UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

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GROUP 4

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October 10, 2006 3:45 p.m.

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

FACILITATOR: ABBY DILLEY, RESOLVE

PARTICIPANTS:

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MR. JIM GILLIAM
MR. LOREN LANGE
MR. RON HICKS
MR. CHRIS WALDROP
MS. NANCY DONLEY
MR. MARK SCHAD
MR. LLOYD HONTZ
MS. LEAH WILKINSON
MR. DON RATLIFF
MR. BILL GRIFFITH
MR. MARK DOPP
MS. KIM RICE
MS. CHARLOTTE WALLER
MR. GARY TREAT
MR. KEVIN ELFERING
MR. MALIN BENICEK
MS. ROSEMARY MUCKLOW

I-N-D-E-X

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

(3:45 p.m.)

MS. DILLEY: Is it working? Hello. Oh, golly. Okay. It's working too well. Can you hear me now --

COURT REPORTER: Yes.

MS. DILLEY: -- as they say. Okay. So try and capture as much of the information as we can. The flip chart notes and the notes that Irene will be taking will be used to help put together a report back to the large group tomorrow. We're going to do that almost first thing in the morning, so that everybody has a chance to hear some of the highlights. It won't be a blow by blow in terms of the discussion, but more trying to extract out some of the highlights, and somebody needs to do that, not me. So, you know, I'll be looking for somebody to do that or somebody who would be willing to volunteer to do that before we adjourn this afternoon. And the way --

UNIDENTIFIED SPEAKER: We ought to lock the doors.

MS. DILLEY: Lock the doors.

UNIDENTIFIED SPEAKER: So we all don't run out.

MS. DILLEY: Yeah, just remember, you can be volunteered if you leave. So -- no.

Well, we need to do all that in the course of the hour and a half that we have, and I want to be sure we have adequate time to get to all the different pieces. The reason we're starting in two different places or with the two different papers is we want to be sure that each paper gets a thorough going over. So hopefully, even if we spend a little more time, 45, 50 minutes on the establishment risk control, another group may be doing the same thing but with the other paper.

And then we'll have an opportunity tomorrow after the report backs to have some more discussion about each of those pieces, what came out of the groups, additional questions that were raised, the whole range of things. And then get into some of the other pieces in the afternoon on implementation, and then if there are pieces like -- I'm just pulling this out of the air, but if volume continues to be one of

those issues that people really want to spend some more time wrestling with a big and talking through or severity of illness or some other topic that is particularly important, and people want to talk about it in more detail, we've got a little bit of time in the afternoon to put that hour to some additional topics that you want to take up or come back to the vision issue or some of the other things that have come up over the course of the day so far.

So that kind of gives you a sense of what we're doing for the hour and a half, and then what we're going do -- how that's going to be used for tomorrow, report backs and continued discussion, and then some opportunity to highlight some other topics later in the day.

Nancy, did you have a question?

MS. DONLEY: Are these FSIS posed questions or is this something that RESOLVE along with FSIS came up with or are these RESOLVE questions?

MS. DILLEY: Exact ownership. That's a good question. So the papers that went up on the website, whenever they did, I think July has been used. I

can't remember exactly when they went up, originally had some questions, and in the course of our doing interviews with people, they gravitated towards different questions, and so we fed that back some to FSIS. As a result, I think they did some reconfiguring that, not all as a result, but I think it helped. It's kind of reflective of the fact that their thinking is dynamic, and it's continuing to evolve. So the questions that they came up with are their questions. They didn't ask us if these are the right questions or are these what you're hearing from stakeholders. Some of them do reflect some of the input that we have fed back in terms of some of the questions that we're hearing about some of these things, are these kinds of things. So they're developed by FSIS informed by some of the things we've been hearing from stakeholders, not only through our interviews, but also from you all directly and other venues, the advisory meetings, with industry and consumers and other venues that they've been hearing, NACMPI and other places. So --

And, and I think one of the questions is, 12

questions is a lot to tackle in an hour and a half, and we know that there may be other things that just aren't triggered by these question that you really want to talk about. So we're trying to do all of that in the hour and a half, and hopefully not only with the small groups, but then through the discussion tomorrow morning, we can capture as much as we can.

Other questions about what we're trying to do and how we're going to do it?

(No response.)

MS. DILLEY: What I thought would at least be helpful since we didn't have a chance to do it is kind of quickly just have people introduce themselves and your affiliation, so we kind of get to know each other a little bit more than in the formal process of, you know, I'm an academic or I'm a facilitator or I'm a whatever. So, Irene, if you don't mind starting, I would appreciate that. I'll just pass the mic around, and we have this one, too.

MS. LEECH: Irene Leech. I'm here as a consumer, President of the Virginia Citizens Consumer Council which is a member group of the Consumer

Federation of America. I teach consumer affairs at Virginia Tech. I also have connections with the family beef farm.

MS. DILLEY: Thank you.

MR. GILLIAM: My name is Jim Gilliam. I'm Director of Quality Assurance for Henningsen Foods in Omaha, Nebraska. We produce dehydrated meat, poultry and egg products.

MR. LANGE: Loren Lange, with the Office of Public Health Science and FSIS. I guess I've been with the Office of Public Health Science since late 2001, and been with the Agency forever, actually only 1979.

MS. DILLEY: It just feels like forever. Is that what you're saying?

MR. HICKS: I'm Ron Hicks, Chief Operating Officer, FSIS, and I'm here just to take notes and listen to see what kind of input we get.

MR. WALDROP: Chris Waldrop with Consumer Federation of America.

MS. DONLEY: Nancy Donley, with STOP, Safe Tables Our Priority.

MR. SCHAD: Mark Schad. I own and operate Schad Meats in Cincinnati. It's a very small plant.

MR. HONTZ: Lloyd Hontz, Food Products Association.

MS. WILKINSON: Leah Wilkinson, National Cattlemen's Beef Association.

MR. RATLIFF: Don Ratliff, Maple Leaf Farms.

MR. GRIFFITH: Bill Griffith, Perdue Farms.

MR. DOPP: Mark Dopp, AMI.

MS. RICE: Kim Rice, Crider.

MS. WALLER: Charlotte Waller, Virginia Poultry Growers Cooperative.

MR. TREAT: Gary Treat, Pilgrim's Pride Corporation.

MR. ELFERING: I'm Kevin Elfering. I'm the Director of the Dairy and Food Inspection Program in Minnesota, and I'm also an Adjunct Professor at the University of Minnesota in Food Science and Animal Science. I'm a member of the National Advisory Committee for Meat and Poultry Inspection. I've also been around since 1979. So that's not forever. Just damn close.

MS. MACKZA: Carol Mackza, the Office of Food Defense and Emergency Response, and I'm an observer.

MS. DILLEY: Okay. Thank you.

DR MANN: I'm Curt Mann, also with USDA

MS. DILLEY: Well, you're observing from a very far aspect. If you want to move up, that would be great. If you want to stay there, that's perfectly fine. I think we got everybody.

So also just as I was reminded when Rosemary's cell phone went off, if you do have it on, if you could just put it to vibrate, that would be great.

How do you turn these off? Oh, here you go. Thank you. I'm always technologically challenged.

And then thank you for introducing yourselves, so you get a good sense of just who all is in the room and who you're spending the next hour and a half with. And I just wanted to -- I think using the same basic ground rules would be helpful in terms of staying with one conversation and trying to keep track on the task at hand and some of the other things

that we had mentioned.

So I know there's a lot to cover here. So we'll try and move through these as efficiently as possible but also if there are particular dimensions that you really want to spend a little bit more time on, I think we should be able to do that because I think that adds, you know, some additional insight into some of the thinking on the papers and some of the questions that are being proposed.

So we are going to start with the establishment risk control paper, and obviously we've been spending some time talking about this topic on are these six components appropriate and adequate, and the second question is a lot -- is kind of building off of that in terms of how would you -- would you and how would you weight these, and questions have already come up in terms of these have different kinds of pieces in each of them. So it's kind of hard to get conceptually how this all factors in as a wheel, spoke and wheel kind of process.

But if you look at the overview, and look at the six components that are pieces of this, just

comments in terms of the presentation this morning, questions that came up, are these the components, right components? Did you hear anything that just absolutely was missing that you'd really like to see as part of the consideration in looking at establishment risk control?

So I think we should just dive right in, and see what you want to talk about and your comments on the six components and the concept in here. Anybody want to get going?

MS. DONLEY: I'll start.

MS. DILLEY: Yes, please. Nancy.

MS. DONLEY: Do you need --

MS. DILLEY: Yeah, you do because for the -- and it's off. So put it back on there. Okay. Good.

MS. DONLEY: If it would be helpful, I'll just start with rather than go on and on with all six areas, I'll just start with the first one which happens to be system design.

MS. DILLEY: Right.

MS. DONLEY: And I think which that's a very, very important, certainly a very important

component. I would like to suggest that one, one flaw that goes back to in my -- to my view since HACCP was implemented is that there's been some real problems with plants that are just not able to put together a good HACCP plan, and therefore run into a few more problems than others might.

When we had first worked on the HACCP regulation, one of the things that we had -- my organization had proposed at the time, is that HACCP plans be validated by Government, and I think under risk-based inspection, I think this is even needed more so now, that plants at a minimum, of course, they can't -- the Government cannot design the HACCP plan for the plant, but certainly plants could be given the hazardous analysis. Then they work it from there and put it in place, and the Government then validate to see that the HACCP plan is effective as designed.

So I think that would be a very way to strengthen the system design.

And then just as another -- as a comment on this, as a concern I also had, is that the plants right now have the ability to really change their

HACCP plans at will, and I see this as a real problem with, with -- if it's constantly changing, how the heck can inspection be done at its very best?

MS. DILLEY: I apologize for having to step out there for a second. I heard -- Nancy, I caught the tail end of it, but the validation of HACCP plans, how often they're changing and how they're being used to be factored into establishment risk.

MS. DONLEY: But it's not just validation of HACCP plans because they are required to be validated now.

MS. DILLEY: Right.

MS. DONLEY: It's FSIS validation of HACCP plans.

MS. DILLEY: So it's FSIS validation.

MS. DONLEY: Yes.

MS. DILLEY: That's the key.

MS. DONLEY: That's the key.

MS. DILLEY: That I missed, and then how often they're changing and how that affects how they're being --

MS. DONLEY: Yeah.

MS. DILLEY: -- used.

MS. DONLEY: Yeah, the fact that right now plants can and do change their HACCP plan on a regular basis, and just how is FSIS going to manage that.

MS. DILLEY: Right. Okay. Okay. Yes, please. Mark.

MR. SCHAD: Mark Schad. I -- really I agree with you totally, Nancy. I was asked this question about a year ago, you know, Mark, what do you think is the most important part of risk-based inspection? Well, I said the first thing is a plant has to have a good, sound HACCP plan. I just -- for a plant that's going through a couple EIAO reviews, the reality of being in it everyday, we don't really just change our HACCP plan at will. There's a lot of review process going on now. We have to prove our plan. We just don't change our plan on a whim.

MS. DONLEY: Oh, I don't mean capriciously.

MR. SCHAD: Yeah, okay. Yeah. But I just wanted to -- as far as I'm concerned, I agree. That's the foundation of this whole thing. It has to be a sound HACCP plan to begin.

MS. DILLEY: So it's the HACCP plan and how that's being factored into this part of the component, and that's really critical. And so there needs to be a lot of clarity around that. Okay. Good. Mark in the back, and then Kevin, you had a question, too.

You know what? One of the things we use is to just put your card up like this so you don't have to sit there with your arm up. So then I know you want to talk and I'll get to you as quickly as I can. And we can use two microphones.

I'm sorry. Mark, go ahead.

MR. DOPP: The first thought that comes to mind when I listen to what Nancy's suggestion is and frankly as a sidebar, having talked to enough of my members who have gone through FSAs, et cetera, you know, they come in now and they say your plant is inadequate, et cetera, and six months ago when the guy did another one it was perfectly fine, on one level, there might be people out there who would embrace enthusiastically a Government validation because it removes a requirement that's on the plant right now. Frankly, it might have some merit. I guess my

question is I don't quite -- I don't understand how this concept ties into how the Government is going to measure or determine the establishment risk control factor.

MS. DILLEY: So you're wondering how HACCP, the information from HACCP actually --

MR. DOPP: Well, I understand --

MS. DILLEY: -- has a direct link to calculating establishment risk control?

MR. DOPP: I understand.

MS. DILLEY: Okay.

MR. DOPP: My question is the idea of Government validation of the HACCP plan, how does that tie into how the Government is going to assign a value or help -- this is a contributing factor to assigning a value in terms of the establishment's risk control. I'm not following the -- I don't get from A to B.

MS. DILLEY: The direct link. Nancy, you want to respond to that.

MS. DONLEY: If I may comment on that --

MS. DILLEY: Yeah.

MS. DONLEY: -- is frankly what that would

then mean is Government can then focus their intention on the implementation of the HACCP plan because again, once again, you can have a great HACCP plan but if it's not implemented correctly, it's no good. So what it would do basically is, is it can free up them to concentrate on some -- it would be starting them knowing that the plants are starting all a good basis, a good baseline. Did I kind of answer your question?

MS. DILLEY: So your perspective is it would shift the attention on all that energy going towards developing a plan to implementing a plan. Am I getting that right?

MS. DONLEY: Yeah, what it would do is, is it sets the bar. It sets the bar from the beginning for the plants to be starting off from a good -- I want this to start off from a good starting point.

MS. DILLEY: Right.

MS. DONLEY: And I think this would, this would put I think a lot of credibility into the whole risk-based inspection system, and give a little bit of confidence I think certainly to the -- I can't speak for all the consumer community, but certainly to my

community.

MS. DILLEY: Let me get Don and then Kim.

MR. RATLIFF: I just wanted to make the point that I don't think currently and the point was made earlier, that there's really not enough FSIS data to effectively assess everybody's plans, you know, right now I don't think.

MS. DILLEY: So on the validation or any other kind of plan, there's not enough data to evaluate or validate?

MR. RATLIFF: Yeah, in the system design, there's really no data, you know, there's some FSAs, there's a lot of things going on. So I don't know if the right approach to start with wouldn't be for FSIS to develop a criteria, if you will, for self-assessment by these plants to say, okay, what type of micro controls do you have, you know, all these different prerequisite programs and then as a result of that assessment, you fall somewhere in this as a starting point. And then somebody made the point, that your FSAs come in and validate whether or not you're in alignment with that or not.

MS. DILLEY: Okay. So really find out the data and what are you collecting and --

MR. RATLIFF: I mean how can, at this point in time, they assess 5,000 plants for program effectiveness or program design for that matter, and different programs are designed, you know, we heard about some people have testing, some people don't.

MS. DILLEY: Yeah.

MR. RATLIFF: And that should be, you know, how they fall out at the beginning.

MS. DONLEY: But part of the inspector's function is evaluating the HACCP plan.

MS. DILLEY: Kim. Okay. Kim and then Kevin.

MS. RICE: Kim Rice. I don't know if you need me to say that or not, but --

MS. DILLEY: Yeah, actually identifying yourself is a good idea.

MS. RICE: Kim Rice from Crider. Back to a comment that Nancy made related to the same subject, handing a hazard analysis to a facility, the hazard analysis is based on the flow diagram. The flow

diagram has to be specific to the facility. Not all poultry slaughter facilities are set up exactly the same way. The process does not flow exactly the same way. So the handing of hazard analysis to a group of plants doesn't work. It's not how you do HACCP. You start with your flow diagram. Then you do a hazard analysis based on the flow, as well as all the information relative to that facility. What prerequisite programs do you have in place? What testing are you doing? What other historical data, yada, yada, yada. So it's a process. It's not simply hand them a list of things and here you go, go from there.

Validating the program is then based on the decisions that the facility made, and your validation is based on all that information flowing. So the Government or a third party coming in to "validate" a program and its design, it doesn't work that way. They can come in and look at it and say was your thought process right, did you consider all the regulatory things and other food safety issues that are current, and do you have all the things in place

that you should? That's the way it should work. That's the way it's designed to work.

Whether it's working perfectly or not right now, you know, I have a lot of suggestions to make it better related to people. So it's not necessarily the concept and the design. It's related to the people implementing it which gets to the next piece of it which is implementation of the programs which is just as important, if not more important than the system design because as Nancy said, which I agree with it, is you can have the best designed program, but if you're not implementing it correctly, then it's all for naught.

MS. DILLEY: Okay.

MS. RICE: And then just one more thing. Food defense, I am not sure that food defense as it is being looked at today is really a good -- should be one of the six components, because quite frankly, just because you don't have a fence around your plant and you're out in the weeds in South Georgia, doesn't mean you're any more risky than a plant that does have a fence around it in the middle of downtown Detroit. I

mean, I'm sorry. It has nothing -- they don't, they don't fit.

The food defense things that are designed into your food safety programs, related to controlling ingredients and controlling traffic in and out of your facility and those things, yes, but that's already part of your food safety system design.

MS. DILLEY: Okay. So that was a lot. So there --

MS. RICE: And I'm sorry.

MS. DILLEY: No, no, that's fine. I'm just trying to capture it. So a question about how food safety defense fits into this whole picture because it may be kind of an apples and oranges problem is what I hear you saying.

The other piece is food safety design, it works a little bit differently in terms of, you need to have a design but the real key is implementation is what I hear you say. So I'd like to get a little more comment on food safety design in terms of how could it be, at least if it's not, yeah, the primary component, at least how could it help contribute to figuring out

establishment risk control. Being a factor, does it and then we'll move on to implementation and pick up more on that vein of thinking.

Kevin, I think you put your card up. So I think it was with regard to system design, right?

MR. ELFERING: Yes, I'll probably add a couple of extra things.

MS. DILLEY: That's fine.

MR. ELFERING: One thing is, with all due respect to USDA, they've never had a real good grasp of HACCP. And unfortunately, the industry is subjected to having an inspector looking at a HACCP plan, and then having a front line supervisor come in and making some modifications, a circuit supervisor perhaps making some modifications and an EAIO officer coming in and making other modifications. They're right in the HACCP plan.

MS. DILLEY: So is that --

MR. ELFERING: They're pretty much telling the industry what they have to have in their HACCP plan, and that is totally the opposite of the basis of HACCP. HACCP is an industry-based system. It's not a

very good regulatory system. It never has, and they try to kind of push it a little bit. It certainly, it certainly can help in some regards, but to have FSIS validating HACCP plans is not the way to go. Industry needs to be doing their own validation.

I also agree with the food defense, that that's not appropriate in this point. And some of the other issues, I think they need to be modified a little bit. In regards to even looking at, you know, some of the in-commerce data, I think needs to be looked at from a standpoint of CDC data, and from public health, food-borne illness investigations and I think that should be one of the primary areas that should be looked at is not only food-borne illness outbreaks. I think that should probably be number one.

MS. DILLEY: So they're kind of in-commerce.

MR. ELFERING: Well, I don't really know if they clearly define what in-commerce is because you're talking about consumer complaints. You're talking about recalls, and really from my standpoint, recalls have dropped dramatically because more plants are

holding product.

MS. DILLEY: Okay. So if you're not sure it's there, I mean what are the dimensions of food-borne illness? I think there are a lot of comments about food-borne illness.

MR. ELFERING: You've got to look at public health data which CDC should have, and they should be able to look at -- and if there's going to be able to do a trace back to a particular product, you'd even be able to identify it into this system that they've developed of what are the highest risk products.

MS. DILLEY: So that needs to be -- that data is at CDC and you need to look at it to determine which are the most high risk products. Is that what you're saying?

MR. ELFERING: CDC should have data on all food-borne illness outbreaks in the United States, and if there has been a food vehicle identified, they would know what that vehicle is. And because all the states are going to report to CDC.

MS. DILLEY: Okay.

MR. WALDROP: Can I clarify that?

MS. DILLEY: Yes. Chris, and then, Mark, do you have your card up?

MR. WALDROP: Is that under the heading of attribution data or is that something different, the way you've connected the CDC to the -- I just want to know how you're sort of thinking about that?

MS. DILLEY: So is it something different than attribution data or were you referring to attribution data? Are they one in the same or --

MR. ELFERING: Pretty much one in the same, yes.

MS. DILLEY: Okay.

MR. ELFERING: Definitely.

MS. DILLEY: Okay. I don't know whose card went up first. We've got a couple. Rosemary's was first, okay, and then Malin -- Malin, why don't you go and then Rosemary and then Mark. How's that?

MR. BENICEK: You know, just looking at the model, it appears to me that there's almost two -- in here, you know, around system design and system implementation and piggybacking on Kim's. Everything else with the exception of food defense, which

doesn't, in my opinion, fit on here, are consequences of the other two.

If you have an appropriately designed system, and you're implementing it properly, you -- your pathogen control is consequential to that. So is your in-commerce. So is your enforcement actions.

So I mean instead of over complicating the model if you will, if you focused on system design, system implementation, and verification and validation thereof, everything else just falls into place.

MS. DILLEY: So rather than doing a spoke with wheels, you're looking at it as system design, system --

MR. BENICEK: Well, a lot of --

MS. DILLEY: -- implementation, and then those are other things that come off of those.

MR. BENICEK: Yeah. A buzzword I hear a lot, being used and maybe not in this context but, you know, upstream, upstream.

MS. DILLEY: Yeah.

MR. BENICEK: You know, HACCP is an upstream type program, and again it's a process control, not a

regulatory. If you're going to look at the perspective of this, in my opinion, you would figure out how you would verify the system and the implementation thereof.

MS. DILLEY: Okay. Rosemary, and then Mark. Okay. Mark, go ahead, and then Rosemary, Nancy, Chris and Gary.

MR. DOPP: I don't know. I'm not sure if I'm batting out of order, but there is something about this, and I'm trying to look at these six questions that you've --

MS. DILLEY: Yep.

MR. DOPP: -- placed out there. Something that struck me, and I'm going to hearken back and reference Rosemary a little bit. Something that struck me earlier was there is -- for those of us who have been doing this a long time, or even for that matter those that haven't been, one of the key issues is subjectivity, and this is something, Rosemary, I think you talked about earlier today.

A suggestion for the Agency, and it's not addressed in the paper on establishment risk control,

but a suggestion is that if they're wedded to a concept of an algorithm, and wherever that algorithm puts you in either giving you a value or putting you in a box in a matrix, however you want to get there, I have some views on that, but however you get there, you get there.

One of the things that struck me was if the Agency can't quantify it, if they can't put it in a number, it shouldn't be incorporated into the algorithm. And I would set a couple of examples. It may be possible to do this. I think Don Anderson was talking about how there were some ways to do it. I'm not really convinced that they really work but, for example, in the context of food safety assessments, most of it is qualitative, not quantitative. Test results are quantitative. I think something's not clean is not. A NR written because the inspector thinks something isn't sufficiently sanitary is not quantitative. My suggestion is if the Agency cannot incorporate a way to quantitatively measure an assertion, it doesn't belong in the algorithm if, in fact, an algorithm is the correct approach to follow.

Because there is way too much subjectivity already in the system, and introducing that subjectivity into a system that is based on numbers, is going to be garbage in and garbage out.

MS. DILLEY: Okay. Rosemary.

MS. MUCKLOW: We're dealing with a law that was passed 100 years ago. It has been amended twice. In 1967, it was substantially updated, and in 1986, processed products was passed by Congress and helped us to carry forward with PBIS as I said this morning. That law was actually sunsetted and we never realized the value of discretionary inspection or improved process inspection which it was supposed to bring us. It sunsetted in 1992.

In 1996, the then Administration pushed the limits in developing the HACCP rule, and it was a very ambitious rule. In the first year, as everybody will remember, we implemented Sanitation Standard Operating Procedures, on the 1st of January 1997.

And then three successive years thereafter, we did the large plants, the small plants and the very small plants. So we're coming up on the first 10 year

anniversary of the implementation of the law that -- of a rule, a regulation, that pushed the limits of the Federal Meat Inspection Act.

And I think it's remarkable how well it has worked. It has had substantial results. The Agency recognizes and has done in the last year, that it needs to reach out maybe to some firms that may not have implemented and designed a HACCP system. They have the small and very small plant outreach in the last year. And that's an excellent effort on their behalf to bring those people in.

Trying to go back and change the HACCP rule at this point, I think would be a great mistake. It isn't going to contribute to risk-based inspection. It's moving remarkably well given that it's only a 10 year old regulation this year, and it was a C change in approach, the USDA. So I'm not in favor of tampering and changing the game plan on the HACCP rule. I believe that the industry has cooperated keenly with the Government to improve it, and again it's fairly new in the regulatory scheme of things.

MS. DILLEY: Rosemary, do you see the

concepts in here as changing the HACCP rule or supplementing the --

MS. MUCKLOW: Well, the notion that Nancy put on the table is that we need the Government to do the validation. That's not HACCP. Kim Rice has spoken well to that, Lloyd, other people in this room. That is not the principle of HACCP. That HACCP rule is readily available to every inspector that walks in the door. He can certainly -- he or she can certainly question it, can raise the issue, they can send in a food safety assessment, they can send in an EAIO, they can write NRs, they have a lot of enforcement action if they don't think it's right.

MS. DILLEY: Okay.

MS. MUCKLOW: But it would not be appropriate at this point to tinker with that. I think we need to focus on risk-based inspection. That is a new generation. I don't think we have enough data yet. I think we need to improve the information that we've got available. I think this is a very good session. We're all going to learn from it, and we're all going to get it into our focus and I hope very

much work with the Agency so that it isn't another 10 year process to move it forward. But it's an appropriate way for us to move forward.

In the meantime, this Agency has worked diligently to increase the capabilities and the competence of its inspection staff. They have a lot of people. You heard me this morning complain about consistency and, you know, looking at the backward window, if you have an inspector for six months on patrol inspection, and he's merry hell for one kind of thing, and he leaves and somebody else comes in and the next guy doesn't write hardly any NRs, you're not going to capture this distinction in a six month retroactive window.

MS. DILLEY: Right.

MS. MUCKLOW: So I tried to get to that point this morning. We need a longer view backwards because we need to improve consistent application of the rules and regulations that they carry out.

MS. DILLEY: Okay. Nancy, Chris and then Jim and then Gary. Gary, were you next? Oh, I'm sorry, Gary.

MR. TREAT: I'm going to have to step out. I have a conference call.

MS. DILLEY: Oh, why don't you go ahead then please.

MR. TREAT: I just wanted to make a comment.

MS. DILLEY: Can you identify yourself, too, please for the record.

MR. TREAT: I'm Gary Treat with Pilgrim's Pride.

MS. DILLEY: Is that working. That's not working. Use that one then.

MR. TREAT: I just want to make a comment that, you know, we, we -- the HACCP program, and they do hazard analysis and everything, has to be a plant system -- designed to be a plant system to improve food safety and it's supposed to be a plant program. It is drifted back into a command and control situation and that is really adverse to what we're trying to do, and there's not a plant out there, even though there's people probably even in this room that think that the industry's the enemy and doesn't want to do the right thing. We do, and we want to be able

to develop our plans to really make a difference.

But we do need a partner in the area of food safety. We need to bring every -- the consumer group, USDA and industry together to partner, and if we would do that, you know, in designing systems and in implementation, we could do an unbelievable job and would make tremendous strides and improvements. But right now, we've got adversarial relationships that need to go away as regards to food safety, so we can concentrate on what's important.

I do want to address just real fast, and like I say, I'm going to have to step out, but volume, talking about volume and big plant versus small plant, and putting a higher risk on a larger plant, I will say this, that most of the larger plants and larger companies have the better systems for food safety. And so to put them a twofold risk doesn't really make a lot of sense and doesn't fit for anybody's model, I wouldn't think.

And then in the expert panels and evaluations and trying to establish a model, we need to really consider, and I didn't hear that this was

being considered, product type. There's a big difference between ready to eat and refrigerated form and then frozen form. There's a big difference between ready to cook in a thawed state and a freezer to fryer operation. So those things need to be considered and whereas the last stage lethality step at the end user, those things need to be worked into the model if you're talking about risk because there's a bigger risk with a refrigerated ready to eat than there are with frozen reconstituted at the end user product. And I didn't hear anything that put that into the model.

MS. DILLEY: Okay. So that's in the other paper, and I know you have to step out.

MR. TREAT: Yeah, I just wanted to throw it out because I knew you'd get to that probably but that's just my opinion. But I think we need to keep HACCP with industry, to do hazard analysis, to develop their program, and there's an everyday review of that, and we never make a change that's not reviewed by USDA.

MS. DILLEY: Okay.

MR. TREAT: Okay.

MS. DILLEY: Thank you. Hopefully you can get back from your conference call and join the rest of the conversation.

Nancy, Chris and then Jim, and I'll come back to Lloyd and Mark.

MS. DONLEY: Okay. Kind of back to the idea of HACCP and then the command and control.

As so often happens, what happened back 10 years ago when HACCP was proposed and we went down the rulemaking road, when something happens, the pendulum swings completely, and that's what HACCP did, and it took it from a command control to a you take care of it, and the reason the Government did not want to validate HACCP plans is because they didn't want the responsibility. They wanted the responsibility of food safety back into the industry and not on them. So it was their way of stepping back from taking responsibility for the safety of the meat and poultry that gets shipped into commerce.

I think they made a big mistake by getting away from command and control, and I think there's a

nice middle ground there somewhere. I'll also say whoever had said that we have an adversarial, I don't know if that was you, Malin, or --

MR. BENICEK: No, Gary.

MS. DONLEY: Oh, Gary. That's really -- I'm really sad to hear that because that is honestly not the truth. I've been in this for 10 years. I've met some wonderful people in industry, and frankly it's the ones that take the time to come and attend these meetings and to work on it. So I just have to say I kind of take exception to that. We don't always agree, but it's always with respect and -- that we can agree to disagree I guess is what it is.

So I still suggest that HACCP is the -- it is not, I agree with the comment, whoever made the comment that it is not an inspection system. It is a plant tool. It is a management tool for the plants to be able to assess their system, and I agree with that entirely. But I do think that if for the consuming public, that if they know that Government has blessed what it is that the plants are doing, and then they're just in there making sure that it's being done

correctly, I think it would be very, very positive to move this along.

So I guess my bottom line is we need more command and control, and I still do maintain that Government needs to validate those HACCP plans and work with the plants obviously in putting it together.

MR. BENICEK: I think for clarity --

MS. DILLEY: Okay.

MR. BENICEK: -- I think Gary was saying that we are now under very strong command and control, the opposite of what you just said.

MS. DONLEY: Well, I guess I really don't understand this. I'm sorry that he's not here that I couldn't ask him that question.

MS. DILLEY: And I think there's a difference maybe in terms of terminology and command and control, what HACCP does and some other perspectives, and we're just getting into the different --

MS. DONLEY: And jut as one last other comment, is that I have talked with small plant owners myself, who over the years have said they really --

they liked it before, that it was easier for them because they knew exactly what was expected of them, and they could then, you know, make sure that what was expected of them, they made it happen. So, you know, you have two ways of looking at this issue.

MR. ELFERING: Small companies will say, yeah, we --

MS. DILLEY: You need to talk into the mic, if you're going to --

MR. ELFERING: Small plants are going to say we love command and control in lieu of HACCP. Give us one or the other. We don't want both. We either want our HACCP plan that we're going to be writing, or we want command and control, but we don't want command and control and HACCP and that's --

MS. DONLEY: But wouldn't the HACCP plan be command and control?

MR. ELFERING: It's too much command and control right now. I mean right now you have a system that's not working very well because it is command and control, and that's the -- I've worked with HACCP for nearly 30 years, and that is absolutely opposite of

the basics of HACCP.

MS. DILLEY: We're bouncing all over the place, and what I want to do is make sure we get to some additional comments on -- I'll get to you, Kim, but other people have been waiting. So let me get Chris and Jim, and then I've got Lloyd, Mark and you. And we'll try to do it as expeditiously as possible.

I do want to make sure that if you have comments on the additional components, we started in that direction, we sort of bounced all over the place. Gary brought in some comments on the inherent risk paper. I don't want to go there yet. If we can hold off on those, and get some more feedback on the component piece, that would be helpful, and then we will go to that paper. So, Chris, please.

MR. WALDROP: I just -- you had a diagram on the next page. That's sort was saying pathogen control, in-commerce findings.

MS. DILLEY: Kind of reconfiguring.

MR. WALDROP: Yeah, we're sort of a part of it.

MS. DILLEY: Yeah.

MR. WALDROP: And I think we're talking about weighting more than we are sort of subsuming pathogen control --

MS. DILLEY: Yeah, it could be.

MR. WALDROP: -- and enforcement action into something, and I think they all have a certain weight and I can't give you that weighting right now, but I think it's a matter of taking these parts separately and trying to figure out what the weight is, and not just kind of pulling them into one of the other.

MS. DILLEY: Oh, you mean pulling these into there.

MR. WALDROP: Right.

MS. DILLEY: Yeah, I don't -- I wasn't intending to do that. What I heard from Malin, was it Malin? No, it was Mark, did you give me this? I don't know who did, but it was kind of these, to me, you were weighting these heavily and then these flowed from that. It wasn't that you were trying to subsume them into those, but I can just think graphically, and if the graph's wrong, then I can certainly go -- but you're right. We need to talk about each of the

components and how you would weight them. They're not disappearing. They're -- it's just a different way to configure the flow chart.

Jim, you had a comment and then Lloyd, Mark and Kim and Malin.

MR. GILLIAM: I don't know if I completely agree that the HACCP system has become more command and control. It certainly has been more difficult but that's because I think the HACCP system, FSIS' system has evolved a lot over the years. There's been numerous directives, guidelines, performance standards that were put out that you have to follow, and I think that's a valid way to, to manage HACCP from FSIS' standpoint. It has put a lot more burden on the industry, which I think is where it belongs. I mean you can't have an inspector in your plant 24 hours a day. I mean the industry people, they're the ones that are there around the clock. It's their product. It's their reputation that's on the line, and I think HACCP is a much better system than it was. It's more difficult for industry, of course, and that's not bad. I think that's where the responsibility should be.

But to tie that to the RBI, I don't know, is there any reason to think that the RBI system wouldn't follow this same path that HACCP did. I mean you can make an initial improvement in food safety, and then build on that which I think is what's happened with HACCP.

MS. DILLEY: It could be. Lloyd, and then Mark, and then Malin.

MR. HONTZ: Lloyd Hontz, Food Products Association. I just wanted to add a couple of thoughts.

First of all, I would agree 100 percent with Jim, that food safety is the company's responsibility, and we've argued for that for a long time, and we're very happy to see the Agency going along with that. And we think that the proper role for the Agency is to oversee that industry is doing what they say they are doing to protect food safety.

Also I wanted to follow up a little bit on what Rosemary was saying. Her history of HACCP was excellent. I would like to add that in the earliest days of HACCP, the Agency, the primary job that they

had was checking for basic compliance, that is seeing that -- it wasn't how well the SSOPs were put together, but whether or not, in fact, a company had a SSOP plan, and then the same thing with HACCP.

In more recent years, the Agency has started doing the food safety assessments, and the primary purposes of this is to go beyond whether or not you have a plan, but to actually look at the basis for the plan, the supporting documentation for that. And so I think that the concept is a correct one.

I would also think that these are two very important features of establishment risk control, that is the design of the system and the implementation of that, and certainly the Agency is looking at both of those. It's primarily the food safety assessments, that the EAIO goes into a plant and spends up to a couple of weeks or more, looking in great detail at all the elements of the company's food safety system, and so I think that is quite appropriate.

And as far as implementation, that's primarily whether if he's got a sound food safety system, and a HACCP, are they actually following that,

and that's the role of the in-plant inspector, to take a close look at that and make sure that they are doing what they say they are doing. So that's my comments.

MS. DILLEY: Okay. So a lot of discussion around role of industry, Government, is it oversight, is it validation, kind of terminology, command and control. If you could also fold that into some other comments on the factors that would also be helpful.

Mark and then Kim and then Malin.

MR. SCHAD: I've just got a couple of brief comments. I wanted to thank Kevin for that comment he made about small and very small plants because it's something very small plants go through because an inspector came in and wanted to change something, and my advice to those very small plants, what I do is I said, you know, you can't have it both ways, you know. I believe in my system. It's a sound system. So we're going to go with that, and you can't come in here and say this is the way it's going to be and then leave me with the responsibility.

And there was a comment that Gary made, and tell me if I'm getting off on inherent product risk

here, if I'm getting off the subject here, but he made a comment about big plants having better food safety systems than very small plants, and I don't take it personally, but having worked for a big plant and working for a very small plant, I've been on both sides there, I really disagree with that. After running a very small plant, it seems a lot easier and straightforward.

MS. DILLEY: I think it was linked to volume, that you just can't assume -- yeah, okay. Kim and then Malin and then Charlotte.

MS. RICE: I'll try and make sure I stick to the questions at hand, but again, to echo everything else, it is our program. It is our responsibility. Our name's on the front door. Our name's on the product as it goes out. We're responsible.

Command and control gets in the way of that. Inspectors who don't understand all of the ramifications of changes they're being asked to make because they are not trained in all the things that we are trained in, microbiology, food safety, food chemistry, et cetera, changes they ask to be made

because they think it's the way it should be, will often at times hinder food safety rather than make it safer. So it is our responsibility and it needs to stay that way.

Volume is part of the discussion for the inherent risk. I think it needs to move into this establishment risk instead. I think volume does have a role to play, just not the same way that the Agency has put it in there. And that's all.

MS. DILLEY: Okay. Malin, I believe you're next and then Charlotte.

MR. BENICEK: Kim got most of what I wanted to say.

MS. DILLEY: Okay. Charlotte, and then Loren.

MS. WALLER: I will agree with that statement as well. Charlotte Waller, Virginia Poultry Growers.

I guess I would be curious, Nancy, why you feel that command and control, why you're so adamant with command and control versus HACCP? I agree with the previous statements. I think, Nancy, if you were

in an industry role, you, too, would want HACCP versus someone telling you that this is the way it needs to be done. Not always is command and control from my experience, which has been 25 years probably or longer in the industry. Most of the times with command and control, there's no scientific basis for it, and sometimes it's not regulatory requirement. It's their thinking of the way it should be.

When it's your program, you have total responsibility for it, and as Kim stated, her plants are responsible for the product, and that's the way it should be. I think the burden of food safety needs to be on the industry.

Back to Malin's comment about system design and implementation, I think those weigh heaviest because if you have those two in place, you should have no problem with the others, and I also agree with, I think everyone has this consensus, that the food defense pretty much needs to be obsolete.

MS. DILLEY: Okay. Loren, and then Mark, your card's back up. Okay.

UNIDENTIFIED SPEAKER: Speaker, Loren, you

get to speak.

MR. LANGE: I didn't say I was an observer.

UNIDENTIFIED SPEAKER: Loren, turn it on.

MS. DILLEY: Yeah, you've got to flip the little switch on the bottom there.

MS. MUCKLOW: You always do such good things, Loren. We're pleased to have you speak.

MR. LANGE: I just wanted to add a little bit of some history to what Rosemary had brought up earlier today, and it is in the context of trying to allocate resources based on Agency data systems. Rosemary mentioned 1986, Processed Product Improvement Inspection Act, said something like the Agency should vary the intensity and frequency of inspection based on history of compliance, volume of production and the nature of the plant's products and processes. I think that's what the statute said.

And just to keep things, because we heard a lot today about data the Agency doesn't have, in 1986, when that law was passed, we didn't have 60 to 70,000 microanalyses a year. We didn't have NRs. There was no documentation of non-compliance. There were no

consumer complaints, and there were no FSAs. So as we now in 2006, we spent a lot of time today hearing about the lack of data and the lack of information, but some of us were trying to implement a statute in '86 and, of course, it failed, as Rosemary pointed that out, but we had none of this information.

And it did give us PBIS, and whether people think about it, PBIS did reallocate resources. There were 104 procedures and the plant's level of inspection was based on how many of those procedures occurred in that plant, and that sort of allocated resources on that.

HACCP as a reallocation of resources. The factor that came under HACCP is, for those of you familiar with PBIS, is that there were 02 and 01 tasks, and they were processes. So if you had nine processes, HACCP -- PBIS scheduled 202s and 101 per week per process per shift. So if you had 9 processes, you got 27 inspection tasks, and if it was a plant, you know, that only had two, you got 6. So it was allocating on a variable that was a count, kind of an arbitrary count of how we define those

processes.

Now there were some size considerations in there. So just a little history. Reallocating inspection sources based on data and variables has occurred over history, and one thing we do have today, with the micro data and NRs, whether -- well, I'd like -- the micro data is good, our labs but, you know, there's a lot to debate that it is, but we certainly do have more information today than we ever had before. So I just wanted to add that.

MS. DILLEY: So let me just do a quick process job, because it's about 7 of 5:00, and we have until 5:30, and we've talked a lot about the issue of system design and implementation and roles and responsibilities, a lot of back and forth on that. We've had a little bit of discussion about the different components and, and have talked a little bit about the look-back period as well.

We could stay on this paper and just not get into inherent product risk, if you want to stay on this, that's one option, but I think we need to make the decision that if you do want to talk about

inherent product risk, and obviously it's not your only time to talk about that document because we'll have a chance to talk about it tomorrow, but I'd rather collectively make a decision about what we're going to do. Either move to wrap this up in the next 10 minutes and move to the next paper or are we just saying we're going to stick with this paper and continue this discussion.

So would anybody -- you're looking at me quizzically, Malin.

MR. BENICEK: I look at everybody quizzically.

MS. DILLEY: Anybody have a -- just checking. Anybody have a serious problem with not touching on the inherent product risk people because I don't want to -- and it's not to say that this paper is more important. It's just where we started and I feel like if we move too quickly, then we're shortchanging this paper. So --

MS. DONLEY: What opportunity will we have?

MS. DILLEY: To talk about it? In the report outs, there will be some additional discussion,

groups will give their presentations in terms of what they did talk about it, and then I think there's two hours of that. There's also some opportunity, some of this is in the implementation piece of it, and there's an obvious link. You can't completely take them apart.

So I think we'll get back to some of the inherent product risk thing in the implementation, but there's also that hour from 2:30 to 3:30 tomorrow where we can come back to some key things that people want to get back to. So there's lots of different answers. There's lots of different possibilities. I think the best time would be those first two hours where people give their report backs and we have some additional discussion.

MS. DONLEY: That discussion will be open to everybody?

MS. DILLEY: Yes. So if -- so we'll make the call, we're going to stick with the establishment risk control and spend our 35 minutes on that? Okay. All right. Then we'll do that.

MS. MUCKLOW: We might as well do one job

and do it well than half cook two jobs.

MS. DILLEY: Yeah. Exactly. And I know that, you know, everybody wants to talk about each of these, and they're both very important. So I just -- yeah.

Okay. With that, again I'd like to get some additional input on the components piece and talk a little bit -- we haven't touched at all except for some minor comments on the food safety assessment and our pieces. We talked a little bit about it, but we haven't had a concentrated period of time to discuss those.

Let me take the cards that are up, and then if we can transition back to some of the -- we can talk about the in-commerce component, the enforcement action, some of the other pieces. Jim, I believe you were next, and then Kim, Mark and Malin.

MR. GILLIAM: I just want to make I guess a suggestion. It was mentioned numerous times today, that you find in the industry, so many different types of inspectors, personalities, attitudes, background, whatever, and you get a lot of different opinions on

your food safety systems, and that the way things are currently structured now, the appeal process takes such a long time especially when it involves a question of science.

I guess I would suggest that the Agency consider restructuring the way that process works. Instead of having to go through the inspector, through the circuit, through the district, to Washington, to the Tech Center, why couldn't it just go everybody at once, and then you can delegate the person, presumably the most expert person in the field, to make the final decision. I think right now there's too much weight given to the field staff in these types of matters. I realize that they have to be intimately involved because they're on the scene, but I think that needs to be looked at because there needs to be a way to referee these types of situations and do it quickly so that it isn't drug out for weeks and months.

MS. DILLEY: And is this the appeals process, Jim, you're talking specifically about or it's just the whole thing of making a decision quickly --

MR. GILLIAM: Yeah.

MS. DILLEY: -- more quickly and being able to work that through more rapidly.

MR. GILLIAM: The Tech Center serves a purpose now, but it seems like the Tech Center is strictly an advisory group. That's my perception, but maybe somebody at the Tech Center or one of the science groups in Washington, could be tasked to make these types of decisions, science-based decisions at a plant, when it involves a disagreement between the establishment and an inspector, just a way to get the information in front of the right person to make the decision instead of doing it by -- sometimes it seems like it's a committee, you know, it goes up the line, everybody gets to take a shot at it.

MS. DILLEY: Okay. Mark or Kim, you're next. I'm sorry. Kim, go ahead.

MS. RICE: Okay. Back to question, I think question 1 where we're okay, but question 2, if you look at the six or five components, if we throw food defense out, system design and system implementation are probably, if you rearrange your diagram and go

back to the one you drew --

MS. DILLEY: Yeah.

MR. RICE: -- where they were side by side, then the other three components, the pathogen control, in-commerce and enforcement actions --

MS. DILLEY: Down here?

MS. RICE: Yeah. They basically are factors that tell you whether your implementation is working correctly, and a little bit whether your design is right, but generally when you get into a situation where something has occurred, and there is an enforcement action, design is rarely the issue. It's implementation. I've never been -- I've been involved in a lot of enforcement actions, and fortunately not with my companies per se, but in previous lives, and it was generally with implementation. You may rearrange the paperwork a little bit --

MS. DILLEY: Uh-huh.

MS. RICE: -- on the design, but generally the design did not change. The CCPs didn't change. The critical limits didn't change. You know, it was more implementation. So those other things feed into

that.

MS. DILLEY: So would you weight those three any differently in terms of --

MS. RICE: I would weight them lesser. If you're asking me for a number, I don't have one right now.

MS. DILLEY: No, I'm not asking you for a number.

MS. RICE: But I would say they build into or fall below the other two. The other two are -- I think should be weighted heavier. NRs and FSAs, whether you like them or not at the moment, folks, those are the only babies we've got. So we can't throw them out. They may be ugly, but they're our babies.

Can we make improvements? Yes, and again it gets to implementation of food safety assessments and writing NRs, not necessarily the theory or the philosophy behind them. It gets down to who's doing it, how well trained are they, how objective are they, are they coming in with an agenda already before they get there or are they really coming in to do a true

third party assessment, somebody who's not emotionally involved in the facility. And I think there's room for improvement in both of those areas, and they do have some usefulness in determining the establishment risk.

MS. DILLEY: Did you hear any -- just as a follow up, did you hear anything different on the NRs in terms of making improvements in that concept, did you hear anything that's having any reaction to what they are considering in terms of what NRs, not all NRs are created equal I guess.

MS. RICE: No, I agree with that, and I think we've put forward, the industry has in the past put forward the idea that the NRs should be weighted different based on, and the Agency's taken some of that, especially related to sanitation, you know, non-product contact are listed as -- excuse me -- product contact are listed as food safety issues, non-contact are facility issues. So I mean the Agency has taken a lot of that into account already. It's just the next evolution of that, moving it just a little bit more forward, closer to the goal.

MS. DILLEY: Okay. Mark and then Malin, Kevin and Nancy.

MR. DOPP: A couple of thoughts. I'm going to go back to what I said earlier.

MS. DILLEY: Can you speak up just a little?

MR. DOPP: I'm going to go back to what I said earlier with respect to NRs and FSA. Again, if the Agency isn't capable of assigning a quantitative value, and you can assign a quantitative value to some things on the NR front, and you can do it on the FSA front as well, but if you can't assign a quantitative value, and you're going to follow this approach, then it should be incorporated into the mix which leads me to sort of query whether -- let me ask you a question. Do you think it's the consensus of this group --

MS. DILLEY: Me?

MR. DOPP: Okay. You're the wrong person to ask about consensus, I understand that. Does the rest of the group, is it the consensus of that group that food defense probably doesn't belong in this mix generally? I mean that's what I'd vote.

MS. DONLEY: I think it belongs in the mix

but in a very low --

MR. DOPP: De minimis, if at all. Is that fair?

MS. DONLEY: Pardon me.

MR. DOPP: De minimis, if at all.

MS. DILLEY: De minimis, he's saying.

MR. DOPP: De minimis.

MS. DONLEY: Yes.

MR. DOPP: All right. Because I want to raise another -- I'm sort of going back, you've got to be sometimes wrong, never in doubt. I would question whether the enforcement actions box or circle or whatever you want to call it, oval, really belongs in this mix at all. And I say that because they seem to be capturing something that I'm not quite sure what it is frankly. I'm not quite sure what -- I mean I've been doing this for 22 years, and I'm --

MS. DILLEY: So you need to know more explanation in terms of what the enforcement action --

MR. DOPP: I'm not sure --

MS. DILLEY: -- and how that's incorporated?

MR. DOPP: Yeah.

MS. RICE: Well, that would be the results of FSAs.

MR. DOPP: But it says not resulting from FSAs, and not resulting from these other things.

MS. RICE: Oh, you're right.

MR. DOPP: So if it's not resulting from an FSA and it's not resulting from a NOIE and it's not the function of NRs, query, whether you can quantify it --

MS. DILLEY: Well, it's saying conjunctive actions, consent decrees. So it goes on to explain --

MR. DOPP: I understand but --

MS. DILLEY: -- examples.

MR. DOPP: -- I've been, like I said --

MS. DILLEY: To your point.

MR. DOPP: My point is I don't know how you're going to quantify that. I don't think a lot -- I'm hard pressed to -- I've been practicing in this area for 22 years, and I'm hard pressed to figure out how you're going to get into that mix and make that meaningful in the context of again the question is, how do we determine what the risk value is of this

plant? I mean that's what these questions are about. We tend to get off track a little bit but again, focusing on the target, how does that issue tie into the riskiness of a plant? I would argue it probably doesn't, and if it does, until they can quantify it, I don't want it in the algorithm.

MS. DILLEY: Okay. Malin, Kevin and then Rosemary and then Nancy.

MR. BENICEK: I'm going to speak to number 4 specifically, are there other ways besides food safety assessments, and not only that but, you know, what is the vehicle? If USDA or the Agency wants, as its primary objective to have a more robust and distribute or allocate resources appropriately, you know, this type of system in my opinion seems to be going the wrong direction. I mean the amount of resources that are going to be required to implement something of this complexity is going in the exact opposite direction.

What I might suggest, you know, for number 4 is why wouldn't the Agency allow industry to prepare and put the onus on industry to prepare their position

taking in all these elements in here, a means to prove their position in how their system is designed, and how their system is executed, and the results that they're getting. I mean put the onus on industry to go to the Agency and say, look, you know, here's our pathogen control program. Here are the pathogen control results. Here's our system. It's been validated by these three third parties, as well as your own in-house inspectors, you know, and at that point in time, the Agency then decides on the basis of how comprehensive that position is, whether or not to reduce the inspection or the resources dedicated to that facility.

So I guess what I'm advocating is, you know, where it says are there other ways besides food safety assessments and stuff like that, yeah, there are. The plant comes forward or the company or the business comes forward and says, you know, on the basis of these criteria here, here's how we are performing. Now you can validate it anyway you like, but here's our position. That takes the resource piece out of it. It -- in my mind, it greatly expedites this whole

process, and you get to a position where a lot -- with the onus being put on the plant, they're going to make sure that the effectiveness of their programs and can be verifiable.

MS. DILLEY: Okay. Kevin and then Rosemary.

MR. ELFERING: And I think one of the really difficult parts of all this is there's so many different plants out there, so many different processes to try to actually try to weight some of these, and I was just trying to come up with a couple of ways that you could actually put a weight to them. We just -- actually in last year, I had a number of food-borne illness outbreaks associated with chicken entrée products that are breaded and browned but it's a raw product. Now the *Salmonella* levels in that product are not going to be any different in that product than raw poultry, but it actually ends up to actually become a labeling issue of advising consumers that this is a product that could be prepared in a microwave. So how do you weight a food-borne illness outbreak like that compared to an *E. coli* outbreak in ground beef, and I think that's one of the

difficulties. But I still think that that's where you've got to start, is you have to be looking at hard facts of what has caused food-borne illness outbreaks? What products have been recalled of a human health significance? And then look at positive samples where you're doing -- if you have a plant that's not meeting their *Salmonella* performance standards, that's certainly is going to be much more of an evaluation to me of a plant's sanitation and their process controls than whether or not there's been a NR written.

So I think you have to look at first microbiological data and data that have been linking a particular facility to a food-borne illness outbreak and recalls. Then start looking at things like enforcement issues, and there again, you're going to have to have an awful lot of oversight from not having the inspector making those decisions. It should actually be probably be done more at the district office level, and start getting the district office involved in what is really significant in a plant rather than having the inspectors make all of those decisions.

So if you try to weight things, I would do them first with actual facts and then issues that are more opinions.

MS. DILLEY: Okay.

MS. MUCKLOW: I appreciate, Jim --

MS. DILLEY: Rosemary, you've got to --

MS. MUCKLOW: Okay. I appreciate, Jim, reinforcing the appeal system. The industry will receive things like 30-day notices or 3-day notices and God forbid that they don't meet those deadlines or they don't have a formal request in for an extension to that deadline if they have to find some additional data. The Government should be held to a similar standard.

The second point I would make and I didn't tell you when I traced the history, but in the old days of PBIS, and the Bobby Palesano and Loren may remember this, there was a thing called a deficiency classification system, and a deficiency, a NR, could be -- it was called a PER in those days. It could be major. It could be critical, major or minor. And critical stopped the line. Major might or might not

stop the line, and minor is if you haven't cut the grass outside the inspector's office.

And that system worked, and one of the things that we need to build in for risk based is based upon public health food safety, and we need another system of deficiency classifications that distinguish between some piece of non-product contact surface, a floor that needs to be redone, versus whether something is harming the production of safe food.

MS. DILLEY: Nancy, were you next? Yes. Nancy and then Chris.

MS. DONLEY: Okay. I believe that the enforcement actions box does have a place to play. I know, Mark, you said you were struggling with that. I do think that it's not an important box because frankly it is helpful to see a plant's, an establishment's history of compliance and non-compliance. I have to disagree with what Kevin said a minute ago about the fact of -- that plants that have had recalls or have had illnesses associated with their product, I don't think that's a very good

identification. There are more illnesses that are never ever linked up to a product, a specific product or plant, and a plant cannot say just because they have not ever had anything traced back to them, that they have not, in fact, made a person sick or even -- or contributed to a food-borne illness outbreak. So it's like trying to prove a negative, and it just doesn't.

But I do think that the enforcement actions does have a place in this, but again weighted correctly.

I want to mention something that Dr. Raymond, I was very interested in his, and I'm going to make some enemies here and I can just feel this coming. Dr. Raymond's analogy this morning about the football. And I found that very, very interesting that there are penalties and the penalties vary. You have your 5-yard, your 10-yard, your 15-yard penalties. Now that's about the extent of football that I know, but they are penalties nonetheless. And I think that it would be very helpful -- for FSIS to be able to assess penalties and fines for companies

that routinely violate food safety practices. So I think that would be a wonderful component to put into this risk-based inspection model.

MS. DILLEY: Okay. Chris, I believe you were next.

MR. WALDROP: I was going to agree with Nancy and Mark about the enforcement actions and that it's probably a matter of weighting less than the others, and also that we probably need to get more information from FSIS about that, you know, kind of what they mean and what they're referring to there.

I also just wanted to kind of bring out some points that were brought up earlier in the large group discussion about some of these different elements and maybe holes or elements that are missing from them, like the pathogen control box --

MS. DILLEY: Yeah.

MR. WALDROP: -- and how a percentage of plants don't actually get FSIS sampling verification. So if you're going to give that element a certain weight, how do you take into account that maybe that plant doesn't have any sampling verification. And

then the in-commerce findings, that was brought up as well about, you know, plants not getting as much -- or I'm sorry -- FSIS not receiving all the complaints because they're actually going to the plants as opposed to FSIS. So they don't really have a good handle on the consumer complaints in that area.

MS. DILLEY: Okay. Go ahead, Nancy, and then Mark. Kim, did you put your card down?

MS. DONLEY: I just want to make it known to my industry friends here that I have heard, and I do have a certain amount of sympathy here of the subjectivity of inspectors and how that can be really problematic. I really understand that. I really, really get it, and I think maybe that's where there might be need to a little bit more definite -- clear definitions in command and control. So I do see that but I will say that with the current NR system and what they've got and what -- there's a lot of holes. This is a Swiss cheese product we're dealing with here right now, with what the Agency is trying to base their data on what, what data they have on NRs right now.

MS. DILLEY: Mark.

MR. DOPP: Yeah, thanks. I wanted to -- well, I'm responding to Nancy's comment. I guess, Nancy, what I was confused about with respect to the enforcement actions is the way I read that particular box, or whatever we're calling it, doesn't appear to incorporate or reference penalties that you call them. Those, as I -- if I'm reading this correctly, those types of issues are incorporated into the implementation reference, that box, because they're they talk about FSIS continues under RBI to document all regulatory non-compliances.

Now my take on reading that and listening to Don, yeah, Don earlier, was that that is the part -- that's the element where they look at whether you've got NRs, which NRs matter. Were you subject to a retention action? Was there a detention with respect to some product? Were you subject to a suspension action? Were you subject to a regulatory control action? All of those things, I take from the way this is structured, to fall into food safety implementation, not into the enforcement actions

section.

Now the point that you made about the penalties. Those detention, retention, NRs, suspension, NOIEs, 3 day letters, those are all penalties and frankly, some of them are deserving. I would never sit here and tell you that there aren't companies that don’t make mistakes and unfortunately some people who do things that they shouldn't do. That works into the implementation section, if I'm reading this correctly, and if I'm not, then I'm happy to be educated. But do you see what I'm getting at, Nancy?

MS. DILLEY: Is that a fair interpretation of the division between implementation and enforcement action?

MS. DILLEY: Don.

MR. DOPP: As long as I've got this thing down, then what were you referencing when you put enforcement actions in there?

MS. DILLEY: Yeah. That's the question.

MR. ANDERSON: No, I think that some of the things you've laid out do fit into implementation.

Bobby may be able to correct me, but my understanding of this, terminologically the product is detained in commerce. It's not detained in an establishment.

MR. DOPP: It is retained.

MR. ANDERSON: It is retained, and so some of this is terminology, but if product is held in an establishment or in someplace that is the control of the establishment, it's considered a retain. If the product goes into commerce, and then we realize that it shouldn't have, then we detain product, and we seize the product in commerce. So some of it is semantics and I think we've got the things in the right place.

In terms of enforcement actions, when we talk about this internally, there seems to be -- the general consensus seems to be that these enforcement actions that are not elsewhere captured in the system, are going to be unusual but they do occur. We're not saying they're common. In fact, we're saying they're uncommon. So what we're trying to get to here is if -- is when they -- it's not a question of it. It's a question of when they do occur, should we bring them

into our measure because if we don't, they're not being captured anywhere else because it wasn't the result of a FSA. It wasn't the result of cumulative NRs. It just happened.

MS. DILLEY: So it's other actions and what does or doesn't that mean basically?

MR. ANDERSON: Yes.

MS. DILLEY: It's kind of a catchall.

MR. ANDERSON: I think, and that is my understanding of it in these injunctive actions. What's an injunctive action? An example of injunction. That was one of Bill's terms.

MR. DOPP: Don, if I could interrupt. I'm really hard pressed to come up with a circumstance where you can identify something that's either detention or seizure or an injunctive actions, some sort of consent decree that you can't lay into either implementation or in commerce. It's really hard to do. MR. ANDERSON: I'm not going to --

MR. DOPP: And you weren't here earlier and I'll repeat what I said before. If you can't quantify it, and I frankly don't think you can on the

enforcement actions, it ought not be in the mix right now.

MR. ANDERSON: I'm not trying to argue the point. I'm just trying to explain why I think --

MR. DOPP: I'm articulating my perspective.

MR. ANDERSON: Right.

MS. DILLEY: Bill, you had a comment? And then we need to start wrapping up actually.

MR. GRIFFITH: Yeah. Okay. Just a couple of things, and one is, you know, there's been a lot of discussion around system design and implementation. I think everybody agrees that that is something that's very important to the overall HACCP plan. I mean that is the basis and to food safety and industry.

Again, system design is very subjective as to how you look at that and how you can score it. I want to a second or agree with one of Mark's comments earlier on if we are going to come up with an algorithm, that's going to define risk in a facility, that it needs to be from quantitative measures, and certainly system design is almost -- I think it would be very difficult to give a measure to that, but many

of those other components that are listed on the page, food defense notwithstanding, I think there's a place for food defense, and it's very important, but I don't know that it would be considered a big enough part of establishment risk control to be in this list. But those are measures again that would help you determine if system design is appropriate and if implementation is appropriate.

And I agree with another of the comments that NRs and FSAs are simply that's what we have, and I think again, this may be a play on terminology, but system design and validation should be performed by the industry while verification of our validation is what needs to happen through the food safety assessments, and that's pretty much how it's working to date.

MS. DILLEY: Let me just make sure I got the right language. Verification of validation.

MR. GRIFFITH: Right. Industry is tasked with the responsibility to validate their food safety systems, and in turn FSIS verifies that that validation is appropriate basically to defend that

plan.

And the last thing is since NRs and FSAs are pretty much our only -- well, not only, but one of the tools that we can use, and I think Rosemary was getting to this earlier in the day, a NR that under appeal should not be utilized in contributing to that risk algorithm. It can't be looked at until after the appeal is up.

MS. MUCKLOW: We like that idea.

MR. GRIFFITH: Because again NRs are subjective, and they can be appealed, and I think that is industry's responsibility if you feel that the NR was administered inappropriately to appeal that NR.

That being said, we just need to make sure we don't have that going against our algorithm.

MS. DILLEY: Okay. Kim, you had your card up and then I'll start looking over what we talked about.

MS. RICE: I just wanted to say that there are a lot of us in this room that have responsibility for multiple facilities, and we can't sit in our offices and look at plants on paper and tell whether

they're doing a good job or not, whether they're in trouble or not. We have to actually go out and be in that facility and walk through the facility and watch what's going on, and doing all those things.

So the algorithm, while we're probably going to have to come up with something, it is not the thing to be the be all, end all. It should determine whether a plant falls into one category or another, because there are too many things being fed into there where the data or the quality of the data is questionable, especially in the beginning. It is still going to require that people -- that those classifications of plants are, and I hate to use the word, but it's the only word we've got, are validated. Okay. NRs along, looking, and the Agency has found this again and again, looking at the number of NRs written in a plant does not tell you whether it's a good plant or a bad plant, because you can go in there and the NRs that are being written may not be good quality NRs, and the plant may not be appealing them and getting those bad NRs taken out. That's just the reality.

So we need to be very careful that we don't use a math equation to determine whether plants are alone. It needs to be get in the plant, looking at what's going on, and using all that information to determine where a plant goes.

MS. DILLEY: Irene, did you have one last comment?

MS. LEECH: I'm curious about that look-back window, and how long information -- I think of it as how long information should be available and, you know, I heard a response in terms of another inspection, but do you start over or do you carry some history?

For example, our consumer credit reports, they keep all the data for seven years, and it rolls off after seven years. What in terms of -- do you want to see that there's a track record? Positive or negative. If you keep a track record, a positive for a long time isn't as hurt badly by one little problem, and yet somebody who has a lot of things, that's where it shows up. So that's why I'm wondering if you need some kind of a combination there.

MS. DILLEY: Does the look back need to be standardized? I mean would you have the same look-back period for all, regardless of category of plants?

MS. LEECH: Well, you have a starting point in the reg. There's a requirement basically that falls in line with the shelf life or general shelf life of the product in terms of record retention. That's one place -- one thing we have, one set of numbers.

MS. DILLEY: So shelf life --

MS. LEECH: One year, two years. I think one years and two years -- one year and two year are the only two, and then there's a yearly reassessment on HACCP and on your SSOPs, it's an as needed, and maybe a minimum of one year. I think it's as needed. I don't think it's -- SSOPs aren't yearly, yeah.

And I would tell you that while the industry average is three years for FSAs, that is not my experience at all. It is at least yearly if not more often. So -- and that is not for cause. It's really frequent if it's for cause, but your not for cause are at least yearly.

MS. DILLEY: So are you saying that an annual, yearly look --

MS. LEECH: Yearly --

MS. DILLEY: -- is kind of what you're doing anyway?

MS. LEECH: I think yearly is a good, is a good -- once a year, sitting down, going through all of your data, looking at all the changes. I mean there's a requirement that if I change my process, I've got to go through the whole -- change my flow diagram, change my -- go through and do a reassessment, make sure that the decisions and the assumptions that I made in the initial design are still good and accurate. Do I need to change my monitoring frequency? Do I need to change my critical limit? You know, there are those requirements and those are good general scientific practices. If you change something, you've got to make sure that what you have in place to monitor it is still good and accurate.

So I think if a look back, a year, is a good place to start.

MS. DILLEY: Okay. Chris, you had a comment on look back?

MR. WALDROP: I have a clarification question from Kim's previous statement. You were saying that you can't like sit in the office or sit in your office, look at the algorithm, you have to get into the plants. So are you saying that it's not -- it shouldn't be 100 percent data driven? Are you saying there's qualitative things involved there or not? I was confused by where you were headed with that?

MS. RICE: I think that you can't rely on a math problem that's based on subjective data. I mean in order -- the algorithm as I understood it, and may be I don't understand it, Mark's already pointed out one thing I didn't understand today, yeah, victory for you -- but they're going to assign numbers to inherent risk, blah, blah, blah, NRs, FSAs and what not and come out with a number that says you're going to go here. And I don't think you can use FSAs -- I don't think you can assign a number to a FSA or to a NR and it be completely accurate. I still think you need to

get out and look at what's going -- trained people, who are not attached to the plant, need to get out there and look at what's going on.

MS. DILLEY: Okay. So I mean part if it may be the question, Chris, because I heard the same thing, and I wondered, you know, how do you actually start at a baseline level, and then how does that get modified up or down I guess is a way to look at it. What's a first cut at a level, a level of inspection effort, and then what are some variables that do include qualitative, getting out and looking at what's going on at the plant and then how does that factor in. I think we'll actually get into that in the enforcement discussion tomorrow a bit, and I'm sure it'll come up again.

Mark, you had a comment on look back, and then we need to review and wrap up.

MR. DOPP: On the look back, I just want to -- I may be the only one in the crowd who thinks this, but I'm a little reluctant to say one year, at least without the caveat that a plant ought to be able to petition or -- there ought to be some mechanism for

a plant to go to the Agency and say, you know what? Rather than do this annually, I have made changes, and the one that comes to mind is I think that for example, when they did the expert elicitation, I think they told them to assume everybody who was making RTE product was making alternative 1 or 3, 3, right?

You know, if a company invests a whole lot of money to move from producing alternative 3 to alternative 1, that may warrant a more frequent look back because they may be in a very different circumstance and may not, you know, frankly it may not be appropriate to have them be subject to inspection at level X, whatever X is, when they have changed their processes or they've done something else that is markedly different, that changes the analysis, and if they have to wait for a whole year, one, it doesn't make any sense and, two, it's a waste of resources.

MS. DILLEY: Okay. So really it sounds like maybe a year is kind of your baseline, but it may vary up or down --

MR. DOPP: It allows somebody the opportunity to request a change.

MS. DILLEY: Yeah. Did you have a question along that line, Don, and then Lloyd, but you need to use the mic. That's what you were reaching for. Sorry.

MR. ANDERSON: Yeah, there's been some confusion about the look-back period. You used the term once again that -- if we talk about a one year look-back period, we're not talking about doing downloading data once and then coming up with a score and then waiting a year and then downloading the data again and coming up with a new score. We're envisioning something more like a moving 12 month window, where we would have -- we would look back for 12 months of NRs and look back at the last FSA, and look back at 12 months worth of pathogen data. And then in some -- and then next month, for example, maybe we would do it weekly. Maybe we would do it quarterly, but maybe every month we would say, okay, another month has passed. Maybe what we would do is we would drop off the oldest month of data, bring in the newest month of data. It would be a 12-month moving window or a 6- month moving window. Because we

do recognize that things change. Plants put in new interventions. Plants bring in a new manager who does a better job at sanitation, whatever. So things can turn good or things can turn back almost overnight.

Now having said that, your point is still, you've still got a good point which is we need to make sure when certain types of things occur, that won't get caught with our regular inspection procedures, like if an intervention is put in, or if the plant starts doing its own testing or something, we need a way to make sure that we capture that in real time, and -- because some of these things tend to only get caught when we do FSAs, and if we only do an FSA once a year, then it would take a year to get that piece of information into the system. Does that help?

MR. DOPP: Yeah, because it's a completely different issue -- it's completely different than the way you described it.

MR. ANDERSON: Then if -- the way it came across is my fault. What I'm trying to do is clarify what we meant, and by the way, I thought I answered that question in the whole forum, in a six-month

context. But, no, we're talking about a moving window of data capture, absolutely. Not, you know, one snapshot every year or every six months.

MS. DILLEY: And, Don, does that -- is that done every month at the district level? Conceptually, where are you thinking that's happening? Is that happening here in the ivory tower or is that --

MR. ANDERSON: I don't know what ivory tower you're referring to. I don't work in one.

MS. DILLEY: Is it happening in the South Building or is it happening in the Annex or is it happening out in the hinder lands in the district offices?

MR. ANDERSON: I'll try to clarify this tomorrow, too, but all of the data on that -- all of the data in the six components that go under risk control, all of that data either is or soon will be fully automated electronic data in the Agency data warehouse that's part of our enterprise architecture. We are looking, we are most keenly considering that data, those data, because they are machine readable by the Agency databases or soon will be.

MS. DILLEY: Okay. So it's 23 of. I don't want to hold you any longer than quarter to, and you're going to be out of here and on your way home or to your hotel here shortly, but there are two things we will need to do.

One is to have one person be willing to report out the highlights. Again, we're not doing kind of a blow-by-blow piece of conversation but trying to extract out some of the key things that were discussed over the course of the hour and a half, and then try and just hit the highlights of what that might be.

Tonight, I will make a PowerPoint presentation so the people can see it tomorrow, and then those will be presented. Everybody will kind of have a chance to embellish or hit your favorite topic or whatever, but we want to have one person at least kind of give the highlights of the discussion, and I just wanted to make sure that I can reflect it back to you from my perspective, and see if we get it right so that I've got the information to go do the PowerPoint tonight.

Would there be somebody willing to volunteer to do that task? I want somebody designated to do it so that --

MS. MUCKLOW: Why don't we volunteer tomorrow.

MS. DILLEY: I mean does anyone want to volunteer themselves, and then otherwise, we'll turn to those who are being volunteered. This is the point in the conversation where everybody starts looking down and they start getting ready. Anybody dying to give a presentation tomorrow? Mark, would you be willing to do it?

MR. SCHAD: Yes.

MS. DILLEY: Good. Great. Okay. So let's just go along the lines of the questions. I won't take long to do this. We've got feedback on the six components. It sounded like food defense really dropped down, unless there's more information as to how that all fits into here. It's not like it really dropped down in terms of its weight, if you will.

The design and the implementation pieces seem to really be emphasized in terms of where they

fit in, in important. The others, the pathogen control and I guess the in-commerce pieces are ones that are very important, and I think there was more interest just in information in terms of what those mean, et cetera.

And I'm not sure -- let's see. What else did we say about the --

MS. MUCKLOW: Where are you going to put in the deficiency classifications for the NRs?

MS. DILLEY: Yeah, we're going to get -- we'll get to that. That's part of the implementation piece. We need to kind of go back and embellish on some of the discussions there. And we talked about -- let's see. That is later on in here, the NRs -- I mean the NRs and the FSAs were talked about. That's data that we have to work with in terms of looking at some information. I think the question -- there's also some really big questions in terms of things that came out of the discussion, the whole issue of how do you quantify kind of subjective information, where's that fit into the whole process and how do you incorporate that into -- where you do the kind of

numbers piece and then how you fit that with actually going on site and looking at what's happening. There was a whole discussion about roles and responsibilities in terms of is Government's role validation? Is it verification of validation? Is it oversight? What does that look like, and how's that fit with industry's role and how you're doing system design and implementation and verification of what you're doing on site. So those don't go to the particular questions but that obviously was a subject that we spent a fair amount of time on.

Let's see. There's some discussed of the category of enforcement actions. Again, some more information of what exactly that means and it seems like the penalties issue is an important one but it just doesn't seem to stick out as kind of a heavily weighted piece. Am I saying that right or is that incorrect? I mean it seems like an important thing, and penalties need to be assessed in terms of not following procedure, but it's a hard link to make with the rest of these components. And maybe they're subsumed into the implementation piece of it.

MS. MUCKLOW: The penalty that this Agency has is to stop operations.

MS. DILLEY: Right.

MS. MUCKLOW: And that's a very sever penalty.

MS. DILLEY: Yeah.

MS. DONLEY: What I'm saying is use penalties as a means --

MS. DILLEY: Short of that.

MS. DONLEY: Other than a piece of paper.

MS. DILLEY: But I think that -- and that could be part --

MS. MUCKLOW: That's a change in the law. That cannot be done under --

MS. DILLEY: And the pieces that I heard in terms of other areas that just haven't been, where does it fit in, is the -- let's see here. The attribution data, and how that -- does that drive it from looking at what has caused food-borne illness and how that fits into it? Does that drive it more in collecting that, and how you move that -- that that's maybe the data you start from and work into the

other -- the opinion, the subjective analysis later into the chain.

I think the whole question of human factor and subjectivity, I think that's whole -- Mark, you raised the issue of how do you take -- if you're using an algorithm, what's in and what's out of an algorithm? And if it's qualitative information, don't try to force it into a quantitative number but then how do you fit that in there, information in there at some point in terms of figuring out the risk of a plant or an establishment.

MS. LEECH: We need to change the appeal process.

MS. DILLEY: Yes. Thank you. We need to change the appeal process, how rapidly it happens and when, and does the appeals process go quickly enough to hold up its incorporation into how you're determination establishment risk. So timing of that, and the ability to do that rapidly. Am I missing anything? I'm just looking through these notes. And I have to admit, I'm a little tired. So I may not be saying it as articulately as I should be.

MS. DONLEY: So the NRs would be --

MS. DILLEY: To the NR flip chart, yes. I think we talked a couple of things about NRs. I think generally people agreed with the concept that not all NRs are created equal and that the ones that really should be looked at are those that have food safety relevance. They're not perfect but --

MS. DONLEY: I mean that's also a very subjective --

MS. DILLEY: How you determine that?

MS. DONLEY: How that is determined?

MS. DILLEY: Which have food safety relevance and which don't.

MS. DONLEY: Yes.

MS. DILLEY: Yeah. And -- okay. There's the referee one that we had talked about.

MR. TREAT: Can I --

MS. DILLEY: Yes, Gary. Can you please use a mic.

MR. MUCKLOW: Gary's come back.

MS. DILLEY: He snuck in just at the end for the summary there.

MR. TREAT: FSAs, when we first started having FSAs, it was consumer safety officers and they came in, CSOs and we have three different components. We had -- you were either perfect, it was a no action. You had a 30-day letter or you had a NOIE. They have in their changes removed the 30-day letter. So now you can be near perfect and you're going to get a NOIE rather than, you know, you're either no action or NOIE, and that 30 day letter was very valuable in a medium risk situation where you could address it without going through an NOIE.

So, you know, I think we would benefit a lot if we could get that, you know, have that three tier thing back, where it's either perfect, no action, a 30 day letter for minor adjustments or notice of intended enforcement action, but right now it's either you're perfect or it's a notice on enforcement action. And we need the 30-day letter inserted back into the system.

MS. DILLEY: Another step. Is that what you're saying?

MR. TREAT: Yes.

MS. DONLEY: Could you explain to me about the 30-day letter? Was there one 30 day letter or did you get one 30 day and then another 30 day and --

MR. TREAT: No. It was one 30 day and you had to react to that, and you had to satisfy --

MS. DONLEY: And then it went to --

MR. TREAT: And actually, when the consumer safety officer program started, it was a benefit to the plant. It was a let's work together to make things better, but right now it's, you know, you come in and you get a NOIE that you don't have a bad plant, but you're not perfect. And the 30-day letter, that says here, you need to -- you've got 30 days to respond and make correction, and it's a permanent correction. It's not a, if it doesn't happen, you get -- but, you know, there could be multiple -- if they came back in again, they could give you another 30 day letter but it wouldn't be on the same thing because you already have that corrected, but the 30 day letter was just a valuable tool for both USDA and industry, and now we've got that tool removed. It hurts them. They don't know what to do, and it hurts

the industry because we can't respond at that level.

MS. DILLEY: So it's quarter to. You guys have had an awfully long day, and I want to thank you for sticking it out the entire time, and spending time in these small groups.

Tomorrow, again, we'll -- Mark, you'll have the -- you'll do the presentation, and I'll have some PowerPoints ready for you. Maybe if you and I could get together like at 8:30 tomorrow.

MR. SCHAD: Yes.

MS. DILLEY: And then we start at 9:30, just to remind so you can sleep in a little bit.

So thank you very much everybody.

(Whereupon, at 5:45 p.m., the meeting was concluded.)

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 4

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.

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Timothy J. Atkinson, Jr., Reporter

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