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 2

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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

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MR. CHRIS BRATCHER
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DR. CRAIG HENRY
MR. TONY CORBO
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I-N-D-E-X

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

(3:45 p.m.)

MR. DeMORGAN: Let's turn our attention to question number 1 and, you know, as they said, they tentatively decided to use the median of the expert score in the inherent risk algorithm. Is there an alternative that FSIS should consider?

I think Bob had raised his card up.

DR. O'CONNER: I think there were a lot of good points brought up this morning about not having an upper limit, having a ridiculous -- I mean you could almost put a -- as your answer if you wanted to some of those risk assessments. So it's sort of a -- I think just that alone throws a lot of weakness in my mind as to what we get out of this analysis.

MR. DeMORGAN: Out of the expert elicitation piece?

DR. O'CONNER: Yeah. I don't understand why an upper limit was not set. I mean I think, when I as a veterinarian, when I look at, if I test birds or their titers, for their -- levels for certain diseases, I'll use a geometric mean in order to throw

out the -- because in some ways they're inexplicable.

MR. DeMORGAN: Okay. So more about -- and I mean clearly I guess let's spend a little bit of time, Bob's done it, and the question presumes at some level the expert elicitation makes sense to everybody, and clearly we heard downstairs that that's not the case, and we're hearing from Bob again and those are fine points to put out onto the table. Anything else on that, Bob? Dane?

MR. BERNARD: First of all, I think we heard very clearly that there's a lot of desire to take another look at that risk ranking, and I think that absolutely needs to be done, either a second level of review, a more open process, whatever.

Regarding the specific question, I don't know that we understand what the Agency intends to do with the median number in order for us to be able to determine whether that's a correct approach or not. I think if you look at the risk ranking, there might be some movement within the ranking that someone may -- but the ranking, I don't think is so bad. That doesn't mean it shouldn't be reviewed. It should be

reviewed. I think it should be another process, but for now we don't know what the median would be used for. Would that be used to allocate resources specifically against the number or would resources be allocated against the risk rank. And there needs to be some ability to adjust the ranking of the plan. That ranking of product would be a -- but we heard discussions about severity today. That is something that is a risk management decision. I think it should be the province of the Agency. Again, it can be done transparently and openly but the Agency has got to make some decisions relative to how it's going to use the concept of severity and make adjustments in risk ranking according to severity.

MR. DeMORGAN: So what I would encourage, folks, just because I know there's a lot of comments and conversation, is to not necessarily reiterate, not that Dane's done, I'm doing it before you start doing that, because we don't need -- I mean these are just going to be summary points. We're not striving for consensus. That's not what we're striving to do but it is helpful to hear, I mean if you've got different

opinions, that's also useful to hear, but I do want to mean, I mean what it seems to me what you're saying is I guess clearly we're hearing a lot of desire to reexamine the ranking, and possibly do more, different ranking processes.

But to the specific question of number one, I think what I'm hearing you say here, Dane, is that you don't know what FSIS wants to do with any number, whether it's the median or the mean or the high end or low, whatever it is, there isn't a clear understanding of what -- how that would factor into the algorithm from your perspective. Okay.

MR. BERNARD: The question is two parts. The alternative would be just to use the ranking rather than the median.

MR. DeMORGAN: Okay.

MR. BERNARD: The -- rankings.

MR. DeMORGAN: Let me get that down. I think it was -- so the alternative is -- an alternative is to just use the ranking. Again, you don't really know to what end, right?

MR. BERNARD: Right.

MR. DeMORGAN: But that's an alternative. Felicia.

MS. NESTOR: The first expert elicitation was packed with industry affiliated scientists. So I mean to consider the outliers on that, you know, is something to discard I think is, you know. There's a reason they were outliers, because they -- possibly because they were the public health professionals. So, you know, I just wanted to add that to --

MR. DeMORGAN: Yeah, I can actually put that piece up, but that was an alternative.

MS. NESTOR: And any other expert elicitation really has to be a lot more -- have a lot more legitimate credentials.

UNIDENTIFIED SPEAKER: For a variety of things?

MS. NESTOR: Yeah.

UNIDENTIFIED SPEAKER: And what is -- credentials?

MS. NESTOR: Credentials?

UNIDENTIFIED SPEAKER: Yeah. Educational, background.

MS. NESTOR: Yeah, that would definitely be one --

MR. DeMORGAN: So just --

MS. NESTOR: Is there a source of bias, you know? I mean even though there were a lot of academicians on that group, if they're academicians that depend on industry for their livelihood, you know, that's a source of bias -- potential bias.

MR. DeMORGAN: So just any new expert elicitation needs to have what?

MS. NESTOR: I think cannot be dependent on industry for its livelihood.

MR. DeMORGAN: So are you saying dependent on any one group or are you saying on a -- I mean are you looking for a balanced expert elicitation. Is that -- I'm just --

MS. NESTOR: We already have this elicitation. I don't see that we really need to hear more from industry but, you know, if it could be balanced, that's fine with me.

MR. DeMORGAN: So recognizing that we already have an industry perspective from -- Barb.

MS. KOWALCYK: I was just going back to the first point, and that was removing outliers. I would be reluctant to do that in this situation, although I would not completely rule it out down the road, in that you only have 23 data points here which is hardly a large enough sample size to then start eliminating -- actually if you look at it, there's like five or six people that had very -- five or six panelists that had very large assignments or scores that they used, and that's one quarter of the data. So I would be reluctant to remove that.

At this point in time what it would show to me is that there is some disagreement among the panelists and a large disagreement as to what the risk should be, and it would warrant further investigation.

Not only that, I mean when you're developing a model, and basically here they're kind of developing a scorecard, you want to validate it, and I think that, you know, what, what has the Agency done to validate whether or not the median is appropriate to use? I mean if they go ahead and apply this to the products and, you know, it doesn't kind of mesh up

with the data that they do have, although it be very little, such as number of recalls, things like whatever food-borne illnesses they have, things like that.

MR. DeMORGAN: So just to -- you said what has the Agency done to validate the median.

MS. KOWALCYK: Well, anytime you're going to have a measure or risk or measure of anything, you want to validate that as an appropriate measure, and I haven't seen whether or not that's been done. So I can't tell you whether or not the median is appropriate because they haven't done any validation step on whether or not it is appropriate.

MR. DeMORGAN: Okay.

MS. KOWALCYK: And you have to go back and look at the data and apply it to, apply it to what they have and say, does this jive with the other data we have in house to show us whether or not we've actually identified the riskier products or assigned risk appropriately in the situation, using the median, and if not, what is the other alternative?

MR. DeMORGAN: Okay. We'll go to Craig, and

then maybe we can transition to question two and see what thoughts there are about that.

DR. HENRY: The value certainly of the data as right now, I think you need to understand that none of the products currently inspected by FSIS to my knowledge or anyone else's, is risk ranked under any circumstances. In actuality, allocation of resources today clearly has merit, and this is more data driven now, depending on the expertise of at least by my count, 23, of which 4 were industry affiliated, all of the rest come from the university end or the Agency. Then if the universities are industry oriented, then this is heavily biased, but there is no reason to assume that be the case.

However, I think what's fascinating which Dane did bring up, which has merit, whether we do a geometric mean or whether we use a straight median or the straight ranking. I don't think anyone has brought any question to the table that the evaluation of the products is that far off. We're not seeing anything, even if you take the 300 million or the 2 million or the 2500 and look at those, there's not

been any discussion here about the lack of validity of the current ranking of the products. So it's as good a place to start, unless someone has a better one available right now to challenge it, which right now I'm not aware that there is any other data to challenge that.

The recommendation that I had made for NACMCF was a reiterative process that certainly has as much merit or more than any other that I know right now, be it selected by one stakeholder group versus another. The NACMCF is certainly quite herald and represents all the stakeholder entities, and which to go back now and if they're looking for consensus, use the NACMCF to get a consensus, because at least you have everybody in the same room and, of course, that can be done in possibly less than two and a half years.

But I think that we certainly need to take into consideration this evaluation as it stands today has merit and could be useful at least for the purpose of --

MR. DeMORGAN: Okay. So if you were going

to move forward, consider using this despite the concerns about the way it was developed conceivably?

DR. HENRY: Yes, unless we can come back and say that the people on here do not have sufficient credentials by which to do the ranking because the data that they used was quite expansive. I mean they used their knowledge as was the direction and process that they were challenged with, to consider these different products and how they would rank them. So there's quite a bit of information that they had available, including other models that were used by some of them.

MR. DeMORGAN: But what you have heard at least, I mean at least what we heard downstairs was there were a number of groups that felt like maybe they weren't represented in that.

DR. HENRY: Certainly, which I mean there's a whole lot of groups that are not represented but, you know, a simple question would be well, is there an ideal number. Should it be 100, 200, 300? How many would be correct, and do you need a balance of those to get to the science? Because this has nothing to do

with position. Either the science that the people used are correct data to evaluate the products or its not. Whether they work for the Agency, why they work for the university, whether they work for the industry, or whether they work for a consumer group or a public health agency, it makes no difference unless there's going to be an argument about the data, and I think that's the driving point here. Was the ranking based on current scientific data. That's the first point.

Obviously the outliers will have, and I don't care how many, that's a normal distribution that you'll see. You'll see the highs. You'll see the lows. You'll see the mean, and I think that's what needs to be taken into consideration.

MR. DeMORGAN: Okay. Dane, Barb, Kim and Tony.

MR. BERNARD: I'll be quick. Barb's suggestion about validating the model is right on target. Any model which you come up with should -- you should try to ground truth it somehow and the only way you can do that is to go to the outbreak data and

see how that rank holds up against what is known about public health outcomes from each of those product categories, and I think that's an excellent suggestion. We heard a lot about attribution during the meeting which is obviously very important. Unfortunately we have -- well, we have to designate what we've got but it's still not good enough relative to sporadic cases, et cetera. It is what it is and I think we should try to use it.

MR. DeMORGAN: Okay. Barb.

MS. KOWALCYK: I'm going to follow up on. I think you're absolutely right. I think the one point that needs to be made though is the outbreak data only constitutes four to six percent of all food-borne illnesses, and actually the definition of an outbreak can be kind of subjective to what the state decides having learned this personally. For those of you who are not aware, my husband and I lost our two and a half year old son, Kevin, to an E. coli infection in August 2001, and despite three family members testing positive with E. coli, we were not considered an outbreak. We were considered an isolated case.

But I think that we need to -- that's a good place to start but we also need to put in place mechanisms where we can actually get attribution data to continue to drive this thing forward. The expert elicitation, to go to Craig's point, the expert elicitation, I mean when I look at this form, that lists out each individual panelist, I see a lot of variation going on here which tells me that there's a high variance, in which case you would want a large sample size to kind of get a good idea of what the distribution is like. I can't tell you off the top of my head whether it's 100 or 200 or whatever. They would actually have to be some sort of an analysis that would go into it, and I think that the other problem with this specific expert elicitation is the fact that they were asked to assume a healthy population, to ignore vulnerable populations and to ignore severity of risk, and I don't know exactly how you can do that and actually assign risk, because it's not like you can have some guarantee that only healthy, middle-aged Americans are going to be eating these products. I mean a hot dog, a lot of kids eat

hot dogs, and that would certainly change its risk ranking.

MR. DeMORGAN: Okay. So I'm going to take the cards that are up and then I do want to make sure that we get a chance to touch on some of these other questions. Maybe there aren't answers. Maybe this is where everybody's energy is but I do want to move us there.

So, Kim, did you have an additional comment? Tony.

MR. CORBO: The only thing I wanted to add was the fact that I've had problems with what RBI has done for the Agency in the past, and this is another example, and very few of the experts did take the time to justify their scores here in the paper. So this has become big -- contention for us. Once the Agency -- I mean we had to wrestle this out of the Agency for them to give us this information. This paper has serious problems.

MR. DeMORGAN: And just so I've got something rather than paper has serious problems, what I think I heard you say was there's no laying out of

any rationale for numbers.

MR. CORBO: Yeah, there's very few -- very few of the scientists took the time to put their rationale --

MR. DeMORGAN: Yeah, or at least what's been shared.

MR. CORBO: Right.

MR. DeMORGAN: Okay. I'm going to move on and let's --

MS. KOWALCYK: I just have one quick other thing, and I don't see it up there, so maybe it's not important, but I do serve on NACMCF and I just want to get to -- I'm the only consumer representative that serves on NACMCF, and while I think NACMCF is a good committee, it certainly needs more consumer representation, and should not be the only thing -- the only place. Similarly, NACMPI only has three members, three or four members maybe that represent consumer interests. So you need to have a better balance in that respect, too.

So I don't want it to be -- I just wanted to clarify we're not just going to rely on NACMCF and

NACMPI.

MR. DeMORGAN: And that's N A --

MS. KOWALCYK: That's N A C M C F.

MR. DeMORGAN: Okay. So to the suggestion earlier this afternoon and then maybe a little bit here, that that may be vehicles for other --

MS. KOWALCYK: They're good ones.

MR. DeMORGAN: -- avenues, not necessarily sufficient consumer rep to cover the concerns.

MS. KOWALCYK: Right.

MR. DeMORGAN: Okay. Let's move onto question number 2, and I recognize, you know, a lot of this stuff, I don't think we need repeat this because it's going to relate anytime we talk about the elicitation, but let's see. The canned products weren't included in the elicitation. How exactly should they be fit into the range of species/process values now? So whether it's now or whether you did another expert elicitation, don't worry about that question, rather just generally speaking, how would you fit that issue in? Dane.

MR. BERNARD: I'd rank them high.

MR. DeMORGAN: High?

MR. BERNARD: High risk. The degree of control over that process is exquisite which translates to a very low level of public health concern but absent that degree of control, that's a very risky product.

MR. DeMORGAN: Okay. So 300,000?

MR. BERNARD: No. In the elicitation, I followed the rules and colored inside the lines and went 1 to 10. Had everybody done that, you wouldn't have outliers.

MR. DeMORGAN: Well, I did -- at least I heard FSIS say they didn't set an upper rule. So -- but I know you were part of it. So you'd have a take on that, but that's at least what I heard them saying. So -- but regardless, you use the 1 to 10. So you'd give them -- that don't really matter. We don't need to get into that, but you'd rank these canned products as a high risk?

MR. BERNARD: Low acid canned foods, absent that exquisite control that's in place, it's high risked canned foods. And since the Agency's model

separates out degree of control from inherent risk, then I have to say the inherent risk is high.

MR. DeMORGAN: Okay. So using the assumptions that they showed previously.

DR. HENRY: Yeah, correct. Just to concur with Dane, the other factor to take into consideration, you now throw in severity.

MR. DeMORGAN: What?

DR. HENRY: Severity, you know, should that be part of this, the answer's no, from the standpoint of -- I mean you can kill the child and you can kill the adult, with botulism just as quick as you can kill anything else, but now if you're going to roll this in, and Dane has already spoken to it I think in part, how many constraints do you put on the panel when they begin to go down that road? Do you always and acknowledge? Do you work to the worst side, you know, the youngest and the one with allergies, the one who is immune compromised? To what level do you constrain the elicitation to the point of ranking?

MR. DeMORGAN: Okay. And number 6 does speak directly to severity. So we will get to that

question. I know it's come up a lot this afternoon.

DR. HENRY: But they should certainly be included in the ranking.

MR. DeMORGAN: Okay. David.

DR. CARPENTER: I guess I have to address it to Dane. Why do you call commercially -- product high risk? I mean it's hermetically sealed. The documentation -- airtight and there's no environmental exposure.

MR. BERNARD: You're combining the degree of control with the inherent risk. Without that control, if it wasn't processed to the degree it's supposed to, then you have a high risk item. So it's the degree of control that's been implemented and adopted by that industry segment and enforced by the regulatory structure results in the safest supply of food that you've got in anyone canning, but it's the two together.

MR. DeMORGAN: And was that -- Dane, was that an assumption? I mean I understand it's also reality, but was it an assumption that was given to the folks that were doing the ranking for the other

products?

MR. BERNARD: Panel.

MR. DeMORGAN: The panel?

MR. BERNARD: I can't remember the exact instruction, but I'm responding to the model we saw today.

MR. DeMORGAN: Right.

MR. BERNARD: We're supposed to separate the two, and I'm assuming that that's --

MR. DeMORGAN: David.

DR. CARPENTER: Did the panel consider food-borne outbreak or illness attributable to -- product?

MR. BERNARD: In the risk ranking that we did?

DR. CARPENTER: Yes.

MR. BERNARD: Well, you know, as --

DR. CARPENTER: Historically --

MR. BERNARD: You know, we're going to jump ahead to six, but as personally, if you look at that list ranking exercise, it's impossible to separate out severity up here because you can't do a risk ranking without understanding the hazards that are associated

with the product, E. coli O157:H7. Otherwise, you wouldn't be able to do the ranking at all. So severity is kind of in there. You can't tease it out, even though we're instructed not to consider that.

Canned foods, if you look back at the history of food safety, back into the twenties and around the turn of the 18th, 19th Century, a lot of deaths from botulism, an uncontrolled situation until the science came in to put that whole process on scientific footing, imposed the controls that are there that was also a successful process to reinforce those with the inspection system. You have had a risky situation. Now we don't even think about it.

MR. DeMORGAN: Okay. So Barb and then Chris and Kevin.

MS. KOWALCYK: Well, I concur with Dane. I think it is a high risk product because if the process breaks down, you do have botulism as a big worry, and right now there has recently been an outbreak of botulism due to carrot juice, and so I think that this is still, you know, if the process breaks down, you have -- the consequences can be severe, and I agree

with Dane. You can't separate the two.

MR. DeMORGAN: Okay. Chris.

MR. BRATCHER: I concur, and I think you need to remember that if the Agency does not look at this and consider it a high risk, there would little or no inspection in those facilities. So it needs to be there. I'm not sure what presence it needs to be, but it has to be there.

MR. DeMORGAN: Okay. Thanks. Kim.

MS. KARWEIK: All I wanted to point out is that the actual instructions to the expert panel are included in our packet that we received today in a RTI memoranda, and it states that, "While scoring the categories, we will ask that you consider the biological, chemical and physical hazards inherent to both the source material and the processes used to produce the products in that category."

MR. DeMORGAN: That's page 8.

MS. KARWEIK: That's page 6, Attachment A to the RTI documents.

MR. DeMORGAN: And therefore --

MS. KARWEIK: Dane's comment that based on

risk that he would risk it high would be appropriate.

MR. DeMORGAN: It would be. Thanks. Okay. Anything else on that one?

(No response.)

MR. DeMORGAN: Okay. Question 3. If a processed product is to receive further processing at another establishment, how should we account for its inherent risk? If further processed at a retail site, how should we account for its inherent risk?

Kim, and then Felicia.

MS. KARWEIK: My comment to this is more of a question but if the -- if the process is to identify facilities that require greater inspection versus those that may require less because of risks associated, whether the product is further processed someplace else should not be part of the equation. The products that a company produces should be held to the same standards as --

MR. DeMORGAN: So from your perspective, it doesn't need to factor in.

MS. KARWEIK: Correct.

MR. DeMORGAN: Okay. Felicia.

MS. NESTOR: Well, I kind of understand that comment, and it would make sense to me if they hadn't told the experts to assume consumer processing habits. I mean if you're going to assess the risk of the problem at the problem door, then don't add in the factor of whether consumers are cooking it properly or not. As soon as you take that into account, as soon as you're going to take any of that into account, it seems to me with deli products, you really have to take a lot of them can be subject to temperature abuse. So if the product has a lot of pathogens or even some pathogens, when it leaves the plant, and then we know it's going to get subject to a lot of temperature abuse and will allow listeria to grow, that whole process is the thing that's going to possibly routinely make it a very high risk product, and the fact that they told experts to ignore that issue suggests to me why the RTE product is so low in the relative rankings of this group whereas RTE is considered very high risk in other rankings.

MR. DeMORGAN: And can you just note where that is? Is it -- do you have that?

MS. NESTOR: What?

MR. DeMORGAN: The directions to the expert elicitation?

MS. NESTOR: I'll look for that.

MR. DeMORGAN: I'd just like to pop that up there.

MS. NESTOR: Yeah.

MR. DeMORGAN: Because that will help. John and then Dr. Kim.

MR. MUNSELL: I believe that for this purpose, every plant needs to stand alone, and simply because one plant is sending products shall we say to a plant, for further process to a plant that makes canned ham, that is assumed to be sterile, that we should assign -- inspectors to that supplier plant I think is faulty. Each plant needs to stand alone on its own merits.

MR. DeMORGAN: Kim.

MS. KARWEIK: I just want to say there's really two parts to this question. And my question is relative to the first part, and that for products further processed at another establishment. The

second part of this question is if products are further processed in retail, they get equally ranked as well. And I'm not answering that.

MR. DeMORGAN: Okay. Great. Felicia and then Bob?

MS. NESTOR: It's the bullet, second bullet on page 8.

MR. DeMORGAN: Do not account for products that --

MS. NESTOR: Yes.

MR. DeMORGAN: -- are prepared at the retail or institutional level.

MS. NESTOR: Consider preparation only by the plant and the consumer.

MR. DeMORGAN: And the consumer. Right. Okay. Great. Thank you. Bob.

DR. O'CONNER: I'd like to say we're putting a lot of emphasis on microbiological data. It also depends on the chemical and physical. So really any plan has to consider, regardless of where that raw product is going to end up, at a ready-to-eat facility, they need to consider physical and chemical

as well. So I think that would be a reason to consider that first --

MR. DeMORGAN: Physical and biological?

DR. O'CONNER: Chemical.

MR. DeMORGAN: Chemical.

DR. O'CONNER: Most of our emphasis, and I understand, is on biological microbes, but physical and chemical should be considered, too.

MR. DeMORGAN: And so because of that, you think that -- you're saying that you should consider another establishment piece?

DR. O'CONNER: Yes, the first facility that produces any product needs to -- you can say microbiologically less negated because it's going to end up at another plant that sterilized at level 1. I'm saying it still needs to be under inspection --

MR. DeMORGAN: Right.

DR. O'CONNER: -- physical and chemical.

MR. DeMORGAN: So you're agreeing with John then. Every plant stands alone.

DR. O'CONNER: Yes.

MR. DeMORGAN: Okay. And that's rationale

for that. Okay. Dane and then Chris.

MR. BERNARD: And we're on number 3 here?

MR. DeMORGAN: Yeah.

MR. BERNARD: I have a different approach to this. Let me speak to what Felicia mentioned earlier about number 2. At least in my interpretation of that, and this is tough when you get this list of things and say, well, nobody eats raw chicken. You would have to consider that it's going to be cooked by somebody and, you know, forgive me, but consumers are a less controlled environment to insure proper processing than a commercial establishment. That's the way I approached it, and that's not in the instruction. So that's just my reading into this, what as a food safety -- I hate the term expert, but as one of the elicitors, if that's appropriate, that's the way you have to approach it, is to look at each of the products and determine whether it was going to be prepared by the consumer, what residual risk is left, and we know that ground beef for example, there's a lot of uncooked ground beef on purpose, 35 percent or so. On the other hand, with chicken, rarely is it

undercooked. At the same time, you have a much greater potential for cross-contamination with that item just because it's handeled. There's a lot of data on that. So as we went about that, at least from my standpoint, that's what I looked at in that particular step.

The way I'm reading question 3 here is as a processor of hamburger, if I have a customer and that customer happens to be a, I'll pull a name, Stouffer's, and they're using all that hamburger in meatloaf that's prepared in their establishment, are you as concerned about the inherent risk of that product? Should that influence the inherent risk assigned to that particular plant? And it's a question, not a statement. My answer to my own question would be if that relationship can be documented and proven, then the Agency may want to consider that. On the other hand, if the plant that it's going to has an over inventory supply and they sell off into the marketplace and there's all kinds of things that can happen in that scenario, I think it would be virtually impossible for the Agency to

consider that. I think it should be on the table for discussion, but I think it's virtually impossible to lock that in tight enough that establishment A would receive a lower risk ranking because of the customer base.

MR. DeMORGAN: Okay. So you've posed a new question, answered it, and then taken it off the table.

MR. BERNARD: I wouldn't say it's impossible, but it's going to be difficult considering the market conditions that are out there, to say it's always going to happen that way.

MR. DeMORGAN: Okay. I just need to check in. We're getting onto 4:30 already, and we're on question 3. We've got three more in this one, and then we want to go. So I just want to note for folks is that we're going to spend a little less time on the establishment risk control. So how much discomfort does that cause anybody.

UNIDENTIFIED SPEAKER: Some discomfort.

MR. DeMORGAN: Some. Okay. So then I would just encourage, recognizing that there are mechanisms,

you can submit comments to these questions to the FSIS' website after this, we will have more opportunity to discuss it in greater detail tomorrow, but let's be honest, it's a large group. So you won't get a chance necessarily. So keep that in mind as we go through the next few questions so that we can move onto that establishment risk control. Chris and then Lamar.

MR. BRATCHER: The next to the last bullet and the bullet before that, we talk about every plant should stand on its own and we need to consider chemical and physical.

MR. DeMORGAN: Yes.

MR. BRATCHER: We need to remember as a group that there are small plants out there that provide products for a lot of people. It's not uncommon for them to prepare fully cooked food and send it somewhere to be smoked at an off-premise smoking facility or something like that. So you have to consider I guess the risk for the microbiological at that facility because you don't know what they're going to load that product on, you don't know what the

condition of the equipment is during the transportation, and you could introduce all kinds of hazards, post -- and those types of -- so these would be considered particularly in the smaller plants I think because they have less control. They're not working on as huge a budget.

MR. DeMORGAN: Okay. Lamar.

MR. HENDRICKS: The answers to number 3 is no and yes. How should we account for the inherent risk? You're talking HACCP systems, take them through HACCP analysis, the -- processing is inspected based on risk assessment of the product and the HACCP plan. So it doesn't need further inspection. It's addressed as incoming from another establishment. So it's already coming in and they have to address it at that point when it comes into the establishment.

As far as retail, I think it would be -- because it's our responsibility under our food safety systems to go all the way to the consumer. So it's our responsibility to make sure the systems are in place and the product is safe all the way --

MR. DeMORGAN: Okay. So a little bit of

some diversity came in there, primarily people are saying no, at least for another establishment that it's captured. Chris pointed out that at least for small groups, small plants, it's not as simple as that, not as cut and dry, but let's move onto 4.

How do we translate volume data collected for each type of processed product produced at each establishment into an exposure variable for that establishment? John.

MR. MUNSELL: I feel that if plant A produces 10 times as much product as plant B, it should be a 10 to 1 ratio. It's also true that the inherent risk of that product needs to be added into the variable also but volume is volume. We're talking about the same item, 10 to 1, 20 to 1, or 2 to 1.

MR. DeMORGAN: Which one I guess would be my only question?

MR. MUNSELL: What if plant A produced --

MR. DeMORGAN: Oh, I know, but what's the one that starts that all. Is there a one that starts that all off, you know.

MR. MUNSELL: Well, 1 would have to be a

minimum that they might anticipate a very small plant.

MR. DeMORGAN: Okay. I think Lamar went up and then let's go to Felicia, Craig, Barb, and then we'll just do what we can. Lamar.

MR. HENDRICKS: I respectfully disagree with that, and I can tell you what my thoughts are on it.

MR. DeMORGAN: Yes.

MR. HENDRICKS: And I thought about this earlier today when we were talking about volume. I ran into a friend of mine who produces one product, small by comparison. He produces that one product very good -- If I produce that same product, that one product, I can produce it as safe as he does because I'm an expert in it, I have the resources, my CCPs are in place. I monitor, I validate all those systems. I have money to put behind that validation. So my product is just as safe.

However, if I produce 500 products or 50 products, I might not be. So I think it doesn't relate specifically to volume. I think it relates to the complexity of the system as far as volume is concerned.

MR. DeMORGAN: So it depends on the complexity -- I mean I understood what you're saying, but I'm trying to --

MR. HENDRICKS: I think it's dependent more on the complexity of the system rather than strictly related to volume.

MR. DeMORGAN: So the plant system, what's happening at the plant, number of products.

MR. HENDRICKS: Right.

MR. DeMORGAN: Felicia.

MS. NESTOR: I think there should be a minimum amount of inspection at every plant regardless of the volume that they produce, and regardless how low risk the product is, if a plant makes a large volume, it has to have, you know, the volume has to factor into how much inspection they have because one mistake at a huge plant, I guess that sort of adds onto the complexity point, one mistake at a huge plant has real public health repercussions.

So I don't know exactly how that should be factored in as a multiplier or as added or how that should be but definitely even with low risk products,

a high volume plant needs a significant amount of inspection.

MR. DeMORGAN: So you're saying, I mean not that you're answering saying Lamar or John, but you're saying more like John's model at least, that if it does a lot of volume, then it's going to have in your mind a lot higher likelihood of needing more inspection.

MS. NESTOR: Yeah.

MR. DeMORGAN: Without knowing whether it's a 2 to 1.5 to 1 ratio, or an actual something to a 1 ratio, but you're saying that. Okay. So establishment risk control to decide. Craig, Barb, Kim, Chris, Dane, Kathleen, John.

DR. HENRY: It should be third dimensional, the balance between the two.

MR. DeMORGAN: What?

DR. HENRY: Third dimensional.

MR. DeMORGAN: Three dimensional.

DR. HENRY: Yes. Not to either X or Y enterically.

MR. DeMORGAN: Like somebody suggested.

DR. HENRY: Right. It should be third dimensional because that way you can take your --

MR. DeMORGAN: Is that clear, understandable concept to -- I mean if you said that to everyone, is everyone going to understand third dimensional, what that means? Yes, you're shaking your heads. No nos. Okay. Thanks. Barb.

MS. KOWALCYK: I would agree with Craig and that was actually one of the things I was going to bring up, is it should a Z axis. However, I think that there's some -- I also agree with what Felicia says, that there needs to be a minimum amount of inspection. If you are a plant that produces the high risk product, and you are a plant that has poor establishment control, i.e. a level 5 plant, I don't care how much or how little you produce, you should have more inspector resources. So I mean when you get into the high risk categories, on the level 4s and level 5s, I think that volume really doesn't play as big a role as it does when you're looking at high product risk categories that are being done well or low product risk categories that are not being done

well, where volume would be hazard.

MR. DeMORGAN: Okay. Kim.

MS. KARWEIK: No, I --

MR. DeMORGAN: Dane.

MR. BERNARD: I believe John was up first.

MR. DeMORGAN: Kathleen.

MS. KRANTZ: I was just going to agree with Lamar, that the integral processes of multi-species, multi-product lines would be a consideration versus --

MR. DeMORGAN: Okay. Great. Thanks. Chris, then John, then Dane.

MR. BRATCHER: I think we heard Barb say some things about if they had one process, for example, O3G in a plant, and that's all they produced, that the inspection would be based on what they're doing, and the things they're doing.

MR. DeMORGAN: Barb Kowalcyk or Barb --

MS. KOWALCYK: Masters.

MR. BRATCHER: Masters.

MR. DeMORGAN: Okay. Just confirming.

MR. BRATCHER: And we saw that when they did the method of reassigning the work in the plants

earlier in the year. I guess it was last year actually, and put a lot of these process plants on patrols.

To give you some background, I have a plan like that in my circuit that produces 12 to 15 million TV dinners a week. So we put that on a patrol assignment because they only have one process. It has the highest number of NRs of any plant in the circuit. It's also the second or third highest in the district. So for my thought process, I feel that there's risk involved there in that particular establishment because of the volume and because of the background that we have, although the Agency has chosen to take and put that with other plants on a patrol assignment, to take away from the amount of time that our inspectors spend there.

MR. DeMORGAN: Because it's -- just to clarify, because it's one product. Is that what you're saying?

MR. BRATCHER: Well, it's not one product. They produce one process.

MR. DeMORGAN: Okay. One process. Thank

you.

MR. BRATCHER: So the process is the same. They produce TV dinners with pork, beef, chicken and turkey.

MR. DeMORGAN: Okay. John.

MR. MUNSELL: The gentleman brings up a good point back here in regards to complexity, and I agree. But something else he said I believe even has much more impact, and that he mentioned about -- . If indeed that plant and in -- USDA sampling validates the efficacy of that HACCP plan, then that plant should be eligible for reduced coverage. To me the bottom line in this is ongoing validation and from a risk-based inspection standpoint, if a plant can consistently validate their success, then they deserve diminished inspection.

MR. DeMORGAN: Okay. And obviously that's going to happen. We're starting to talk a little bit about things in that establishment risk control PC equation and clearly that's -- I mean ultimately that's what so complex about this, I mean integrating all these different factors. So I think Dane was last

on this question and then we're going to question 5.

MR. BERNARD: On a hot dog by hot dog basis, the risk presented by a hot dog, big plant, small plant, may be the same depending on the controls in place but let's assume it's the same. The population based risk from the large plant is much greater than the smaller plant. That's the volume part of the equation. Increased population based risk goes up, and in that case, you do need a higher level of assurance of risk control in that facility. I heard John disagree with Felicia, that that does not translate into more inspectors in that facility. What it means is what are they doing, how well is it controlled, can they validate and verify that it's controlled and the canned foods example is a classic example. It doesn't take much inspection to insure safety in canned goods. The FDA visits the plant twice a year. We're not advocating that as a system, but we're known to have great problems from low acid canned foods from a FDA facility. We don't have great problems with low acid canned foods from a USDA facility. There's different level of inspections but

it gets to the level of control and how can you verify and validate that level.

MR. DeMORGAN: Okay. And, Kathy, is that back up?

MS. KRANTZ: I apologize.

MR. DeMORGAN: No, it's squared off. So I can't tell if it's up or down. Okay.

Question 5. Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented?

So at some level -- well, that's not quite the same question. Barb.

MS. KOWALCYK: Well, I think if you're going to go at this from a public health standpoint, you would want to take the riskiest type of product and assign that to be the inherent risk for that establishment just because of cross-contamination purposes and so forth.

MR. DeMORGAN: So if you've got three products, one's a 1, one's a 3, one's a 5, whatever scale, you take the 5 to all 3 products.

MS. KOWALCYK: You apply it to the establishment.

MR. DeMORGAN: To that establishment. Okay. That's what it says. Thanks. Craig.

DR. HENRY: Just to hinge off that, I think ultimately at the end of the day when we get done with this, you can take any plant regardless of what it's making, and find a reason why we should have -- around the clock and have 100 of them regardless if you find the reasons. Our goal though is certainly to try and take the available resources and apply them in some reasonable fashion from high risk to low risk, which is like what Dane said, to take a plant that has very good inspection for canned soup, that goes through the same process, just because there's chicken in it, and now we throw full-time inspection where under FDA it's not there, certainly defeats part of the process in getting the allocation of resources. I would submit that taking the process which Barb brings which is correct, if you've got somebody that has a very high risk, I would suggest that that be balanced against the volume associated with that product, you know, if

I'm making 1,000 pounds of ground turkey, and I'm making a 1 million pounds of full cooked chicken in a bag, it doesn't make sense for me to throw that much resource at something that has ground turkey of 1,000 pounds. So if it's balanced geometrically, so that you weight the average weight with the resources against the risk associated with the product volume. Now you have better control over how many people you throw in the process and, of course, that gets back to establishment control.

MR. DeMORGAN: What was the word you used. The balance -- not geometrically.

DR. HENRY: You balance against volume.

MR. DeMORGAN: Right.

DR. HENRY: Risk balance against volume associated with that product.

MR. DeMORGAN: So that's another conceivable way to do it. Kathleen and then Barb.

MS. KRANTZ: I just think that we also need to consider the inspection process. Now we're looking at inspection. Is it science based? Is it the style of verification? What is the type of inspection for

this process that we're looking at as well, and that that is also something for consideration in this issue when you're looking at the inspection and the heightened inspection for the inherent risk product. What are we actually looking at?

MR. DeMORGAN: Barb.

MS. KOWALCYK: Well, in the example that you gave, Craig, about producing ground turkey and ready-to-eat products, I mean the problem is, even if you're not producing a high volume of ground turkey, the potential for cross-contamination, and then you've got a ready-to-eat product that could cause serious illness because it's probably not going to be further cooked by the consumer before it's consumed. I'm not convinced that volume plays as much a role in it as what you suggest. I think that, you know, if you're going to go at this from a public health standpoint, and you have a facility that is producing multiple types of product, the most conservative approach to protect public health would be take the riskiest product and assign that overall. And really volume is on your Z axis. So that's going to be kind of I think

taken care of if you're going to a three dimensional model.

MR. DeMORGAN: Right, and I mean I think that's helpful to just remind us. I mean it's hard to because sometimes we're just -- you're just looking at the one thing you're being asked to look at as the factor and then you step back, and right now at least, there's a whole slew of establishment risk -- to get you to that final number.

MS. KOWALCYK: Well, I guess in this situation, I would -- I'm assuming that you are working with a three dimensional model because it makes the most sense, where volume is your third dimension.

MR. DeMORGAN: And, Felicia, you have agreed that that's a good way to consider moving forward. Dane. That is the Z axis. Dane.

MR. BERNARD: I've got this situation in one of my plants that produces ready-to-eat meat and poultry products. There's already a risk ranking system in place for listeria control and those kind of plant, category 1, 2, 3. 98 percent of the products

produced in the plant are category 2, because of the way they're processed with deserts, so one, et cetera. To afford customers from that plant a full line, to serve their whole line, we have got to accommodate some category 3 products in the plant. Because of that small volume that's run a couple of days a week, that plant is now classified as a level 3 which means we get sampled more often by the Agency which means we get a different level of inspection -- is that a waste of resources or not? We're handling it. It doesn't bother us. That's the cost of -- of doing business, but is that really the best use of resources?

MR. DeMORGAN: Okay. And then you're pointing out that at least from a company perspective you're okay with it. The question is, as Craig was saying, if it's from FSIS' perspective --

MR. BERNARD: Is there something else that should be considered --

MR. DeMORGAN: Right. Okay. Last comment on this. Kim.

MS. KARWEIK: On question number 5, and this is really warrant of a comment about the 24 categories

that were ranked. Number 1 and number 2, when you talk about the complexity of the facility or the product base at the facility, one of the things to me that is certainly missing from this whole equation are raw materials other than meat and poultry -- FSIS has focused in on raw materials, meat and poultry, and not so much on raw materials that maybe are going into a finished product that don't go through a -- step in that final mix. For instance, raw vegetables going into chicken salads or raw vegetables going into other kinds of ready-to-eat products.

So when you look at number 5, yeah, I guess I feel like there's a dimension that's still missing in the entire process, or at least there's some categories in products that aren't being incorporated. So the only place to pick them up is looking at the complexity of the product that they use.

MR. DeMORGAN: Okay. Okay. Question 6, then and then we'll be done with this, and we'll move to establishment risk control. But before we move there, this will be the only incentive, the leverage point I have left to me. I need to identify somebody

who's going to help present this tomorrow. So before we move to establishment risk control, I'm going to need to find -- and what I might ask is two people to kind of represent different perspectives help walk through this after so we can spend the time talking and kind of highlight some of the key points that we collectively want to represent for the group.

But before we get there, question 6, about severity -- how should we, FSIS that is, account for severity of possible illness when calculating the risk inherent to each type of meat or poultry product? Is that a tough question or is it fine? Barb.

MS. KOWALCYK: I feel like we've already kind of talked about this question --

MR. DeMORGAN: A little bit, yes.

MS. KOWALCYK: -- before and I'm going to -- I think it's really impossible to or very, very difficult to separate the severity out from the different product, from the rankings to begin with. So I don't -- I guess I don't understand the question. I think it should have been considered right from the beginning.

MR. DeMORGAN: Okay.

MS. KOWALCYK: I disagree with them asking experts to not consider severity of illness to begin with.

MR. DeMORGAN: Okay. Dane.

MR. BERNARD: I don't have an answer for it either. It's tough not to consider severity because you've got to consider the hazards associated with the product before you can come up with any kind of ranking or rating. At the same time, if you were to consider some low severity, there's a range of severity ranging from mild to a couple weeks' illness to hospitalization to mortality, and the same thing for virtually every syndrome. So in an expert elicitation, you can deal with that sort of segmentation in a risk assessment, where you can say, give me the risk of, and then you put it down by severity -- but when you have to combine all of that and come up with a single output, I don't know if anybody was ever successful to integrate it to the concept of likelihood of occurrence and severity, come up with a single number that represents risk for an

item. It's always done in two parts. It's always done in the likelihood of an adverse consequence, and then it's done as here are the adverse consequences broken down by percentages of the population affected, the population that may be affected by those particular syndromes. And so while I agree that it should be done, I don't know that anybody's solved the equation adequately.

MR. DeMORGAN: Okay. Lamar.

MR. HENDRICKS: I tend to agree that it's too complicated a question. If you look at the first piece of that, it's tough to answer that question. If you look at the second piece of it, how should we account for the severity of the possible illness when calculating risk, I think perhaps that, depending on the product that's produced and the segment of the population that you intend to sell the product to, maybe a piece of that answer, I'm not sure, but when you put your programs together, you intend to sell your product to children, for example, you have to address that in your system. And you have to put in processes so that that segment that you're selling the

product to is addressed totally.

MR. DeMORGAN: Okay.

MR. HENDRICKS: If you're selling to the general population, that food safety system addresses the general population. If you're selling to the aged, it's addressed to the aged. So it's a very complicated question to begin with, and I think too complicated to address.

MR. DeMORGAN: Okay. David.

DR. CARPENTER: I have to concur with that because not only determining what the product and the population is, you have to consider the severity of -- for instance, if you sell soft cheese, and there's salmonella and it's consumed by a healthy individual, the impact is going to be a lot less than soft cheese consumed by a pregnant woman who -- listeria in the cheese. So there is two very different levels for one product. So the two populations. So I agree that it's complex.

MR. DeMORGAN: To throw it into that first, the ranking.

DR. CARPENTER: How would you require -- I

mean think the best --

MR. DeMORGAN: So how do you do it in the step -- I mean it just what Lamar's saying which is, you know, it depends on the product and who it's intended for? I mean then you can't necessarily say that all that soft cheese is going to go to healthy people obviously in that example. How -- is there a way to account for it maybe not in the risk rank phase but in that second phase or step that you can think of?

DR. CARPENTER: I don't know. You can disagree with me if you like, but probably the best data, the meat article back in '99, when it talked about 76 million food-borne illnesses and how if it's an -- toxin, a very small percentage gets reported, and we're just using numbers that were almost -- well, they derived statistically. Whereas, the effects of listeria was like 50 percent reported. And so that severity of illness generates or drives the reporting which could give data regarding or better data, but it's up to the consumer in terms of it getting reported if it is a food-borne illness or outbreak.

MR. DeMORGAN: Okay. The cards that are up right now, and then let's see where we are so we can at least spend, you know, 20, 25 minutes on establishment risk control. Bob, Dane.

DR. O'CONNER: Using the example you used with listeria and cheese -- as the most vulnerable population, you would assess your risk on -- it's a fact that a lot of people, the general population, but then within that general population there are the most vulnerable, and look at them and the severity --

DR. CARPENTER: That would be, I guess, the worst case scenario, right?

DR. O'CONNER: Right.

MR. DeMORGAN: Okay. Dane.

MR. BERNARD: Well, Bob really had the point. I think from our perspective, if you can't say that a particular of the population is excluded, you've got to assume that the general population means that there's some adverse -- populations that are going to be consuming your product --

MR. DeMORGAN: Barb.

MS. KOWALCYK: I concur with Bob, and that's

the way I think it should be done.

MR. DeMORGAN: You concur with Bob. Okay. So we have nine flip charts, some good conversation. I guess are there -- what I'd like to do is we have a little PowerPoint for the six questions. We're just going to put in a couple of bullets under each one and not try to -- this is not a consensus by any means. We're going to do it for this paper, and then to the extent we get through some of those as well. Is there one or two of you, if it's two, to kind of represent different groups or interests, that would be willing to just stay with me a couple of minutes after. I'll do all the work in terms of putting it together, but just kind of walking through the flip charts.

DR. HENRY: How about Barb and I?

MS. KOWALCYK: Okay. It depends on how long.

MR. DeMORGAN: Barb.

MS. KOWALCYK: It depends on how long.

MR. DeMORGAN: Yeah, 5, 10 minutes at the most.

MS. KOWALCYK: And we can even adjourn, you

know, we had to do it as a group at some level, but I think you'd rather -- so we'll adjourn around 5:25, in this group. So we've got 25 minutes to talk about establishment risk control.

Is there any problems? Does anybody else want to get in there instead of Craig or Barb, or everyone's okay with those two working with me to present, and you'll all get an opportunity obviously once they kind of talk through the points to add anything of note. Okay.

Okay. Let's go to the establishment risk control. That is the other July 19th paper that's in your document, and there are no I think additional documents related to that as there were for the product inherent risk. So -- yes.

UNIDENTIFIED SPEAKER: My question I pointed out earlier with this, this paper --

MR. DeMORGAN: Yes.

UNIDENTIFIED SPEAKER: -- should be raw and processed meat and poultry products instead of one side of it raw and the other processed and it's all titled processed.

MR. DeMORGAN: I see. Okay. So I think there might have been a copy error in looking at this. Okay. Yes. Thank you. I'll just note that on the flipchart to make sure we don't forget.

Okay. Question number 1 related to establishment risk control, are these six components, and those are the six listed. They're not actually listed in there. I guess they're listed in his presentation in this thing.

MS. NESTOR: They're in the little circles.

MR. DeMORGAN: Yeah, it's the circles. Right. It's the six circles. It's not listed in the paper. For some reason there's five of them there. I'm not sure which one is missing. Food defense I think is missing. Okay. So those six on that, that we all spent some time talking about. Are these appropriate and adequate, and what I think, I think it was Don mentioned this, that really there's kind of two sub-questions. Are these six appropriate? Are there others that should be added? Kim.

MS. KARWEIK: Actually I guess one of the things that I heard earlier today and I thought it was

a good question is in the actual matrix, the X Y matrix or X, Y, Z, whatever it is, who are above level 5, what happens to that facility, and then I feel bad when I look at the wheel that we have, and I see enforcement action, it says if the facility is in the middle of an enforcement action, they're already increased inspection frequency. So how that actually fits into this I'm not sure, for general inspection assignments. If a plant is an enforcement action, there's a whole other set of parameters that's already being implemented at that facility.

Now if you mean by enforcement actions that we're all done with the enforcement and your inspection is continuing and it's held in abeyance or whatever terms are used, and you have a six month window which you're looking at data, and that's what they mean by enforcement action, great.

But I guess I have some -- the definition of some of these is not necessarily clear in order to answer the questions whether or not they're appropriate. And, too, if you have a NOIE, NRs are being written, you have sort of a double whammy. You

have the enforcement action plus you have the NRs that are written as a result of the NOIEs, so you're getting hit twice. So you're kind of double dipping if you will under that scenario. So there's some overlap I guess in this wheel I guess is what I'm trying to say.

MR. DeMORGAN: Okay. So overlap and definition. Okay. Felicia.

MS. NESTOR: There are a sign number of plants that do not have standard inspection because of inspector shortages. We don't know whether the lack of NRs is because the inspector hasn't been in the plant. The Agency absolutely needs to figure out which plants don't have NRs because the inspector hasn't been there or because the inspector's been doubled and tripled up and has been doing drive by inspection, running in the front door, waving and running out the back door.

That was an instruction, Dane. That's an instruction to inspectors in a southern district.

MR. DeMORGAN: So FSIS needs to figure out which plants don't have NRs and why. Okay. Dane.

MR. BERNARD: I'll borrow from Lamar the yes and no on this. It depends on the weighting and how these things are going to be utilized. I think we heard today in the public meeting about a good many concerns about the adequacy of the data that has been found in each of these databases.

MR. DeMORGAN: It depends on the weighting and --

MR. BERNARD: It depends on the algorithm that's going to be applied and how each of these factors are going to be considered. I think a lot of us on the industry side have a great deal of concern about how NRs are being used, numbers of NRs, quality of NRs, a lot of variance there, a lot of variance. And the FSA is the same way. Our experience is that we've got some great EIAOs out there, and some are still learning -- and all are out doing FSAs to a certain degree and the quality of the FSAs vary widely. So I think we have a lot of concern about the quality of the database that can be derived from each of those sources, and that's where the black box comes in. What's the algorithm? How's it going to be used?

So I don't have any problem theoretically with the elements there. I just don't think we know the quality of the databases.

MR. DeMORGAN: Craig.

DR. HENRY: I think we'll tag along with what Felicia said, but I think we need to have a little different perspective. I don't think the issuance of a NR is an indicator as to whether the plant should be or is not being inspected. The fact should be that plants must be applying with the statute and the regulations. So if a district, for whatever reason, is not able to access a program inspection to that plant, and FSIS has a problem whether there's been a NR issued or not, the NR is an ancillary issue because you can have top flight plants that get virtually no NRs, producing a billion pounds a year, and that doesn't mean that the inspection doesn't occur. So I think that FSIS needs to be held accountable if, in fact, they have a problem with resources in meeting the statutes and regulations.

And the second part relative to the other components, I raise a question again about the food

defense and that certainly should be a much lower element on ranking or rating.

MR. DeMORGAN: So that would be the next question. Okay. Let's see. Lamar and Barb and Chris.

MR. HENDRICKS: I agree food defense ought to be out of the picture. It has nothing to do with it. It's addressed separately through an entirely separate bureaucracy system, the carver shop and all that type of stuff. Those fit in here. I concur. That's where I was going.

MR. DeMORGAN: Well, no, you didn't -- he just was -- he answered the question. It's not necessary at all. You were just saying it's a lower ranking.

UNIDENTIFIED SPEAKER: Well, we had to. We had to.

MR. DeMORGAN: That's good. That's good. That helps. I understand. So, Lamar, you're saying it's dealt with elsewhere and it doesn't need to be part of this, and at least one person's concurring. Okay. Yeah, Barb.

MS. KOWALCYK: I actually concur with that. That wasn't my --

MR. DeMORGAN: Thought.

MS. KOWALCYK: Yeah. In my mind, it's kind of like it gets to -- you don't build a fire engine just to deal with arson fires. You build a fire engine to deal with contamination and I don't really care whether it's intention or not intentional, and when your child is in the hospital, you don't care either.

The thing that I think is missing here is food-borne illness, the food attribution data. It doesn't really show up anywhere. It kind of comes in, in the -- oh, I don't know which one it is, the in-commerce findings when you talk about customer complaints but there's really no consideration as to, you know, if a plant has caused a huge outbreak, how is that kind of -- or caused a large number of illness, how does that kind of play into this.

I'm going to use a personal example right now. In our son's case, his PFGE pattern matched that of a meat recall in the same time period from a plant

in Wisconsin. Now we were never able to conclusively conclude that that's what caused his illness, but I would hope that the fact that you have a child who died from a food-borne illness that matches the same PFGE pattern as a positive E. coli test from a plant, would trigger added inspection at that plant, whether or not the family could actually prove that the child consumed that recalled meat. Now the fact is, it took our family three years, several threatened lawsuits to even find out that he matched that meat recall. You know, I have real issues with this idea of validated -- what did they use? Verified and validated consumer complaints. That is the only place that they actually even hint towards, you know, whether or not these establishments have caused food-borne illness.

And also whether or not this is an ongoing issue. The plant in question, in our son's case, had had a recall in December 2001, had positive *E. coli* tests in February 2000 or a recall in December 2000, positive *E. coli* test in February 2001. In July 2001, there was an outbreak traced back to this plant that

resulted in an E. coli test that my son's test matched.

Now I would hope, you know, do you have verified and validated consumer complaints there? It kind of depends on what you find as verified and validated and how would that fit into this? Is that a consumer complaint? It doesn't fit into any other category from what I can tell.

MR. DeMORGAN: So this is -- just so I'm getting it down right, this is too restrictive from --

MS. KOWALCYK: Well, it depends on how it's interpreted.

MR. DeMORGAN: It's not clear what it --

MS. KOWALCYK: No, and it certainly doesn't look at food-borne illnesses. And there's no mechanism for victims of food-borne illnesses to easily trace their source. So it's almost impossible to get that information in a timely manner at this point in time.

MR. DeMORGAN: Thanks. Chris.

MR. BRATCHER: Just an example. If you were going to give a salmonella based FSA, and you were in

the process of presenting interventions to your facility at the time, if they came in and did that and they found that you hadn't gotten those in place and validated, you could have a failure for your pathogen control, system design, system implementation and end up with a NOIE. So you just picked up four out of the six, and you're probably going to get a NR on top of that. So there needs to be some mechanism in place to balance the consequences.

The other would be the same as if you had all those things in place. There should be an incentive for the companies to have less inspection, and I don't think they mentioned that but it's been brought up before. So there should be a mechanism in place for people to have premier systems in place and not have to worry about repeated FSAs and things like that.

The other thing, we talked a lot about NRs and the data that goes into the system, and I work with that every day, and there's an inherent problem in the system and that's the span of control of the supervision above those levels, starting at the

district office all the way down but primarily at the front line supervisor position.

The Agency has identified that as a major problem for the last several years -- and the only way I see that we get quality data entered into the system is if somebody, one, is accountable, two, is able to do something to make sure that the NRs that are written are appropriate and for the right reasons. Three, they're written in the first place according to the reg and they shouldn't have been written that they're held accountable for doing that as well. The same thing applies to the other information that's going into the system as well, and that we would hope that you would send a message that the Agency needs to be held accountable for the correlation process that's ongoing and should be ongoing.

MR. DeMORGAN: I missed that last part because -- just because I was moving around. So for the NRs, you're saying there needs to be some mechanism to correlate between who's writing what and whether --

MR. BRATCHER: Whether it's for the right

reason or not.

MR. DeMORGAN: Right.

MR. BRATCHER: Whether it's for the right regulations or not. I mean it just goes on and on and on, and there's not a mechanism of checks and balances in place to make sure that those things are being done because there's too many other tasks, interference things that are going on in addition to that. And I can see from this meeting that when I get back, there's going to be a hammer coming down on my supervisors to make sure all the NRs are written correctly.

MR. DeMORGAN: Okay. Tony.

MR. CORBO: Going back to the -- issue, I think the Agency's got to figure out what it wants to do in this whole subject area because as I indicated earlier today, I've been listening to some of the audio tapes of some of the feedback sessions that the Agency conducted, and originally food defense was supposed to be part of the discussion and they decided to drop it off. Yet in listening to some of the employees, you know, talk about variability to do

their inspection functions properly, a lot of them say they're being pulled more and more into doing the food defense activities. And, you know, I was interested to hear the industry today saying, you know, this was like out of the blue, all of a sudden, you know, this thing just showed up. It's part of the wheel.

So, you know, the Agency has got to figure out what it wants to do here. Another thing, a lot of the food defense programs that they have, are voluntary by the industry, but it seems now that they're at least inspection personnel more into playing a more active role in that, and this wheel now all of a sudden has food defense.

MR. DeMORGAN: Okay. Thanks. John.

MR. MUNSELL: I believe two parts of that wheel, and correct me if I'm wrong, Paul, but aren't they pathogen testing and in-commerce findings?

MR. DeMORGAN: Oh, yes. Sorry. You don't have it in front of you. Pathogen control and in-commerce findings, those are two of them, yes. Thank you.

MR. MUNSELL: I think those are both very

valid components. However, I think that they should be further defined. I would like to see the Agency explain further on both those issues that those are best utilized when -- Agency attempt to find the true origin of contamination. And from a public health standpoint, as long as that leak can be -- as long as the contaminated leak can be detected and removed from the marketplace, then probably health benefits. But if the effective corrective action is to be implemented to prevent recurrences, we need to get back to the source. I think that's what this is all about.

So I believe that the results of pathogen testing and also the in-commerce findings need to be coupled with a very aggressive attempt to find out the true origin of contamination and existing Agency policy in some cases is designed to prevent that.

MR. DeMORGAN: Okay. Felicia, are you up again?

MS. NESTOR: It is up.

MR. DeMORGAN: Sorry. Go ahead, and then Bob.

MS. NESTOR: I really am concerned that we just don't have enough data to make these assessments of these plants. If, you know, as I was mentioning in the bigger meeting, if FSAs are done every three years, and then at certain plants you don't have any inspectors writing NRs and, you know, and 25 percent of the plants don't have any pathogen control, I mean I hear people saying that, you know, you can get a double -- it sounds like double, triple, quadruple whammy, if you've got a problem at your plant, but how many plants are out there where we don't really have any substantial data on any of these six factors. And I would really like to see an analysis by the Agency to tell us, what percentage of plants are we going to have data for six of these factors, for five of these factors, for four of these facts, because I suspect that, you know, it could be a good half of the plants we're considering that there's a really a minimal amount of data.

MR. DeMORGAN: Okay. Bob and then Barb and then Kim, and then it's going to be close to the end, to wrap up unfortunately. So at that point, if we

have any time, I'll just say, is there anything about these other five questions that we didn't get to that you really want to put on the table at this point, but recognizing that we've got limited time. Bob.

DR. O'CONNER: I'll try to --

MR. DeMORGAN: No, that's all right.

DR. O'CONNER: I think that -- the fear that a plant should truly be a category 5 comes out as a category 1, and I believe Dr. Raymond said that probably wouldn't happen, that it's too extreme. It may be too extreme but I could easily see if NRs in particular that we use to assess processing plants, plants being in this category, and in both ways, you know, good plants being seen as bad and bad plants being seen as good, and I kind of have personal experience with that. In the -- who work for me, I look at their NRs every week and I can see that there's a disparity between plants, but it's not necessarily based on that quality control -- in his or her program. It really is subjective, and there are things that are out of control for that facility.

So I'll give you an example. If an FSA, a

rumor that a FSA is coming in that plant, you will see an increase in NRs and, you know, that just shouldn't be. It should be consistent -- you know, throughout that year. And I have one example of a plant that has very low NRs, and they are a good facility but I kind of know why they have low NRs, because ISC there is very communicative. He takes, you know, discrepancies or situations that he comes upon, and instead of writing a NR, he will -- he has said to me, I use it as a teaching tool, and he will communicate with the processing plant vendor. This is very well what we need to do in this situation, but that does keep their NRs low, but that doesn't mean they don't have any situations similar to the plant manager whose plant has, you know, twice as many. So I just think it's a very, very subjective piece, and I even use the word data in accordance to use.

MR. DeMORGAN: Okay. Thanks. Barb.

MS. KOWALCYK: I think that there's a lot -- well, let me just back up. I mean I have, as I stated earlier downstairs, I have serious concerns about the quality of data and whether or not they are reflecting

the data, and I think that there are some things that the Agency needs to take into consideration.

Felicia brought it up. You have this wheel, and where are some plants that are going to have missing data for different spokes on the wheel, and sometimes multiple. But one of the things the Agency's going to have to do is come up with a way of dealing with missing data. I'm a statistician by training. I've worked in clinical research my whole career prior to this, and when you collect data you do build in numerous mechanisms of asking the same question.

The one I'm going to use just because I think it can translate readily here is when you're collecting adverse event information in a clinical setting, you are going to ask what the outcome of that is, and one of the outcomes could possibly be death. Well, you also have a death form that you're going to ask. Was that because of an adverse event, and you're going to cross check these things. You don't rely on one question because people mistakenly, just out of human error, will check the wrong box or mark the

wrong thing. So you want to ask the same question multiple times so you can kind of get into the validation which I think, Dane, you brought up earlier.

But then you also have to deal with the fact that what are you going to do when you have missing data? Now if you're going to think of this in terms of public health, you're going to assign the worse case scenario in order to assess public -- in order to protect public health, and I think that those are things that the Agency really needs to look at.

I think you're right, the way NRs -- I had never seen a NR form before today, and I think that's very subjective and as a statistician, I would never want to analyze anything off of that thing. But I think you can certainly improve it so that you could get -- try and get better at the truth, and you would want to do that one objectively and with subjective assessments from the inspector.

I would think that you would want to set up a criteria for what is an objective way of assessing, will this NR -- was this NR written because it has a

public health outcome, but you would also want to get a subjective assessment from the inspector. Did you write this because you thought it may affect public health? And then if there's a discrepancy that you have an inspector saying, I wrote this because of public health but it doesn't technically meet the criteria, you would have to do some further investigation. You know, ideally you would have situations where they would both match but it doesn't always work that way. And how are you going to deal with -- this is very complicated. I do not see how they're going to solve this quickly.

MR. DeMORGAN: Okay. Kim.

MS. KARWEIK: My comment is more general, and I think it's been mentioned here today but the entire process of risk-based inspection cannot be set up as a -- it has to be a real, living system, and to that end, there needs to be quality assurance as well as quality control within that system, there needs to be feedback loops and process improvement opportunities that are built into the process and they're forced to occur in the process. And I guess

that's my comment. Whether you're looking at product risk or you're looking at process and plant risk, to me is just I think something that to me as an industry or anybody in consumer advocates would want to promote with the USDA continuing to drive home because it is a breathing, living process. However, whatever path they go down, they need to close the loop. When they have discrepancies in data, when they have missing data, they need to figure out how to adjust the system to prevent that from happening again.

MR. DeMORGAN: Thanks. Lamar. Last comment for now.

MR. HENDRICKS: Well, you opened the NR box, so I have to comment. There are two types of NRs you need to consider. The rest -- Number one, HACCP NRs related to critical control points in the process. You should never -- a plant's modification should never have a HACCP related NR because their system has failed. So I think that is the most critical -- some of the subjective components to these things. Those NRs related to the grass is high on the west end of the parking lot doesn't matter.

The second type of NRs that should be considered are those that do not properly address corrective action relative to food safety. That means it --

MR. DeMORGAN: Those that do not properly what?

MR. HENDRICKS: Address corrective actions related to food safety. Now you appeal those if you don't agree with them, but usually corrective actions and preventive measures need to be put into place for anything relative to the safety of the product, whether that's a potential situation where you have a -- with respect to following SSOPs or something, but primarily the HACCP ones, those related to your system, not producing or having a deviation in your system. Those are just key, and I think you need to look at the risk associated with those, that's where the risk is.

MR. DeMORGAN: Okay. It's almost 5:30. We'll take Felicia's, and then if there's anybody else who puts theirs up again, we'll take that one.

MS. NESTOR: This is in direct response to

his.

MR. DeMORGAN: Sure.

MS. NESTOR: The industry has studiously taken everything that it can out of its HACCP plan and stuck it in its SSOP plan or its pre-requisite programs. So to get a violation of a HACCP plan, you know, you've got to go out of your way because pretty much all of your controls are in every other plan.

Secondly, to that -- a failure to implement corrective or preventative action, is the only other important -- I disagree with that. If you got a NR, you already failed. You don't fail when you -- after you're instructed by the inspector that you have a problem, you fail to fix it, you failed the first time, because it was your responsibility to begin with not to get the NR. So -- no, I very strongly disagree with the corrective action is the only other important one.

SSOP, I have in my folder, I have a facilities based NR for direct product contamination, you know. Using the little tick offs is not going to be sufficient. There are too many food safety

problems that occur under other categories.

MR. DeMORGAN: Okay. Dane. This is the last comment, and then we are going to need to break, just for the summary folks.

MR. BERNARD: There are a number of other questions here that I wanted to address.

MR. DeMORGAN: And I think what we're going to do, what I would say, is that given it's 5:30, it's been a long day, I apologize that we didn't get to them. What's going to happen tomorrow is the groups that did talk about it, we are going to have -- that did talk fully about establishment risk control, they'll present their thoughts, and then you'll have an opportunity, all of you to offer additional comments at that point.

MR. BERNARD: So I don't get to talk?

MR. DeMORGAN: So I apologize. You can, but I'm just not sure anybody's going to listen, that everybody that needs to leave, that wants to leave. It's 5:30. I'll be happy to stay, but I know Barb and Craig have already agreed they'll stay a little further after to help summarize. So you should

have --

MR. BERNARD: Well, this is in direct response to Felicia. Actually, if anybody wants to go, bye. But I just wanted to mention the question I asked in the general session, the plenary, or the comment I had, the top circle here, the oval, pathogen control. We have lots of data. It's good data. I can't understand why a facility that is running as low in salmonella for a poultry slaughter plant that some of the plants represented here are, have to put up with the same level of inspection, the same frequency of FSAs as people who are running on the borderline of a performance standard or over. There isn't any incentive to that level of performance at the moment. I think Chris said it best, there can be a way to use that data. It's there, you can have it. We'll share our listeria data from fully cooked. We'll share our E. coli data from our ground beef plant. We'll share our salmonella data from our poultry slaughter plants. We'll show you that we're meeting and beating the performance standards, and we'll do whatever you want. And I think that data should be considered. It's

better than looking at the FSAs to judge a plant's performance. It's better than looking at the NRs to judge a plant's performance. And there ought to be some incentive to make that happen and get other plants moving in that direction.

MR. DeMORGAN: Okay. All right. Barb, did you want to --

MS. KOWALCYK: No, I was just going to -- I would agree that I think more pathogen testing would be useful and to use that as a measure, not just at certain points along the -- a single point along the process, but in multiple points.

But I think the other piece that we really didn't get a chance to talk about is that the HACCP plans need to be verified and validated. I think that's a missing component in this situation. I mean plants, and that kind of gets to the FSAs, you know, they are done once every three years but plants can change their HACCP plans at will, and there should be a minimum kind of requirement as to what the HACCP plans contain. I get very concerned when I hear about plants that produce ground beef that don't have E.

coli identified as one of their hazards. So I think there needs to be some minimum level in the Agency or some other authority needs to verify and validate HACCP plans.

UNIDENTIFIED SPEAKER: We get FSAs more often than once every three years. I'm sure there are plants in that category but we just haven't been that lucky.

MR. DeMORGAN: Okay. I want to thank all of you for your active participation today and throughout. Tomorrow morning, we are getting started at 9:30 again with just kind of some reflections on today and looking at what the agenda is, and then at 9:45, we'll turn to the small group presentations. So hopefully you all will be there to help Barb and Craig present those thoughts.

So thank you all and have a good evening, and we'll see you tomorrow.

(Whereupon, at 5:30 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 2

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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Sean Williams, Reporter

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