meet the
9 basic minimum requirement, okay, and that is you have
10 scientific support for eliminating the hazards you
11 identified and they're sufficient to meet all
12 regulations. What it doesn't take into account is
13 that I may have two plants making ready-to-eat meat
14 and one of those two plants has post-packaging
15 pasteurization, okay, which is a 6 log reduction for
16 *Listeria* and *Salmonella* and *E.coli* O157:H7. It
17 doesn't differentiate that plant from the other.

18 MR. GOVRO: That's the inherent risk.

19 MR. REINHARD: In other words, that plant
20 has less inherent risk because of an intervention they
21 put in and so the idea would be for a risk-based model
22 to include it.

1 MR. GOVRO: So it would be a factor of the
2 inherent risk.

3 UNIDENTIFIED SPEAKER: You're confusing the
4 topics here. Or would it be in the inherent risk?

5 MS. TUCKER-FOREMAN: No, it --

6 MR. SPANGLER: Staying on track with the
7 queue. So a little bit of -- Michael about
8 intervention as something that's not being considered,
9 being other useful information. So I believe that
10 covers it. We can highlight, you know, I mean it
11 sounds like most of the group is sort of on board with
12 this idea? Angelo and Mike are a little uncertain.

13 MR. FILI: I think it's redundant. I think
14 we ought to move on.

15 MR. SPANGLER: We'll just highlight it as
16 something, you know, a highlight -- okay.

17 Any other comments on question 3, the topic
18 of intervention right now?

19 (No response.)

20 MR. SPANGLER: All right. Now it's 4:40.
21 We want to try to get through a couple more of the
22 questions on the establishment risk control before we

1 get into the Product Inherent Risk topic. So are
2 there ways besides food safety assessments to evaluate
3 establishment food safety system design? Okay.

4 UNIDENTIFIED SPEAKER: What about question
5 2, the weight?

6 MR. SPANGLER: Okay. Let's go back.
7 Question 2, are some components more important than
8 others, and thus should some be more weighed than
9 others?

10 UNIDENTIFIED SPEAKER: Yes.

11 UNIDENTIFIED SPEAKER: Yes.

12 MR. SPANGLER: So now it's yes. Additional
13 answers. I think James wants to elaborate.

14 UNIDENTIFIED SPEAKER: I've been doing this
15 for years.

16 MR. SPANGLER: James.

17 DR. DENTON: Following on what you said a
18 while ago about the in-commerce findings, I think to
19 answer to question 2 is yes. In my view of the world,
20 in-commerce findings, particularly a food-borne
21 illness outbreak, is probably the least desirable
22 outcome of them all. And because a failure in the

1 system design, the system implementation includes
2 pathogen monitoring and pathogen control process. Now
3 whether we want to include the in-commerce findings
4 that relate to food-borne illness outbreaks under
5 enforcement -- one way or the other, but just in
6 thinking about how we would assess a risk-based
7 inspection system --

8 MR. SPANGLER: Meaning that --

9 DR. DENTON: How to weight that.

10 MR. SPANGLER: How to weight that. Anyone
11 else. How to assign weighting.

12 MS. TUCKER-FOREMAN: Well, I understand I
13 think we understand why you would rank those high?
14 Why would you rank the in-commerce finding high?

15 DR. DENTON: If it's a food-borne illness
16 outbreak.

17 DR. RICE: Industry has failed in system
18 design or implementation. The USDA has failed to
19 detect that we haven't done our job and we have people
20 sick and dying.

21 MS. TUCKER-FOREMAN: I'm sorry. We're
22 looking at it through opposite ends of the telescope

1 again. Your positions I think are not unreasonable
2 but my view is, that if somebody has already gotten
3 sick, the fact that you're finding that they're sick
4 is not very important. There's got to be a way to say
5 this better, to capture your view but I'm seeing that
6 in saying -- you want to wait until it gets to that
7 point.

8 DR. RICE: No, I'm not.

9 MS. TUCKER-FOREMAN: I know that's not what
10 you're saying but that's how I --

11 DR. RICE: I would much rather we could
12 prevent it all.

13 MS. TUCKER-FOREMAN: I know but we have to
14 find some way I think -- I will be eager to see if we
15 reach --

16 MR. SPANGLER: We have Bob and then Mike and
17 then Resha. So -- and then Pat. Bob, Mike, Resha,
18 Pat, but before we move on, do either of you have a
19 way to sort of put a nuance to this that would get at
20 what you're saying? Should we just say, yes, in-
21 commerce finding comes out saying --

22 DR. DENTON: No, you have to define it with

1 regard to a public health event.

2 MS. BUCK: What I would say is that what you
3 are talking about is a reactive approach and I think
4 what Carol Tucker-Foreman and I are all about is a
5 proactive approach in our views.

6 DR. RICE: We don't have a proactive
7 approach.

8 MS. BUCK: That's what we want is the
9 proactive approach. When you look at your recalls,
10 when you look at the consumer complaints, those are
11 all -- they're in the past. We're reacting to them.
12 We want to put a system in place that anticipates
13 those, so that we can prevent them.

14 MS. TUCKER-FOREMAN: But we're back to
15 suggesting that that's why that component should be
16 weighted heavily because the preventing failed. But I
17 find that, I find that there ought to be a better way
18 to say that.

19 DR. DENTON: It's a difficult concept, but
20 if we get to that point --

21 MS. TUCKER-FOREMAN: I'm just --

22 DR. DENTON: -- we have the worst outcome

1 that we can possibly have. And it means that what we
2 were doing with regard to system design and system
3 implementation and trying to monitor the pathogens was
4 not successful.

5 MR. SPANGLER: Okay. Let's see if anyone
6 else can maybe say it a different way?

7 MS. HOVDE: I think I can sum up what James
8 is trying to say because -- spoke on the wheel and --
9 worst case scenario, James' point, you can look at
10 something in commerce. That is your number one thing
11 to look at. You know, the things that we do in
12 industry to prevent that from happening is obviously
13 what we are focusing on, but I think he was saying
14 that's the worst case scenario -- verify your system,
15 those might be just as important.

16 MR. SPANGLER: Let's get some more ideas on
17 this. Mike.

18 MR. SARACHMAN: Yes. I just wanted to
19 comment, I have put a bunch of thoughts together.
20 It's not a static system. It is proactive as well as
21 reactive, and that looking at a plan, drawing a line
22 in the sand today, we can rate a plan based on

1 weighted averages against certain risks, but as you
2 travel down through the timeframe or the timeline,
3 based on an encompassed finding, other things that can
4 come -- new information that can come to light, that
5 may change the risk ranking of that facility, all
6 other things being equal.

7 MR. SPANGLER: So new info -- I'll do my
8 best with information.

9 MR. SARACHMAN: You're summarizing.

10 (Laughter.)

11 MR. SPANGLER: I just want to make sure I
12 got your idea.

13 MR. SARACHMAN: It's not a static system.
14 It can be both proactive or reactive depending on your
15 point of view looking at that facility, and I agree
16 that there should be weighted components to each of
17 those components. And that it almost in -- and Dr.
18 Masters, you may know about this, it's almost case by
19 case because you have to really look at that facility
20 and what parts of that process are riskier versus
21 others. We talked about slaughter versus ready-to-eat
22 versus other processes.

1 MR. SPANGLER: I was thinking more on
2 question 2 that we brought it to a conclusion which is
3 that everybody agrees, yes, they need to be weighted
4 but I think all the stakeholders need to go back and
5 think about how would they be weighted and what would
6 we do within this model, and actually what I thought I
7 heard is stakeholders saying the same thing, but
8 oppositely in their semantics, you know, in the event.
9 So I think this is one of those things where we're all
10 saying yes. Now the next step is we have to come back
11 to the stakeholders at FSIS and ask them how would
12 that be. How would we weigh it? What would be the
13 best step?

14 MS. TUCKER-FOREMAN: I think I'm persuaded.
15 I think I'm persuaded that -- I think the word
16 components would be weighted more and that's up there,
17 and I think that must be -- I think that must be it
18 because you have got the recalls in there. It takes
19 me a while to get through it but I think I would
20 agree.

21 MR. SPANGLER: We have Mike and then Pat.

22 MR. GOVRO: Assuming now that we're only

1 talking about 5 spokes rather than 6, food defense is
2 out, we --

3 MR. SPANGLER: Your argument is safe in this
4 room, yes.

5 MR. GOVRO: Yes. In my opinion, we have two
6 distinct kinds of components here. One is system
7 implementation and system design which go to what the
8 firm is actually doing to control its risks, and the
9 other three which are essentially after the fact
10 checks, pathogen control, I assume we're talking about
11 laboratory data, in-commerce findings, again reports
12 after the fact. Enforcement actions, again kind of
13 after the fact. I think, although that's kind of a
14 gray area, but I think the first two, system design
15 and system implementation really get to what the firm
16 is doing to control the risk and those should be
17 considered one for one.

18 MR. SPANGLER: Okay. Pat.

19 MS. BUCK: Well, I do understand what you're
20 saying but the other way that I look at this because
21 of my own experience which is limited, is that what
22 was that failure of USDA because what happened in my

1 line. So what is their weakness and at times we have
2 to be flexible I think you're saying and start looking
3 at where they have their weakest part. And is it in
4 the pathogen control where they're weakest? Or is it
5 in commerce that they're weakest like in reporting
6 recalls? Or is it in their enforcement capability and
7 authority where they're weakest? And it's because
8 they are the Agency that's running the inspection. So
9 why we would be -- system design and system
10 implementation, those are just major, major.

11 I also look at the Agency and I see
12 weaknesses there that need to be corrected. And so I
13 would temporarily, in flexibility, right now put more,
14 as we go through it, you have to keep restructuring
15 where is the weakest link and let's correct that.

16 MR. SPANGLER: Rod and then Carol.

17 MR. LEONARD: We're really talking here
18 about public policy and there's no answer because we
19 have to use -- the company is better equipped to make
20 the determination as to whether the product is safe to
21 consume, whereas the law says that we inspectors in
22 the plant is given that responsibility and instead --

1 so the question really is, are you willing to have an
2 inspector equipped scientifically, intellectually,
3 morally to make that decision as to what product
4 leaves your plant? And that's really the question
5 we're the question we're talking about and who has to
6 carry the burden of making of that decision? The
7 plant owner, the manager, or is it the inspector who
8 is representing the public in the plant?

9 Now the problem that we are dealing with is
10 that the reason the Department has failed is that
11 they're trying to intercede in various ways by
12 representing the view of the company's management, and
13 as they do that, they are restricting increasingly the
14 ability of the inspector to carry out what the law
15 says. And what you're really arguing about here is
16 maybe we better go back to Congress and have them
17 write a law that says the company knows more about how
18 to produce safe food than the Government does. That's
19 the big picture.

20 MR. SPANGLER: We'll put that in the big
21 picture area. There have been a few picture comments
22 though. I'm going to have to have someone help me --

1 I'm going to have you all help me work on what might
2 go in your slide. We can have one slide to sort of
3 big picture comment outside of the other comments.
4 Carol.

5 MS. TUCKER-FOREMAN: You know, I'm still
6 trying to get my head around this. If you had a
7 continuum of these components and they roll somewhere
8 to the middle of the continuum to provide for all of
9 the control elements, and somewhere to left, to the
10 failure that are described in the in-commerce
11 findings, at least that makes it through my head. I'm
12 seeing a lot of puzzled looks. If you've got --

13 MR. SPANGLER: Are you --

14 MS. TUCKER-FOREMAN: -- 1 to 10 and this is
15 5, and all of the things you do over here, the system
16 design and implementation and the in-commerce findings
17 that we failed somewhere along the way is off here
18 over to the side. Then I'm seeing --

19 MR. SPANGLER: I'm trying to figure out how
20 to capture it.

21 MS. TUCKER-FOREMAN: I think the spokes in
22 the wheel are -- that's the problem.

1 MR. SPANGLER: It's 5:05.

2 MR. FILI: Just to following that
3 conversation, I know, and I guess because I've worked
4 in a plant most of my life, I think that plants
5 somewhat see, and the reason I may have said that,
6 sometimes first -- meat you put in sometimes a million
7 pounds for every bad pound you produce, 5 million
8 pounds for every bad pound. For every mistake that
9 happens, you might have spent 750 days without no
10 accident and then somebody cuts their finger off. I
11 mean if you've done a lot right, but oftentimes the
12 first time that you notice something, especially now
13 that we've lowered this down to a -- level for a
14 microbe, that oftentimes validates, and I've seen
15 this, people haven't been a write up I think in some
16 plants for years, but the reality is oftentimes it is
17 the person -- that something went wrong with their
18 system and as sad as though that might be, you may
19 have produced a billion pounds before you had the
20 first mistake, but often times it is the first
21 mistake, a piece of glass in ground beef or whatever,
22 but it's a huge problem and it stops your production

1 at least for us, and you don't do anything until you
2 figure out what's wrong. That sometimes is actually
3 the first notice you have that it's gotten past. I
4 think it's -- it seems like we're a little bit more --
5 a big chain hanging around -- and the inspector says,
6 what is that, or a big grease spot, we're way past
7 that anymore. It's down to microbes. I'm not saying
8 it's right or it's -- but nowadays sometimes that is
9 actually is the first notice anybody has because the
10 inspectors can't see --

11 MR. SPANGLER: You're saying sometimes the
12 first notice is --

13 MR. FILI: I'm just saying in a comment
14 earlier, she had said that the one that he had
15 mentioned was the in-commerce. That should be
16 extremely important. Obviously someone being ill,
17 there's nothing more important than that but the
18 comment about that's not a good way to judge when
19 somebody gets sick, for a lot of people anymore --

20 MS. TUCKER-FOREMAN: I think logistically
21 that the spokes, when we ask the question about -- the
22 spokes are confusing to me and it depends on which

1 spoke.

2 MR. SPANGLER: Mike.

3 MR. GOVRO: I run an inspection program at a
4 state level, and I've spent 22 years with the state,
5 and I've been in the program for 8 years. And I'm
6 going to throw my two cents worth in again. I can
7 tell you that consumer complaints are unreliable and
8 bizarre. Food-borne illness reports are vastly under
9 reported and relatively meaningless as an indicator of
10 what is going on in any particular firm, and
11 laboratory data, if you get enough of it might be
12 useful. The enforcement, that varies from inspector
13 to inspector, but what really matters, is what a firm
14 decides to do and how they carry it out. Those are by
15 far -- I mean we shouldn't -- we don't want to throw
16 the others out but in my opinion, it's far and away,
17 those two things are the most important.

18 MR. SPANGLER: Again, reiterating design and
19 implementation.

20 MS. TUCKER-FOREMAN: Yeah, I would --

21 MS. BUCK: You're right. They're very
22 unreliable.

1 MR. SPANGLER: Mike.

2 MR. SARACHMAN: I just wanted to circle back
3 on the comment and I think lately that I agree
4 wholeheartedly --

5 MR. SPANGLER: Can I just pause for a
6 second? Is everyone sort of agreeing with Mike's
7 statement that consumer complaints are not necessarily
8 reliable?

9 MS. TUCKER-FOREMAN: -- well said.

10 (Laughter.)

11 MR. SPANGLER: So you would not agree with
12 that?

13 UNIDENTIFIED SPEAKER: Well, I think you
14 have to clarify what they do serve because they are
15 very useful and one of the most useful things about
16 consumer complaints is that if there are enough of
17 them, you can get the Government to get off its ass
18 and move.

19 MR. SPANGLER: I'm going to star that.
20 Mike. Sorry to interrupt.

21 MR. SARACHMAN: What I was coming back to
22 was, based on weighted averages, weighted components,

1 and the flexibility around that is you might decide
2 to -- the model might be that a certain component has
3 a higher weight, and there may be a minor deviation
4 from compliance or whatever in that particular one.
5 Now is that is any less than a major move and a less
6 major component? So once again there has to be a
7 whole look at the big picture and see what's going on,
8 even weighted components.

9 MR. SPANGLER: So you're kind of talking
10 about a system that can adapt to what new employees
11 should --

12 MR. SARACHMAN: Yeah, it's not going to be a
13 hard and fast rule. I simply want a mathematical
14 formula and we can have one that has weighted
15 components to it, and then there's some human agents
16 and thought process behind how you make those and
17 information that flows into that formulated risk
18 assessment for that product.

19 MR. SPANGLER: Is this getting to your
20 point?

21 MR. SARACHMAN: Yes.

22 MR. SPANGLER: Okay. So we're now at 5:00

1 and we're supposed to stop around 5:30. We have a
2 couple of more questions we haven't even touched on
3 yet. So everyone, we're moving onto a new question.
4 Assuming we want to stay on this topic, I think we're
5 doing pretty well in getting through these and two
6 groups did start with the Product Inherent Risk paper.
7 So they might only talk about that, too, but at least
8 we'll have two groups focused on each paper.

9 Question 4, are there other ways besides
10 food safety assessments to evaluate establishment food
11 safety system design? That is other than FSAs, beyond
12 FSAs. Bob.

13 MR. REINHARD: I mentioned earlier for
14 comment that I thought that allowing an establishment
15 or producer or process to complete a questionnaire to
16 be used to determine their establishment risk control
17 level would be of benefit, and I want to stress I
18 still believe this. And I don't want everybody to
19 think I went and fell out of bed and hit my head. I
20 didn't. What the thought process would be would be
21 that an establishment would be able to go through and
22 know based on what they had chosen to do or what

1 events that occurred at their establishment based on
2 what they've done or chose to do in essence, that
3 they're going to fall someplace along this X axis,
4 okay, and if they choose not to have good
5 implementation of their program, well, then they're
6 going to fall to the right, and they're going to have
7 to -- then when they complete a questionnaire and
8 decide where they think they should fall, I don't
9 think their eyes could say, wow, this is why I'm
10 falling over here, this is what I'm doing, versus the
11 Government agency coming out and saying this is where
12 you fall. I also think that all the data that the
13 Agency has in their models, that they would share
14 with -- or what they have in their data warehouse, if
15 they would share down to their inspectors, could still
16 be incorporated, that it could be shared with the
17 establishment and the establishment could then put
18 that into their questionnaire, sort of echo the
19 Agency's ability and the way they're set up to do
20 oversight, could effectively monitor that system for
21 good quality data.

22 But aside from that, what this also builds

1 is an opportunity for, is for industry to add data or
2 validated data to be used into the system, and that
3 being that within that questionnaire, and the dream of
4 requiring everybody in the industry to have the same
5 data or everybody being required to give all the data,
6 is not going to happen in this short time. It isn't.
7 I mean people -- some people want to keep their data
8 close. Some people want to open their data and show
9 everybody. But throwing that option in, of them being
10 allowed to share that, so the Agency took 12 samples
11 last year for LM and *Salmonella*, and the establishment
12 took another 600, okay, that could be used if the
13 establishment chose to provide it, in the model,
14 versus the opposite of an establishment took -- well,
15 maybe took 100 -- and it doesn't get used. So the
16 numbers there would be different. It doesn't get
17 included. At anytime there's a differentiation along
18 the X-axis, and I think being able to do that would
19 strengthen, you know, the relationship and the way
20 that all the stakeholders are able to determine, where
21 do we fall in risk and what are our opportunities. So
22 I'd encourage it to be considered at least.

1 MS. TUCKER-FOREMAN: He fell on his head
2 and --

3 (Laughter).

4 MR. SPANGLER: Let me make sure I got this.
5 The caveat built in there, which there would be an
6 option for industry to provide that data. It would be
7 sort of voluntary or --

8 MR. REINHARD: It would have to be an option
9 based on what they felt was a fair model. If somebody
10 didn't want to participate --

11 MS. BUCK: Could you make it mandatory?

12 MR. SPANGLER: I'm not sure which one --
13 Carol or Pat, do you know who was first?

14 MS. TUCKER-FOREMAN: I continue to have a
15 problem that the Agency operates in a way that assumes
16 that if a plant is incompetent, that the Agency will
17 invest more time in that plant in order to perform a
18 business is the bottom line. I don't have much
19 sympathy for that. I don't like the food safety
20 assessment. I think they're label intensity for the
21 Agency and they're really in some instances saying to
22 a company that's incapable or unwilling, to extend the

1 time to do these things until they -- by the Agency.
2 I think those people are getting an economic advantage
3 over folks who tend to do and do it. So my idea is --
4 if you have regular -- every company is required to do
5 more tests to validate that the HACCP system and
6 everything else is working the way it supposed to be,
7 and they said they are available to the inspector. I
8 think we have a less -- I think we have a more
9 objective determination that the system really is
10 working, and we have one that -- obviously the
11 Government is never going to be able to do enough
12 tests to validate a system in any rational or
13 reasonable way. So we have more data and you have
14 objective data and the company and the taxpayer is
15 supporting the cost for doing that. Now if you do it
16 very, very well, it seems to me that you -- there
17 might be some incentives there that might be offered
18 to the --

19 MR. REINHARD: To reward you in the system.

20 MS. TUCKER-FOREMAN: Yes, because, you know,
21 everybody who does it exactly right -- this person
22 doesn't just pass. They're spectacular.

1 MR. SPANGLER: Anyone -- Pat, you --

2 MS. BUCK: Yeah, in keeping with that sort
3 of a line, I agree with Carol, but I'd even go a
4 little further. I think what risk-based inspection is
5 all about, you probably have in this room and as a
6 whole downstairs, too -- and what we're trying to do
7 is identify those at the bottom, that bottom 20
8 percent that are doing a bad job and putting our
9 efforts to either get them out of the business of
10 producing food or improving their efforts as to what
11 they can do. So I would go along with the idea about
12 sharing information except I probably would say that
13 we need to have some kind of mandatory requirement or
14 guidelines of what type of information is really
15 needed to help us bolster the good companies and put
16 in place real issues for those companies that are not
17 performing in a fashion that what most of the people
18 in this room would say are good food safety practices.

19 But we need that to -- we say that that's critical
20 and we save consumer lives by doing it that way. We
21 want to get rid of bottom 20 percent.

22 MR. SPANGLER: What words do you want to use

1 there?

2 MS. BUCK: Shame on you.

3 MR. SPANGLER: I'm asking you for the words.

4 MS. BUCK: Penalize.

5 MR. SPANGLER: Penalize.

6 MS. BUCK: They don't meet the mark on --

7 MR. SPANGLER: They're -- yes. Let's see.
8 Suzanne.

9 MS. FINSTAD: I was just wanting to note on
10 what Bob said in relation to the establishment data.
11 Food safety assessments are certainly -- for
12 assessment of the accuracy of the design in a plant,
13 but establishment data is collected, if it's collected
14 and if the establishment is willing to share the data,
15 it's probably I would venture to guess, collected at a
16 frequency that's much greater than when a food safety
17 assessment comes around. So, you know, probably on
18 negative data, I think it's incumbent upon us to
19 consider looking at that data.

20 MS. TUCKER-FOREMAN: Can I ask a question?
21 There appears to be the need to make it voluntary
22 because you're afraid --

1 MS. FINSTAD: No, I don't think so. I
2 personally, I guess I don't want to speak for everyone
3 else like I represent their company, you know, I think
4 we all -- I'm going to guess, we all --

5 MS. TUCKER-FOREMAN: Do you have to show the
6 bad stuff?

7 MS. FINSTAD: We do. You know, I can't
8 speak for everyone else. I would imagine you do.

9 MR. SPANGLER: So you agree with the idea of
10 the option to share the data.

11 MS. FINSTAD: I do.

12 MR. SPANGLER: Okay.

13 MS. TUCKER-FOREMAN: I want to point out
14 that the option to share the data let's the company
15 get just the -- just keep on reminding FSIS to come in
16 and hold their hand and the taxpayers pay for it and
17 I --

18 UNIDENTIFIED SPEAKER: Very --

19 MS. TUCKER-FOREMAN: You're doing
20 assessments.

21 MR. CLEMANS: And the bad guys --

22 MR. SPANGLER: I'm just going to capture

1 that as disallow some share.

2 MS. TUCKER-FOREMAN: That's really not my
3 view. I'm saying something that's a lot tougher here.
4 I don't believe the food safety assessments are the
5 appropriate way to operate a program because it's
6 inefficient, ineffective, expensive, and it rewards
7 the company, that then decides they will not spend the
8 money to do things the right way. The taxpayer has to
9 pay for the food safety assessment.

10 MS. FINSTAD: Let me make another run and
11 because I think I can give a specific example and make
12 this --

13 MR. LEONARD: I think I want to get into
14 design. Carol and I have done this for decades.
15 Let's not call it an argument but we'll --

16 MS. TUCKER-FOREMAN: You are --

17 MR. LEONARD: -- argue with each other, but
18 my point is to make the observation, I'm going beyond
19 the norm. The reason a company would do that is to
20 insure that when they get into Court and are being
21 sued, that they can plead the mercy of the Court
22 because they really were trying hard not to hurt

1 people. When you go into the system based on risk
2 assessment, or on risk inspection, you have to
3 understand that risk is an issue over who's liable for
4 injury relating to that risk. So that if the company
5 goes beyond the norm, Carol will give them a gold star
6 and the Courts may look upon them more leniently. The
7 bad companies that don't do that, Carol says they'd be
8 up for a black star.

9 MS. TUCKER-FOREMAN: I just like them to in
10 the market system to not really --

11 MR. SPANGLER: Suzanne. Let's take
12 Suzanne's comment and we still have -- we didn't even
13 get to NRs. We heard a lot about that already in the
14 other groups. So maybe we can hear from Suzanne, take
15 five minutes and talk about the look-back period which
16 we heard a little bit about today, and we'll just kind
17 of set NRs aside, with the understanding that there's
18 been a lot talked about that already, and we'll talk
19 about how we want to pull together a little report for
20 tomorrow morning.

21 MS. FINSTAD: I guess precisely what I'm
22 trying to say is that the regulations provide that the

1 establishment will collect -- will have to collect
2 certain data and then, you know, perhaps FSIS collects
3 additional data. Some companies choose to proactively
4 collect data, possibly the same data that FSIS
5 collects, possibly different data, perhaps because
6 they don't want to wait for FSIS to tell that company
7 that they have a problem. So that's the reason for me
8 saying option. It's not provided in the regulations
9 that the establishment will collect data on, you know,
10 everything known to man.

11 MR. SPANGLER: Some of the benefits go
12 beyond the regulations --

13 MS. FINSTAD: Correct.

14 MR. SPANGLER: -- with your testing,
15 sampling --

16 MS. FINSTAD: Correct.

17 MR. SPANGLER: -- and they share that if
18 they have it.

19 MS. FINSTAD: Exactly.

20 MR. SPANGLER: So let's skip down to the
21 last question. We're running out of time.

22 MS. TUCKER-FOREMAN: That's not in agreement

1 within the group, right?

2 MR. SPANGLER: Sure. Yes. The only things
3 that we'll comment as agreements have stars.

4 MS. TUCKER-FOREMAN: Gold stars?
5 Incidentally, there is no other regulatory -- in this
6 country that goes in and says several thousand
7 taxpayers supporting people who hold hands and tell a
8 company how to stay in business and --

9 MR. SPANGLER: Question 5, there were a
10 couple of questions earlier made about the appropriate
11 look-back period and I want to see if you all have any
12 thoughts about that. Bob.

13 MR. REINHARD: I have a comment on the
14 length of time they keep the data and that would be
15 that the data would be kept a length of time that was
16 adequate to make a determination on the establishment.
17 And this goes into currently FSIS has some things they
18 do where they look at the data to make assessments.
19 The data is kept for a relatively short period of
20 time, and in the case of linking a NR three months or
21 whatever the standard policy is, it is probably
22 appropriate. But the other side of the equation is

1 that if you look at sampling of products if FSIS does
2 it, you only look at a snapshot of few months of data,
3 it wouldn't be sufficient to make a determination,
4 okay. So in lots of cases, they need to look out
5 extending out the amount of time beyond the time they
6 hold their data, and the only thing I think here, and
7 this goes back to what was raised earlier, is that if
8 you have a minor event in an important category, it'll
9 change the model some, but if you have a major event
10 in a unimportant category, it'll change more, too. I
11 mean it's going to be this idea of if you didn't have
12 an event where you were looking at long ranges in data
13 that occurred, a negative event let's call it, which
14 could be a positive product sample and, you know,
15 totally change your processes in the way you do things
16 and implement to do it right, then the question
17 becomes, well, how long does that become a penalty to
18 you, okay.

19 MR. GOVRO: Is it a penalty?

20 MR. REINHARD: You have face that because
21 they threw the flag. You're doing something about it
22 and then how long does that carry on, I don't know.

1 So but it needs to be looked at as to what's adequate.
2 But I don't know what the answer is.

3 MR. SPANGLER: You need enough time to
4 commit --

5 MR. REINHARD: Well, you need enough time to
6 make a determination is what I said.

7 DR. DENTON: That's question 6.

8 MR. SPANGLER: Thank you.

9 DR. MASTERS: Just quickly in response to
10 Bob, the Agency obviously, whatever time period is
11 determined and we're getting a PowerPoint slide put
12 together for tomorrow on the questions you had on
13 data. That's why they were called out of the room, to
14 talk about the data structure. I talked a little bit
15 in my opening remarks about a data warehouse. There's
16 a lot of -- data warehouse that's currently in the
17 data warehouse, what slated to go into the warehouse
18 next. We have made significant progress over the last
19 year on building our data warehouse. So we're going
20 to present that in the morning related to same thing,
21 as far as what's in the data warehouse and how it
22 could affect the data warehouse over the next year.

1 And obviously whatever the determination is, as to
2 what timeframe, what that will drive, how long we
3 store that either at the -- level or at the level for
4 which people working at the -- maintain it in that
5 data warehouse. So I think that will drive --

6 MR. SPANGLER: Mike.

7 MR. GOVRO: I just have a little bit of a
8 different interpretation of what the result of risk-
9 based inspection is and Bob mentioned that he referred
10 to it has a tendency to be inspected more, and I hope
11 that we don't look at in quite those terms. It's not
12 a penalty. It's allocating resources where they
13 belong, and I think that whatever algorithm we use,
14 should reflect appropriate allocation of resources for
15 the period of time which that's appropriate, and maybe
16 that's what he was getting at. And then we talked
17 about increased inspection and penalty. Maybe it's a
18 pain in the neck but --

19 DR. RICE: I think there should be decreased
20 inspection if you doing a great job.

21 MR. GOVRO: Exactly.

22 DR. RICE: That's what --

1 MR. GOVRO: Using the word penalty, I'm
2 afraid it gets too caught up and this is some sort of
3 new club that the Agency has when I don't think that
4 they look at it that way.

5 MR. SPANGLER: Ann.

6 MS. RASOR: I don't know that I have the
7 answer, but I have a couple of questions I guess.
8 Number one, is once they get placed in the level, is
9 there an appeal process for that based on the fact
10 that this could be based on -- factors? And the thing
11 I want to know, is when you're about the back period
12 and when you bring up the amount of data, and I'm
13 asking how often will we be reassessed during that
14 period? Is there going to be a venue for the plants
15 to request a reassessment basically if they've
16 added -- you know, I think risk-based inspection is
17 going to -- for a lot of plants to incorporate, you
18 know, meet their burdens more or less, and if they
19 gone and done this and they're not due for
20 reassessment for another two years, can they request
21 one to get themselves into that, whereas -- I don't
22 know, they changed the products they make. The

1 process for --

2 MR. SPANGLER: A vehicle for requesting
3 reassessment.

4 UNIDENTIFIED SPEAKER: That could work the
5 same as the listeria questionnaire and --

6 DR. MASTERS: The first comment I would make
7 is any inspection --

8 UNIDENTIFIED SPEAKER: Right.

9 DR. MASTERS: The second comment I would
10 make is whatever time period we make a determination
11 on, how quickly that look-back window, I think what
12 Don was suggesting, the Agency deems is appropriate
13 for the window. So whatever that window is, you need
14 to recognize it's going to be continuous, data coming
15 in instead of going out, just like you're annual
16 inspection for HACCP -- processes, interventions, et
17 cetera. That's why we're saying that as the last
18 month goes off, the new month would come in. So it
19 will leave --

20 MS. RASOR: All right. And then if --

21 DR. MASTERS: So in that process, that one
22 month that comes in --

1 MS. RASOR: Okay. Then they look at it from
2 that point.

3 DR. RICE: You look at the 12 months already
4 in?

5 DR. MASTERS: No.

6 DR. RICE: Is that what you're saying?

7 DR. MASTERS: No. We're suggesting that
8 whatever time period is determined to be appropriate,
9 we believe that it will be a rolling window. If it's
10 12 months or 6 months or 3 months, whatever is
11 determined to be appropriate, we don't mean it's a
12 static period of time. If it's just three months,
13 it's three months, drop the last month and take on the
14 next month. Three months, drop the last month and
15 take on the next month. So whatever time period is
16 appropriate, we believe it's a rolling period of time
17 because there's always -- and the -- of it is a whole
18 new process --

19 MR. GOVRO: A quick question.

20 MR. SPANGLER: This will be the last comment
21 and then we have to wrap up.

22 MR. GOVRO: Do you anticipate that this is

1 going to be set up on some sort of a computer system
2 so that the data gets automatically input and you come
3 up with a new score or whatever it is as opposed to
4 somebody doing calculations. I mean you're going to
5 have a program for this. So you literally could come
6 up with a new score every three months or every month
7 or whatever time period you choose?

8 DR. MASTERS: Yes.

9 MR. SPANGLER: Okay. So we're now at 5:25.
10 We touched on --

11 MS. TUCKER-FOREMAN: We're going to start on
12 the inherent risk product.

13 MR. SPANGLER: Do you all want to stay until
14 7:00? I think we have to get out of the building.

15 So if we can just cycle back through and I'm
16 going to -- I asked Bob if he would be willing to do
17 the report and he agreed.

18 Question 1, the input was two to add, two
19 things to add, food safety process interventions and
20 intended use of product. Again these are just -- this
21 is just --

22 MR. REINHARD: I think we all agreed on

1 that.

2 MR. SPANGLER: Questions 3 and 4 was the
3 small plants may not be financially able to implement
4 intervention. So consider a scale for plants, with
5 the idea that intervention in play. We, in fact, can
6 deal with that. Other suggestions, they're looking
7 the plant -- the data each plant has to support its
8 process. And on question 1, the food defense thing
9 which you've got captured here, the agreement that we
10 eventually got to.

11 We had a comment about staying away from --
12 inspectors staying away from out of plant information.
13 We need detailed categories of consumer complaints
14 listed in the database. Dr. Masters responded to that
15 but we'll do that as question or recommendation.

16 Everyone, on number 2, there was resounding
17 yes about should it be weighted?

18 MR. REINHARD: So that gets a star?

19 MR. SPANGLER: I think the yes gets a star,
20 and then the remaining comments were not necessarily
21 all agreed upon. We had comments from Mike about
22 design implementation.

1 Just a couple of more minutes, folks. You
2 suggested it needs to be weighted more. We'll put
3 that in. Identify weak spots. The big picture
4 comment about a post-process production and -- a
5 couple of other points. The other agreement area was
6 that consumer complaints are unreliable. They do
7 provide information but they may be -- could be a
8 major factor in the RBI model. Carol.

9 MS. TUCKER-FOREMAN: I think it's important
10 to say that obviously if you have somebody who goes to
11 the doctor saying I've got a food-borne illness,
12 that's one thing. If you have people who say I had
13 extraneous material in food that I bought or there is
14 a complaint level in that, that I the consumer will
15 acknowledge together with what's historically been --
16 It's just to say that there are classes of consumer
17 complaints that are -- that can perhaps support --

18 DR. MASTERS: But that's not --

19 MR. SPANGLER: Some classes of consumer
20 complaints lack supporting data.

21 MS. BUCK: And then there are the classes of
22 people that have supporting data and it doesn't go

1 anywhere. I mean we had, we had a fingerprint that
2 matched a recall and we could not get it to go
3 anywhere. So we had the supporting data, and it
4 didn't go anywhere and it's because of the
5 restrictions that were put up with the Freedom of
6 Information Act.

7 MR. SPANGLER: Okay. Can you live with this
8 statement about --

9 DR. RICE: The other thing you've got is
10 just the consumer complaint that we didn't touch on,
11 an actual food-borne illness outbreak which is more
12 than two parties getting sick from the same food.
13 That is much more of an issue than an individual
14 complaint saying I got sick from eating your chicken.

15 MS. TUCKER-FOREMAN: Well, I've actually
16 been kind of assuming that verified incidents of food-
17 borne illness don't fall into this category.

18 DR. MASTERS: We'll talk about that
19 tomorrow.

20 MR. SPANGLER: Like I said, everyone will
21 have -- we'll give people a chance to add a couple of
22 points. We're just trying to get the highlights now

1 so everyone else knows what we talked about.

2 So the idea on question 4, just out of the
3 brainstorming today, other ways besides FSAs, about
4 giving industry an opportunity to share data
5 through --

6 MR. REINHARD: Did everybody agree that we
7 should come up with a way for industry to share data
8 or not? No.

9 MS. BUCK: I think we all agreed.

10 MR. REINHARD: There was an agreement to use
11 industry data to support appropriately and then
12 everything else was how what, where, when, why, who.

13 MR. SPANGLER: So everyone sort of agreed on
14 use industry data and how that would happen, with some
15 supporting bullets, we don't have an agreement on
16 that. Okay. Current FSAs from Carol, we'll capture
17 in the bullet. We talked about sharing data, and
18 again sharing data, and then we didn't get any
19 specific ideas about a year, two years, or whatever
20 for a look back, but FSIS should hold onto the data to
21 go back. We have two questions from Ann which we
22 captured, sort of additional questions.

1 MS. RASOR: I know the answer. I just want
2 to make sure --

3 MR. SPANGLER: I know you've got an answer
4 but we just don't want to let everybody know.

5 MS. TUCKER-FOREMAN: It may not be --

6 MR. SPANGLER: Right. Okay. And the report
7 again has to be in early. So I'll try to be just real
8 basic and stick with what's on the flipchart.

9 Okay. Thanks a lot for your participation
10 and I'll see you tomorrow morning. We're only five
11 minutes late.

12 (Whereupon, at 5:35 p.m., the meeting was
13 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:

RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

GROUP 3

Arlington, Virginia

October 10, 2006

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.

Timothy Bond, Reporter

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