UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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RISK-BASED INSPECTION (RBI) PUBLIC WORKSHOP

GROUP 1

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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: KATHY GRANT, RESOLVE

PARTICIPANTS:

DR. DOLORES BEBLO
MS. PATTY LOVERA
MR. BOB McKEE
DR. JOE HARRIS
DR. JOE BLAIR
MS. JENNY SCOTT
MS. SANDRA ESKIN
MR. CHARLES LINK
MR. KEVIN DENNIS
MR. MICHAEL KOWALCYK
MR. JOHN ALLAN
MR. MATT COOK
DR. ANDREA GRONDAHL
MR. BILL POTTER
MR. SKIP SEWARD
MS. DORIS SIEFRING
MS. CHRISTY MARR
MR. BRYCE QUICK

I-N-D-E-X

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

(3:45 p.m.)

MS. GRANT: So why don't we just start with going around and just saying your name and, you know, what stakeholder you include yourself in, for everybody's benefit.

DR. BEBLO: I'm Dolores Beblo. I'm with the FDA, and I'm working on a model for risk-based inspection for the FDA.

MS. LOVERA: I'm Patty Lovera, and I'm with Food and Water Watch.

MR. McKEE: I'm Bob McKee (ph.). I'm with FSIS. I'm here as an employee representative.

DR. HARRIS: I'm Joe Harris with Southwest Meat Association. We represent mostly small meat packing facilities.

DR. BLAIR: I'm Joe Blair. I'm with the HACCP Consulting Group --

MS. SCOTT: I'm Jenny Scott. I'm Vice President of the Food Safety Program for the Food Products Association.

MS. ESKIN: Hi, I'm Sandra Eskin and I do --

for a number of consumer groups, and I'm also a consumer rep on the National Advisory Committee on Meat and Poultry Inspection.

MR. LINK: Is it my turn?

MS. GRANT: Yeah, it is.

MR. LINK: I'm Charles Link. What am I supposed to tell you? I'm the Manager of Technical Services for Cargill -- Meats in Wichita, Kansas. I'm on the National Advisory Committee --

MS. GRANT: Can you fill out one of these?

MR. LINK: I will.

MR. DENNIS: I'm Kevin Dennis with Perdue, Incorporated.

MR. KOWALCYK: I'm Mike Kowalcyk with Safe Tables Our Priority and I'm also a member of the National Advisory Committee for Meat and Poultry Inspection.

MR. ALLAN: John Allan with the American Frozen Food Institute.

MR. COOK: Matt Cook, Moroni Feed.

DR. GRONDAHL: Andrea Grondahl. I'm with the North Dakota State Inspection Program and also on

the Advisory Committee.

MR. POTTER: I'm Bill Potter, QA Tech Services with George's Inc. We're a poultry company --

MR. SEWARD: Skip Seward, American Meat Institute, trade association.

MS. SIEFRING: I'm Doris Siefring, Cooper Farms, Quality Services.

MS. MARR: Christy Marr, National Turkey Federation --

MR. QUICK: Bryce Quick, FSIS.

COURT REPORTER: Can I say one thing? You're going to have to speak just a little bit louder and enunciate because of the kind of strange set up we have here.

MS. GRANT: If we just came a little closer?

COURT REPORTER: Oh, yeah. But there's a lot of you and it's going to get crowded but --

MS. GRANT: We're obviously not using all the chairs. So --

COURT REPORTER: It would help though, yeah.

MS. GRANT: So we want to give this first

paper, inherent product risk, about a half an hour. So we're going to work through the questions, get as many comments, as many comments that you want to give, comments, options, that FSIS can take back and take into consideration. Any questions about what we're going to do?

(No response.)

MS. GRANT: All right. So the first question you have it on your papers, Michael Matthew -- Matthew Michael raised these questions when he was doing his presentation but the first question, FSIS has tentatively decided to use the median of the expert score in the inherent risk algorithm. Is there an alternative they should consider? Sandy.

UNIDENTIFIED SPEAKER: I'm sorry. Can I ask a threshold question --

MS. GRANT: Sure.

UNIDENTIFIED SPEAKER: -- that's related to this?

MS. GRANT: Sure.

UNIDENTIFIED SPEAKER: I know you want to get to the questions. There's obviously a lot of

concern about the expert elicitation that was done. Can we have a show of hands of people that have serious concerns about the validity of that? And I don't know if the decision would be you want to do it over from start or you would want to have some other group look at it, but to me that underlies my answer to that question.

MS. GRANT: Go ahead.

MS. SCOTT: Jenny Scott. Can we rephrase that question?

MS. GRANT: Please do.

MS. SCOTT: I would not want to go out saying I have serious concerns about the validity of that, but I would agree that more information would be better. This is one whole access of how plants are going to be ranked, and they need some more substantive basis for that.

MS. GRANT: I feel -- in general, I think everybody else wants to comment on that, but we certainly did want to, in addition to these six questions, if there were other things that are just really important that you want to say about these

papers, and we want to take some time to actually do that. So I'm sure FSIS would want us to do that as long as we're also getting to this.

Now are you saying you want to do that first or --

UNIDENTIFIED SPEAKER: To me what this question assumes is that (a) people are comfortable with the elicitation as it was done, and as to Jenny's point, that it's sufficient. That's all that needs to be done to plug into that axis to get the data. So I think they're absolutely related.

MS. GRANT: So would other people agree that it would be a good idea to just take a few minutes to get your comments about this expert elicitation and other suggestions for making it better?

MR. SEWARD: I think that's an okay idea, as long as when people speak they have something constructive to say about what their recommendation is to make it better. If you don't have anything constructive to add about how to make it better or how to achieve the objective, then there's no sense in raising it as an issue. So if people have, you know,

specific bullets this is what you should do, and I think a lot of them have already been stated previously in the meeting. So there's no sense in going over what's already been captured, but if someone has something new to add to what's already been stated, it's probably time well spent, but I don't want to rehear everything I've already heard about suggestions on how to make it better. So if someone has something new to add to make it better, then we should capture that.

MS. GRANT: Yeah, I agree that we definitely want -- we definitely want ideas, any ideas that people have. I think people have a concern that wasn't expressed, that we need to -- for any of these questions, if there's any concern, you know, in the way you want to answer any of these questions, I'm sure that's something FSIS wants as well as any, you know, specific concrete answers to the questions. Did someone else have their hand up?

DR. HARRIS: Joe Harris. Along Skip's line, one suggestion that I have, and I do have some concerns with the way it was approached in terms of

the assumptions that were given, while at the same time, it's -- I don't want to get too carried away with my concerns on that because when I look at the bottom line, the ranking that they ended up with, frankly I somewhat am in agreement with the actual ranking, if you took the bottom line after they compiled everyone's ranking together. So I don't want to, I don't want to throw too many rocks at the process, but I do think that the assumptions that were given to the experts in order for them to do their rankings definitely need to be clarified and frankly I thought were a little too restrictive and did contribute to some of the sort out in left field responses that were noted earlier today.

MS. GRANT: Joe.

DR. BLAIR: I would like to look at it as a dynamic process, that this should be continually changing and improving as more data becomes available.

MS. GRANT: Everything?

DR. BLAIR: Right, this whole Y axis, and I would use that -- it's sufficient for me for a starting place. It's a reasonable starting place, but

not an ideal -- point.

MS. GRANT: Bill.

MR. POTTER: I'd like to talk about alternatives if we can.

MS. GRANT: Say your name.

MR. POTTER: Bill Potter. And the first comment, I thought the panelists had good credentials, the panelists had good credentials. The instrument that was used could have been better, and how to measure risk, there's a lot of people in this room that spend a lot of time measuring risk and do risk analysis. And the way that most people do that is they use formulas or equations and various things other than just road rankings and using the median.

For example, if you look at the panelists -- I'm repeating a little bit what I said, and I apologize for that, but some of the panelists have certain products at the very highest risk and other panelists have those at the very lowest risk. The panelists were of equal credentials.

So I think what you have to do, you have to look at the components of the risk, one being, for

example, the likelihood of that product category -- I don't know how to say this quick -- the likelihood of the product category causing a food safety illness and then the severity. This is getting back to the HACCP principles. And the severity of what would happen if there were an illness, and then somehow for raw products, you know, they were comparing raw and ready-to-eat products there. And somehow, there's got to be some measure of the -- shall we say the likelihood of products being fully cooked versus not fully cooked by the consumer.

So all of those things have to be put together in a model to develop risk, not just a road ranking, if I'm making sense there.

What we do in our HACCP programs, in the industry, what we do in HACCP programs, we try to come up with two things. The first two is the likelihood of the occurrence as well as the severity, and you can give those scores. You know, this can be scored, and then you could do the product of those, a simple multiplication product and come up with a risk factor. That might necessitate a third part of that equation,

the likelihood times the severity times the -- for raw products, the likelihood of the product being cooked or for ready-to-eat products, the likelihood of recontamination. Does that make sense?

So all of those can be put together to come up with a relative risk.

And I think what happened in the panel, I think the panelists all made assumptions about those in various ways. Some of the panelists, you know, were assuming that fully cooking products would never be recontaminated. Some were assuming that raw products would always be fully cooked, and that's not necessarily the case.

MS. GRANT: Mike.

MR. KOWALCYK: Michael Kowalcyk for Safe Tables. I can follow up on that point, Dr. Harris' point earlier about what the final ranking was and the reservations I have was the scope being so narrow. It's to your point of how you measure risk -- severity. But also before making a recommendation that median measure is a good measure, to start with that, it would be interesting to see that what Joe is

seeing as a reasonable ranking, does the data bear that out? Does the data that FSIS has, to put up against this, like the recall data, if it's food-borne illness data, from CDC, to validate that these experts are on the right track because it is a sample of 23 experts, albeit they are experts. We shouldn't even be talking about them, and I'm not questioning that. It's just the scope is very narrow and if you need a place to start, you should try to -- does the data actually bear that out.

MS. GRANT: Okay. Other comments or concerns? Jenny.

MS. SCOTT: You might have a point there. Also if you look at the expert documents that's on the website and look at the individual comments, you can see some thought process by some of them and why they did what they did and I think that if they had been put in a room together, they would have talked it out and they would have come out with a ranking that is probably more closer than the spread that they had on some of these. So I think it is a good idea to take it before some other group. I don't think the

National Advisory Committee on Microbiological -- is going to meet Caroline's requirements for --

MS. GRANT: That was just another panel of experts is what you're saying.

MS. SCOTT: Yes. But I think they can use it as a starting point, and it's a good starting point, and as Joe said, I think we're not in total disagreement with some of the high risk versus some of the low risk, while there may be some outliers, there was some justification for why people did that, and we're just having a group discussion to flush this out, will give a better picture for the Agency.

MS. GRANT: Other comments on the elicitation?

MS. ESKIN: Well, it kind of goes sort of this, not a verification, but a balance -- data anywhere relative to food risk. So I guess that would be important, sort of a way to cross check -- data from -- whatever's out there in the public domain, there are some groups that have done their own sort of attribution studies. I assume there's literature out there, too, that's publicly available maybe.

Back to Jenny's initial point, just don't use this one source of information to fill out your Y axis. Use as much as you can and if you realize there are gaps as was suggested, this is ongoing, make it a priority to fill those gaps in.

MS. GRANT: That was Sandra Eskin. Do you have that?

COURT REPORTER: Yeah, I'm sorry. Sandra Eskin. Thank you.

MS. GRANT: Other comments, concerns, suggestions on the expert elicitation?

Okay. So let's go back. That's good. The other things under these questions that we will also revisit but let's go back and start with this question again, should they use the median of the export score? What do you think? Jenny.

MS. SCOTT: Well, if they ever refine this and come out with a closer spread than what they have now, it would probably make sense to use that. Even with what they have now, the median is the best -- tendency as opposed to the average because we have such skewed results there.

DR. HARRIS: The 300 million --

MS. GRANT: Other thoughts? Do people agree with that? Does anybody disagree?

MR. POTTER: I do. I disagree.

MS. GRANT: Okay. Bill Potter.

MR. POTTER: Bill Potter. First of all, how did they rank them? They ranked them somehow. Based on what, you know? Median of what? Which category was the median?

MS. SCOTT: It was the ranking. It was the median of the rankings.

MR. POTTER: The ranking was based on what?

MS. SCOTT: Everybody ranked these from --

MR. POTTER: They ranked each.

MS. SCOTT: -- 1 to some number.

MR. POTTER: Okay. They ranked each category of food product. So which category did we use to rank them?

MS. SCOTT: But everybody has a ranking. They have 24 and the numbers that they assign to those gave rankings. So whatever the spread was, you could figure out this is 1 and this is 23 and 24, whatever,

and then the Agency took those and said, okay, even though this one rated at 300 million, was that 24th in the ranking or not. And so they went and assigned a specific ranking to the ranker and then they take the median of that.

MR. POTTER: The median by category, by food product category?

MS. SCOTT: Yes.

MS. GRANT: So in that case --

MR. POTTER: Well, I'd say no. I don't believe that's a good instrument of measure of risk. I would create a mathematical formula more something like we did with HACCP which is like -- this is really general but I'd say something like the likelihood of --

MS. GRANT: What did you say before?

MR. POTTER: The likelihood of a food safety hazard times the severity of the occurrence times the likelihood of mishandling.

MS. GRANT: I'm sorry. So likelihood of hazard --

MR. POTTER: Times --

MS. GRANT: -- times --

MR. POTTER: We're being redundant here but times the likelihood of occurrence or the severity times the likelihood of mishandling.

DR. BEBLO: Dolores Beblo. It seems that you're discussing different factors to consider whereas the question it poses, you have a distribution of data and how do you want to use the data, and so I think there's two different things being discussed here. If the question is how do you use the data, perhaps you could just use the whole distribution and you can do a probable risk assessment if you didn't want to lose any information.

MR. SEWARD: Skip Seward. MR. SEWARD: Skip Seward. Isn't it also possible for everybody's response to normalize those on a 1 to 100 scale and then, you know, so that they're all just 1 to 100, based on, you know, whatever their spread was for that individual investigator and then use that number to pick to the median they test, the same value.

MS. SCOTT: They just normalize based on what the 24 --

MR. SEWARD: Well, for each product category, you're going to have a range of responses from 1 to 3 million, 1 to 100, 1 to 10. If you normalize all those to a 1 to 100 scale, based on that individual's ratings, then you can at least normalize them across the same scale. You'd have the same distribution for each individual person but then it would be easier to pick the median as 55 or whatever that number is without skewing the results or bias in the results I believe.

DR. BEBLO: Yeah, I thought about that. But the question comes up is the confidence in the expert opinion then, my question -- I'm not familiar with all the details of the questionnaire that went out, why would a responder -- if given a high limit, why would a responder choose to either adhere to it or not. What is the message, and so you would have -- I think you're losing information of the confidence of the results if you do that. Perhaps before you do that, you want to go back and find out the answers to these underlying questions about --

MS. GRANT: About -- what was the thought

process? I need to --

DR. BEBLO: What was the thought process by the experts.

MS. MARR: Christy Marr, National Turkey Federation. The original expert solicitation told them to pick 1 as the minimum, the lowest possible risk. They did not ask them to give a maximum. There was no maximum. So it's not that people weren't adhering to it. It's that they weren't given that advisement.

UNIDENTIFIED SPEAKER: They were told to pick what they thought was the least and the most and then give the reason why and then what portion -- what number would you give the most and then fill in --

DR. BEBLO: And the highest was relative to the risk --

MS. GRANT: Okay. That was your clarifying hers. Okay. Charles and then Mike.

MR. LINK: Charles Link. Just to build your point, I think if you look at the data, the median might be a good way to take a number to put into your formula. If they were categorized in -- based on the

severity or -- something. You've got to start somewhere. So you take two or three guys and you pick your median -- but you do have to get back to, I think, before getting into doing all that --

MS. GRANT: Michael.

MR. KOWALCYK: To follow up on that, I think it's -- to use the median we're really not sure what context that median should be looked at in. If you've got some people on that panel that assigned a value of 300 million, obviously they thought that product was so much more risky than the least risky product, and then you also look at other expert scores, it's the same value over and over and over again. So a limited scope with the assumption as far as they have no severity of illness and albeit they are experts, it's only 23 experts at that point in time. Before agreeing to use a median that would be a key input to a model to help allocate inspection resources, I would be very hesitant to agree to that. I'd like more a risk-based methodology like Mr. Potter discussed.

MS. GRANT: So you're saying it's hard to do without knowing the context in which they made them,

how they come up with those numbers?

MR. KOWALCYK: Yes.

UNIDENTIFIED SPEAKER: You said risk based?

MR. KOWALCYK: Yes.

MS. GRANT: Okay. Any other comments on this question?

(No response.)

MS. GRANT: Okay. We can always come back. If something occurs to you, we can always add more.

So let's move onto question number 2. I'll read it. Thermally processed, commercially sterile products, which involve canned products, were not included in the elicitation for scoring by the experts. How exactly should they be fit into the range of species/process values now? Yes. Joe.

DR. HARRIS: I'll take a shot. Joe Harris. Obviously I think they need to be included. They are a USDA inspected product. So they have to be included in the list. Honestly, I'm -- I guess I'm not really sure why they didn't give them to the experts to start with. It would have been a likely place to start your risk with the lowest --

MS. GRANT: You heard that the explanation why they didn't.

DR. HARRIS: I did. I suppose I did. It must not have registered.

MS. GRANT: That that was so low that they thought it was -- that if that were a 1, it would skew the rest of them. And I'm going to say that's what I understand was the explanation.

DR. HARRIS: But the funny part about this is I looked at all the individual reviews regarding expert responses and they -- some of them specifically discussed in there how likely that product was to be undercooked or overcooked or whatever, and if the expert was willing to take those things into consideration, obviously a canned product, if you don't properly process it during the canning would be enormously high risk. It's just that the likelihood of that happening is it just virtually never happens anymore. So I mean it's got to be in the list. So I would suggest that it be fit in as the lowest risk product.

MS. GRANT: Okay. Do others agree with that

or would you do something different? I see a lot of heads nodding.

MR. SEWARD: I think we'd all agree unless somebody disagrees, speak up but it's the lowest risk.

MS. GRANT: Okay. I'm going to say that because I don't know if that's going to happen too often.

Okay. Let's move on to number 3. If a product is to receive further processing at another establishment, how should we account for its inherent risk? And it's the same question for retail. But for right now, let's just say --

UNIDENTIFIED SPEAKER: Further processing.

MS. GRANT: Is there -- well, they ask a different question. So is there a difference?

UNIDENTIFIED SPEAKER: Yes.

UNIDENTIFIED SPEAKER: Yes.

MS. GRANT: Okay. Let's start with another establishment.

MR. LINK: This is Charles Link. Is there a reason we don't look at it at the same establishment? I mean we're looking at a salmonella outbreak, for

example, we test, test, test a product that's going straight out of our chiller, straight to cook processing across the plant and around the corner, to where we're going to cook it. And we treat it just like a plant that -- sending it out to the retailer -- and it makes a lot of sense to do that.

So to answer your question how do we do it, how we do we rank the risk number, I'm not really sure, but I certainly think it needs to be taken into consideration, whether it's -- same stuff or -- the street. Retail's different. So I don't know. The question is how do we deal with it? How should we deal with the risk?

MS. GRANT: For this establishment, how do we account if it's going to be further processed at another establishment? It's like how do we account for it when looking at this establishment?

MR. LINK: I think it kind of gets back to Bill's point. If you look at the particular product category that you're manufacturing in plant A, and you go through the risk likelihood and severity, knowing that every bit of it is going to plant B to be cooked,

then you almost have to treat it as cooked. I mean you really can't -- it's not going to the marketplace, the raw product. So you can't treat it as raw. It's kind of confusing. I'm not sure how to answer that.

MS. GRANT: Jenny.

MS. SCOTT: I think it should have a reduced risk if it's going for further processing. That's what I'm hearing, regardless of whether it's processed at an integrated plant or if it’s shipped to another plant for further processing.

MR. SEWARD: It then assumes the risk ranking of that finished product, the cooked product or further processed product.

MS. SCOTT: As far as inherent risk, yes.

MR. SEWARD: Yes. So it assumes the product inherent risk of the product after it's been further processed. Skip Seward.

MS. GRANT: Does everybody agree with this?

DR. HARRIS: It -- yes.

MR. SEWARD: Well, if it's under the control of the establishment and it moves to another federally inspected establishment or to a different area of the

same federally inspected establishment and it's formed into patties and cooked, has a CCP to insure lethality at the required level, and then you have a fully cooked or partially cooked, which we'd have a different product inherent risk, but a fully cooked patty, which is exposed after cooking prior to packaging, that it would assume the product inherent risk of the finished product ultimately.

MS. SCOTT: But I think there's another scenario. There's the patty one. What if I'm making diced cooked chicken that's going into canned food? What if I'm making diced cooked chicken and it's going into chicken salad? Is my diced cook chicken then going to assume a canned food, a very low risk? Is that what we want to say? We have to picture a scenario and make sure how it works.

MR. LINK: Well, it's kind of like when you -- I guess when you do your hazard analysis to begin with. You have to know exactly where it's going, how's it being used. So you've got to go through the process. If it's going in chicken salad, it assumes a different risk.

UNIDENTIFIED SPEAKER: But it could be going to many. It could be going to both, right?

UNIDENTIFIED SPEAKER: Assuming the highest risk of a product line --

COURT REPORTER: I'm sorry. I have to ask again that you say your name because -- for the record.

MS. GRANT: So that was Charles making that point.

COURT REPORTER: I've got everybody's name. I know the characters (laughter), but for the record, it has to be on here. So thank you.

MS. GRANT: All right. So --

COURT REPORTER: I'm okay.

MS. GRANT: You're okay now.

COURT REPORTER: Yeah.

MS. GRANT: Okay. All right. So I actually didn't hear the end. So if it goes to both, it assumes the one that's most risky. Is that what the end result of that was?

DR. HARRIS: Joe Harris. I believe it's going to be dictated by the HACCP plan, the intended

use is going to be extremely important when it comes down to determining the risk of the product. It should be stated in the HACCP plan.

MS. GRANT: Sandra.

MS. ESKIN: This is Sandra, and also back to the HACCP formula, are you assuming other formulas like -- wasn't there also another factor as far as likelihood to be mishandled. There are many things besides further processing that would have to be factors into that.

MS. GRANT: So it does, it does assume the same inherent risk and/or other factors that have to be factored in. Is that what you're saying or it doesn't?

MS. ESKIN: No, I think it depends, it depends what we're saying. It depends on a number of factors. If it's chopped chicken going into chicken salad or chopped chicken going into chicken noodle soup, that's going to make a difference, as well as other factors that are considered in HACCP. Dr. Harris mentioned end user.

MS. GRANT: No, intended user.

MS. ESKIN: Intended user. Sorry. And I guess this issue of possible mishandling along the way, I guess that's something that --

MS. GRANT: Okay.

MR. POTTER: Bill Potter. Under HACCP, we typically make these decisions at the point the product enters commerce, and we describe products at the point they enter commerce, and I would think that that's when we would want to assign risk, is at the point of entry to commerce.

MR. McKEE: Bob McKee. I think though, Bill, that -- It skews the -- We can't assign risk there unless you consider commerce, the transaction between -- So you still have to be concerned with the initial risk and what kind of risk -- that product -- from there.

MR. POTTER: This is Bill Potter again. I agree 100 percent with your -- conceptually with those comments. However, if the product transfers ownership, it also transfers risk accountability. If the product -- once the product goes into commerce, let's say you've got a slaughter plant, they're

producing product, and they sell that to a further processor. Well, by transferring the ownership, they assume risk at that point. Therefore risk must be measured. If they did not, if they were -- if it was an internal transfer from a slaughter part of their operation to a further process that's just 100 feet down the way in the plant, I'm not sure that it's necessary to measure risk. I would think once that product was ready to enter commerce, it would be the appropriate time to measure risk.

UNIDENTIFIED SPEAKER: I thought we were dealing with transfer from one establishment to another?

MS. GRANT: Right. We are. In this question. Jenny.

MS. SCOTT: Jenny Scott. There's another aspect to this. If you think about some of the products that are shipped to another facility for in the package lethal treatment that reduces the risk, and should the inherent risk at the initiating plant be as high. Let's take lunchmeat which might be considered higher risk for listeria, but if it's going

to be shipped for high pressure processing at another facility, it comes out with a much lower risk, and it seems reasonable in that sense to assume that this product takes on the lower risk category. So there may be different cases. It may be case by case, and we're trying to make a -- statement here.

UNIDENTIFIED SPEAKER: We maybe can't jump --

MR. POTTER: Bill Potter here. I think we're probably in agreement on that. Back to what you're saying. I would suggest that when a product is transferred from one establishment to a different federally inspected establishment, that is an entrance into commerce. So there would need to be risk analysis in both places not either or.

MR. LINK: Charles Link. What if it's your own establishment 15 miles down the road? Is that entering commerce? I still own it. I still control it. I'm just moving it from plant A to plant B -- So that's another caveat I guess to throw in there.

MR. COOK: Matt Cook. I think that it should be treated separately just because you have to

meet certain requirements, temperature, regulations and all that within the first establishment before you move it. So I think that it should be treated separately because it really is treated separately in both plants or at least you assume it --

MS. GRANT: I want to encourage us to -- we're only on question 3-A, and I'd like to get moving.

DR. BLAIR: Joe Blair. I need to get back a little bit back to more basics. I think that FSIS is going to continue to depend on HACCP for the safety of the product, wherever it's produced or wherever it's cooked. What this system is doing is trying to figure out a more systematic and better way of utilizing resources within the inspection service rather than categorizing individual plants or inspecting their food safety programs. How are we going to verify what these plants are doing, in the most efficient, cost effective way, and that's a whole different thing than what we're talking about in terms of assigning risk in a HACCP plan. I think the HACCP plan is going to remain the basic food safety system.

MS. GRANT: So 3-B asks the same question but has to do with after it's processed and further retailed. Is there anything you want to say different about further processing and retail? Everything you said before applies?

DR. GRONDAHL: This is Andrea Grondahl. I think you have a completely different scenario with the product going to retail. There's no -- some retailers are going to have HACCP plans, but there's not the same regulatory controls in a retail parameter. So I think this is a whole different situation.

MS. GRANT: So -- and so how would you answer the question?

MR. LINK: This is Charles Link. If we're settled on -- I know you asked earlier, if we're settled on at the time it leaves the plant's back door, it's going into commerce and you already assessed that risk and it doesn't -- I mean you're basically saying it doesn't matter what happens to it down the road -- I don't necessarily agree with that. We don't have consensus. That's what I heard. If

it's going in commerce when it goes out the back door of the plant, we should assign risk --

MS. GRANT: Right. At that point.

MR. LINK: -- regardless of what happens to it afterwards is kind of what I heard. If that's the case, it doesn't matter where it's going to be processed.

MS. GRANT: And you disagree with answering the question that way. So how would you answer it.

MR. LINK: From the retail side, I think I agree with saying, once it leaves the back door --

MS. GRANT: Okay.

MR. LINK: -- all bets are off.

MS. GRANT: Okay.

MR. LINK: If it's going to another -- establishment, I think --

MS. GRANT: Okay. Others? Jenny.

MS. SCOTT: Jenny Scott. I agree with Charles. I think we can probably all agree on retail. It's different when you're sending something raw into retail to be cooked, to rely on them to do it properly as opposed to a federal establishment which has a lot

of oversight.

MS. GRANT: Right.

MS. SCOTT: But going back to what Joe was saying, using this as a tool for putting your resources where they ought to be, I think we have to take into account some of the risk. If I am making chicken that is going to go into a canned product, I'm slaughtering or I'm cutting up chicken and I'm going to stick it in a can, it shouldn't need the same amount of inspection on the cutting up side that it does on some other facility that is going to do something else with that product.

MS. GRANT: That's going back to part A.

MS. SCOTT: Yeah, going back to part A.

MS. GRANT: Okay.

MS. SCOTT: We hadn't reached consensus on it --

MS. GRANT: No, you didn't reach consensus and you had certain -- a list of factors that needed to be weighed. Okay. But I -- did you want to --

MR. SEWARD: This is Skip Seward, and I just want to see if we can't get consensus on what Jenny

just said which when it comes to risk-based inspection and allocation of resources, if the product is being produced at one establishment and goes to another area of that establishment, or to another area establishment, to another establishment that's under federal inspection, where there's a risk reduction step, that that product doesn't necessarily need the same degree of oversight as some other type product from another location. I mean does anybody have real exception to that or feel uncomfortable with that?

MR. McKEE: Bob McKee. Skip, in the real world, we find that the products are sent out with the intended use, the intended end user gets them, they don't approve and now they end up out in other areas of commerce where there's not complete understanding of what that product is, and it may be different from what people expect to get. So I think that we've got to be real guarded about lowering the risk when that product leaves plant A.

MR. SEWARD: Okay. Skip Seward. I think -- I agree that without really good traceability on that product through the system for it's intended use or

further processed use, that what you said is something that could be of concern. Yeah, I agree with that.

MS. GRANT: Okay. Let's move onto number 4 which is a question on volume. How do we translate volume data collected for each type of processed product produced at each establishment into an exposure variable for that establishment? Michael.

MR. KOWALCYK: This is Michael Kowalcyk from Safe Tables Our Priority. This is a tricky question because it's not really the product attribute. It's really the amount of that product. So we discussed earlier that would it be more appropriate in assessing establishment risk? It was also mentioned should that be on its own axis and I find that idea intriguing because it's not as simple as a two dimensional problem here. What scale it should be? I think that should be open for discussion. I think there were some good ideas -- rhythmic scale or some scaling to get a better measure than what was -- out there in that paper. So I think what I would recommend personally is some additional analysis into how that can be more integrated as an establishment attribute

or as an attribute on its own.

MS. GRANT: Okay. Anybody else?

DR. HARRIS: Yes. This is Joe Harris, and without actually jumping ahead to the next question, number 4 and number 5 are a little bit interrelated because if we're talking about inherent product risk and the volume of that product, and we're about to get to in number 5, the vast majority of establishments make a lot of different products, and now we're going to be talking about volumes of different products all have a different inherent risk and the relative volumes of those, and I'm at a little bit of a loss on how we could go about assessing a product risk for that plant as a result of all those interrelated factors.

MS. GRANT: So are you suggesting that we try to deal with both questions at the same time.

DR. HARRIS: I don't know that I'm suggesting to deal with those questions at the same time but we better be keeping number 5 in the back of our mind.

MS. GRANT: All right. Then just for

simplicity sake, let's stick to 4 with that caveat. Any other comments on 4? Any suggestions?

MR. POTTER: Bill Potter. I was just going to say that the only thing that comes to mind is that there is a plant profile that each establishment has to fill out every time there's a change of management or every time there's a new type of product that they run, and I hadn't seen one in a while, but I think you might even have to check the product HACCP -- the nine HACCP product categories that your establishment runs. It's not probably out of the question to have those plant management officials once a year or something like that go in and estimate, you know, their volumes, be it number of shifts or -- in fact, you already have to list number of shifts, but number of shifts or estimated volume, pounds, birds, whatever, head kills.

MS. GRANT: Okay. Other suggestions? Jenny.

MS. SCOTT: I was the one who suggested the third dimension, that it captures the volume -- and I'm hearing some support for that. So I'd just like to get that captured. They should look at that.

UNIDENTIFIED SPEAKER: That was the second point that Mike made on number of volume --

MS. GRANT: Okay. That's something I should add here?

UNIDENTIFIED SPEAKER: No, no, no.

MS. GRANT: Okay. Other comments on this or suggestions on this question number 4?

(No response.)

MS. GRANT: All right. So on number 5. Given that most establishments produce more than one type of product, how should inherent risk data for each establishment be presented?

DR. HARRIS: Clarification of the question. Are we talking about processed categories by saying different types of products? The 24 categories.

MS. GRANT: So does someone else have their card up? Sandra.

MS. ESKIN: I just -- yeah, Sandra Eskin. Again, it should be presented the way I read this, and maybe I'm reading it wrong, is, you know, how do you take if you've got multiple products with multiple inherent risk factors, how do you, how do you measure?

And my reaction is looking only at public health, you would want to base that score on the most risky product, again from a public health point of view, not averaging it, not -- just look at the most -- the product that presents the greatest risk.

MR. SEWARD: Skip Seward. I agree with you Sandra. I think that the caveat would be that if their algorithm and assignment of resources is specific enough, there would be no reason why you couldn't detail that out for the inspection staff, indicating that in a given establishment there is a specific production line of a specific product, that has this high inherent risk. So if they're able to get it on that level, then when the inspector or inspectors are in that establishment, or go there, they know within that establishment what was their resources. So --

MS. ESKIN: In theory, yes.

MS. SEWARD: Yes, right.

MS. ESKIN: But if push comes to shove, you don't have that ability, then I would argue again on the -- basis, the level of inspection be based on the

most risky product.

MS. GRANT: Okay.

MR. LINK: This is Charles Link. If I could -- just a little bit. I know we're basing it on 24 categories. If I use kind of a different example of alternative 1, 2 and 3, ready-to-eat products. There may be a plant that produces an alternative 3 product two weeks out of a month and not for another three months and then produces it again, and the rest of the time would do 2s and 1s, and to say that that plant is an alternative 3 plant or a high risk plant, compared to the plant down the street that does 90 percent alternative 3 products, doesn't seem to be -- to me. So I don't know if there's a fourth dimension, when you look and say, well, based on volume, based on how frequently you run the alternative 3 products, versus someone else. I'm not sure how that would --

MS. ESKIN: I guess that wouldn't necessarily be reflected in volume because it's volume as well as frequency.

MR. LINK: Yeah, yeah, but if we just say they run alternative 3 products, therefore they're

classified as an alternative 3 plant, which I think is kind of a different -- we're going to assign a lot of resources to a plant that probably doesn't need to be always there, all the time --

MS. GRANT: Okay. Michael and then Jenny.

MR. KOWALCYK: Michael Kowalcyk, Safe Tables. Charles, I think you raise a valid point. We have -- production work in that manner and this has sort of brought out that caveat that you need to know where in that facility riskier products are being produced. It's a valid point. I think this gets to how is volume going to be defined? Is it annual volume or is it volume during the month of October? Because if you see a plant that's producing higher risk product and low risk product at the same time, there you bring in that caveat that was mentioned earlier where -- plant. Charles' example was that during the month of May through July it's high risk product in this plant. So I guess it would go, we're defining, you know, what timeframe am I looking at for volume? How does volume apply? We need some more clarity on how that variable is going to be used.

MS. GRANT: Okay. Good point. Jenny and then Bob.

MS. SCOTT: Jenny Scott. I'm just trying to think what's inside the box in this case. We've got a little grid there, we've got little boxes there, and we've got multiple products and control measures. So you could plot every one of those products based somewhere on that grid and the could make a determination based on where the majority of the products fall to make --

MR. McKEE: Bill, Skip, Charles and --

MS. GRANT: Sandra.

MR. McKEE: -- Sandra, we do manipulate those plant profiles as things change within a plant, and I would expect that at some point the Agency could develop those where we could plan those low volume, high risk products and come up with some kind of a factor to consider those, rather than allocate the resource all year round or for extended periods of time. We might be able to apply that -- we can identify those production periods, get someone in there and start -- So hopefully that's something

that we can --

MS. GRANT: Okay.

DR. BLAIR: Another huge restraint here is these resources aren't fluid and immediately available in one place or another. I mean they may have a lower workload in New York City and all of a sudden a heavier one in Los Angeles, you're not shifting the resources to do that work for one week or two weeks or a day or two. So there's another practical consideration of assigning people and the relative cost.

MS. GRANT: Patty.

MS. LOVERA: I work for consumer groups. This is a really painful discussion for my brain to have about any concept of minimums and what Pat focused on this morning about cutoffs. You go up so far up, after so far, over X and up one Y, that something has to happen in inspection there. And so we get into this about seasonality or the things we're raising here, like we're not down risk-based inspection yet. I don't know if we will be but we're never going to get there unless we get some kind of

like guarantee that some things aren't going to happen without inspection, that some things are so inherently risky. I mean we keep talking about slaughter and it's always going to be there for slaughter, but I think there's some things in processing that we have to have, inspection, and that takes me to your issue about having a guarantee that there's going to be something there in doing it this way. We're starting to give examples, scenarios, like they have this kind of record and making this kind of product and -- concerns me.

DR. BLAIR: I think the difference -- Joe Blair. I think the difference in the slaughtering process is really, really obviously for people who are in the industry. In slaughter, you have very specific tasks that the inspectors perform on each carcass or each bird, and it's the number of the people required, related to the speed and the configuration of the floor and all that, and that's why. But this is already dictated in terms of use of resources. Now there is work being done to try to figure out more efficient ways to do that but I think on this project,

we have to set aside slaughter because it is like the apple and orange in terms of resource allocation.

MS. LOVERA: But from our perspective, it's really hard for us to -- all the processing, not having -- maybe some parts but some activities that are at that level, that meet that level of --

DR. BLAIR: That is every --

MS. LOVERA: No, I'm saying -- that's what I'm talking about these axis, like where do you -- what is that line there?

DR. HARRIS: Joe Harris, and somebody will correct me if I'm wrong, and I probably will be but to the best of my knowledge, we are still going to be bound at least at the one end by the statutory requirement of daily inspection. So there's going to be some level of inspection every day. So that's statutorily required. So when you're asking for boundaries, that's one that's already there.

MS. LOVERA: Yeah, we could have a long discussion about --

MS. GRANT: Okay. Any other comments on number 5?

(No response.)

MS. GRANT: Okay. Let's go to the last question, number 6. To better ensure comparable expert data, FSIS did not ask expert to consider severity of illness resulting from consumption of contaminated meat and poultry. How should they account for severity of possible illness when calculating the risk inherent to each type of meat and poultry product?

DR. HARRIS: Joe Harris again. The Agency has some experience in doing this in some of the risk assessments that they have conducted for specific pathogens over the years. I'm not a risk assessor, but there are people who are very well equipped to make these kinds of calculations. There are risk assessment experts out there.

MS. GRANT: Go ahead. Sandra.

MS. ESKIN: Yeah, I would agree that -- I think -- I hope the consensus is for the first part of that question, yes, and the second of part of the question, what Joe just said. There are experts out there who have done this. Again, I just want to

emphasize on that first part, severity, again many of us have expressed a concern that when you're determining the severity of illness, who is your target population, and a healthy, middle-aged man is going to have a much different sort of illness than a young child or an older person. So I would want to say both severity and -- take into account severity as it relates to particularly vulnerable populations, acknowledged in most cases to be children and older persons and people with suppressed immune systems.

MS. GRANT: And use the experience of other experts.

MS. ESKIN: Yes, it should be considered, and there are experts that FSIS has used before and there are experts out there in the community that can help, but it clearly needs to be -- among other things that if concerned would be the expert elicitation, that that was taken out or not included.

MS. GRANT: Okay. Jenny.

MS. SCOTT: Jenny Scott. I think what I heard here is that, yes, severity needs to be taken into account here. I'm not sure we completely

answered the question though in how should we account for severity when calculating risk inherent to each type of meat or poultry product. So are we suggesting that they should then take these rankings, whatever we come up with, and then apply the severity factor to the risk assessment and then adjust the rankings as a result of that? Because if you look at these products, at least half a dozen of them could have raw poultry, turkey, meat, you know, whatever. So they may come out to be very similar, the salmonella, the campylobacter, the red meat O157, and I'm not sure there's going to be too much more in terms of juggling the rankings, but certainly it would be appropriate to make this calculation perhaps through some suggestions.

MR. POTTER: This is Bill Potter. You could review the CDC data, how severe are the illnesses when they're contracted.

MS. GRANT: Michael.

MR. KOWALCYK: Michael Kowalcyk from STOP. Following up on Jenny's comment, I would agree that the logical next step would be that raw ranking

initially and then adjustment to account for severity and --

UNIDENTIFIED SPEAKER: --

MR. KOWALCYK: Yeah, I think if that were to make sense.

MS. GRANT: Adjust the rankings of the raw product?

MR. KOWALCYK: Well --

UNIDENTIFIED SPEAKER: He said raw just as a descriptive.

MS. GRANT: Okay. Okay.

MR. KOWALCYK: Not the raw product. Starting with the initial rankings and then the assigned factor -- results.

MS. GRANT: Okay. Any other comments on number 6? Go ahead. Sandra.

MS. ESKIN: I just want to follow up. That may make sense. I'm not a numbers person. I would just want to make a point that that may be one way of doing it, what you're suggesting. There may be other ways to factor it in, and I just want to throw it out there, that consulting with the appropriate experts

that we need to do it this way, that way.

MS. GRANT: Okay. Joe.

DR. BLAIR: I see severity already considered in the expert evaluation. I mean you told them not to use it, but I see it in the results.

UNIDENTIFIED SPEAKER: Severity to what population?

DR. BLAIR: Well, the one they have the most severe which are mostly the raw product. That is not the number of diseases. It is the severity of that O157 that would cause that to be in the highest risk -- higher risk category. I think --

MS. ESKIN: I still think it needs to -- this is Sandra. Given the concerns we've all had about the elicitation, was this -- you may very well be right, but I think we need to go back and cross check. So I'm not sure if it was adequately covered.

MR. COOK: Well, wouldn't it change it? Wouldn't the demographics change and all of a sudden you're targeting another group of people?

DR. BLAIR: Well, I think that's why canning was left off, low acid canning was left off of that.

I can't think of anything more severe than botulism. It was left off of it because it was taken out of the HACCP -- They really follow this set of regulations and we know it works, and because we know it works, we're going to keep doing it, and therefore that's why you put it at the lowest risk category because it has a system that's taken care of an extremely severe hazard.

MS. GRANT: Michael.

MR. KOWALCYK: Michael Kowalcyk from STOP. I think this points out a key shortcoming if the expert elicitation is looking at the results, you can make the interpretation that the fact of severity, they were instructed not to factor that into the analysis, nor to assume high risk populations in that analysis. This is to look at the healthy population. So that's why a lot of folks have been struggling with using that as -- using it as a benchmark because of the way the scope was defined --

MS. GRANT: Okay. I want to wrap up this paper. We have about a half an hour left. Before we do, is there anything that was not captured in those

questions that you think is really important to say. You've already made a lot of comments about the expert elicitation. Is there anything else that rises to that level that you want to say about this paper that isn't asked by these questions?

MR. POTTER: This is Bill Potter again. If it's okay, Kathy, we've talked about a lot of different factors that go into something that people typically call a risk index --

MS. GRANT: Uh-huh.

MR. POTTER: -- or a score and index or something. And if it's okay, I'd like to at least put the proposed score, the proposed index in front of everybody. I know it would be a little bit redundant. Is that all right before --

MS. GRANT: This is a proposed index for?

MR. POTTER: Inherent Risk Index.

MS. GRANT: Okay.

MS. ESKIN: So would -- excuse me. This is Sandra. So that would be one of the variables you plug into that equation that they gave us?

MR. POTTER: Yeah, it would take me just

about one minute, and I can write it faster than I can tell you.

MS. GRANT: Okay.

MR. POTTER: Do you all mind if I do that? Write it up there.

MS. GRANT: Okay.

MR. POTTER: And this is just based on --

MS. GRANT: Do you need a fresh sheet of paper?

MR. POTTER: Yeah, that might be good. This is just a starting point. Start with the likelihood of food safety hazard, and all of these -- I just have a continuum of 1 to 10, with 1 being low and 10 being high, okay. Times the severity of the hazard, if it occurs, again the 1 to 10 continuum, 1 is low and 10 is high. Times likelihood of consumer mishandling and, of course, the key factors here are, you know, ready-to-eat or maybe just mishandling is a better term. For example, ready-to-eat products that are contaminated or raw products that are undercooked. Okay. And then you have a low to high continuum, 1 to 10. And then this thing, someone said about a fourth

dimension which I thought was really good, and I mentioned -- I'm just calling this a volume factor, and you could also do it low to high. I just, you know, wrote down if I was doing low to high, I would say, you know, low is 1, somewhere between 1 and 3, medium volume is 4 to 7, and high is 8 to 10. Okay. So, anyway. But that's kind of the idea. And then each product category in each plant could be given, you know, a risk index -- inherent risk index.

MS. GRANT: Okay.

MR. POTTER: That's just taken from a safety -- human safety risks. That's kind of what OSHA folks do.

MS. GRANT: Jenny, do you want to respond?

MS. SCOTT: Yes. The problem I see with that is the likelihood of a food safety hazard is solely dependent on controls in the plant. So it's hard to put that in on an inherent risk index that covers the industry as a whole. I mean that's going to figure in all the interventions we've talked about, how well they apply, how well they're validated and things like that. So this almost takes the place of

the higher two dimensional, three dimensional matrix that was put on the table before. So we can certainly throw that out as something for consideration, but --

UNIDENTIFIED SPEAKER: It goes to not just inherent risk is what you're saying.

MS. GRANT: Okay. I don't want to take too much more time on this paper. Jenny, you're the person who is going to report back on this paper. Would you like some help on what you should highlight or do you think you have it, you have a sense of that?

MS. SCOTT: I think I have a sense but I will certainly welcome us agreeing on the points that we want to convey because we have had some disagreement.

MS. GRANT: Okay. And I'm going to -- I'll try to do this in order. You started out with the elicitation, and that's the first time we heard the beginning of your formula.

MS. SCOTT: So what I'm getting from this --

MS. GRANT: The scope was too narrow, does the data really bear out the ranking, should we take it before another group of experts, cross check the

data and other -- data on the public domain. Robert has more extensive notes on it which could be made available.

MS. SCOTT: Well, I've got pretty good notes, too. I just want to make sure we agree upon --

MS. GRANT: Does that sound right? Those are the key points that you want to point out. And then with regard to the median. There was agreement that, yes, you could use it if you -- closer spread. I think there was agreement on that. Another formula again. It was hard to say yes to this without knowing the context in which the individual panelists come up with their numbers and then we switched to thermally processed. There was just all in agreement that it should have been included. Bob is going to have a lot more notes on this. And as far as further processing in another establishment versus further processing in retail. Retail was simpler, with the regard to further processing establishments, there were a lot of factors that people wanted to have considered, including the likelihood of intended use, likelihood of mishandling, further processing, retail, volume.

People really liked the idea of taking a real look at the third axis. Additional analysis about how it should be integrated.

MS. SCOTT: Mike said it would be an establishment attribute or on its own.

MS. GRANT: Or on its own. Suggestion to use the plant profile that plants fill out. If there's more than one product, based on the most risky product, if you're looking at a public health perspective. There are ways of detailing that out. Another suggestion, you just detail out frequency, factor in frequency. Some plants don't do the risky processes all the time. How you define volume. Is it an annual thing, or is it something that's done -- are you looking at it for a month? Someone said the plants could give some information about when they do the risky products. And then think about frequencies, seasonality. Severity, definitely factor this in. Go out and look for risk assessment experts who know how to do this, take into account effects on vulnerable population, look at CDC data. Yes, maybe you should adjust the initial ranking after you've done this

based on this information, but there may be other ways of doing that. Some people felt that severity was already factored in the way -- that they just couldn't separate it from their thinking about having come up with the rank. And I think your point is well taken. I think everybody agreed with it that it does include more than inherent risk. It includes some establishment risk control. Okay.

Now we have, let's see. We have about 20 minutes on the risk control papers. There are six questions to this, the first being, are those six measures that they had in that circle, design, implementation, in-commerce, food security and other enforcement, all of those, are those the right -- are those appropriate and adequate? Go ahead. Joe.

DR. HARRIS: Joe Harris. I feel pretty strongly that food security doesn't belong in this particular arena. Food defense is -- I think we're unnecessarily muddying an already muddy stream.

MS. GRANT: I see some other people agreeing with that?

UNIDENTIFIED SPEAKER: Yes.

MR. KOWALCYK: This is Michael Kowalcyk from STOP. I would like to assume that that's part of the system design already because you expect a facility to protect its assets in some way. So it seems to me that it is redundant.

MR. McKEE: Bob McKee. That isn't always the case. The bigger corporations certainly go to great lengths to show that, but the small and the very small plants, maybe the small size plants don't have emphasis on good defense, and it would amaze a lot of people in this room to see how vulnerable they really are in terms of -- and things like that. So it may be -- you want to think about --

DR. BLAIR: Joe Blair. But would assigning additional inspection resources mitigate that?

MR. McKEE: I believe it would have an impact on it.

MS. GRANT: So you're not agreeing with that first statement that it doesn't belong?

MR. McKEE: I'm not comfortable with that.

MS. GRANT: Okay.

MR. DENNIS: Kevin Dennis. When it comes to

food security -- target which is physical security -- I don't think the same principles apply when it comes to food safety.

MS. GRANT: So you're not --

MR. DENNIS: Not for this.

MS. GRANT: So you are in agreement that it should not be one of the six. Go ahead. Jenny.

MS. SCOTT: I agree that it shouldn't be there but to Bob's point, I think that we don't want to indicate that we don't think it's important. It is something that --

UNIDENTIFIED SPEAKER: It doesn't belong in this system.

MS. SCOTT: -- it just doesn't belong in this --

DR. HARRIS: I was the one that voiced the opinion first that it shouldn't be there, and I just finished writing a long article last week trying to convince people why they need to be doing this. So I'm definitely not against food defense. I just don't think that it has a place at this table.

MS. GRANT: Anything else anybody wants to

say about that?

MR. POTTER: Bill Potter. Could you expand on why you don't think it does? I mean I'm not disagreeing with you.

DR. HARRIS: For one, I don't think we understand the risks and how the food defense risks are going to play into public health consequences. We keep hearing about vulnerability, but they're so top secret nobody will even tell us what they are, and here we're supposed to be addressing them, and beyond physical security and trying to make sure that you have the facility secured and you have the employees' security, there's not a whole lot that people can do, and again, I don't think the assignment of inspection resources is really -- is going to be effected greatly by variations in that. Again, obviously everyone won't agree with me on that.

MS. GRANT: Okay. Any other comments on that?

(No response.)

MS. GRANT: So the next question really is about are some more important than others. So

let's -- you made your point about this one. What about the other five? So this is really about weighting them. Michael, do you have your card up?

MR. KOWALCYK: Michael Kowalcyk, Safe Tables. I think where I'm struggling with this is determining why each of these elements that lead into this overall measurement, I'm still not sure of the reliability data from each of those sources, how to utilize that data and how will that data be appropriated into a ranking for establishments. So to me, this was an issue that was brought to the NACMPI Committee a while back. It's really difficult to determine which one should be more important than the other. For example, NRs, which NRs are more important than others. That's within a specific data source and -- question about that. So me I struggle with determining, they seem appropriate. Are they adequate? I don't know. That's the first question, but determining how should be weighted. To me it seems like there's not enough information to make that determination.

MS. GRANT: Okay. Do others feel

differently?

MR. SEWARD: Skip Seward. I think with pathogen control, that's something that's actually measurable and more factual than perhaps all the others which in many cases are left up to interpretation and you're going to get that subjectiveness in there, but I think pathogen control sticks out as something that, you know, it's there, it's not there, and it's measured and, you know, how equitably that kind of testing takes place across all establishments is the issue that I think perhaps FSIS could work on in their sampling program, but that stands out as perhaps, you know, the one that it is, you know, should be represented fairly highly on the program.

MS. GRANT: And partly because the data is more reliable. Is that what you're saying?

UNIDENTIFIED SPEAKER: More objective.

MR. SEWARD: Yes, it's objective. That's a good way to put it.

MS. SCOTT: It has a bigger impact on public health.

MR. SEWARD: Skip Seward. With regard to the design, I think when they talk about the design, they talked about gauging the efficacy, and to me that's just that efficacious in doing what, and so I was a little -- I think if you get away from the efficacy and just say does the design of the food safety program have all of the elements that a HACCP plan should have and so forth, that again could be measured fairly objectively without getting into gauge the efficacy because that gets more into the implementation aspect of it. So I think those two, you know, whether your food safety system is designed properly, is fairly straight forward because it has to have certain elements which are defined by HACCP and in the regulatory environment. So those two stand out, pathogen control and design stand out as fairly objective in their measurement. When you start getting into implementation and enforcement actions, it becomes a little bit more difficult to be I think objective because, you know, it involves the human element of making judgments about things, and you're going to get some inconsistencies there and those

types of things. So just a couple of comments.

MS. GRANT: And do you weight design high also like you said with pathogen control or are you just making a point that that --

MR. SEWARD: Well, I think it's less than, in my opinion. This is Skip. It's less than the pathogen control but at least the design of something and what's supposed to be there could be measured fairly objectively.

MS. GRANT: Okay.

MS. SCOTT: And I'm not sure -- Jenny Scott -- where this fits in though. They said it would come back to interventions. It doesn't fit into design but to me interventions and their validations being part of the design, that can have a real impact on public health. So that would rank higher in my mind.

MR. SEWARD: That's a good point.

MS. GRANT: Validated -- right.

DR. HARRIS: This is Joe Harris again. In my opinion, if -- of those factors there, the pathogen control sort of stands out as being a good objective,

direct measurement of pathogens of human health concerns, and that sort of stands out as being pretty high on the list, while a lot of those other things are important, that one does sort of stand out --

MS. ESKIN: Sandra Eskin. Again, in theory, I think there's a disconnect just to the global point, as Mike was saying it before, and a number of people said it in the plenary session. I mean this looks good, FSIS has said it has this data and that data and this data, but that's actually audit, where you can see what data they have, and again they said that these FSAs, maybe they happen once every three years, are not necessarily done as to -- basis. Consumer complaints aren't necessary. So again we're talking about a theoretical construct here but it bears repeating again and again that if they don't have the data that accurately reflects reality, then the determinations that are being made are just not going to be accurate. So, yes, again back to even the point of pathogen control, there's data for sure but is it representative -- is it really accurate? Does it really tell -- is it a picture of what's happening in

a plant, an individual product? I'm looking at it rhetorically.

MS. GRANT: I didn't get the last part of your sentence. So if we don't have data that accurately reflects reality, you can't --

MS. ESKIN: You can't make accurate determinations of risk and therefore base any kind of resource allocation on risk.

MS. GRANT: Okay. Jenny.

MS. SCOTT: I'm just wondering if -- Jenny Scott -- if they are interpreting or limiting themselves too much on pathogen control to just the pathogen testing results that they do.

UNIDENTIFIED SPEAKER: --

MS. SCOTT: Yes. And this raised the question that we raised earlier with respect to industry data and industry has a lot more data than they contribute to this. These are data that the Agency has access to and I think that they should find a way to let the industry data play a role in the evaluation.

MS. ESKIN: Sandra Eskin. We've said that

multiple times in multiple ways at the Advisory Committee meetings. We've been asked data questions, and I don't know if any progress has been done on that. I'll certainly ask on Thursday.

MS. GRANT: Okay. Michael.

MR. KOWALCYK: Michael Kowalcyk. Another source of data would be public health data. During the meeting, I was sketching out how the database -- looking at how this database would look like. If you look at data elements that for every plant you would know the plant's ID, where the plant was located, possibly where their distribution is going to, and seek out geographically -- CDC data that reflect outbreaks in certain areas with possibly allocate resources to plants that are distributing to those specific areas, if there's an outbreak. So public health data seems --

MS. GRANT: For specifically pathogen control or for any one of these, any one of the six?

MR. KOWALCYK: I think it would be number 3, other useful information.

MS. GRANT: Okay. So other data. I don't

know if anyone had anymore to say on the weighting of it. Was there an agreement that pathogen -- you know, because of the concerns that you raised, you're not willing to say that pathogen -- that you believe that pathogen is the highest because of the concerns.

UNIDENTIFIED SPEAKER: Yes.

MS. GRANT: Okay. I just want to be clear. Joe.

DR. HARRIS: I want to kind of follow up Michael's comments on public health data. One of the things to me that is missing in this picture is we've got, if you will, these little spokes coming out. We don't have a linkage between that and reduction in food-borne illness. That's the part to me as we went through the discussion today of the big picture of risk-based inspection is how do we actually tie this whole picture to a reduction in food-borne illness. And I would be interested in that kind of data.

MS. SCOTT: This is Jenny Scott. Following on to what Joe said, attribution was brought up several times here and it was implied that nobody was doing anything about it, but that's not true. CDC and

the Agency has gotten together and had discussions about how to get to better food attribution data, and they're looking to putting in a system. So as this evolves, we'll also have a system for getting better food attribution data that should be entered into this.

MS. GRANT: From CDC did you say?

MS. SCOTT: Yes. It'll be joint projects between the Agency, among the Agency and CDC, but we will have more data coming in.

MS. GRANT: Okay.

MS. MARR: Christy Marr, National Turkey Federation. It was my impression that that attribution data would be considered in the inherent risk side, not the establishment side. So that information can be separated from the establishment and not what we're doing right now.

MS. GRANT: Okay.

MS. SCOTT: It can be both.

MS. ESKIN: Public health data generically is a category that Mike mentioned. Do you agree that some public health data will be relevant to these

issues of establishment control?

MS. MARR: Yes. Yes. I'm sorry. Also I want to remind --

MS. GRANT: Okay. So it can be used for both. Okay. Anything else, additional information?

(No response.)

MS. GRANT: Are there other ways besides FSAs to evaluate the food safety design? Are there any thoughts on that one? No ideas.

MR. KOWALCYK: Michael Kowalcyk, Safe Tables. I guess this is just from my own personal education. I know that the food safety assessments, it was thrown out there the frequency is every three years. Now I work in a different industry, but we change the way we do business. Certainly if we did everything the same way over three years, we wouldn't be in business very long. I guess from a practical point of view and maybe those in industry can educate me on this, is that an accurate reflection? I mean if you're looking at data that's held by the Agency and it's looking at let's say Mike's plans two and a half years ago, and I was doing things a certain way, and

now I bring in the good quality guy and I clean up all of my processes, and I have a whole new system in my plant, there's no mechanism to account for that, to revisit my systems or is it just stuck in this three year pattern, so the data that you have is kind of stale. Is that the way it happens?

MR. POTTER: This is Bill Potter. When we're talking about an every three year assessment, we're talking about a person coming into a plant, a third party, that every shift, every hour, every week, for a federal inspector assessing the food safety systems and implementation of the program. There's veterinarians in the plants that are overseeing the inspectors and then -- I'm talking about in slaughter plants. We also do processing. And then there's circuit supervisors and they have district FSIS management. So I think the question is worded a little funny but --

MS. GRANT: Well, FSAs are the primary way of evaluating the design, the system design. So they're asking are there other ways.

DR. HARRIS: I think what you're missing in

here is the PBIS data.

MS. GRANT: Are you going back to number 3?

UNIDENTIFIED SPEAKER: That's the NRs.

DR. HARRIS: Well, no, it's not NRs. The NRs are noncompliance. PBIS is they're given a task to go out and review something, and they report back on that task and there could be very positive findings that everything is fine. That is data that should be used in terms of the risk in that plant. I'd be happy if you put it under system implementation.

MS. GRANT: Okay.

DR. HARRIS: I think it's a good point. We seem to have sort of missed that in our discussion.

MR. SEWARD: Skip Seward. I think, you know, just throwing out things, it might of value. I mean a lot of companies are audited by at the request of the customers and part of that may involve a review of the design of the HACCP plan and so forth. It's sometimes reliable and sometimes not, but it's another avenue.

MR. COOK: So you're saying third party audit.

MR. SEWARD: Yes.

MR. POTTER: I guess I would say that in my opinion, it is acceptable to have local inspectors and circuit supervisors be involved in their design, food safety design since it's on a frequent, ongoing basis.

MS. GRANT: Local inspectors and --

MR. POTTER: And inspection supervision. Inspection management.

MS. ESKIN: Sandra Eskin. Just a question, on that audit data, that's private though, right? That's not something that would be acceptable. Again, if it's a factor -- if it were to be considered in the determination of establishment control, the data itself would be available to look at -- I mean I assume it would be private --

MR. SEWARD: No, I agree with you. This is Skip. I agree. It's something that an establishment would have to be willing to turn over and share with the inspection staff so that they would have it in order to evaluate it or -- so you're exactly right.

MS. ESKIN: Right, as with other data as well, right. What's collected that the Government

doesn't collect.

MR. SEWARD: That's correct.

MS. GRANT: In the last minute, does anybody have any comments on the last two questions. The last one, what is an appropriate look-back period? It's already been stated that they're considering six months and then that list of things or types of things, the type of NRs that you were suggesting were the appropriate ones to look at. Is that inclusive or are there other NRs that should be included?

DR. HARRIS: The way that was phrased seems a little broad. Someone pointed it out in a comment earlier today that just the fact that I had a NR related to a verification activity, that could mean before it got to the initial record when you reported the data. It could be anything. So somehow or another we still have to narrow that down a little bit and be more specific on when a NR is food safety related, and I would contend that even within the scope of a given regulation cited on the NR, there are going to be food safety related ones and non-food safety related ones.

MS. GRANT: Okay. Do you have a comment on either one of these? Look back or --

MR. COOK: Matt Cook. I agree with the look-back window being changed to a year to account for some -- rather than the six months.

MR. SEWARD: This is Skip Seward. I think on that look back, they ought to be able to do it as often as their system allows them to do it. In other words, if it's an automated system, if this is all mathematically generated, it seems like they could do that -- it would almost be an automatic update system as it went along. So I think you're right. You would have to be aware that if it wasn't a year, it may not be long enough. To me that's something that should almost be built in and if they get this thing working, they're not going to be doing all of these manually anyway I would imagine. It's going to be an automated system. So they ought to be able to do that at whatever frequency they choose to or that they can do it.

MS. GRANT: Michael and then Patty.

MR. KOWALCYK: Michael Kowalcyk. I agree,

it should actually be a rolling window, rather than just a fixed snapshot, and I would even recommend that it go beyond the year, as far back as feasible, I would say at least 12 months to capture, and if they could go further back, that would be better. I would like to take --

MS. GRANT: So it should be more than a year. Is that what you just said? I'm sorry.

MR. KOWALCYK: Minimum of a year.

MR. SEWARD: This is Skip Seward. You know, I think you have to be -- they have to be able to do this depending on what you're looking for. You know, in other words, you don't want to be accumulating NRs that were written over a year ago and having that affect your current status but, you know, depending on what you're looking for, you know, you want to be able to go back as far as you want to go back, to see trends or things like that but, you know, that's a caution I would have is that --

MR. KOWALCYK: I agree with you but you want to lay more recent activity --

MR. SEWARD: Yes.

MR. KOWALCYK: That's part of the bodily process --

MR. SEWARD: I agree.

MR. KOWALCYK: But I would agree with you that what happened yesterday is more relevant than what happened nine months ago.

MS. GRANT: Okay.

MR. POTTER: And establishments ought to be able to petition for a more current look-back period. If they implement new technologies that would say, for example, reduce pathogens by 5 logs, they should be able to request a shorter window of look back.

UNIDENTIFIED SPEAKER: Five logs?

MR. POTTER: Just as an example. If pathogens can be reduced --

MS. GRANT: New technology --

MR. POTTER: -- by new technology, the look-back window ought to be less far back.

UNIDENTIFIED SPEAKER: When you implement them back or --

MR. POTTER: Yeah.

MS. GRANT: Okay. All right. Thank you all

very much.

UNIDENTIFIED SPEAKER: About the NRs, I just want to turn out like a word of caution about this urge to narrow which NRs are food safety. Having spent a painful period reading about 1,000 NRs that we got from ESD, a number of times, it's just the HACCP plan problem. The HACCP plan problem was they had no way to deal with an O157 and that's what happens in HACCP violations.

MS. GRANT: Okay. Thank you all very much. There will be a discussion after the presentation. That will be your last opportunity to make any comments.

And, Jenny, I'm not exactly sure what we're going to have for you tomorrow.

MS. SCOTT: Why don't we meet early.

(Whereupon, at 5:40 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 1

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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Keith McGuire, Reporter

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